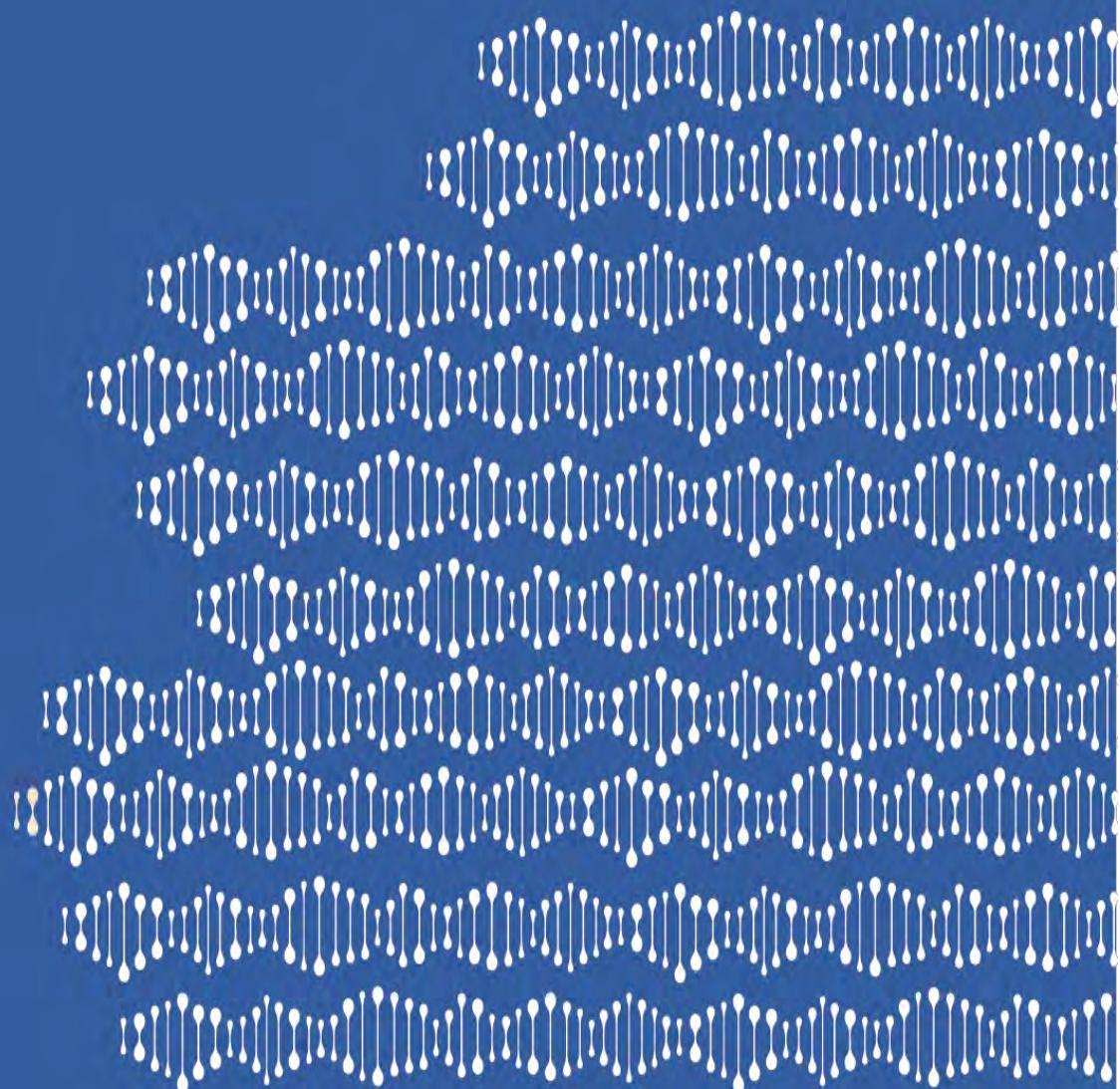




CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Meeting

August 20, 2014





CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

Summary Overview of the August 20, 2014, Oversight Committee Meeting

Please find enclosed the meeting packet for the next meeting of the CPRIT Oversight Committee to be held on Wednesday, August 20, 2014, at 10:00 AM. This summary overview of major agenda items provides background on key issues for Committee consideration.

CEO Report

Wayne Roberts will present the CEO's report and address issues including new staff, office relocation plans, legislative activities update, and the compliance program design report.

Chief Compliance Officer Report

David Reisman will report on the status of required grantee reports, the compliance program design report, and a proposed ethics training schedule to comply with CPRIT's administrative rule §701.7(d), which requires period compliance program training.

Chief Prevention Officer Report and Grant Award Recommendations

Dr. Becky Garcia will present the Program Integration Committee's recommendations for 15 prevention awards and provide an update regarding the current review process and upcoming requests for applications. Dr. Garcia will also speak to a potential collaboration on colorectal cancer initiatives.

Chief Scientific Officer Report and Grant Award Recommendations

Dr. Margaret Kripke will present the Program Integration Committee's recommendations for 84 scientific research awards and provide an update regarding the current review process and recently released requests for applications. Dr. Kripke will also report on the June meeting of the University Advisory Committee.

Chief Product Development Officer Program Overview, Grant Award Recommendations, and Proposed Contract Terms for Product Development Grants

Dr. Tom Goodman will provide an update on the Product Development program and present the Program Integration Committee's recommendations for two product development grant awards and seek approval for agency authority to disburse grant payments in advance for the two grants following execution of award contracts. Dr. Goodman will also present some revisions to the proposed contract terms for the Product Development grant awards that were approved at the May 21st Oversight Committee meeting.

Information related to the prevention, scientific research, and product development grant applications recommended for funding is not publicly disclosed until the Oversight Committee

meeting. The information has been made available to board members through a secure electronic portal.

Scientific Research and Prevention Programs Committee Appointments

The Chief Executive Officer has appointed 22 new members to the CPRIT's Scientific Research and Prevention Programs Committees. CPRIT's statute requires the appointments to be approved by the Oversight Committee. A biographical sketch for each appointee is included in the board packet.

Program Priorities Project

Dr. Becky Garcia (staff project lead) will report on the Program Priorities Project activities, including the in-person subcommittee meetings with the project facilitator, Robert Mittman and preparations for the upcoming Oversight Committee working session to be held September 3.

FY 2015 Honoraria Policy

The CPRIT's enabling legislation requires CPRIT's Chief Executive Officer, in consultation with the Oversight Committee, to adopt a policy regarding honoraria paid by CPRIT for peer review services. Mr. Roberts will present the FY 2015 Honoraria Policy for consideration.

FY 2015 Conflict of Interest Waivers

Health & Safety Code Section 102.1062 "Exceptional Circumstances Requiring Participation" provides a process for the Oversight Committee to consider and approve a waiver of statutory conflicts of interest for individuals involved in the grant review or award process. Renewing the FY 2014 waivers approved for Dr. Margaret L. Kripke, CPRIT's Chief Scientific Officer, and Dr. David L. Lakey, Commissioner, Texas Department of State Health Services, is proposed. In order to approve the waivers, the Oversight Committee must find that there are exceptional circumstances justifying the conflicted individual's participation in the review process. Dr. Kripke's proposed waiver is necessary so that she may effectively perform her duties as Chief Scientific Officer. Dr. Lakey's proposed waiver is necessary so that he may participate in the Program Integration Committee meetings as intended by changes to CPRIT's statute. The proposed waivers include limitations and other protections in place to mitigate the opportunity for the award of grant funds to be driven by anything other than merit and established criteria.

Manager of Internal Audits

The Audit Subcommittee expects to interview the finalist to fill the position of Manager of Internal Audits prior to the August 20 Oversight Committee meeting. The Audit Subcommittee may recommend that the Oversight Committee approve hiring the candidate. In the event that a candidate is not suitable, CPRIT will repost the position.

Internal Audit Reports

Heidi McConnell will provide an overview of the internal audit program. Grant Thornton, LLP, CPRIT's internal auditor, has finalized two operational audits, *Expenditures Internal Audit Report*

and *SRA International Managed Information System Internal Audit Report*, as well as completing field work and draft reports of the other audits scheduled in the 2014 Internal Audit Plan.

Agency Contracts

The Oversight Committee will consider approval of several services contracts for FY 2015. Four of the five contracts address support services integral to CPRIT's peer review process. The fifth contract, for an independent financial audit, is necessary to fulfil the statutory mandate that CPRIT commission an annual audit of the agency's activities. Once approved by the Oversight Committee, these contracts will be sent to the Legislative Budget Board for final approval.

Advisory Committee Actions – the University Advisory Committee and the Advisory Committee on Childhood Cancers

CPRIT's statute creates two advisory committees, the University Advisory Committee (UAC) and the Advisory Committee on Childhood Cancers (ACCC) to advise the Oversight Committee on important research issues. Oversight Committee approval is sought for the UAC's charter, which was approved by the UAC membership earlier this month and will be adopted upon a vote by the Oversight Committee. Oversight Committee approval is also necessary for the proposed appointments to the ACCC.

Changes to Agency Administrative Rules and CPRIT's Code of Conduct

- Texas Health and Safety Code § 102.108 authorizes the Oversight Committee to implement rules to administer CPRIT's statute. Proposed rule changes are recommended for final adoption following a period of public comment. No public input was received. The Board Governance subcommittee recommends formal approval of the rule changes that were provisionally approved by the Oversight Committee in May.
- The Board Governance Subcommittee also recommends two rule changes and one new administrative rule for provisional approval by the Oversight Committee. The proposed new rule, § 701.35, addresses a statutory requirement that CPRIT provide a process for the public to request initiation of a rulemaking project. The rule changes to §§ 703.11 and 703.13 provide clarity for grantees regarding required reports. Once approved, the proposed administrative rule will be published in the *Texas Register* for public comment.
- Two proposed changes to the Code of Conduct are recommended to establish deadlines for certain annual filings and reports. The changes, recommended by the Board Governance subcommittee, are ministerial and will assist in ensuring that CPRIT complies with state laws and administrative policies.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Meeting

Texas State Capitol Extension
1400 N. Congress Avenue, Austin, Texas 78701
Room: E1.012

August 20, 2014
10:00 a.m.

The Oversight Committee may discuss or take action regarding any item on this agenda, and as authorized by the Texas Open Meetings Act, Texas Government Code Section 551.001 et seq., may meet in closed session concerning any and all purposes permitted by the Act.

Opening

1. Call to Order
2. Roll Call/Excused Absences
3. Adoption of Minutes from May 21, 2014 meeting

TAB 1

Public Comment and Staff Reports

4. Public Comment*
5. Chief Executive Officer Report
6. Chief Compliance Officer Report
7. Chief Operating Officer Report
8. Chief Prevention and Communications Officer Report
 - Communications Report

TAB 2

TAB 3

TAB 4

TAB 5

Program Activities

9. Program Priorities Project
10. Chief Prevention and Communications Officer Report
 - Grant Award Recommendations
11. Chief Scientific Officer Report
 - Grant Award Recommendations
12. Chief Product Development Officer Report
 - Contract Terms for Product Development Grants
 - Grant Award Recommendations

TAB 6

TAB 7

TAB 8

TAB 9

- | | |
|---|--------|
| 13. Scientific Research and Prevention Program Committee Appointments | TAB 10 |
| 14. FY2015 Honoraria Policy | TAB 11 |

Agency Business

- | | |
|---|--------|
| 15. Health & Safety Code Section 102.1062 Waivers | TAB 12 |
| 16. Personnel Action – Manager of Internal Audits | |
| 17. Internal Audit Reports | TAB 13 |
| • Expenditures Internal Audit Report | |
| • SRA International Managed Information Systems Internal Audit Report | |
| 18. Due Diligence Contract | TAB 14 |
| 19. Pre- and Post-Award Grants Management Support Contract | TAB 14 |
| 20. Peer Review Monitoring Contract | TAB 14 |
| 21. Independent Financial Audit Contract | TAB 14 |
| 22. Outside Counsel Contracts | TAB 14 |
| 23. University Advisory Committee Charter | TAB 15 |
| 24. Advisory Committee on Childhood Cancers Membership | TAB 16 |
| 25. Final Order Approving Amendments to 25 T.A.C. Chapters 701 – 703 | TAB 17 |
| 26. Proposed Amendments to 25 T.A.C. Chapters 701 - 703 and Authorization to Publish in the <i>Texas Register</i> | TAB 18 |
| 27. Proposed Amendments to Oversight Committee Bylaws, including Code of Conduct | TAB 19 |
| 28. Subcommittee Business | TAB 20 |
| 29. Consultation with General Counsel | |

Closing

- | | |
|---|--|
| 30. Future Meeting Dates and Agenda Items | |
| 31. Adjourn | |

** Anyone wishing to make public comments must notify the Chief Executive Officer in writing prior to the start of the meeting. The Committee may limit the time a member of the public may speak.*



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**May 21, 2014 Open Meeting
Minutes**

1. Meeting called to order

Meeting called to order by William Rice, M.D. (chair) at 10:01 a.m.

2. Roll call/excused absences

Secretary Mitchell called the roll.

Present:

Angelos Angelou
Gerry Geistweidt
Pete Geren
Ned Holmes
Will Montgomery
Cynthia Mulrow
William Rice
Craig Rosenfeld

3. Adoption of minutes from February 19, 2014 meeting

There being no discussion, a motion to approve the minutes of the February 19, 2014, Oversight Committee meeting was made by Mr. Angelo and seconded by Dr. Mulrow.

MOTION CARRIED UNANIMOUSLY

4. Public Comments

Dr. Rice (chair) announced a change in the normal order of the agenda. Noting the critical nature of public input and CPRIT's commitment to transparency and accountability, Dr. Rice explained today and in the future the public comment agenda item will appear at the beginning of Oversight Committee meetings.

Two requests for public comment were heard by the Oversight Committee:

- Dr. John Morony, biologist/college professor of biology-retired, submitted a one-page summary of his comments (Attachment 1). His wife is a survivor of malignant melanoma but received her treatment in Mexico, where she was cured in three weeks. He is a proponent of a biological protocol based on the stem cell/trophoblast paradigm of cancer. He requested that Dr. Rice and Dr. Kripke accept copies of his book for review.
- Dr. Greg Aune, a pediatric oncologist and physician scientist at The University of Texas Health Science Center San Antonio, is a childhood survivor of Hodgkin's

Lymphoma. He spoke as a childhood advocate for childhood cancer research funding and thanked the Committee for their service.

5. Chief Executive Officer Report

New Employees, Title Changes and Status of CPRIT staff vacancy postings

- ***The following new employees were introduced to the OC:***
Dr. Tom Goodman, Chief Product Development Officer
Cameron Eckel, Attorney
Dan Limas, Grant Accountant
Mary Gerdes, Special Assistant to the Chief Executive Officer
- ***The following employees have title changes:***
Sandra Balderrama, Grant Specialist Manager
Oralia Huggins, Grant Accountant
- ***The following positions are filled effective June 1:***
Purchaser
Three Grant Specialists
- ***Manager of Internal Audit*** – The position description will be modified again and reposted. Mr. Roberts explained that State Auditor John Keel told him that these positions are difficult to fill for a variety of reasons. Mr. Keel suggested the changes in the new job postings. At the November 1, 2013, meeting the Oversight Committee decided that CPRIT staff would screen initial applicants and identify candidates to be interviewed by the Audit Subcommittee. The subcommittee would then recommend a finalist to the Oversight Committee for final approval.

Status of Grant Funds Available for Awards in August (Dashboard)

A verbal update was given by Mr. Roberts. He presented a spreadsheet estimating the amount of funds remaining for grant awards in August from FY 2014 appropriations (Attachment 2).

Facilities Update

The agency is required to move into temporary space in August due to the fact that the Facilities Commission moved the availability date of our permanent space in the Travis Building to February of 2015. However, CPRIT's lease at 211 7th Street expires at the end of August, which is why the agency must move into temporary space until the Travis building is ready. CPRIT will see a considerable saving, approximately \$2 million, by moving to state-owned space.

Status of Funds Available

If the Oversight Committee approves the \$82.3 million in recommendations today, the remaining balance will be \$63.2 million, which Mr. Roberts considered good news. The net amount could go up if recruits reject offers. The Program Integration Committee (PIC) considers funds available in making its recommendations.

Quarterly Meeting Book

The meeting book has become much thicker than it was a couple of years ago. More information is included to provide as much transparency as possible.

6. Chief Compliance Officer Report

The Chief Compliance Officer is responsible for creating, supporting, and promoting an effective Ethics and Compliance Program and assuring the CPRIT Oversight Committee controls are in place to prevent, detect and mitigate compliance risk. In addition, the Chief Compliance Officer must inquire into and monitor the timely submission status of required grant recipient reports, and notify the Oversight Committee and General Counsel of a grant recipient's failure to meaningfully comply with reporting deadlines.

Monitoring Submission Status of Required Grant Recipient Reports

Mr. Reisman gave the following report: As of May 9, 2014, the date the report was run, information regarding delinquent grant recipient reports was as follows:

- 42 grant projects, either active or in close out, at 15 separate entities, have not fulfilled required quarterly financial status (FSR) reports by the deadline. At the last Oversight Committee meeting, on February 19, 2014, Mr. Reisman reported that 20 grant projects had not filed required FSR's by the deadline. An FSR is due to CPRIT within 90 days following the close of the fiscal quarter. Of the 42 delinquent reports, 11 are less than 30 days overdue. Thirteen are more than 30 days but less than 90 days overdue. Eighteen FSR's are currently 90+ days overdue.
- Ten grant projects, either active or in close out, have not filed required progress reports by the deadline (at the last meeting 7 projects were reported). All grant projects must file annual progress reports; prevention projects are also required to file quarterly progress reports. Annual progress reports must be filed with CPRIT within 60 days following the anniversary of the contract effective date. Of the 10 delinquent progress reports, two are less than 30 days overdue and eight are currently 90+ days overdue.
- On March 7, 2014, a report indicated 76 overdue FSR's and 18 overdue progress reports. Mr. Reisman asked the research and prevention programs, and the CPRIT finance division, to address the issue of late FSR's and progress reports by researching these delinquencies and by making contact with the grantees to identify where and what issues might be preventing them from submitting those outstanding reports. The research and prevention program staff contacted the grantees and has made progress identifying issues and facilitating the filing of many late reports. However, from information gathered in consultation with program staff and review of the CPRIT Grants Management System (CGMS) records, the issue of overdue FSR's and progress reports continues and is

estimated to continue for at least the next several months while CPRIT staff addresses the processing of late report filings.

Additionally, CPRIT program staff identified that the report identifying delinquencies run from CGMS identifies whether an FSR is overdue. However, additional quarterly FSR's, that may have become due from a grantee while that FSR is waiting to be either submitted and/or approved, are not identified by the report. In some instances several FSR's are "backed up" waiting in line for the initial FSR to be filed and approved, and then each subsequent FSR must be individually processed and approved before each succeeding FSR may be submitted. As a result, the actual number of delinquent FSR's is difficult to quantify due to the daily changes in filings, but is estimated to be significantly greater than the number identified in the report on delinquencies run from CGMS.

The causes for the number of reports on the delinquent report may be attributed to several factors including grants that are coming off the grant moratorium, resulting in past reports being immediately due, delinquencies in filing by the grantees, and the ability of CPRIT staff to process the incoming reports. While these are separate factors, due to the timing of grants coming off the moratorium, and limitations of staff, the factors do affect each other, and can compound the overall delinquency issue.

CPRIT staff is working to resolve these issues. Program staff contacting grantees regarding submission of delinquent reports has resulted in a significant reduction in the number of delinquent reports, as well as an opportunity to educate grantees. Also, in April, CPRIT sent a memo to all grantees that had one or more outstanding FSR's. The memo noted the issue of the backlog of FSR's and requested the grantees' assistance by submitting their next FSR within ten days after the approval of one FSR to diminish the time between FSR approvals. Another communication was sent to all grantees to educate them on the consequences of new administrative rules, with respect to late FSR deadlines, as well as other requirements going into effect June 1, 2014. It will take some time and effort to work through the FSR issues because new grants are coming in and need processing in addition to the end of quarter reports coming in and working through the backlog. CPRIT has hired an additional staff member for the finance division and three grant specialists to work with grantees on grant monitoring, including upcoming reporting deadlines and overdue reports. A third grant accountant is expected to be hired in late May or early June.

These actions should help to address the issue of delinquent reports. However, CPRIT should continue to examine current procedures and possible causes, and continue to identify and implement solutions to resolve this issue. Agency management is committed to attaining full reporting compliance for CPRIT grantees.

Discussion:

Dr. Rice noted that on the dashboard there are delinquent progress reports but not delinquent FSR's. He asked if that is something that could be added along with

information indicating which grants have multiple FSR's delinquent. Mr. Reisman indicated that information could be added.

Dr. Rice then asked who in the organization is responsible for the solutions to the delinquent FSR's. Mr. Roberts responded that he is ultimately responsible, as well as Ms. Heidi McConnell as Chief Operating Officer and the Grant Accountants who report to her. The Grant Specialists have split reporting responsibility to both the General Counsel, Ms. Kristen Doyle, and the Chief Compliance Officer, Mr. David Reisman. Now that the agency is near fully staffed, there will be weekly staff meetings to continue to work through the reasons for these delinquencies. Mr. Roberts is not willing to wait until the numbers are fully parsed to take action. Mr. Roberts expressed that he felt while some of the issues are due to staffing, some issues are due to the moratorium. CPRIT had 118 research and prevention awards that have now all been contracted for, along with 26 recruits. So the grantees could now be three or four quarters behind in reporting just due to the timing of the contracts. As soon as a grantee gets one FSR done, another is already due and taking its place in the count. Mr. Roberts explained that it's going to take some time to work through all of those, but the agency is committed to seeing this resolved. Until that time, the numbers will fluctuate. CPRIT's goal is complete compliance.

Mr. Geren explained in his limited experience, entities are serious about the research but not about the reporting and that CPRIT needs to find a way to have them comply willingly without always having to tell them to comply. Mr. Reisman responded that CPRIT is in a reactive mode right now but that improved communications is meant to change the noncompliance culture. Mr. Roberts said it is CPRIT's goal to prevent noncompliance before action is needed.

Mr. Roberts commented that universities don't worry about funding being dependent on reporting because they will pay researchers from other funds until the reporting catches up and the CPRIT funding is released. The rules have been changed such that if they don't report on time, the funding will be forfeited. CPRIT has notified grantees of this change, though CPRIT has not yet had to implement it. Before it gets to that point, though, Mr. Roberts expects our tracking to be such that he will call the president of a delinquent institution or non-profit and alert the president to the possibility of forfeiture of funds.

Mr. Geren asked how NIH handles delinquencies. Mr. Roberts responded that NIH does draw-downs of funds, where CPRIT does reimbursement of funds. Mr. Roberts characterized CPRIT's process as more stringent.

Dr. Rosenfeld commented that requiring reports every six months instead of quarterly would possibly make the reporting less onerous for the grantees and also lessen CPRIT's monitoring burden. Mr. Reisman responded that waiting longer could just increase the possibility of delinquency.

Dr. Rice asked for more information on the reporting requirements of NIH and whether or not CPRIT's reporting requirements are seen by grantees as too burdensome. Mr. Roberts said he would continue collecting the metrics on this,

but at this point he is a long way from recommending shortening the reporting periods.

Ms. Doyle commented that the provision waiving the reimbursement for the period of reporting delinquency is found in the Administrative Rules at Section 703.21. She explained, this was part of the administrative rules project changes that were adopted by the Oversight Committee on January 24, 2014. For rulemaking projects, the public is provided 30 days to comment on rule changes. CPRIT did not receive any public comments from any of the institutions. CPRIT has received comments on other rules projects and changes, but none have been received suggesting there should be fewer reporting cycles or on the waiver issues. In the automated reporting system being developed, there is a process for the grantee to seek a deferral if they can't file their reimbursement request within the allotted period. Additionally, grantees have 90 days from the close of the quarter to file and a 30 day grace period during which CPRIT can be communicating with them.

No further discussion.

7. Chief Operating Officer Report

Financial Overview for Fiscal Year 2014, Quarter 2

Ms. McConnell gave the following report:

FY 2014, Quarter 2 Operating Budget

CPRIT expended or obligated approximately \$2.2 million in Indirect Administration in the second quarter (slightly more than 50%). It is expected, with the cost of the peer review meetings, all funds will be expended by the end of the fiscal year.

The agency has also expended almost \$4.9 million in Grant Review and Award Operations (slightly less than 50%). It is expected that with actions today and in August, all funds will be expended.

Debt Issuance History

The agency authorized a \$47 million debt issuance in March, providing \$7.3 million for agency administration—approximately half a year of the agency's total operations including grant review—and \$1.5 million for the transfer to the Department of State Health Services for Texas Cancer Registry operations. The remaining \$38.2 million allows CPRIT to make reimbursement payments due to grant recipients for award expenses.

Ms. McConnell stated changes to CPRIT's reimbursement periods could significantly affect bond issuances. Projecting these will become more difficult, especially if reporting periods are extended. She noted that some of CPRIT's smaller grantee organizations have asked the agency previously to reimburse them on a monthly basis (though all grantees must be treated equally so this has not occurred).

Items Requiring Oversight Committee Action:

1. Amendment to the SRA International Pre- and Post-Award Grants Management Support Contract

- This is the fifth year that SRA has provided support services for CPRIT's pre- and post-award grant operations.
- The contract for this year is about \$7.8 million and is needed to augment CPRIT staff resources for grant applications processing, peer review meeting support, and programmatic review of grant award progress reports. The amount includes direct costs for peer review travel, honoraria, and meeting costs. CPRIT estimated only one full award cycle would take place.
- SRA has submitted a contract amendment for approximately \$1.3 million to continue providing these services and to pay other direct costs from June through August 31, 2014, as it estimates the current contract budget will be fully expended sometime in June. This is because CPRIT has actually completed one grant cycle for 2014 and has started the first cycle for fiscal year 2015.
- With approval from the Oversight Committee, CPRIT will seek authority from the Legislative Budget Board to transfer money from the Research Grant Award appropriations strategy to the Grant Review and Award Operations appropriations strategy to support this cost.

2. Approval to transfer funds to CPRIT's capital budget to pay for construction expenses

- Texas Facilities Commission estimates the cost of moving to new offices in the state-owned Travis Building in February 2015 to be \$1.3 million, the bulk being constructions expenses (estimated to be \$955,700) to prepare the space for occupancy.
- CPRIT does not have capital budget authority for the construction project costs associated with preparing the space in the Travis Building.
- The General Appropriations Act requires the agency's governing board to request approval from the Governor and Legislative Budget Board for CPRIT to transfer from a non-capital budget item to a capital budget item to pay for a capital expenditure.

Mr. Montgomery asked if the SRA was doing a good job. Ms. McConnell responded that SRA has been doing a good job supporting all CPRIT's grant management operations and that CPRIT could not have done what it has in the past five years without that external contract. Mr. Roberts stated that within a year, when the contract is renegotiated, CPRIT may have options that will allow CPRIT to do more of its own support.

Mr. Montgomery asked whether the move to the Travis Building would take care of the agency for a "lifetime." Mr. Roberts responded the space will give CPRIT room for the 32 employees currently authorized, in a mostly cubical style. In the future if CPRIT is authorized more FTE's, the ability of the space to

accommodate that increase is unknown. Also, since the space is state-owned, occupancy is controlled by the Texas Facilities Commission.

Dr. Rosenfeld asked if there were any special or high-priced items in the construction budget. Ms. McConnell responded there is sound proofing and wiring for video conferencing units that is more than some other state agencies require. However, CPRIT owns the equipment and would like to continue to utilize it. Mr. Roberts stated CPRIT will not have full video conference capabilities in the temporary space because of the expense to set up the equipment. The equipment will be put in safe storage and the expense of wiring the temporary space will be saved.

Ms. Mitchell stated that the cost of construction seemed reasonable for the amount of space being renovated.

Mr. Angelou presented the Audit Subcommittee Report:

The Audit subcommittee met on May 16th to discuss various audit issues, including a proposed amendment of CPRIT's contract with SRA International for pre- and post-award grant management services. The Audit subcommittee recommends approval of an amendment to the SRA contract for additional costs associated with grant application processing, peer review meeting support, and programmatic review of grant award progress reports. The contracted amount also includes other direct costs for peer review travel, honoraria, and meetings costs.

Motion:

There being no further discussion, a motion to approve an amendment to the SRA International contract for approximately \$1.3 million was made by Dr. Mulrow and seconded by Ms. Mitchell.

MOTION CARRIED UNANIMOUSLY

Motion:

There being no discussion, a motion to approve CPRIT's request to transfer funds from non-capital budget items to a capital budget item to pay for construction project expenses was made by Mr. Angelou and seconded by Ms. Mitchell.

MOTION CARRIED UNANIMOUSLY

8. Chief Scientific Officer Report

Dr. Kripke gave the following report:

Update on the Research Grants

The Scientific Review Council met on April 17, 2014, to review 25 applications. The number of reviews was unusually high due to the moratorium. The RFA responses

evaluated were for Recruitment of: Established Investigators, Rising Stars, and First-time Tenure Track Faculty.

There were 583 responses to the RFA's for Individual Investigator and High Impact/High Risk grants and are currently under peer review. The peer review meetings will be held next week in Dallas and recommendations will be forwarded to the Scientific Review Council for prioritization.

Dr. Kripke explained that because they are the most popular award, two more individual investigator RFA's are open right now: one untargeted RFA, and two new RFA's for CPRIT: one RFA targeted towards Prevention and Early Detection Research, and one RFA for Cancers of Children and Adolescents. These will close July 26, 2014. New recruitment awards are also open and will run continuously.

In July, it is expected that CPRIT will release RFA's for Multi-Investigator Research (very popular, large and complex to review), Core Facility Support grants that support a number of different investigators), and another round of High Impact/High Risk awards, which provide seed money for generating more grants.

Research Subcommittee

The Research Subcommittee met twice since the last Oversight Committee Meeting. In March the subcommittee discussed the advisory committees and decided to call a meeting of the University Advisory Committee. The subcommittee also discussed nominations to the peer review panels, and the program priorities project. In May, the subcommittee received an update on the pending recruitment awards, reviewed additional nominations, and a follow-up discussion of the meeting with the University Advisory Committee. The subcommittee presented to the Oversight Committee 42 nominations for review panels. Dr. Kripke acknowledged that this is a lot and, when the Review Councils saw how many applications were being received, more review panel members were added.

University Advisory Committee

The University Advisory Committee (UAC) convened on April 30, 2014, in Houston. Dr. Kripke explained this is a statutorily mandated committee. Mr. Roberts requested that the university presidents or provosts nominate people for the 9-member council, whose makeup is also mandated by statute. The minutes were included in the meeting book. The UAC discussed the fact that the majority of grants were in urban areas of the state and that few go to places like West Texas. CPRIT staff and Dr. Rice were part of the meeting and asked the UAC about CPRIT's processes for feedback. Dr. Rice also asked the UAC about the program priorities. The UAC will have a second meeting to discuss input into the priorities project.

Mr. Roberts commented that he was interested in talking to the UAC about diversity to expedite the work of the Oversight Committee Diversity Subcommittee meeting in a while. The UAC understood CPRIT's desire to increase underrepresented groups participation in its programs. CPRIT has training grants that partially serve underrepresented people in the Research program. In addition, state agencies are required to meet state targets for contracting with historically underutilized businesses, but CPRIT has not done comparatively well due to its large contract with SRA.

Dr. Rice commented that he attended the UAC meeting noted that the participants were well engaged. He considers them an asset to the Oversight Committee and asked that members keep them in mind for future consultations.

Mr. Roberts agreed and invited other Oversight Committee members to attend the next UAC meeting. Mr. Roberts also invited OC members to the peer review meetings in Dallas, even if only for a short time.

Dr. Mulrow inquired if CPRIT could use the UAC as a way to inform the universities of our compliance issues. Dr. Rice agreed that it could be an agenda item for the UAC.

Mr. Geren asked how the two new programs were selected (referring to the two RFA's going out). Dr. Kripke's staff proposes RFA's and the committee approves.

Dr. Rice clarified that Mr. Geren was asking how the two particular areas (Prevention or Pediatric research) were chosen—how did Dr. Kripke get the information to make the decision. Dr. Kripke responded that it was mostly based on her experience of being on the President's Cancer Council and working in the cancer field.

Program Integration Committee Recommendations

Mr. Roberts announced that Dr. Kripke would make the presentation of the PIC committee recommendations for Research awards.

Summary of Awards:

Application ID	Institution	Nominated Candidate	Budget*
RR140023	The University of Texas Southwestern Medical Center	First-Time Tenure-Track – Gary Hon	\$2,000,000
RR140027	The University of Texas M.D. Anderson Cancer Center	First-Time Tenure-Track – Priscilla Brastianos	\$2,000,000
RR140052	The University of Texas M.D. Anderson Cancer Center	Established Investigator - John Tanier	\$6,000,000
RR140025	The University of Texas Southwestern Medical Center	First-Time Tenure-Track – Jian Xu	\$2,000,000
RR140042	The University of Texas Southwestern Medical Center	First-Time Tenure-Track – Laura Banaszynski	\$2,000,000
RR140012	The University of Texas M.D. Anderson Cancer Center	First-Time Tenure-Track – Cullen Taniguchi	\$2,000,000
RR140035	Rice University	First-Time Tenure-Track – Samira Azarin	\$2,000,000
RR140036	The University of Texas Southwestern Medical Center	First-Time Tenure-Track – Weibo Luo	\$2,000,000
RR140038	Baylor College of Medicine	First-Time Tenure-Track – Andre Catic	\$2,000,000
RR140033	Baylor College of Medicine	Established Investigator - Matthew Ellis	\$6,000,000
RR140049	The University of Texas Southwestern Medical Center	Established Investigator - Marco Durante	\$3,000,000
RR140053	Texas A&M University Health	First-Time Tenure-Track – Yun	\$1,800,000

	Science Center Institute of Biosciences and Technology	Huang	
RR140013	University of Houston	First-Time Tenure-Track – David Mayerich	\$2,000,000
RR140008	Texas Tech University Health Sciences Center	Rising Stars – Kevin Pruitt	\$2,539,259

Certification of the Slates

Mr. Reisman certified that the three award slates followed procedures and certified them for the Oversight Committee's consideration.

Conflict of Interest Notifications

Dr. Rice noted for the record that the following members reported conflicts of interest with the some of the applications to be considered. Specifically:

Ms. Mitchell reported conflicts with the following applications: RR140008, RR140012, RR140013, RR14023, RR140025, RR140027, RR140033, RR140035, RR140036, RR140038, RR140042, RR140049, RR140052, and RR140053.

Mr. Montgomery reported conflicts of interest with the following applications: RR140013, RR14023, RR140025, RR140035, RR140036, RR140042, RR140049, and RR140053.

In accordance with CPRIT's rules, Ms. Mitchell and Mr. Montgomery were recused from the discussion or action on the applications where they had reported conflicts of interest.

Motion:

There being no discussion, a motion was made by Mr. Holmes and seconded by Dr. Rosenfeld to approve the following seven recommendations made by the Program Integration Committee for First-Time, Tenure-Track Faculty Recruitment Awards: RR140023, RR140025, RR140042, RR140035, RR140036, RR140053, RR14013.

Ms. Mitchell and Mr. Montgomery abstained from voting.

MOTION CARRIED UNANIMOUSLY

Motion:

There being no discussion, a motion was made by Mr. Angelo and seconded by Dr. Mulrow to approve the following three recommendations made by the Program Integration Committee for First-Time, Tenure-Track Faculty Recruitment Awards: RR140027, RR14002, and RR140038.

Ms. Mitchell abstained from voting.

MOTION CARRIED UNANIMOUSLY

Motion:

There being no discussion, a motion was made by Mr. Montgomery and seconded by Mr. Geren to approve the following recommendation made by the Program Integration Committee for one Rising Star Recruitment Award RR00014.

Ms. Mitchell abstained from voting.

MOTION CARRIED UNANIMOUSLY

Motion:

There being no discussion, a motion was made by Mr. Geistweidt and seconded by Mr. Holmes to approve the following recommendation made by the Program Integration Committee for an Established Investigator Recruitment Award to be awarded to UT Southwestern for the Recruitment of Marco Durante.

Ms. Mitchell and Mr. Montgomery abstained from voting.

MOTION CARRIED UNANIMOUSLY

Motion:

There being no discussion, a motion was made by Dr. Mulrow and seconded by Mr. Geren to approve the following recommendation made by the Program Integration Committee for the following 2 applications recommended by the PIC for Established Investigator Recruitment Awards: RR140052 and RR140033.

Ms. Mitchell abstained from voting.

Motion:

Having approved the PIC recommendations for the recruitment grant awards, a motion to delegate contract negotiation authority to the Chief Executive Officer and CPRIT staff and to authorize the Chief Executive Officer to sign the contracts on behalf of the Institute was made by Mr. Montgomery and seconded by Dr. Mulrow.

MOTION CARRIED UNANIMOUSLY

9. Chief Product Development Officer Report

Dr. Goodman gave the following report:

Contract Terms for Product Development Grants

Dr. Goodman presented information on product development grants program principles and strategies. Dr. Goodman identified program strategies and explained how CPRIT should use its resources. He further explained his philosophy for rate of compensation required from commercial grant recipients and revenue sharing. Discussion followed.

Mr. Geren asked why the cap on returns was needed for fairness if the grant was given with the specification of an amount of return and the grantee agreed to those terms. Dr. Rice suggested a detailed discussion could be held by the Product Development Subcommittee and brought back to the committee as a whole for consideration.

Mr. Geistweidt inquired whether CPRIT has received any return revenue. Mr. Roberts responded that it had, around \$700,000. Mr. Geistweidt then inquired where the revenue goes. Mr. Roberts explained that the money goes into a fund and it cannot be spent without legislative appropriation.

Mr. Montgomery asked Dr. Goodman to explain the favorable terms at the start up and end to a company. Dr. Goodman explained the rationale is that CPRIT wants to encourage companies to build businesses in Texas. He further explained that if the company exercises a buyout earlier, then risk is reduced for CPRIT.

Dr. Mulrow expressed concern for companies that might fail early on while funded by CPRIT. Dr. Goodman explained that is why the contracts contain tranches for the grantee to meet.

Dr. Rosenfeld asked what happens when a grantee goes into bankruptcy. Ms. Doyle responded that grant funds and the purchases made with those funds by non-profit organizations are handled differently in bankruptcy. If that situation arises, CPRIT would work with the Attorney General's Office to determine to what CPRIT has rights. Mr. Rosenfeld then asked about intellectual rights. Ms. Doyle responded CPRIT does not have rights to intellectual property of grantees under our contracts.

Mr. Montgomery inquired if there were other models on which rates could be based and how much CPRIT might be leaving on the table. Dr. Goodman replied that the current models are based on balance and he would research other models used.

Dr. Rosenfeld brought up the idea of the state having an observatory board position on various grantee's boards. Ms. Doyle explained that would require a statutory change to have CPRIT sit on the board of a grantee.

Dr. Rosenfeld then presented the Product Development Subcommittee recommendation to execute the awards pursuant to the terms as presented by Dr. Goodman.

Conflict of Interest

Dr. Rice noted that Ms. Mitchell had previously disclosed a conflict of interest with two of the companies, ESSA Pharmaceuticals and DNATRIX, and she was recused from the discussion or action on this application.

Motion:

There being no further discussion a motion to delegate authority to the CEO to execute award contracts consistent with the terms discussed here today for the companies Beta Cat

Pharmaceuticals, CerRX, and ProPep Surgical was made by Mr. Angelou and seconded by Mr. Montgomery.

MOTION CARRIED UNANIMOUSLY

Motion:

There being no further discussion a motion to delegate authority to the CEO to execute award contracts consistent with the terms discussed here today for the companies ESSA Pharmaceuticals and DNatrix was made by Mr. Angelou and seconded by Mr. Montgomery.

Ms. Mitchell abstained from voting.

MOTION CARRIED UNANIMOUSLY

Established Company Product Development Award Recommendations

Dr. Goodman presented the Program Integration Committee's recommendations for two Established Company awards: AERase (\$19,806,145) and Mirna Therapeutics (\$25,147,614).

Established Company Product Development Award Recommendations

Summary of Slates

Application ID	Company Name	Project	Budget
DP140031	AERase, Inc.	Pre-IND Development, Phase I Clinical Trials, & Predictive Evaluation, for Engineered Human Arginase Targeting the Metabolic Vulnerability of Tumors	\$19,806,145
DP140067	Mirna Therapeutics, Inc.	Preclinical and Clinical Development of Synergistic MicroRNA + Targeted Drug Combinations	\$25,147,614

Certification of Slates

Mr. Reisman certified that the slates followed procedures and certified them for the Oversight Committee's consideration.

Dr. Rosenfeld inquired about the budget. Ms. Doyle explained that the amount approved by the Oversight Committee is just a maximum amount.

Conflict of Interest

Dr. Rice stated Ms. Mitchell had reported a conflict of interest with application ID number DP140067. In accordance with CPRIT's rules, Ms. Mitchell was recused from the discussion or action on this application.

Motion:

There being no further discussion, motion to approve the PIC's funding recommendation for the AERase to receive an Established Company Product Development Award in an amount not to exceed \$19,806,145 was made by Dr. Rosenfeld and seconded by Mr. Holmes.

MOTION CARRIED UNANIMOUSLY

Motion:

There being no further discussion, a motion to approve the PIC's funding recommendation for Mirna Therapeutics to receive an Established Company Product Development Award in an amount not to exceed \$25,147,614 was made by Mr. Montgomery and seconded by Dr. Rosenfeld.

MOTION CARRIED UNANIMOUSLY

Ms. Mitchell abstained from voting.

Motion:

Having approved these companies for product development slates, a motion to delegate contract negotiation authority to the Chief Executive Officer and CPRIT staff was made by Mr. Holmes and seconded by Mr. Angelou.

MOTION CARRIED UNANIMOUSLY

Authorization to Disburse Grant Funds by Advance Payment

Mr. Rice stated that Mr. Roberts notified the Oversight Committee by letter on May 15, 2014, indicating that he seeks authority to disburse grant funds in advance to AERase and Mirna Therapeutics, as well as for the six companies with awards ratified at the February 2014 meeting.

Mr. Rosenfeld asked for an explanation of advance payment. Ms. Doyle stated advance payment of grant funds is done only after an executed contract is signed and only with Oversight Committee approval after receiving justification for the advance payments.

Motion:

Pursuant to the General Appropriations Act, Article IX, Section 4.03(a), a motion to authorize CPRIT to disburse grant funds via advance payments to the eight Product Development Award recipients (CP130013, CP130020, CP130023, CP130050, CP130058, CP130066, DP140031, and DP140067) was made by Mr. Holmes and seconded by Mr. Montgomery.

MOTION CARRIED UNANIMOUSLY

10. Chief Prevention and Communications Officer Report

Dr. Garcia presented the Chief Prevention and Communications Officer Report. There were no prevention grants up for approval by the Oversight Committee. However, for the next review cycle Dr. Garcia explained two RFA's will be released: Evidence-Based and Competitive Continuation/Expansion. Dr. Garcia gave a communications update and told the Oversight

Committee that there was approval for CPRIT to work with Hahn Public Communications, which is important to promote the work of CPRIT. Dr. Rice asked if there were any questions or discussion. None was heard.

12. CPRIT's Programs Priority Project

Dr. Rice asked Dr. Garcia and Mr. Roberts to provide an update on the Programs Priority Project. Dr. Garcia gave a brief introduction of the project, which is to set priorities for CPRIT. As requested, a facilitator had been identified to guide the agency through this process. Robert Mittman was introduced and gave a presentation to the Oversight Committee of the project process.

Mr. Geren commented that CPRIT is responsible to the Legislature for responsible use of public funds. He suggested CPRIT should think of the state as a whole to determine where Texans would want their funds invested. He requested the agency examine the incidence of certain types of cancers in Texas and areas where more cancer appears and consider those when setting priorities.

Mr. Mittman commented that would be a logical way to proceed.

Dr. Mulrow would like to see more background information about environmental effects on cancer and whether CPRIT might be able to help fill gaps in that area.

Mr. Geren asked Mr. Mittman to compare Texas to other states and have that information available as CPRIT considers priorities.

11. Appointments to Scientific Research and Prevention Programs Committees

Dr. Rice recognized Mr. Holmes to lay out the Nominations Subcommittee recommendation related to the Chief Executive Officer's appointments to the Scientific Research and Prevention Program Committees.

Mr. Holmes stated the subcommittee discussed the Chief Executive Officer's appointments and recommended approval of the CEO's 58 appointments to CPRIT's Scientific Research and Prevention Program Committees, which were provided electronically to the Oversight Committee.

Dr. Rosenfeld commented that several of the people nominated had exceptional qualifications.

Motion:

There being no further discussion, a motion to approve the Chief Executive Officer's appointments to the Scientific Research and Prevention Programs Committees was made by Mr. Angelo and seconded by Ms. Mitchell.

MOTION CARRIED UNANIMOUSLY

13. Acceptance of a Donation Pursuant to Texas Health and Safety Code §102.054

Dr. Rice called on Ms. Doyle to explain the donation. Ms. Doyle stated the agency is statutorily authorized to accept gifts and grants for any purpose. CPRIT's Administrative Rule §702.7 requires gifts exceeding \$10,000 to be accepted by the Executive Subcommittee of the Oversight Committee. However, there is no such subcommittee currently. Therefore, the donation is being presented to the full Oversight Committee. The \$29,877 donation is from the Texas Cancer Coalition Liquidating Trust and is a result of the settlement with the CPRIT Foundation. CPRIT staff notified the Audit Subcommittee of the donation and it was discussed at the subcommittee's May 16, 2014, meeting.

Dr. Rice then called on Mr. Angelo as chair of the Audit Subcommittee, to give their recommendation. Mr. Angelo stated the subcommittee recommends the Oversight Committee accept the donation on behalf of the Institute.

Motion:

A motion was made by Mr. Geren and seconded by Ms. Mitchell to accept the donation of \$29,877 from the Texas Cancer Coalition Liquidating Trust and to designate the use of the funds for peer review expenses.

MOTION CARRIED UNANIMOUSLY

Dr. Rice stated this gift will be listed on CPRIT's website.

14. Agency Strategic Plan

Dr. Rice called on Mr. Roberts and Ms. McConnell to present the agency's Strategic Plan.

Ms. McConnell stated the plan is a required legislative report at the beginning of the biennial budget cycle. CPRIT's plan is due on June 23, 2014. The structure of the plan is set by the Legislative Budget Board and the Governor's Office of Budget, Planning and Policy. The document must be signed by the chair of the Oversight Committee.

Mr. Angelo, Chair of the Audit Subcommittee, stated that the subcommittee met on May 16 to discuss the Strategic Plan and recommends that the Oversight Committee give its approval.

Motion:

There being no further discussion, a motion to authorize the Chair to sign a final draft of the Strategic Plan and approve transmittal to the appropriate offices was made by Mr. Montgomery and seconded by Mr. Angelou.

MOTION CARRIED UNANIMOUSLY

15. Legislative Appropriations Request

Ms. McConnell stated the Legislative Appropriations Request (LAR) is due in early August. The draft LAR reflects a request for \$600 million in general obligation bond proceeds for the 2016-17 biennium, \$300 million per year. The structure of the plan is set by the Legislative Budget Board and the Governor's Office of Budget, Planning and Policy. The Oversight Committee must approve the document and its transmittal to the appropriate offices.

Mr. Angelo, Chair of the Audit Subcommittee, stated that the subcommittee met on May 16, 2014, to discuss the LAR and recommends approval. In the event the Oversight Committee does not meet again before the LAR is due, the Audit Subcommittee will review the final LAR prior to submission.

Motion:

There being no further discussion, a motion to approve the draft LAR, subject to final review by the Audit Subcommittee, was made by Mr. Angelo and seconded by Mr. Montgomery.

MOTION CARRIED UNANIMOUSLY

16. Authorization for Request for Financing to Texas Public Finance Authority and Bond Review Board

Dr. Rice called on Ms. McConnell to describe the resolution that needs to be approved in order for the Texas Public Finance Authority (TPFA) to issue debt on behalf of CPRIT in FY 2015.

Ms. McConnell stated that CPRIT expects to request that TPFA issue \$241.6 million in commercial paper notes four times in FY 2015 on behalf of CPRIT to pay for administrative operations and reimbursement/advance disbursement of grant funds made in FY 2011-2014, and potentially 2015. The resolution requesting these issuances must be signed by the Oversight Committee chair and attested to by the Secretary. The resolution and description of the process is provided in the Oversight Committee Meeting book.

Mr. Angelo stated that the Audit Subcommittee met on May 16, 2014, to discuss the request for financing and recommends approval of the resolution.

Motion:

There being no further discussion, a motion to approve *A Resolution Authorizing A Request for Financing and the Execution and Delivery of Documents Required to Effect Such* and to authorize the Oversight Committee Chair and Secretary to sign the resolution was made by Mr. Angelou and seconded by Mr. Holmes.

MOTION CARRIED UNANIMOUSLY

17. Internal Audit Report Status

Ms. McConnell provided an update on the status of the Internal Audit. Three audits (Expenditure, Governance, and SRA-managed IT systems) are currently underway. Two more audits (Information Technology and Grants Management) are scheduled to begin in June.

There were no questions for Ms. McConnell.

18. Proposed Amendments to 25 T.A.C. Chapters 701-703 and Authorization to Publish in the Texas Register

Ms. Doyle summarized the rule changes contained in the agenda packet. The proposed changes will be published in the Texas Register so that public comment can occur. A final version is expected to be considered at the August meeting.

Dr. Rice noted a memo from the Board Governance Subcommittee Chair recommending approval of the proposed changes.

Motion:

There being no further discussion, a motion to instruct staff to publish the proposed rule amendments to Chapter 702 and 703 in the *Texas Register* in accordance with the requirements of the Administrative Procedure Act as proposed was made by Mr. Geren and seconded by Ms. Mitchell.

MOTION CARRIED UNANIMOUSLY

19. Proposed Amendments to Bylaws and Code of Conduct

Ms. Doyle was called to address the proposed changes to the Oversight Committee Bylaws and Code of Conduct. She stated that the proposed changes were located in the agenda packet.

Bylaws:

- Change at Section 4.4(a)(ii) to delete text to remove a conflict with a statutory provision.
- Change at 8.6(b) to update the name of the “Commercialization Advisory Committee” to the “Product Development Advisory Committee.”

Code of Conduct:

- Section IV “Gifts and Entertainment” recommending the wording “Chief Compliance Officer” to track the exact words of the Penal Code.

Dr. Rice stated that there was a memo from the Board of Governance Subcommittee Chair recommending approval of the changes.

Motion:

There being no further discussion, a motion to adopt the amendments to the Oversight Committee Bylaws and Code of Conduct as proposed by made by Mr. Geren and seconded by Ms. Mitchell.

MOTION CARRIED UNANIMOUSLY

20. Subcommittee Business

Dr. Rice stated that CPRIT staff provided a schedule for standing subcommittee meetings to be held the two weeks prior to each Oversight Committee Meeting. Setting the standing meetings would ensure that only one subcommittee meeting is held per day. It would allow members to plan for these meetings in advance.

21. Consultation with General Counsel

The Oversight Committee went into closed session at 2:37 p.m. to consult with CPRIT General Counsel pursuant to Texas Open Meetings Act § 551.071.

The board reconvened in open session at 3:22 p.m. No action was taken.

22. Future Meeting Dates and Agenda Items

Dr. Rice announced the next Oversight Committee meeting would be held on August 20, 2014. CPRIT staff will circulate a tentative agenda prior to the meeting.

23. Adjourn

There being no further business, Chair Rice moved to adjourn the meeting and Dr. Mulrow seconded.

MOTION CARRIED UNANIMOUSLY

Meeting adjourned at 3:23 p.m.



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT: AGENDA ITEM 5: CHIEF EXECUTIVE OFFICER REPORT
DATE: AUGUST 13, 2014

Behind this memo are copies of the June 30 and July 29, 2014, CPRIT Activities Update reports. These updates began in March to provide an overview of significant or unique staff activities that occur in the months the Oversight Committee (OC) does not meet. Some topics will be repeated or updated as needed at the quarterly meetings.

As of this writing, the Chief Executive Officer Report for the August 20, 2014, Oversight Committee (OC) meeting includes the following:

1. New Employees, Title Changes and Status of CPRIT staff vacancy postings

- The following new employees will be introduced to the OC:
 - Cathy Allen, Grant Specialist
 - David Escamilla, Grant Specialist
 - Mark McCollum, Grant Specialist
 - Wilfredo "Freddy" Ruiz, Grant Accountant
- Charlotte Craig, our new purchaser, unfortunately left the agency on Friday, August 15 to pursue an opportunity with another agency. The vacant position is currently posted.
- *Manager of Internal Audit* – As of this writing two internal audit candidates will be interviewed on Friday, August 15 and it is my intent to recommend a finalist for the OC Audit Subcommittee to interview prior to the August 20 OC meeting. At the November 1, 2013, meeting the OC decided that CPRIT staff will screen initial applicants and identify candidates to be interviewed by the Audit Subcommittee. The subcommittee will then recommend a finalist to the OC for final approval.
- *Program Manager for Product Development* – Tom Goodman, Chief Product Development Officer, has completed the initial round of interviews to fill this position. Follow-up interviews are scheduled next week.

2. Facilities Update

Agency staff will pack the office on Thursday, August 21 for the move on Friday. Agency staff should be available on Monday, August 25 and fully operational by Tuesday. As of this writing all of the various moving parts of the move appear on schedule.

3. Update on Legislative Activities

- A verbal report on the agency's testimony on Thursday, August 13, 2014, to the Senate Committee on Health & Human Services will be given. Materials distributed to the committee will also be provided at the August 20 OC meeting.
- CPRIT is also scheduled to testify on September 24, 2014, in Houston before the House Select Committee on Economic Development Incentives. We will provide a 10 minute overview of CPRIT's activities focusing on our economic development incentives and how they benefit Texas.

4. Compliance Program Design Report

Weaver and Tidwell LLP, a Texas-based assurance, tax and advisory firm, provided a preliminary report on the results of its compliance program design for CPRIT pursuant to a \$99,000 consulting contract approved by the Governor's Office in June. Among other things, the report identifies best practices in grant management, provides strategic guidance and direction, and provides two options in how to provide the additional personnel to implement their proposal (additional state employees and/or outsourcing). As presented, the proposal could require a considerable increase in staffing. A final report from Weaver is expected on Friday, August 15. Consequently, CPRIT staff will not have time to review the report adequately for a full report to the OC at the August 20 meeting. Copies of the report will be provided to the OC Audit Subcommittee for evaluation and consideration.

5. Other Topics May be Added as Warranted

CPRIT has awarded **528** grants totaling **\$938.7 million**

- 115 prevention awards totaling \$96.7 million
- 413 academic research and product development awards totaling \$842 million

Of the **\$842 million** in academic research and product development awards

- 30.6% of the funding (\$250.3 million) supports clinical research projects
- 26.2% of the funding (\$214.2 million) supports translational research projects
- 21.7% of funding (\$177.6 million) supports recruitment awards
- 17.9% of the funding (\$146.5 million) supports discovery stage research projects
- 3.6% of funding (\$29.5 million) supports training programs.

CPRIT has 9 Requests for Applications (RFAs) that are open or will open soon:

- 3 Product Development (open August 25)
- 6 Research (Recruitment applications opened June 12, others open September 30)



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT: CPRIT ACTIVITIES UPDATE
DATE: JULY 29, 2014

Topics in this update include: Oversight Committee preparations, CPRIT staffing, office relocation activities, the Program Priority Setting Project, Program updates, Compliance Plan Design status, ethics training, subcommittee meetings, operations (including contracts and audits), ongoing projects, and outreach efforts.

I am out of the office until Monday, August 4. If you have any questions or need more information before I return concerning operations, please contact Heidi McConnell (512/305-8487) or Kristen Doyle (512/305-8486). Questions concerning the programs should go directly to Margaret Kripke, Becky Garcia, or Tom Goodman.

Preparation for the August 20 Oversight Committee Meeting

The Oversight Committee will meet August 20 at 10:00 in the Texas Capitol Extension. The final agenda for Oversight Committee will be posted August 12; a tentative agenda is attached to this memo.

A major agenda item will be consideration and approval of the Program Integration Committee (PIC) award recommendations. The PIC met July 15 to review the grant award recommendations made by the Scientific Research, Product Development and Prevention Review Councils and unanimously approved a list of more than 100 award recommendations totaling approximately \$107 million for the Oversight Committee's consideration.

CPRIT will send you an email with a link and password to access the PIC's recommendations via the grant award portal on or before August 5, 2014. The portal will have supporting documentation regarding each project proposed for an award, including the application, CEO affidavit, summary statement, grant pedigree, and due diligence report (if applicable). Summaries of each award slate have been prepared by the Program Officers and are also available through the portal. Please allow time to complete the individual conflict of interest checks and review the supporting material.

Our intent is to distribute the agenda packet to Oversight Committee members by COB August 13. CPRIT will hand deliver hard copies of the agenda packet to all members residing in Austin. Hard copies will be brought to the Oversight Committee meeting for all out-of-town members.

New Hires and Job Openings

Wilfredo “Freddy” Ruiz started work as a grant accountant for CPRIT on July 1. Mr. Ruiz reports to CPRIT’s Chief Operating Officer Heidi McConnell. Since the Oversight Committee was reconstituted in November, nine new people have joined CPRIT. With the addition of Mr. Ruiz, the agency now has 28 full-time equivalent (FTE) employees and is authorized to employ up to 32 FTEs.

Job postings for two positions, the Manager of Internal Audit and the Program Manager for Product Development, closed July 11. Interviews with qualified candidates for these positions are taking place this week. Because the Internal Auditor will report directly to the Oversight Committee, the Audit Subcommittee will conduct the final Internal Auditor candidate interviews and are expected to make a recommendation to the Oversight Committee for approval at the August 20 meeting.

Position postings for the two remaining FTEs (finance team member and operations specialist) will be posted in August.

Office Relocation and Move to Temporary Offices

CPRIT must vacate its current leased space by August 31. CPRIT’s move to state-owned space in the William B. Travis Building, originally planned for August 2014, is now projected to occur in February 2015. The additional time is necessary to complete construction and renovation of the state space.

The Texas Facilities Commission identified temporary space for CPRIT staff in the Wells Fargo Building, 400 West 15th Street, for the period August 2014 - February 2015. Some preparatory IT work is taking place now with the office move planned for August 23-24. CPRIT staff will report to the new space August 25. Our goal is to minimize disruption in CPRIT activities by scheduling the bulk of the move over the weekend following the August 20 Oversight Committee meeting.

Compliance Program Design Project

As I reported last month, Weaver and Tidwell LLP, a Texas-based assurance, tax and advisory firm, is developing a compliance program design plan for CPRIT pursuant to a \$99,000 consulting contract approved by the Governor’s Office in June. The plan will 1) incorporate best practices in grants management organizations and provide strategic guidance and direction; 2) outline one or more options for an organizational structure that ensures accountability for the operational controls and mechanisms to regulate grant pre-award, award, and post-award processes; and 3) will include a risk assessment, compliance monitoring model, hotline and reporting processes, and a training model and curriculum. The 60-day project is nearing completion. An exit conference is scheduled with Weaver for August 13 with a final report release expected prior to the August 20th Oversight Committee meeting.

Ethics Training

As of this month, 100% of agency staff has completed online ethics training, the first part of a two part ethics training program. The online ethics training is based on general state ethics laws while the second part of the ethics training program consists of face-to-face training focusing on CPRIT-specific ethics issues and requirements. The face-to-face training sessions will be conducted by David Reisman, CPRIT’s Chief Compliance Officer. Staff training is scheduled for August 7 - 8, 2014. Staff will

coordinate with the Oversight Committee on scheduling periodic ethics training for members to be held in conjunction with Oversight Committee meetings.

Program Priority Setting Project

Robert Mittman, facilitator for the CPRIT's Program Priority Setting Project, met with each of the three program subcommittees in Austin on July 16 and 17. Each subcommittee discussed what long-term success would look like for CPRIT's product development, scientific research and prevention activities. The subcommittees also discussed high-level priorities and guidelines for grant-making decisions, as well as guidance for balancing priorities across programs. The work done by each subcommittee sets the stage for the Oversight Committee working session scheduled for September 3 in Austin.

Scientific Research Program Update

In addition to preparing its slate of 84 FY 2014 grant award recommendations for review and approval by the PIC and the Oversight Committee, the Scientific Research Program (SRC) released three new Requests for Applications (RFAs) this month.

- SRC Recommendations for FY 2014 Recruitment Applications: The SRC met July 11 to consider 16 recruitment award applications. The applications included seven for First-Time Faculty awards, six for Rising Star awards, and three for Established Investigator awards. On July 14 SRC Chair Dr. Richard Kolodner sent a letter to the Oversight Committee Presiding Officer and the Program Integration Committee (PIC) with the SRC's recommendations to award eight recruitment grants.

The eight recruitment grant award recommendations totaling \$22 million will be presented at the August 20 Oversight Committee meeting along with the 76 Individual Investigator and High Impact-High Risk grant award recommendations totaling \$54,665,415.

- FY2015 Individual Investigator Research Award (IIRA) Applications: The chairs of the scientific research peer review panels have begun assigning applications to panel members to begin the reviews of more than 400 applications submitted on June 26 in response to three RFAs. In addition to the traditional IIRA, applications were submitted for two targeted IIRA RFAs, one for childhood and adolescent cancer and another for cancer prevention research. Included among the submissions were 57 applications for the targeted childhood cancer IIRA and 66 applications for the targeted prevention research IIRA. These applications will be considered at peer review meetings to be held in October - November 2014.
- FY2015 High Impact-High Risk and Core Facility Support Award Applications: RFAs for Core Facility Support awards and High Impact-High Risk awards were released July 14. Proposals are due November 17, with peer review expected to occur December 2014 – March 2015.
- FY2015 Multi-Investigator Research Award Request for Applications: An RFA was released July 24 for this scientific research mechanism. Applications are due November 17, with peer review expected to occur December 2014 – March 2015.

Product Development Program Update

Much of the Product Development Program work in July focused on finalizing contracts for several company awards that were announced at the February Oversight Committee meeting, reviewing applications submitted for FY2015 product development awards, and preparing two grant award recommendations for PIC and Oversight Committee approval.

- Grant Contract Status for Awards Announced in February and May: CPRIT has executed contracts with CerRx, DNATRIX, and ESSA Pharmaceuticals pursuant to terms that were approved by the Oversight Committee on May 21. The contracts for ProPep Surgical and Beta Cat Pharmaceuticals are taking somewhat more time, but are expected to be finalized in August.

Contract negotiation is also underway with Mirna Therapeutics and AERase, the two product development awards announced at the last Oversight Committee meeting. Dr. Goodman expects to present contract terms for the Oversight Committee's approval at the August 20 meeting.

Some of the companies approved for CPRIT Product Development grants have contacted CPRIT with concerns about the standardized revenue sharing terms presented at the May 21 Oversight Committee meeting. Dr. Goodman has presented his suggestions to the Product Development Subcommittee to address issues raised by the companies and will work with the Subcommittee members. Revenue sharing term modification may be recommended by the Subcommittee; if approved by the Oversight Committee, the changes would be applied as amendments to the contracts already executed.

A company that was recommended for an award at the February meeting, ProNAi Therapeutics, notified CPRIT on July 11 that it declined CPRIT's \$14 million relocation grant and will remain closer to its existing investors in Michigan.

- FY2015 Cycle 1 Product Development Grant Applications: CPRIT's Product Development review panels met July 15 and 16 to discuss 30 grant applications and determine which companies will move forward to the in-person presentation phase of the review process. The panel discussions followed in-depth review conducted by individually-assigned reviewers in June and early July. Seventeen companies will be invited for in-person presentations to the full product development review panels in Dallas taking place August 12 – 15. FY2015 Cycle 1 Product Development award recommendations are expected to be presented for approval at the November 19 Oversight Committee meeting.
- FY2015 Cycle 2 Bridging the Gap: Early Translational Research Awards (ETRA) Request for Applications: CPRIT began accepting applications for ETRA product development grants on June 26. The deadline for applications is August 7. This is the first ETRA RFA issued by the Product Development Program. The ETRA RFA was previously released by the scientific research program; however the scientific research and product development programs agreed that the product development review panels may have more targeted expertise for the review of ETRA proposals. This RFA adds a requirement that a business plan be submitted during the first year of the grant. In addition, with the aim of attracting entrepreneurial management, CPRIT increased the maximum potential amount of the grant

award from \$1 to \$2 million. ETRA grant recommendations will be considered by the Oversight Committee at its November 19 meeting.

- FY2015 Cycle 3 Product Development Request for Applications: CPRIT released three RFAs for Company Relocation, Established Company, and New Company product development awards on July 21. CPRIT will accept applications August 25 through September 29. Award recommendations may be presented for approval by the Oversight Committee meeting at its May 2015 meeting.

Prevention Program Update

This month the Prevention Program began reviewing applications submitted for the first round of FY 2015 grant awards and finalized the 15 FY 2014 grant award recommendations for approval by the PIC and the Oversight Committee in August.

- FY2014 Cycle 2. The Prevention Review Council finalized the FY 2014 recommendations for 15 grant awards and submitted them to the Oversight Committee Presiding Officer and the Program Integration Committee (PIC) on July 3, 2014. Award recommendations will be presented for approval by the Oversight Committee at its August 20 meeting.
- FY2015 Cycle 1 Request for Applications: CPRIT received 16 applications in response to two RFAs, Evidence Based Cancer Prevention Services and Competitive Continuation/Expansion. The applications have been assigned to reviewers and the recommendations for awards from this cycle will be presented to the Oversight Committee on November 19. In order to get back to a pattern of having two application cycles per year, we released these RFAs only three months after the previous release of RFAs. We anticipated the number of applications this cycle to be low due to the short time between the two releases. The review of these applications will be held via teleconference.

Standing Subcommittee Meetings in August

At its May meeting the Oversight Committee directed CPRIT staff to propose standing dates for the seven subcommittee meetings that take place during the two weeks prior to an Oversight Committee meeting. A schedule for the subcommittee meetings was distributed in early July with proposed dates through November 2015. My executive assistant, Mary Gerdes, followed up with calendar invites sent to Oversight Committee members and their assistants. If you or your assistant did not receive a calendar invite from Mary for meeting dates in August 2014, November 2014, February 2015, May 2015, August 2015, please contact Mary at mgerdes@cprit.state.tx.us.

The dates and times for the August subcommittee meetings are listed below:

Audit –	August 7 at 10:00
Diversity –	August 8 at 10:30
Scientific Research –	August 11 at 1:00

Prevention – August 12 at 10:00

Board Governance – August 13 at 10:00

Product Development – August 14 at 3:00

Nominations – August 15 at 10:30

An agenda, call-in information and supporting material will be sent to the subcommittee at least one week prior to the meeting date.

Communications

- Working with Hahn Public Communications, staff has prepared materials and templates for use with the new CPRIT logo (with the state seal) for distribution to all CPRIT communications channels including CPRIT grantees.
- Another of Hahn's key assignments is to develop and implement plans to share and promote CPRIT's accomplishments. We are working on creating a comprehensive CPRIT message platform which will ultimately be used across all audiences and communications activities of the agency.
- Communications staff revised and prepared a 2015 Conference budget and venue RFP. The RFP and budget will be forwarded to the Audit Subcommittee prior to the RFP being sent to Austin area hotels.
- CPRIT is also in discussion with Texas Public Broadcasting Association to explore options to participate in the premiere of Ken Burn's new documentary on the *Emperor of All Maladies: A Biography of Cancer* in Texas.
- Announcements regarding the release of new Research and Product Development RFAs were sent out via our available communications channels.

Operations and Finance (Contracts, RFPs, Internal Audit)

CPRIT's operations staff has been primarily involved with completing year-end reports, preparing the 2016-2017 biennium budget request (see Ongoing Projects), debt issuance, major contract amendments, office relocation, and working with internal auditors to complete several reports.

- TPFA Debt Issuance: TPFA considered CPRIT's FY2015 debt issuance at its meeting on July 10. As part of this process, the Texas Bond Review Board discussed the debt issuance for CPRIT at its planning meeting on July 8 and approved the debt issuance at its open meeting on July 17. The funding from this debt issuance will pay CPRIT operating costs, the SRA International grants management support contract, and grant expenditures from FY 2011, 2012, 2013, 2014, and 2015 prevention, research and product development awards.
- FY2014 Contract Amendment and FY2015 RFP with SRA International: CPRIT finalized the \$1.3 million contract amendment with SRA International, Inc. for continued pre- and

post-award grants management support through August 31 pursuant to the Legislative Budget Board's approval of additional appropriations authority and contracting. On July 3, CPRIT issued a proprietary purchase Statement of Work through the Texas Multiple Award Schedule (TXMAS) purchasing program administered by the Comptroller's Office for pre- and post-award grants management support for the period September 1, 2014, through August 31, 2015. The one year contract is intended to maintain full support for CPRIT's grant activities while the agency explores options for a multi-year grant management services contract.

- Internal Auditor Reports: The internal auditor, Grant Thornton, LLP, completed field work for the audits on governance, information technology, grants management, and the SRA-managed information technology systems according to the schedule in the 2014 Audit Plan. Field work for the 10 grantee audits is underway, and the reports will be completed by August 31.

Ongoing Projects

- Request for Legislative Appropriations: State agencies received instructions from the Legislative Budget Board (LBB) and the Office of the Governor on June 16 to prepare budget requests for the 2016-17 biennium. CPRIT's request is due August 4. A panel of LBB and Governor's Office staff will conduct a public hearing for CPRIT to present our request and respond to questions from the panel. Public comment will also be received by the panel concerning our request at that time. I will request some Oversight Committee representation at that hearing.

Legislative Activities

Opportunities to meet with legislators have slowed down during the summer but should pick up again in the fall.

Several major changes have occurred in legislative committee assignments that could affect CPRIT. Senator Nelson, former chair of the Senate Committee on Health and Human Services (HHS), was named chair of the Senate Committee on Finance. She will remain a member of the HHS committee. Senator Charles Schwertner was named chair of Senate HHS. Senators Estes and Eltife were appointed to the important Legislative Budget Board to replace Senators Williams and Duncan. Speaker Straus appointed Representatives Drew Darby, John Zerwas, and John Otto to the LBB to replace departing members.

Although the committee hearing has not been officially announced at this time, it is likely that the Senate HHS Committee will hold a hearing on August 14. CPRIT will make a presentation regarding the agency's implementation of SB149. Other agencies will also be making presentations unrelated to CPRIT.

Staff Presentations/Meetings

CPRIT program chiefs and I addressed Houston community leaders at the Houston Technology Center on July 10. This event allowed us to publicize CPRIT activities and to enhance professional networks.

Senior staff met with representatives from cancer advocacy groups on July 11 to update them on CPRIT activities since November 2013 and to discuss opportunities for positive messaging and potential legislative and media outreach.

Dr. Garcia has been invited by the American Cancer Society to attend a National Colorectal Cancer Roundtable discussion August 6 in Arlington, Texas, to explore opportunities to collaborate and network with other leaders in the Texas healthcare industry.

CPRIT has awarded 544 grants totaling **\$997,101,232**.

- 115 prevention awards totaling \$96.7 million
- 429 academic research and product development awards totaling \$900.4 million

Of the **\$900.4 million** in academic research and product development awards

- 32.8% of the funding (\$295.2 million) supports clinical research projects
- 23.8% of the funding (\$214.2 million) supports translational research projects
- 23.9% of funding (\$214.9 million) supports recruitment awards
- 16.2% of the funding (\$146.5 million) supports discovery stage research projects
- 3.3% of funding (\$29.5 million) supports training programs.

CPRIT has four open Requests for Applications (RFAs). Six more RFAs will open in August or September.



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT: CPRIT ACTIVITIES UPDATE
DATE: JUNE 30, 2014

Topics in this update include: staff and office developments, the Compliance Program Design Project, Program Priority Project, Program updates, Operations (including contracts and audits), ongoing projects, and outreach efforts.

If you have any questions concerning matters discussed in the update, please contact me at 512/305-8416.

New Hires, Personnel Changes, and Job Openings

Several new people joined the agency in June and one staff member announced his resignation:

- Charlotte Craig started work as a procurement specialist on June 2. Charlotte is certified as a contract manager; filling this position with an individual with her certifications addresses a post-payment audit recommendation from the Comptroller of Public Accounts. Charlotte is a member of our finance team and reports to Heidi McConnell, Chief Operating Officer.
- Three grant specialists (Cathy Allen, David Escamilla, and Mark McCollum) also started work on June 2. The grant specialist team, including Grant Specialist Manager Sandra Balderrama, reports directly to Kristen Doyle, Chief Advisor and General Counsel, as well as to David Reisman, Chief Compliance Officer.
- A third grant accountant, Wilfredo "Freddie" Ruiz, begins work July 1. Freddie will be a member of our finance team and report to Heidi.
- Alfonso Royal, Finance Manager, resigned effective July 7 to take a position at the Texas Lottery Commission. This is career advancement for Alfonso who has been with CPRIT since 2009. His position will be posted as soon as possible.

With these staff changes, CPRIT now has 28 full-time equivalent (FTE) employees. The agency is authorized to employ up to 32 FTEs. CPRIT has two current job postings that will close July 11 (described below). The position postings for the two remaining FTEs (finance team member to replace Alfonso Royal and contract administrator) are expected to be posted in July or August.

Since the Oversight Committee was reconstituted in November, nine new people have joined CPRIT.

- Manager of Internal Audit: Open until July 11, this is a reposting that incorporates changes suggested by State Auditor John Keel, who I contacted concerning the difficulty in identifying suitable applicants. Final interviews of qualified candidates and the hiring decision will be made by the Audit Subcommittee since the Internal Auditor will report directly to the Oversight Committee.
- Program Manager for Product Development: Open until July 11. This position will assist the Chief Product Development Officer, Dr. Tom Goodman, and report to him.

Office Relocation and Move to Temporary Offices

As reported previously, CPRIT's move to state-owned space in the William B. Travis Building, originally planned for this August, is now projected to occur in February 2015. The additional time is necessary to complete construction and renovation of the state space that CPRIT will occupy. Although the start of construction was delayed because CPRIT's new space is currently occupied, a contract with the Texas Facilities Commission (TFC) is now complete and renovation should begin soon.

Since CPRIT's current office space has already been leased to new tenants that will take occupancy on September 1, TFC identified temporary space for CPRIT staff in the Wells Fargo Building, 400 West 15th Street. An existing lease between TFC and the owners of the Wells Fargo Building was modified to accommodate CPRIT for the period August 2014-February 2015. We expect to begin moving to the temporary space on August 21, the day after the next Oversight Committee meeting.

Compliance Program Design Project

After receiving appropriate consulting contract approval by the Governor's Office, CPRIT contracted with Weaver and Tidwell LLP, a Texas based assurance, tax and advisory firm, for an amount not to exceed \$99,000 to develop a compliance program design plan for the agency. The plan will incorporate best practices in grant management organizations and provide strategic guidance and direction. Weaver will outline one or more options for an organizational structure that ensures accountability for the operational controls and mechanisms to regulate the grant pre-award, award, and post-award processes. The plan will also include a risk assessment, compliance monitoring model, hotline and reporting processes, and a training model and curriculum. The 60-day project is to be completed by mid-August.

Program Priority Project – Subcommittee Meetings in July

Robert Mittman, the founder of Facilitation, Foresight, Strategy and facilitator for the CPRIT's Program Priority Setting Project will meet with each of the three program subcommittees July 16 and 17. In preparation for the July subcommittee meetings, Mr. Mittman is scheduling calls with me, the Program Officers and Subcommittee Chairs. The subcommittee input will help set the stage for the Oversight Committee working session that will take place on September 3.

Scientific Research Program Update

Most activity within the Scientific Research Program has been devoted to peer review of grant applications and issuing new RFAs.

- Peer Review Panel Meetings for FY2014 Individual Investigator and High Impact-High Reward Research Applications. Between May 28 and June 6, six research peer review panels met in Dallas to review the nearly 600 proposals submitted for FY2014 Individual Investigator Research Awards (IIRAs) and High Impact-High Reward Awards (HIHRs). The seventh panel met by conference call on June 10. Applications submitted for the FY2014 cycle will be considered for grant awards at the Oversight Committee meeting on August 20, 2014. The peer review meetings went well, especially considering that most of the chairs and a majority of the panel members were new to the process. This is in large measure due to the excellent support provided by SRA International.

Of the 484 IIRA applications submitted, 264 (55%) were eliminated from further consideration during preliminary review, leaving 220 for full evaluation. Of these, 61 were recommended for consideration by the Scientific Review Council (SRC), giving an overall success rate for IIRA applications (number recommended/number submitted) of 13% across all panels.

All 100 HIHR applications submitted received full review. Unlike the IIRA applications, HIHR applications are not subject to the preliminary review process because CPRIT caps the number of HIHR applications that may be submitted by each academic institution. Fifteen HIHR applications were recommended for SRC consideration, a success rate of 15% across all panels.

- Scientific Review Council Recommendations for FY2014 IIRA and HIHR Grants: The SRC met on June 24 and accepted the recommendations of the review panels to award 76 IIRA and HIHR grants for a total amount of \$54,665,415.

SRC Chair Dr. Richard Kolodner submitted the SRC's recommendations to the Oversight Committee Presiding Officer and the Program Integration Committee (PIC) on June 27. The PIC will meet on July 15 to review the SRC's recommendations, as well as the recommendations from the Prevention and Product Development Review Councils. The PIC's final list of grant award recommendations will be considered at the Oversight Committee meeting on August 20.

- Recruitment Applications: Sixteen applications for Recruitment Awards are under review by the SRC. These include seven applications for First-Time Faculty awards, six for Rising Star awards, and three for Established Investigator awards. Depending on the availability of funding, recommendations concerning these applications will come to either the August 20 and/or November 19 OC meeting for consideration.
- FY2015 IIRA Applications: RFAs for another round of IIRAs, including the first time release of targeted IIRA RFAs for prevention research and cancer in children and young

adults, closed on June 26. More than 400 applications were submitted, with 57 applications submitted for the targeted childhood cancer IIRA and 66 for the targeted prevention research IIRA. These applications will be considered at peer review meetings to be held in October - November 2014.

- FY2015 Recruitment Award Applications: RFAs for Recruitment Awards opened on June 12 and new RFAs for Core Facility Support Awards and Multi-Investigator Research Awards are expected to be released in July.

Product Development Program Update

Most of the Product Development Program work in June focused on negotiating final contracts for several company awards that were announced at the February and May Oversight Committee meetings. In addition, review of applications submitted for FY2015 product development awards has begun and new RFAs have been issued.

- Grant Contract Status for Awards Announced in February and May: CPRIT is finalizing contracts with the five companies that were announced at the February 2014 Oversight Committee meeting pursuant to terms that were approved by the Oversight Committee on May 21. Contracts with Beta Cat Pharmaceuticals, CerRx, DNATRIX, and ESSA Pharmaceuticals should be executed soon. The contract for ProPep Surgical is taking somewhat longer, but it is expected to be final before the end of July. The Oversight Committee will be notified when final contracts are executed.

Dr. Goodman is negotiating contract terms with the sixth company that was recommended for an award at the February meeting, ProNAi Therapeutics. ProNAi's board is considering whether to accept the CPRIT award or to remain closer to its existing investors in Michigan. The company will report its decision to CPRIT on or before July 11. If ProNAi intends to accept the grant award and relocate to Texas, Dr. Goodman will present contract terms for the Oversight Committee's approval at the August 20 meeting.

Contract negotiation is also underway with Mirna Therapeutics and AERase, the two product development awards announced at the last Oversight Committee meeting. Dr. Goodman expects to present contract terms for the Oversight Committee's approval at the August 20 meeting.

- Grant Contract for Kalon Biotherapeutics: Kalon Biotherapeutics was approved for a grant of \$7.9 million by the previous Oversight Committee in March 2012 and contract execution authority was delegated to the executive director. Kalon's contract was near completion, but not executed, when the moratorium began in December 2012. Dr. Goodman visited Kalon's management team in College Station on May 29 to continue the delayed negotiations. It is expected that the contract will be executed this month.
- Product Development Review Council Recommendations for FY2014 Product Development Grant Awards: The Product Development Review Council (PDRC) met on June 27, 2014, to consider the due diligence reports for two FY2014 product development applicants. The PDRC recommended both applications for grant awards totaling \$13,580,185. PDRC Chair Dr. Jack Geltosky submitted the PDRC's recommendation to the presiding officers for the

Oversight Committee and the PIC today. If the PIC recommends one or both companies for grant awards, the Oversight Committee will consider the recommendation at its August 20 meeting.

- FY2015 Cycle 1 Product Development Grant Applications: CPRIT received 30 product development grant applications from FY 2015 Cycle 1, which closed on May 29. There were 19 New Company applications, six Relocation applications, and five Existing Company submissions. The applications were assigned to reviewers for in-depth review last week. The review panel will meet in July to discuss the reviews and determine the companies that will be invited to make in-person presentations to the full review panel in August. FY2015 Cycle 1 product development award recommendations are expected to be approved at the November 19 Oversight Committee meeting.
- FY2015 Early Translational Research Awards (ETRA) Request for Applications: CPRIT began accepting applications for ETRA product development grants on June 26. The deadline for applications is August 7. This is the first ETRA RFA issued by the Product Development Program. The ETRA RFA was previously released by the scientific research program; however the scientific research and product development programs agreed that the product development review panels may have more targeted expertise for the review of ETRA proposals. This RFA adds a requirement that a business plan be submitted during the first year of the grant. In addition, with the aim of attracting entrepreneurial management, CPRIT increased the maximum potential amount of the grant award from \$1 to \$2 million. ETRA grant recommendations will be considered by the Oversight Committee at its November 19 meeting.

Prevention Program Update

Following the Prevention peer review panel meetings in early May, the Prevention Program is finalizing prevention award proposals that will be considered by the Oversight Committee in August. The Prevention Program is also accepting applications for its first round of grants to be awarded in FY2015.

- Prevention Review Council Recommendations for FY2014: The Prevention Review Council (PRC) met June 27 in Dallas to consider the recommendations forwarded by the two prevention review panels in May. The PRC's recommendations for funding will be forwarded to the presiding officers for the Program Integration Committee and Oversight Committee.
- FY2015 Cycle 1 Request for Applications: Two RFAs, Evidence Based Cancer Prevention Services and Competitive Continuation/Expansion, were released March 31. CPRIT is accepting applications April 29 - July 10. The recommendations for awards from this cycle will go to the Oversight Committee in November.
- Prevention Program Stakeholder Meetings: Meetings to explore where CPRIT's priorities may align and possible opportunities to leverage activities occurred with the American Cancer Society (colorectal cancer prevention), Methodist Health Care Ministries (primary

care and behavioral health in South Texas regions), and C-Change (improving cancer health disparities). We will report to the Oversight Committee as these discussions progress.

University Advisory Committee

The University Advisory Committee met on June 27 in Houston to discuss CPRIT research program priorities, adoption of its charter, and ideas for future RFAs and items to discuss with the Oversight Committee. Ned Holmes attended the meeting in person, as did Dr. Kripke and Michael Brown. Dr. Bill Rice, Kristen Doyle, Cameron Eckel, and I attended the meeting by telephone conference. The Oversight Committee must approve the UAC charter. This will be on the agenda for the August 20 Oversight Committee meeting.

Standing Subcommittee Schedule

At its May meeting, the Oversight Committee asked CPRIT staff to propose standing dates for subcommittee meetings that will take place in the weeks leading up to an Oversight Committee meeting. I distributed a proposed schedule last week with standing meetings for the seven subcommittees through November 2015. One member responded with a conflict for a proposed subcommittee meeting in August. We will work with that subcommittee's members to find an alternative to this particular August meeting date. The meeting dates by subcommittee are attached to this memo. My executive assistant, Mary Gerdes, will follow up with all Oversight Committee members and their assistants to add the subcommittee meeting dates to your calendars.

Communications

Hahn Public Communications is working with the Communications staff on an on-going project to share and promote CPRIT's accomplishments. Two communications pieces, a fact sheet and a pocket card with talking points on three of CPRIT's projects, were distributed to the Oversight Committee at its May meeting. A new fact sheet and card will be developed every quarter. This is part of the larger project that will include more comprehensive pieces about CPRIT's programs including the creation of a template for overall CPRIT messaging to be used in presentations.

Agency media outreach led to a positive June 22 *Austin American-Statesman* story from interviews with CPRIT staff, grantees, and legislators that focused on CPRIT moving forward and CPRIT's investment in the Austin business community.

Operations and Finance (Contracts, RFPs, Internal Audit)

CPRIT's operations staff has been primarily involved with completing year-end reports and preparing the 2016-2017 biennium budget request (see Ongoing Projects). Other operations work this summer includes debt issuance, major contract amendments, office relocation, and working with internal auditors to complete several reports.

- **TPFA Debt Issuance:** The Texas Public Finance Authority (TPFA) issued \$60.3 million in commercial paper notes on behalf of CPRIT on June 17. The funding from this debt issuance will pay additional operating costs associated with the agency move, compliance program design consulting contract, and the SRA International grants management support contract as

well as grant expenditures from FY 2011, 2012, 2013, and 2014 prevention, research and product development awards.

TPFA will consider CPRIT's FY2015 debt issuance at its meeting on July 10. As part of this process, the Bond Review Board will also discuss the debt issuance for CPRIT at its planning meeting on July 8 and then finalize decisions at its open meeting on July 17.

- Finalizing Contract Amendment with SRA International: On June 27 the Legislative Budget Board approved CPRIT's request for additional appropriations authority and contracting, which was submitted to the LBB following Oversight Committee approval on May 21. CPRIT will finalize the \$1.3 million contract amendment with SRA International, Inc. for continued pre- and post-award grants management support through August 31.
- Internal Auditor Reports: The internal auditor, Grant Thornton, LLP, completed the Expenditures Internal Audit Report, which was submitted to the Audit Subcommittee for review. They have also completed field work for the audits on governance, information technology, and the SRA-managed information technology systems (our third party vendor for pre- and post-award grant support services) according to the schedule in the 2014 Audit Plan. Field work for the 10 grantee audits is underway, and the reports will be completed by the end of the summer.

Ongoing Projects

- Agency Strategic Plan for the Period 2015-2019: This statutorily required document was submitted to the appropriate offices on June 18 prior to the June 23 due date. An early draft was discussed and approved at the May 21 Oversight Committee meeting for submittal pending completion and approval by Presiding Officer Rice. Dr. Rice approved the plan and signed the plan on June 18; a final electronic version was transmitted to Oversight Committee members on the same day.
- Request for Legislative Appropriations: State agencies received instructions from the Legislative Budget Board (LBB) and the Office of the Governor on June 16 to prepare budget requests for the 2016-17 biennium. CPRIT's request is due August 4. After that date, a panel of LBB and Governor's Office staff will conduct a public hearing for CPRIT to present our request and respond to questions from the panel. Public comment will also be received by the panel concerning our request at that time. I will request some Oversight Committee representation at that hearing.

Legislative Activities

I met with Representatives Drew Darby (May 12), John Zerwas (May 13), and Carol Alvarado (May 13) to update them on the progress CPRIT has made since the 83rd Regular Session. Opportunities to meet with legislators have slowed down during the summer but should pick up again in the fall.

The Senate Health and Human Services Committee will hold a hearing on August 14 at which CPRIT will make a presentation regarding the agency's implementation of SB149. Other agencies will also be making presentations unrelated to CPRIT.

Representative Jim Keffer is organizing an informal briefing for legislators interested in advancing CPRIT. This will likely now take place in early fall.

Staff Presentations/Meetings

I was invited to speak at a meeting of the Texas Public Health Coalition on May 30 to address issues related to CPRIT. This was also an opportunity to correct incomplete and inaccurate information concerning CPRIT provided at a previous meeting. The Coalition is made up of 25 public health advocacy groups and associations to guide and influence public health issues in Texas.

CPRIT program chiefs and I will address Houston community leaders at the Houston Technology Center on July 10. This event should allow us to publicize CPRIT activities and to enhance professional networks.

On July 11 senior staff will meet with representatives from cancer advocacy groups to update them on CPRIT activities since November 2013 and to discuss opportunities for positive messaging and potential legislative and media outreach.

CPRIT has awarded 544 grants totaling **\$997,101,232**.

- 115 prevention awards totaling \$96.7 million
- 429 academic research and product development awards totaling \$900.4 million

Of the **\$900.4 million** in academic research and product development awards

- 32.8% of the funding (\$295.2 million) supports clinical research projects
- 23.8% of the funding (\$214.2 million) supports translational research projects
- 23.9% of funding (\$214.9 million) supports recruitment awards
- 16.2% of the funding (\$146.5 million) supports discovery stage research projects
- 3.3% of funding (\$29.5 million) supports training programs.

CPRIT has six open Requests for Applications (RFAs).



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: DAVID A. REISMAN, CHIEF COMPLIANCE OFFICER
SUBJECT: COMPLIANCE OFFICER REPORT
DATE: AUGUST 14, 2014

The Chief Compliance Officer is responsible for creating, supporting, and promoting an effective Ethics and Compliance Program and assuring the CPRIT Oversight Committee that controls are in place to prevent, detect and mitigate compliance risk. One of CPRIT's administrative rules, Rule 701.7, provides in part that, "The Chief Compliance Officer is responsible and will be held accountable for apprising the Oversight Committee and the Chief Executive Officer of the institutional compliance functions and activities." The required reporting includes quarterly updates to the Oversight Committee on CPRIT's compliance with applicable laws, rules and agency policies (701.7(c)(2)(A)). In addition, the compliance officer must inquire into and monitor the timely submission status of required grant recipient reports and notify the Oversight Committee and General Counsel of a grant recipient's failure to meaningfully comply with reporting deadlines.

Monitoring Submission Status of Required Grant Recipient Reports:

As of August 8, 2014, the date the report was run, information regarding delinquent grant recipient reports was as follows:

- 36 grant projects, either active or in close out, at 26 separate entities, have not filed required quarterly financial status reports (FSRs) by the deadline. At the last Oversight Committee meeting on May 21, 2014, I reported that 42 grant projects had not filed required FSRs by the deadline.

Additionally, at the last Oversight Committee meeting I noted that, in addition to the delinquent FSRs being reported, additional FSRs are pending filing upon the submission and approval of the currently delinquent FSR. At the time, it was difficult to ascertain the exact number of pending FSRs. However, with the addition of the grant specialists and further analysis, we are now able to determine that, as of August 8, 2014, the total number of past due FSRs is 180.

- 5 grant projects, either active or in close out, have not filed required progress reports by the deadline. All grant projects must file annual progress reports; prevention projects are also

required to file quarterly progress reports. Annual progress reports must be filed with CPRIT within 60 days following the anniversary of the contract effective date.

Additionally, since the last Oversight Committee meeting, the CPRIT Grants Management System (CGMS) was enhanced to implement new rules and other changes, which included a new section for other financial reports. At about this same time, grants which had been under the moratorium had other annual financial reports due subject to the filing of their 4th Quarter FSRs. The addition of the new section made it possible to identify these reports. A summary breakdown of the all delinquent reports is below:

<u>Type of Report Due</u>	<u>Total*</u>
Annual Inventory Report	87
Financial Status Report (FSR)	35
Historically Under Utilized Business Report	86
Matching Funds Certification Report	103**
Progress Report	5
Revenue Sharing Report	82
Single Audit Determination Form	<u>85</u>
TOTAL	483

*As of August 8, 2014

**The Matching Funds Certification Form was recently revised by SRA. During the process of revision, which required SRA to make programming changes, grantees could not submit the form. The availability of the form very likely impacted the number of timely submissions.

To address this issue of past due reports, the management, personnel and structure of the CPRIT finance division has undergone significant changes over the past couple of months. Three new grant accountants were recently hired to add to existing staff, which resulted in a division of workload in processing incoming reports. Additionally, the new grant specialist team has been working with the grant accountants in reviewing and processing incoming reports and in reaching out to grantees in an effort to expeditiously resolve filing issues. As a result, significant progress has been made in the identifying and processing past due reports. An indication of that would be number of grant reimbursements processed due to submissions of FSRs. The number of grant reimbursements processed has steadily increased over the past several months as follows: May (105), June (156), July (198), and Aug 1st – 11th (114) were processed.

With the processing on CPRIT side improved, a continued, but greater emphasis has been placed on the grantee side to submit those past due reports as quickly as possible.

Compliance Program Design Recommendations

Weaver, the consultant hired by CPRIT to provide a compliance program design recommendations, met with staff at an exit conference on Wednesday, August 13, 2014 and provided a draft of their recommendations. A final report from Weaver is expected on Friday, August 15. Copies of the report will be provided to the OC Audit Subcommittee for evaluation and consideration.

Oversight Committee Ethics Training

Pursuant to CPRIT Rules, TAC 701.7(d), Oversight Committee Members and Institute Employees shall participate in periodic Compliance Program training. Following discussion with Chair Rice, I would like to propose that the Oversight Committee schedule 30 minute training sessions to occur twice annually. They could be scheduled to take place immediately preceding Oversight Committee meetings and cover timely and relevant ethics & compliance topics.



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: HEIDI MCCONNELL
SUBJECT: CPRIT FINANCIAL OVERVIEW FOR FISCAL YEAR 2014, QUARTER 3
DATE: AUGUST 12, 2014

FY 2014, Quarter 3 Operating Budget

CPRIT expended or obligated approximately \$193.2 million in total between agency operating expenditures and grant award encumbrances by the end of May. The agency expended \$2.4 million in Indirect Administration in the second quarter. The expenditures of almost \$1 million in the Professional Fees and Services category are pay for outsourced legal, audit and communications services to the agency.

The agency has also expended almost \$5.7 million in Grant Review and Award Operations. The expenditures reflected in the Professional Fees and Services category are primarily for the pre- and post-award grant management support services provided by SRA International. Because this budget reflects expenditures through the end of the third fiscal quarter, the expenses for the seven research peer review meetings that occurred in June 2014 are not reflected nor are other additional grants management support costs for all three programs.

Debt Issuance History

In June, CPRIT requested another \$60.3 million be issued by the Texas Public Finance Authority (TPFA) for payment of CPRIT's grant reimbursements. This was our final issuance for the year and brought the total Commercial Paper Notes issued to \$162.5 million. The total debt issued to date is almost \$548.8 million. In July, TPFA fixed out \$261.2 million of issued Commercial Paper Notes into long-term General Obligation Bonds at a par value of \$233.88 million based on the interest that will be paid out.

Cancer Prevention and Research Institute of Texas
Quarterly Financial Report
As of May 31, 2014

Indirect Administration (B.1.1.)

	2014 Appropriated	2014 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended
1001 Salaries and Wages	\$ 1,559,830	\$ 1,271,630		\$ 757,490	514,140	60%
1002 Other Personnel Costs	21,400	50,000		30,925	19,075	62%
2001 Professional Fees and Services	350,500	984,137		984,137	0	100%
2003 Consumable Supplies	25,332	22,500		14,187	8,313	63%
2004 Utilities	32,600	63,648		49,775	13,873	78%
2005 Travel	24,176	34,874		15,616	19,258	45%
2006 Rent - Building	427,450	476,075		286,210	189,865	60%
2007 Rent-Machine and Other	16,763	24,150		11,337	12,813	47%
2009 Other Operating Expenses	348,824	342,551		263,253	79,298	77%
5000 Capital	-	1,073,200		-	1,073,200	0%
Subtotal - Indirect Administration (B.1.1.)	\$ 2,806,875	\$ 4,342,765	1.46%	\$ 2,412,929	\$ 1,929,836	56%

Grant Review and Award Operations (A.1.3.)

	2014 Appropriated	2014 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended
1001 Salaries and Wages	\$ 1,026,701	\$ 2,365,935		\$ 1,228,154	\$ 1,137,781	52%
1002 Other Personnel Costs	3,600	100,000		15,697	84,303	0%
2001 Professional Fees and Services	4,285,471	8,608,808		4,384,058	4,224,750	51%
2003 Consumable Supplies	27,324	-		-	-	0%
2005 Travel	24,400	35,430		9,395	26,035	27%
2006 Rent - Building	4,867	43,547		32,661	10,886	75%
2007 Rent-Machine and Other	-	7,500		2,673	4,827	36%
2009 Other Operating Expenses	1,551,996	-		-	-	0%
Subtotal - Grant Operations (A.1.3.)	\$ 6,924,359	\$ 11,161,220	3.76%	\$ 5,672,638	\$ 5,488,582	51%

Grants

	2014 Appropriated	2014 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended
4000 Grants - Prevention (A.1.2)	\$ 29,022,567	\$ 29,022,567		\$ 10,778,222	\$ 18,244,345	37%
4000 Grants - Research (A.1.1.)	261,262,199	252,519,894		174,348,563	\$ 78,171,331	69%
Subtotal - Grants	\$ 290,284,766	\$ 281,542,461	94.78%	\$ 185,126,785	\$ 96,415,676	66%
Grand Totals	\$ 300,016,000	\$ 297,046,446	100.00%	\$ 193,212,352	\$ 103,834,094	65%

* 2014 Budgeted includes a transfer from strategy A.1.1. (Research) into strategies A.1.3. (Grant Operations) and B.1.1. (Indirect Administration) approved by the Legislative Budget Board pursuant to the 2014-15 General Appropriation Act, CPRIT Rider 5, Transfer Authority.

Cancer Prevention and Research Institute of Texas
Cancer Prevention and Research Institute Fund Account - 5136
As of May 31, 2014

	<u>5/1/2014 thru 5/31/2014</u>	<u>AY 14 Year to Date as of 5/31/2014</u>
<u>Beginning Balance : 09/01/2013</u>		499,412
Increases:		
(1) License Plate Revenue Received	\$ 1,184	\$ 10,896
(2) Revenue Sharing / Royalties	149,857	484,425
(3) Settlement - Texas Cancer Coalition	-	274,000
(4) Gift/Donation (Texas Cancer Coalition Designated Gift [Restricted Use])	29,877	29,877
Total Increases	<u>\$ 180,918</u>	<u>\$ 799,198</u>
Reductions:		
Expenditures - Appropriated	\$ 0.00	\$ 0.00
Estimated Transfers for Employee Benefits	-	-
Benefit Replacement Pay	-	-
Total Reductions	<u>\$ 0.00</u>	<u>\$ 0.00</u>
<u>Ending Balance, 5/31/2014</u>		<u>\$ 1,298,610.48</u>

Note: (1) The beginning balance includes \$473,135 in revenue sharing/royalties received from grant recipients from CPRIT's inception through 8/31/2013. Those amounts were deposited into the State Treasury but not appropriated to CPRIT. Additionally, the beginning balance includes \$26,277 in license plate revenue that was not appropriated to CPRIT in the current biennium.

(2) The Institute received a settlement amount from the Texas Cancer Coalition (TCC). This amount represents the final distribution and transfer of all funds from the TCC which ceased operations. These funds have been deposited into the State Treasury but are not appropriated to CPRIT.

Cancer Prevention and Research Institute of Texas

Appropriated Receipts - 666

As of May 31, 2014

	<u>5/1/2014 thru 5/31/2014</u>	<u>AY 14 Year to Date as of 5/31/2014</u>
<u>Beginning Balance : 09/01/2013</u>		0
Increases:		
(1) Product Development Application Fees Received	\$ 6,000	\$ 47,000
(2) Appropriated Receipts applied to payments	-	-
Total Increases	<u>\$ 6,000</u>	<u>\$ 47,000</u>
Reductions:		
Expenditures - Appropriated	\$ 0.00	\$ 0.00
Estimated Transfers for Employee Benefits	-	-
Benefit Replacement Pay	-	-
Total Reductions	<u>\$ 0.00</u>	<u>\$ 0.00</u>
<u>Ending Balance, 5/31/2014</u>		<u><u>\$ 47,000</u></u>

CPRIT Commercial Paper and G.O. Bond Issuance

Fiscal Year	Amount Appropriated	Dated Issued	Amount Issued	Amount Issued for Fiscal Year	Commercial Paper or GO Bond Issuance	Series	Comments	Interest Rate
2010	\$ 225,000,000	September 9, 2009	\$ 9,100,000		Commercial Paper Notes	Series A, Taxable		Footnote 1
2010		September 9, 2009	\$ 3,600,000		Commercial Paper Notes	Series B, Tax-Exempt	Defeased with cash July 2011	Footnote 1
2010		March 12, 2010	\$ 63,800,000		Commercial Paper Notes	Series A, Taxable		Footnote 1
2010		August 26, 2010	\$ 148,500,000		Commercial Paper Notes	Series A, Taxable		Footnote 1
				\$ 225,000,000				
2011	\$ 225,000,000	September 7, 2010	\$ 11,800,000		Commercial Paper Notes	Series A, Taxable		Footnote 1
2011		August 10, 2011	\$ 50,775,000		G.O. Bonds	Taxable Series 2011	Par amount of new money	Fixed Rate Bonds All-In-True Interest Cost 4.0144%
2011		August 10, 2011	\$ 232,045,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2011	Par amount of refunding; Refunded \$233.2M of GOCP CPRIT Series A (9/9/09, 3/12/09, 8/26/09, 9/7/10)	Fixed Rate Bonds All-In-True Interest Cost 4.0144%
				\$ 62,575,000				
2012	\$ 300,000,000	September 7, 2011	\$ 3,200,000		Commercial Paper Notes	Series A, Taxable		Footnote 1
2012		December 8, 2011	\$ 3,200,000		Commercial Paper Notes	Series A, Taxable		Footnote 1
2012		March 2, 2012	\$ 12,300,000		Commercial Paper Notes	Series A, Taxable		Footnote 1
2012		June 21, 2012	\$ 15,000,000		Commercial Paper Notes	Series A, Taxable		Footnote 1
2012		August 16, 2012	\$ 42,000,000		Commercial Paper Notes	Series A, Taxable		Footnote 1
				\$ 75,700,000				
2013	\$ 300,000,000	September 5, 2012	\$ 9,600,000		Commercial Paper Notes	Series A, Taxable		Footnote 1
2013		May 16, 2013	\$ 13,400,000		Commercial Paper Notes	Series A, Taxable		Footnote 1
				\$ 23,000,000				
2014	\$ 300,000,000	November 22, 2013	\$ 55,200,000		Commercial Paper Notes	Series A, Taxable		Footnote 1
2014		March 12, 2014	\$ 47,000,000		Commercial Paper Notes	Series A, Taxable		Footnote 1
2014		June 17, 2014	\$ 60,300,000		Commercial Paper Notes	Series A, Taxable		Footnote 1
2014		July 8, 2014	\$ 233,280,000		G.O. Bond (Refunding Bonds)	Taxable Series 2014	Par amount of refunding; Refunded \$237.88M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 3.327184%
				\$ 162,500,000				
TOTAL ISSUED TO DATE				\$ 548,775,000				

¹The weighted average interest rates for Commercial Paper Notes maturing in each year is as follows: FY 2010 = 0.30%; FY 2011 = 0.32%; FY 2012 = 0.23%; FY 2013 = 0.19%; FY 2014 = 0.20%.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

To: OVERSIGHT COMMITTEE MEMBERS
From: REBECCA GARCIA, PH.D. CHIEF PREVENTION AND
COMMUNICATIONS OFFICER
Subject: COMMUNICATIONS UPDATE
Date: AUGUST 20, 2014

The following report provides an overview of the agency's communications activities from May 2014 through July 2014.

EARNED MEDIA

Coverage: (May 6, 2014 – July 31, 2014)

- 11 features on CPRIT
- 51 mentions of CPRIT (stories primarily focused on work of grantees)

Coverage Highlights: (see clipped articles following report)

- July 18, 2014, *San Antonio Express-News*, Good to see CPRIT back on its mission (editorial)
- June 22, 2014, *Austin American-Statesman*, New focus, energy at CPRIT
- May 27, 2014, *Austin Business Journal*, Big CPRIT grant fuels cancer-fighting aspirations of Austin company
- May 22, 2014, *BioNews Texas*, CPRIT awards 16 grants totaling nearly \$83 million

Grant Awards Announcement: Following the Oversight Committee's approval, on May 21, 2014, CPRIT issued a press release to local, regional and national media announcing the awarding of two product development grants and 14 research recruitment grants which resulted in some of the coverage as represented above.

STRATEGIC PLAN

Communications assisted with coordination and development of the Agency Strategic Plan for Fiscal Years 2015-2019. The final report was distributed before the required June 23, 2013 deadline.

Customer Survey: In late Spring, CPRIT communications team fielded an online customer satisfaction survey to 1,342 grantee representatives to gauge perceptions and identify both successes and areas for improvement. A comprehensive report detailing qualitative and quantitative survey findings as well as analysis of findings and the agency's response was developed and shared with survey participants and posted on CPRIT's website. Additionally, an overview of the survey findings was included in the agency's strategic plan.

AUDIT IMPLEMENTATION COMPLETION

In recognition of the agency fully implementing all 51 recommendations from the State Auditor's *Audit Report on Grant Management at the Cancer Prevention and Research Institute of Texas and Selected Grantees, January 2013, Report No. 13018* and to communicate this important accountability and governance milestone, CPRIT communications created a concise summary graphic. The graphic along with a note from Wayne Roberts was distributed electronically to all 181 members of the legislature on July 3, 2014.

IDENTITY AND MESSAGING

Brand Identity: A critical step in executing effective and consistent communications is establishing a unified CPRIT brand. CPRIT communications developed a new logo mark for the agency incorporating the state seal and a style guide for use of the logo mark as well as designating brand colors and fonts. Templates for memos, letters, presentation slide decks and report layouts have been created within the new brand standards and are in the process of being rolled out for staff use. Website and email templates are also in the process of being updated.

Messaging: As the CPRIT brand continues to be established, key messages to align all communications and effectively share CPRIT's purpose and impact with key audiences are being developed.

Grantee Highlights: To support messaging, the communications team is helping track grantee progress and identify milestones for use across all CPRIT outreach mechanisms.

RFA RELEASES

Announcements regarding the release of new research and product development RFAs were sent out via CPRIT's available communications channels.

HOUSTON TECHNOLOGY CENTER PRESENTATION

CPRIT executives presented to the Houston Technology Center on July 10, 2014. Communications assisted with development of the presentation in alignment with the overall effort to demonstrate CPRIT expertise and scientific excellence by seeking out and taking advantage of opportunities to speak to relevant audiences.

CPRIT 2015 CONFERENCE

The communications team revised and prepared a 2015 Conference budget and venue RFP. The RFP and budget will be forwarded to the Audit Subcommittee prior to the RFP being sent to Austin area hotels.

PBS CANCER DOCUMENTARY OPPORTUNITY

CPRIT is in discussions with Texas Public Broadcasting Association to explore options to participate in the premiere of Ken Burn's new documentary on the *Emperor of all Maladies: A biography of cancer* in Texas.

Good to see CPRIT back on its mission

The Cancer Prevention and Research Institute of Texas appears back on track after a turbulent period that almost compromised the future of the \$3 billion public investment in cancer research, treatment and product development.

Eighteen months ago, the outlook for the cancer fighting agency looked bleak. There were ongoing civil and criminal investigations, which later resulted in the indictment of one of the agency's executives and the ouster of its board.

Legislative efforts to revamp the agency structure, enhance oversight and provide more transparency have placed the agency back on course.

That should be welcome news to researchers and cancer patients everywhere.

Cancer is the second-leading cause of deaths in Texas and the nation. In 2013, Texas recorded 117,371 new cancer patients diagnosed and 41,362 patients who lost their fight against the disease.

CPRIT is the second-largest source of cancer research funding in the nation behind the National Cancer Institute.

Funding for the institute was provided by voters in 2007 with the approval of \$3 billion in bonds. The enabling legislation mandates 10 percent of its grants must be spent on prevention. To date, \$96.6 million has been awarded for 115 prevention projects.

The bulk of the rest of the money, \$717.9 million, has gone to academic research. Another \$206.3 million was awarded for product development.

In the year since the Legislature put in place strong safeguards to ensure the integrity of the grant program and prevent future funding scandals, the agency has awarded \$185 million in new grants.

The funding has created jobs and provided hundreds of thousands of Texans with vaccinations, health screenings and education programs. It has attracted some of the leading cancer research scientists in the country and yielded several new patents.

The University of Texas Health Science Center at San Antonio has been the recipient of 25 awards totaling \$26.6 million and has several more grant proposals pending. The funding received by the UTHSC from CPRIT includes \$6.7 million for seven prevention projects and \$19.9 million in the form of 18 research grants.

The University of Texas at San Antonio has received two research grants totaling \$898,026.

Across the state, more than 80 institutions and organizations have been the recipients of CPRIT grants since the agency began operation in 2009.

It is unfortunate that lax rules, poor management and politics in the awarding of three grants totaling \$56 million forced Gov. Rick Perry, Lt. Gov. David Dewhurst and House Speaker Joe Straus to call for a moratorium on new grants in December 2012.

The moratorium stayed in place for almost a year. It was a necessary measure that allowed for assessment of the problem and corrective action.

We are optimistic that with its new management team and a new oversight committee, which includes a San Antonio doctor, CPRIT can move forward with its cancer-fighting efforts and continue to make the most of the state investment in cancer prevention and research.

Austin American-Statesman

Sunday, June 22, 2014

Breaking news at statesman.com

CONTINUING
COVERAGE
STATE CANCER FUND

New focus, energy at CPRIT

Rebooted after scandal,
cancer agency rethinks
priorities and goals.

By Laylan Copellin
lcopellin@statesman.com

The state's cancer-fighting agency has rebooted since last year's funding scandal with new leadership and new grants – and old questions about how best to spend taxpayers' billions to prevent and treat cancer.

"The past is the past," said Wayne Roberts, the chief executive who guided the Cancer Prevention and Research Institute of Texas back from the brink of extinction last year. "Our doors are open. We're moving forward."

In 2007, Texas voters approved \$3 billion in bonds to create the agency, commonly known as CPRIT, and to finance cancer-fighting efforts at a rate of up to \$300 million a year. But the agency's mishandling of three grants, totaling \$56 million, caused three executives to resign, one to be indicted and the Legislature to reconsider CPRIT's future last year.

The agency now has a new oversight committee and executive team, eight additional staffers focused on compliance and oversight, and a re-

CPRIT continued on A15

CONTINUING COVERAGE: STATE CANCER FUND

CPRIT

continued from A1

built slate of out-of-state experts who do the initial review of applications to avoid conflicts of interest with Texas grant recipients.

State Sen. Jane Nelson and Rep. Jim Keffer, who led the effort to rescue and reform CPRIT, said the agency is back on track.

"The new agency leadership is a strong group who are committed not only to ensuring the previous mistakes are never repeated, but also fulfilling CPRIT's mission of finding a cure for cancer," Nelson said.

Keffer agreed. "I couldn't be happier with the leadership," he said.

State leaders lifted a 10-month moratorium on new grants in October. Since then, the agency has awarded \$185 million in grants, pushing it past the \$1 billion mark since its inception. The latest grants have a greater emphasis on product development as opposed to academic research.

By law, 10 percent of CPRIT's grant money must be spent on prevention. Over the life of the agency, 70 percent of the money has gone to academic research, with the rest to product development.

Since the moratorium was lifted, however, almost 60 percent of the grants have gone to companies trying to move cancer therapies from university labs to patients' bedsides.

Two Austin firms, Mirna Therapeutics and AERase Inc., have received the largest grants — \$25.1 million and \$19.8 million, respectively — since the agency resumed awarding grant money.

"I don't want to say there is a higher priority between academic research and product development," Roberts said. "It's still research. It's just research being done in startup companies."

Development catching up

Part of the shift in grant money can be explained as product development catching up to research.

During the agency's early years, research got off to fast start with the state's large academic institutions. Roberts said product development has always been one or two funding cycles behind.

A debate over whether funding should go to

basic research or to commercialization of that research is nothing new at the agency.

It didn't help that one of CPRIT's first commercial grants, \$11 million to Dallas firm Peloton Therapeutics, was awarded without going through the mandatory scientific and business reviews. That resulted in a felony indictment against Jerry Cobbs, the agency's original commercialization chief. The criminal case is pending.

In continuing CPRIT, the Legislature institutionalized the debate over how best to spend taxpayers' dollars by requiring the agency's oversight committee to reconsider its priorities each year.

Come fall, Roberts said, that process — with public input — begins at the oversight committee, which must decide the level of emphasis among research, product development and prevention.

"How do we want the overall portfolio to look?" Roberts said.

He said CPRIT's oversight committee also will determine priorities within each discipline. For example, Roberts said, there will be a discussion whether to focus efforts on the more common adult cancers or to redirect more of CPRIT's money to juvenile and adolescent cancer research that doesn't attract the same level of private sector funding.

"Bigger money is to be made for common cancers that hit older people," Roberts said of the private sector's emphasis. "Cancer is largely an older person ailment."

There also could be some blending of topics. Cancer prevention could become more than screenings and tobacco cessation programs by blending research with prevention, he said. "What are the factors in our environment and our daily lives that we can influence?"

Given the agency's past, though, commercialization of products is likely to get additional scrutiny.

Thomas Goodman, with a background in life sciences and business, came aboard three months ago as CPRIT's chief product development officer. He most recently was vice president of business development for life sciences at a subsidiary of Arizona State University.

"Our overall goal is to take the discover-

CPRIT



Wayne Roberts, new CEO of the Cancer Prevention and Research Institute of Texas, has helped stabilize and refocus the agency.



Thomas Goodman, CPRIT's chief product development officer, says the goal is to take treatments from research to patient delivery.

DEVELOPING CANCER THERAPIES



Paul Lammers, CEO of Mirna Therapeutics, says his company's promising microRNA therapies warrant the investment money that Mirna has received, including funds from CPRIT. DEBORAH CANNON / AMERICAN-STATESMAN

LEADING THE REFORM



Texas Sen. Jane Nelson, R-Flower Mound, and Rep. Jim Keffer, R-Eastland, worked to overhaul the cancer agency. They believe it is now working toward "getting products to the bedside and helping people," as Keffer put it.



ies in the university labs and get them all the way to the cancer patient," Goodman said. "You need every link in the chain. You can't help anyone until a doctor can prescribe it."

The agency already has doubled its maximum grants for "translational research" to \$2 million to motivate entrepreneurs to work with the state's research institutions in bringing research out of their labs.

Goodman said he's also looking for early stage companies that might be considered too risky for venture capitalists.

"Many times, universities can't get attention of venture capitalists," he said. "We'd like to fund opportunities that they are not aware of or are

apeutics was spun out from another Austin firm. It got \$5 million from the Texas Enterprise Fund two years later and an additional \$10.3 million from CPRIT in 2010.

Venture capitalists came calling in 2012, investing \$34.5 million.

The company is focused on microRNA — fragments of RNA once considered "junk RNA" — as tumor suppressors that are less debilitating than chemotherapy. The treatment is delivered intravenously.

RNA is nucleic acid present in all living cells. Its principal role is to act as a messenger carrying instructions from DNA for controlling the synthesis of proteins.

The company's microRNA therapies, first targeting liver cancer, are now candidates for treating blood-borne cancers.

Patient trials are going on at five sites, three of them in Texas.

Last month, CPRIT awarded an additional \$25.1 million over three years. With that money, Mirna is trying to combine its microRNA therapy with other cancer drugs to reduce the necessary dosage and toxicity for patients with lung cancer.

Paul Lammers, the company's CEO, said the state's early support allowed researchers to gather the data to attract private investment.

He said CPRIT is critical to advancing the fight against cancer.

"What other state has dedicated \$3 billion over 10 years to fight cancer?" Lammers asked.

Despite the company's success, Lammers said it would be 2020 before its therapies get Federal Drug Administration approval and hit the market. "And that's if everything goes right," he said.

The initial research into microRNA began in 2001.

Political challenges

Besides the medical challenge, there's a political one made harder because of the scandal.

"This is a political animal," said Keffer, R-Eastland. "We've got to show those footing the bill we are getting products to the bedside and helping people. I'll leave the mix to CPRIT."

Nelson, R-Flower Mound, said there needs to be "a balance" between basic research and product development, but she agreed about getting therapies to the bedside.

"It is important that not only are treatments and possible cures discovered and studied, but also that they are made available to those who are suffering from cancer," she said.

Though the clock is running on CPRIT, the 10-year life span of the program is no longer the timetable.

The agency lost time starting up and again during the scandal. It has only awarded one-third of the \$3 billion.

CPRIT is in business "until the money runs out," Roberts said, or 2021 — the year that the Legislature will consider whether to continue the agency.

Roberts and Goodman said the \$3 billion investment could be paying dividends for decades, particularly because of the grants, up to \$2 million each, to relocate 56 cancer researchers to the state's most prominent academic institutions and to equip them. An additional 16 relocations are pending.

"They are only here because CPRIT brought them here," Goodman said. "They may come up with an idea 10 years from now. It's going to be an investment that will be giving long after CPRIT is gone."

Contact Laylan Copelin at 512-445-3617.

May 30, 2014

Cancer fighters Mirna, AERase boosted by CPRIT

EMBATTLED AGENCY AGAIN DOLING OUT BIG DOLLARS

The Cancer Prevention and Research Institute of Texas has shelled out \$44.9 million to two Austin companies so they can develop new cancer treatments that build on research previously funded by the agency.

The grants come after the agency recently named a head of product development and plans to put more emphasis on funding medical devices and treatments that could be commercialized.

Mirna Therapeutics Inc. will receive \$25.1 million to fund development of drug combinations that mimic naturally occurring tumor inhibitors. Mirna has received CPRIT funding in the past, including a \$10 million grant in 2010 that kept the company, which was spun off from and funded by Asuragen Inc., in business.

The other grant, to AERase Inc., a holding company for Aeglea BioTherapeutics Holdings, provides \$19.8 million to devel-



David Lowe

a partner in AERase.

CPRIT is a state agency created to fund research and treatments for cancer and stimulate life sciences businesses in Texas in the process. The agency is funded by \$3 billion in bond money approved by Texas voters.

David Lowe, Aeglea's CEO, said the grant will let his company begin clinical trials of one of the three molecules early next year to see what kinds of tumors respond to the human enzyme that is believed to degrade amino acids present in tumors. In addition to developing the therapy, Aeglea will also develop

op and begin clinical trials on a cancer treatment that uses the human enzymes to combat tumors. The treatment is based in part on the research of University of Texas scientist George Georgiou, who is

an accompanying diagnostic test to help determine how a patient's cancer will respond to the treatment.

The CPRIT grant will cover most of the expenses of clinical trials for Aeglea's lead molecule candidate. Lowe said the company will go out for new investor funding in the fall, though he said a target amount has not been determined. In January the company completed a \$12 million round of funding, including \$2.5 million from KBI Biopharma in North Carolina.

Lowe said each of the three molecules licensed from the work of UT scientists Georgiou and Everett Stone is being developed by a different holding company so they can be purchased or licensed individually instead of Aeglea being bought as an entire company if one therapy becomes commercially attractive.

Lowe said CPRIT's increased emphasis on product development, especially by awarding funds to help pay for clinical research expenses that represent some of the last steps before commercial availability, will boost worldwide cancer treatment and fuel Austin's biotech sector.

CPRIT Awards 16 Grants Totaling Nearly \$83 Million

Posted by: [Anna Tan](#) May 22, 2014



The **Cancer Prevention and Research Institute of Texas** (CPRIT) recently gave recognition and much-needed support to two product development projects, plus fourteen more projects in the field of research.

CPRIT awarded over \$44.9 million worth of grants under its product development program. This effort has funded countless studies and advancements aimed at developing improved diagnostic, treatment, and rehabilitative options

for cancer.

As for the institute's research grants, which amount to about \$37.3 million, they are dedicated to attracting some of the most prominent and promising oncologists and scientists to the state's leading academic institutions.

These sought-after individuals include, "promising emerging researchers pursuing faculty appointment; outstanding early-stage researchers; and senior research faculty with distinguished professional careers and established cancer research programs," according to a CPRIT news release.

All grants, before they are awarded, are subjected to the institution's review process, which includes earning recommendations from the appropriate program review councils before vying for the approval of the Oversight Committee.

[Click here](#) for a list of the sixteen recipients of the research, and product development grants from CPRIT.

In a recent BioNews Texas report, Texas State Senator Jane Nelson was honored for her work in reforming the Cancer Prevention and Research Institute of Texas.



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: REBECCA GARCIA, PH.D. CHIEF PREVENTION AND COMMUNICATIONS OFFICER
SUBJECT: PRIORITIES PROJECT UPDATE
DATE: AUGUST 11, 2014

The Priorities project is proceeding as scheduled. Activities since the May 21, 2014 report to the Oversight Committee meeting include:

- Robert Mittman, facilitator for the CPRIT's Program Priority Setting Project, met with each of the three program subcommittees in Austin on July 16 and 17. Each subcommittee discussed what long-term success would look like for CPRIT's product development, scientific research or prevention activities. The subcommittees also discussed high-level priorities and guidelines for grant-making decisions, as well as guidance for balancing priorities across programs.
- A call with the subcommittee chairs, Robert Mittman, and the Program Officers is scheduled for Aug. 15th to continue the discussion on guidelines for grant- making decisions across the three programs.
- The work done by each subcommittee sets the stage for the Oversight Committee working session scheduled for September 3 in Austin. The September 3rd meeting will also include an opportunity for public input.
- Following the September 3rd meeting, a draft report will be made available for additional public comment. The Oversight Committee will consider the final draft report at the November 2014 meeting.



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: REBECCA GARCIA, PH.D. CHIEF PREVENTION AND COMMUNICATIONS OFFICER
SUBJECT: PREVENTION PROGRAM UPDATE
DATE: AUGUST 11, 2014

Prevention Program activities since the May 21, 2014 report to the Oversight Committee meeting include:

- FY2014 Cycle 2. The Prevention Review Council finalized the FY 2014 recommendations for 15 grant awards and submitted them to the Oversight Committee Presiding Officer and the Program Integration Committee (PIC) on July 3, 2014. Award recommendations are being presented for approval by the Oversight Committee today at the August 20 meeting.
- FY2015 Cycle 1 Request for Applications: CPRIT received 16 applications in response to two RFAs, Evidence Based Cancer Prevention Services and Competitive Continuation/Expansion. The applications have been assigned to reviewers and the recommendations for awards from this cycle will be presented to the Oversight Committee in November. In order to get back to a pattern of having two application cycles per year, we released these RFAs only 3 months after the previous release of RFAs. We anticipated the number of applications this cycle to be low due to the short time between the two releases. The review of these applications will be held via teleconference.
- FY2015 Cycle 2 Request for Applications: Requests for Applications for the second cycle of FY 15 are being revised and will be released in September.

Timeline for FY15 Grants Cycles

Steps	Cycle 15.1	Cycle 15.2
RFA Release	March 31, 2014	September, 2014
Applications Due	July 10, 2014	December, 2014
Peer review	October 1-2, 2014	February, 2015
PRC Review	October 24, 2014	April 24, 2015
PIC meeting	November 4, 2014	May 5, 2015

- In other activities we have continued discussions with the American Cancer Society (ACS) on possible collaboration on colorectal cancer initiatives. I attended a meeting on August 6, to discuss their “80% by 2018” initiative. The ACS and National Colorectal Cancer Roundtable goal is to have national screening rates of 80% by 2018. As of 2012 in Texas, the screening rate was 62.6%. We have also had preliminary discussions with the College of American Pathologists on expanding their See, Test, Treat program on breast and cervical cancer to Texas.

Conflicts of Interest for Prevention Cycle 14.1 Applications
(Prevention Cycle 14.1 Awards Announced at August 2014 Oversight Committee Meeting)

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC. COI information used for this table was collected by SRA International, CPRIT's third party grant administrator, and by CPRIT.

Grant ID	Applicant	Institution	Conflict Noted
Applications Considered by the PIC and Oversight Committee			
PP140018	Sauter, Edward	The University of Texas Health Center at Tyler	Montgomery, Will; Mitchell, Amy
PP140028	Jibaja-Weiss, Maria	Baylor College of Medicine	Mitchell, Amy
PP140033	Layeequr Rahman, Rakhshanda	Texas Tech University Health Sciences Center	Mitchell, Amy
PP140049	Morales-Campos, Daisy	The University of Texas Health Science Center at San Antonio	Green, Lawrence; Vanderpool, Robin; Montgomery, Will; Mitchell, Amy
PP140164	Shokar, Navkiran	Texas Tech University Health Sciences Center at El Paso	Mitchell, Amy
PP140176	Ramirez, Amelie	The University of Texas Health Science Center at San Antonio	Green, Lawrence; Plescia, Marcus; Montgomery, Will; Mitchell, Amy
PP140182	Argenbright, Keith	The University of Texas Southwestern Medical Center	Montgomery, Will; Mitchell, Amy
PP140183	Vernon, Sally	The University of Texas Health Science Center at Houston	Vanderpool, Robin; Montgomery, Will; Mitchell, Amy
PP140209	He, Meizi	The University of Texas at San Antonio	Green, Lawrence; Montgomery, Will; Mitchell, Amy
PP140210	Chen, Lei-Shih	Texas A&M University	Montgomery, Will; Mitchell, Amy
PP140211	Penaranda, Eribeth	Texas Tech University Health Sciences Center at El Paso	Mitchell, Amy
Applications Not Recommended for PIC or Oversight Committee Consideration			

* = Not Discussed

Grant ID	Applicant	Institution	Conflict Noted
PP140046*	Parra-Medina, Deborah	The University of Texas Health Science Center at San Antonio	Brandt, Heather; Green, Lawrence; Vanderpool, Robin
PP140184*	Young-McCoughan, Stacey	The University of Texas Health Science Center at San Antonio	Green, Lawrence
PP140191*	Winkler, Paula	The University of Texas Health Science Center at San Antonio	Green, Lawrence; Vanderpool, Robin
PP140224*	Auzenne, David	Texas Department of State Health Services	Bright, Frank

* = Not Discussed



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CEO Affidavit Supporting Information

FY 2014 – Cycle 1
Competitive Continuation/Expansion Projects

Request for Applications



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**REQUEST FOR
APPLICATIONS
RFA P-14-CCE-1**

Competitive Continuation/Expansion

**Please also refer to the “Instructions for Applicants” document, which will be
posted December 19, 2013**

Application Receipt Opening Date: December 19, 2013
Application Receipt Closing Date: February 27, 2014

FY 2014

Fiscal Year Award Period

September 1, 2013–August 31, 2014

TABLE OF CONTENTS

1. ABOUT CPRIT	5
2. FUNDING OPPORTUNITY DESCRIPTION	5
2.1. SUMMARY	5
2.2. PROGRAM OBJECTIVES	6
2.3. AWARD DESCRIPTION	7
2.3.1. <i>Required Services or Interventions</i>	9
2.3.2. <i>Priority Areas</i>	11
2.3.3. <i>Specific Areas of Interest</i>	12
2.3.4. <i>Outcome Metrics</i>	14
2.4. ELIGIBILITY	16
2.4.1. <i>Applicant Organization</i>	16
2.5. FUNDING INFORMATION.....	18
3. KEY TERMS.....	19
4. KEY DATES.....	20
5. SUBMISSION GUIDELINES	21
5.1. ONLINE APPLICATION RECEIPT SYSTEM	21
5.1.1. <i>Submission Deadline Extension</i>	21
5.2. APPLICATION COMPONENTS	21
5.2.1. <i>Abstract and Significance (5,000 characters)</i>	22
5.2.2. <i>Goals and Objectives (download template)</i>	22
5.2.3. <i>Project Timeline</i>	23
5.2.4. <i>Project Plan (15 pages maximum; fewer pages permissible)</i>	23
5.2.5. <i>People/Professionals Reached and Served (complete online)</i>	25
5.2.6. <i>References</i>	25
5.2.7. <i>CPRIT Grants Summary (download template)</i>	25
5.2.8. <i>Budget and Justification (complete online)</i>	26
5.2.9. <i>Current and Pending Support and Sources of Funding (download template)</i>	27
5.2.10. <i>Biographical Sketches (download template)</i>	27
5.2.11. <i>Collaborating Organizations (complete online)</i>	28
5.2.12. <i>Letters of Commitment</i>	28

6.	APPLICATION REVIEW	28
6.1.	REVIEW PROCESS OVERVIEW	28
6.2.	REVIEW CRITERIA.....	30
6.2.1.	<i>Primary Evaluation Criteria</i>	30
6.2.2.	<i>Secondary Evaluation Criteria</i>	33
7.	AWARD ADMINISTRATION.....	34
8.	CONTACT INFORMATION.....	35
8.1.	HELPDESK	35
8.2.	PROGRAM QUESTIONS	35
9.	CONFERENCE CALLS TO ANSWER APPLICANT QUESTIONS	35
10.	RESOURCES	36
11.	REFERENCES.....	37
APPENDIX A	DEFINING CANCER PREVENTION AND CONTROL PROGRAMS AND CANCER PREVENTION/INTERVENTION RESEARCH FOR CPRIT GRANTS	38

RFA VERSION HISTORY

Rev 12/9/13 RFA release

1. ABOUT CPRIT

The State of Texas has established the Cancer Prevention and Research Institute of Texas (CPRIT), which may issue up to \$3 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to:

- Create and expedite innovation in the area of cancer research and in enhancing the potential for a medical or scientific breakthrough in the prevention of or cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the State of Texas; and
- Develop and implement the Texas Cancer Plan.

2. FUNDING OPPORTUNITY DESCRIPTION

2.1. Summary

The ultimate goals of the CPRIT Prevention Program are to reduce overall cancer incidence and mortality and to improve the lives of individuals who have survived or are living with cancer. The ability to reduce cancer death rates depends in part on the application of currently available evidence-based technologies and strategies. CPRIT will foster the primary, secondary, and tertiary prevention of cancer in Texas by providing financial support for a wide variety of evidence-based projects relevant to prevention through risk reduction, early detection, and survivorship.

This **Competitive Continuation/Expansion (CCE)** RFA solicits applications seeking to continue or expand projects previously or currently funded under Evidence-Based Prevention Services, and Health Behavior Change Through Public and/or Professional Education mechanisms. **This award mechanism is open only to previously or currently funded CPRIT prevention projects.**

The proposed projects must continue to provide evidence-based interventions in at least one of the following cancer prevention and control areas:

- Primary cancer prevention (e.g., vaccine-conferred immunity, promoting healthier diets, avoidance of alcohol misuse, enhancing physical activity, and sun protection)
- Secondary prevention (e.g., screening/early detection for breast, cervical, and/or colorectal cancers)
- Tertiary prevention (e.g., survivorship services such as physical rehabilitation/therapy, psychosocial interventions, navigation services, palliative care)

Project activities include, but are not limited to, public education, professional education, clinical service delivery, and include systems/policy change as described in the RFAs under which the initial projects were funded.

CPRIT strongly encourages expansion of current projects into geographic areas not well served by the CPRIT portfolio (see maps at <http://www.cprit.state.tx.us/prevention/cprit-portfolio-maps/>), especially rural areas, or subpopulations of urban areas that are not currently being served.

There are four types of CCE applications: CCE-Health Behavior Change Through Public Education (PubEd); CCE-Health Behavior Change Through Professional Education (ProfEd); CCE-Health Behavior Change Through Public and Professional Education (PPE); and CCE-Evidence-Based Cancer Prevention Services (EBP). Complete details of the goals and objectives of each award mechanism for currently or previously funded grants are stated in the individual RFAs (https://cpritgrants.org/Previous_Funding_Opportunities). When in doubt, contact the CPRIT Prevention Program Office (see [Section 8.2](#)).

2.2. Program Objectives

CPRIT seeks to fund the following types of projects:

- Evidence-based prevention and survivorship services that will:
 - Address multiple components of the cancer prevention and control continuum (e.g., provision of screening and navigation services in conjunction with outreach and education of the target population as well as healthcare provider education);

- Offer effective and efficient systems of delivery of prevention services based on the existing body of knowledge about, and evidence for, cancer prevention in ways that far exceed current performance in a given service area (e.g., partnering with other organizations to overcome barriers in order to make delivery systems more efficient and accessible to the target population);
 - Offer systems and/or policy changes that are sustainable over time (e.g., development of processes such as reminder systems to increase screening rates and adoption of worksite policies supporting screening);
 - Provide tailored, culturally appropriate outreach and accurate information on early detection, prevention, and survivorship to the public and/or healthcare professionals that result in a health impact that can be measured; and/or
 - Deliver evidence-based survivorship services aimed at reducing the morbidity associated with cancer diagnosis and treatment.
- Public and professional education and outreach that include efforts aimed at:
 - Primary prevention (e.g., delivery of vaccines that reduce the risk of cancer, evidence-based screening and counseling services for behaviors associated with increased cancer risk such as obesity, alcohol misuse, etc.);
 - Secondary prevention (e.g., utilizing risk-appropriate cancer screening guidelines for mammography, colonoscopy, and Pap test); and/or
 - Tertiary prevention (e.g., prevention and detection of new and recurrent cancer as well as interventions for the consequences of cancer and its treatment, such as physical rehabilitation/therapy, psychosocial interventions, survivor care plans, and palliative care services).

2.3. Award Description

CPRIT's **Competitive Continuation/Expansion** grants are intended to fund continuation or expansion of currently or previously funded projects that have demonstrated exemplary success as evidenced by progress reports and project evaluations. Detailed descriptions of **results, barriers, outcomes, and impact of the currently or previously funded project are required** (see outline of project plan, [Section 5.2.4](#)).

The **Competitive Continuation/Expansion** award mechanism seeks to fund programs that have achieved outstanding results and that desire to further enhance their impact on their target populations. The proposed program should be designed to reach and serve as many people as possible. The budget should be proportional to the number of individuals served. Partnerships with other organizations that can support and leverage resources are strongly encouraged.

Established infrastructure/processes and fully described prior project results are required.

A coordinated submission of a collaborative partnership program in which all partners have a substantial role in the proposed project is preferred.

The projects proposed under this mechanism should NOT be new projects but should closely follow the intent and core elements of the currently or previously funded project.

Improvements and expansion (e.g., new geographic area, additional services, new populations) are strongly encouraged but will require justification. Expansion of current projects into geographic areas not well served by the CPRIT portfolio (see maps), especially rural areas, or subpopulations of urban areas that are not currently being served will receive priority consideration. CPRIT expects measurable outcomes of supported activities, such as a significant increase over baseline (for the proposed service area). It is expected that baselines will have been established in the currently or previously funded project and that there is an expectation of continued improvement over baseline demonstrated in the current application. However, in the case of a proposed expansion where no baseline data exist for the target population, the applicant must present clear plans to collect the data necessary to establish a baseline at the beginning of the proposed project. Applicants must demonstrate how these outcomes will ultimately impact cancer incidence, mortality, morbidity, or quality of life.

CPRIT also expects that applications for continuation or expansion **will not** require startup time, that applicants can demonstrate that they have overcome barriers encountered, and that applicants have identified **lasting systems changes** that improve results, efficiency, and sustainability. Leveraging of resources and plans for dissemination are expected and should be well described.

Under this RFA, CPRIT **will not** consider:

- **Projects focusing on case management/patient navigation services through the treatment phase of cancer.** While navigation to the point of cancer treatment may be covered when cancer is discovered through a CPRIT-funded project, provision of coordination of care while an individual is in treatment is not a focus of the CPRIT Prevention Program.
- **Projects utilizing State Quitline services.** CPRIT will not entertain applications that seek to restore or expand Department of State Health Services (DSHS) Quitline services that have been reduced from previous funding levels by State agencies. Applicants proposing the utilization of Quitline services should communicate with the Tobacco Prevention and Control program prior to submitting a CPRIT grant application to discuss the services currently offered by DSHS.
- **Treatment of cancer.** While education about treatment options and access to treatment are important in reducing mortality from cancer, this award mechanism **will not provide resources for the treatment of cancer.**
- **Prevention/intervention research.** Research will not be funded through this award mechanism. However, this award mechanism expects rigorous evaluation that will build understanding of and capacity to deliver effective programs through dissemination of findings, particularly from efforts to innovate and adapt evidence-based programs for target populations. Applicants interested in research should review CPRIT's research RFAs (available at <http://www.cprit.state.tx.us>). Refer to [Appendix A](#) for guidance in defining prevention research and cancer prevention and control programs.

2.3.1. Required Services or Interventions

CPRIT requires applicants to deliver evidence-based interventions in at least one of the following cancer prevention and control areas (see [Section 2.3.3](#) for areas of interest).

Clinical Services

- Delivery of vaccines that reduce the risk of cancer
- Evidence-based assessment and counseling services for behaviors established as increasing cancer risk, such as tobacco use, obesity, alcohol misuse, etc.
- Screening and early detection services (e.g., mammography, colonoscopy, Pap test)

- Survivorship services (e.g., physical rehabilitation/therapy, psychosocial interventions, navigation services, and palliative care services)

CPRIT considers counseling services (e.g., tobacco cessation, survivorship, exercise, and nutrition) as clinical services when provided on an individual basis or in small groups.

Applicants are **required** to conceptualize comprehensive projects **or provide a continuum of services** that would increase desired outcomes (e.g., provide colorectal cancer screening services in conjunction with outreach and education of the target population and provide navigation services for follow-up care, if needed). The proportion of the budget allocated to providing direct services will be a consideration when applications are evaluated.

This mechanism **will fund** case management/patient navigation if it is paired with the actual delivery of a clinical service (e.g., human papillomavirus [HPV] vaccination, screening, survivorship service such as physical rehabilitation). Applicants offering screening services must ensure that there is access to treatment services for patients with cancers that are detected as a result of the program. Applicants must describe plans to provide access to treatment services. Applicants offering survivorship services should include an individual needs assessment in addition to the clinical service.

Public and/or Professional Education

- Development and delivery of culturally competent, evidence-based methods of community education, outreach, and support on primary prevention, early detection, and survivorship
- Delivery of education and training for healthcare professionals that are designed to improve practice behaviors and system support related to primary and secondary prevention of cancer as well as cancer survivorship issues that will result in facilitation and sustained behavior change in the patient population

Projects must include active, rather than passive, education and outreach strategies that are designed to reach, engage, and motivate people and must include plans for realistic action and sustainable behavior change. Applicants **must assist participants in obtaining the prevention interventions being promoted** (providing navigation, assisting with scheduling, etc.) **and have a process for tracking participants to document actions taken.**

Systems and Policy Change

- All projects should address local policy or systems change (e.g., change in healthcare systems, worksites, schools) that can lead to sustainable change in desired health behaviors and/or increase access to and delivery of cancer prevention services (e.g., increase screening rates).
- Projects should address barriers to access and delivery of prevention services by addressing systems, policy, or other changes.

2.3.2. Priority Areas

Types of Cancer: Applications addressing any cancer type(s) that are responsive to this RFA will be considered for funding. However, projects focused on screening will be limited to those anatomic sites for which there is strong evidence of effectiveness (i.e., breast, cervical, and/or colorectal cancers).

Target Populations: Priority populations are subgroups that are disproportionately affected by cancer. Priority populations include, but are not limited to, the following:

- Underinsured and uninsured individuals
- Geographically or culturally isolated populations
- Medically unserved or underserved populations
- Populations with low health literacy skills
- Geographic regions of the State with higher prevalence of cancer risk factors (e.g., obesity, tobacco use, alcohol misuse, unhealthy eating, sedentary lifestyle)
- Racial, ethnic, and cultural minority populations
- Any other populations with low screening rates, high incidence rates, and high mortality rates, focusing on individuals who are significantly out of compliance with nationally recommended screening guidelines:
 - Individuals never before screened for colorectal cancer
 - Women never before screened for cervical cancer or who have not been screened in the past 5 years
 - Women never before screened for breast cancer or who have not been screened in the past 5 years

Geographic and Population Balance Priority: For applications submitted in response to this announcement, at the programmatic level of review conducted by the Prevention Review Council, priority will be given to projects that target geographic regions of the State and population subgroups that are not adequately covered by the current CPRIT Prevention project portfolio. Applicants applying for **Competitive Continuation/Expansion** awards are encouraged to review the distribution of CPRIT projects when identifying priority areas as well as geographic distribution of the current projects in order to target underserved areas and populations. For other programmatic considerations evaluated by the Prevention Review Council, see [Section 6.1](#). Maps are available by cancer type, primary focus of program (public education, professional education, clinical service, survivor care, and healthy lifestyle/obesity prevention), and counties served for all CPRIT prevention projects active at the time these awards are made and can be accessed at <http://www.cprit.state.tx.us/prevention/resources-for-cancer-prevention-and-control>.

2.3.3. Specific Areas of Interest

CPRIT has identified the following areas of interest for this cycle of awards.

A. Primary Preventive Services

Priority will be given to projects that, through evidence-based efforts, address and can positively influence **local policy or systems change** (e.g., change in healthcare systems, worksites, schools) that can lead to **sustainable change in desired health behaviors**.

Tobacco Prevention and Control

CPRIT is interested in applications focused on areas of the State:

- That have higher smoking rates per capita than other areas of the State
- Where funds for tobacco use control efforts are not readily accessible from other sources

HPV Vaccination

CPRIT is interested in applications to increase access to and delivery of the HPV vaccine regimen through evidence-based intervention efforts.^{[1](#)}

B. Screening and Early Detection Services

Priority will be given to projects for screening and early detection of colorectal, breast, and cervical cancers.

Colorectal Cancer

- Increasing screening/detection rates in North and East Texas. The highest rates of cancer incidence and mortality are found in East and North Texas.^{2,3}
- Decreasing disparities in racial/ethnic populations and rural communities. African Americans have the highest incidence and mortality rates, followed by non-Hispanic Whites and Hispanics.^{2,3}
- Decreasing incidence and mortality rates in rural counties. Incidence and mortality rates are higher in rural counties compared with urban counties.^{2,3}

Breast Cancer

- Increasing screening/detection rates in rural and medically underserved areas of the State.
- Reaching women never before screened or who have not been screened in the last 5 years, if addressing breast cancer in urban areas.

Cervical Cancer

- Increasing screening/detection rates for women in Texas-Mexico border counties. Women in these counties have a 31 percent higher cervical cancer mortality rate than women in nonborder counties.^{2,3}
- Decreasing disparities in racial/ethnic populations. Hispanics have the highest incidence rates, while African Americans have the highest mortality rates.^{2,3}

For more information about breast, cervical, and colorectal cancers in Texas, visit CPRIT's Web site at <http://www.cprit.state.tx.us/prevention/resources-for-cancer-prevention-and-control> or visit the Texas Cancer Registry site at <http://www.dshs.state.tx.us/tcr>. Clinical services (e.g., HPV vaccination; screenings for breast, cervical, and colorectal cancers) should be evidence based; therefore, the age of the target population and frequency of screening plans for provision of clinical services described in the application must comply with established and current national guidelines (e.g., U.S. Preventive Services Task Force, American Cancer Society).

C. Survivorship Services

CPRIT acknowledges that, while there is evidence showing the benefit of many survivorship interventions in improving various health-related outcomes,⁴ in many cases more evidence is needed to determine which interventions are able to produce the greatest health benefits. In proposing survivorship interventions, applicants should demonstrate an understanding of the available evidence and should draw on this evidence to support their application. Rigorous evaluation of outcomes is required and publication of the results of survivorship projects is encouraged in order to add to the body of evidence.

Priority for funding will be given to survivorship service projects that demonstrate a likelihood of success based on available evidence and can demonstrate and measure an improvement in quality of life.

2.3.4. Outcome Metrics

The applicant is required to describe the results (quantitative and qualitative) of the currently or previously funded project and the proposed outcome measures/metrics for the current application. The ultimate goals of this award are to reduce overall cancer incidence and mortality and to improve the lives of individuals who have survived cancer or who are living with cancer. Interim measures that are associated with these goals should be identified and will serve as a measure of program effectiveness and public health impact. Applicants are required to clearly describe their assessment and evaluation methodology and to provide results and baseline data from currently or previously funded projects. Applicants should describe how funds from the proposed CPRIT grant will improve and expand outcomes from the initial project and how the current application builds on the previous work or addresses new areas of cancer prevention and control services.

Outcome measures/metrics (as appropriate for each project) should include, **but are not limited to**, the following:

For Primary Preventive Services

- Percentage increase over baseline in provision of age- and risk-appropriate, comprehensive preventive services to eligible men and women in a defined service area (e.g., completion of all required doses of hepatitis B virus vaccine)

- Percentage of people reporting sustained behavior change (e.g., for diet and physical activity)
- Estimates of cancers prevented as a result of primary prevention services

For Screening Services

- Percentage increase over baseline in provision of age- and risk-appropriate, comprehensive preventive services to eligible men and women in target populations
- Percentage increase over baseline in early-stage cancer diagnoses in a defined service area

For Survivorship Services

- Percentage increase over baseline in provision of survivorship services in a defined service area
- Percentage increase over baseline in improvement in quality-of-life measures using a validated quality-of-life instrument (e.g., FACT-G, Zebrock Impact of Cancer Scale, SF-12, SF-36, or QLACS), if such an instrument is applicable to the project
- Percentage of people reporting sustained behavior change (e.g., for diet and physical activity)
- Percentage of people showing clinical improvement of cancer treatment sequelae

For Public/Patient Behavior Change

- Increase over baseline in the number of people in priority populations who take preventive actions (e.g., change behavior, access screening services, receive counseling) as a result of participating in the educational program
- Interim measures may include increase over baseline in the number of people who accessed services and were appropriately counseled about health behaviors and evidence-based screening guidelines

For Provider Outcomes

- Knowledge increase:
 - Increase over baseline in healthcare providers' **knowledge and ability to counsel, engage, and motivate** patients on preventive measures, such as screening guidelines, healthy lifestyles, tobacco cessation, and available prevention services

- Increase over baseline in healthcare providers' knowledge of cancer survivorship issues and services
- Provider performance/practice improvement or behavior change (see Moore et al.'s seven levels of continuing medical education outcome measures for an example of an evaluation framework and definition of provider performance change⁵):
 - Increase over baseline in the number of healthcare providers who screen and counsel their at-risk patients about tobacco use and cessation; healthy lifestyles; alcohol misuse; cancer screenings, including the pros and cons of prostate cancer screening, etc.
 - Increase over baseline in the number of healthcare providers who address patients' postdiagnosis issues, including counseling and referral to survivorship programs and services

System Change (for all projects)

- Qualitative analysis of policy or systems change
- Description of lasting, sustainable system changes

2.4. Eligibility

2.4.1. Applicant Organization

The applicant must be a Texas-based entity—such as a community-based organization, health institution, government organization, public or private company, college or university, or academic health institution—that previously received CPRIT funding through Prevention Program RFAs.

The designated Program Director (PD) will be responsible for the overall performance of the funded project. The PD must have relevant education and management experience and must reside in Texas during the project performance time.

The evaluation of the project must be headed by a professional who has demonstrated expertise in the field (e.g., qualitative or quantitative statistics) and who resides in Texas during the time that the project is conducted.

The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application was submitted.

The applicant may submit more than one continuation application, if eligible, but each application must be for distinctly different services without overlap in the services provided. Applicants who do not meet this criterion will have all applications administratively withdrawn without peer review. To be eligible to receive this award, applicants should time the submission of applications for continuation/expansion so that the contract execution date (see [Section 4](#)) of the project comes after the contract expiration date of the initial CPRIT award and there is no overlap in funding. Applications for continuation/expansion submitted in response to a current CPRIT RFA that has a contract execution date that comes before the contract expiration date of the initial CPRIT award will be administratively withdrawn.

If the applicant or a partner is an existing DSHS contractor (e.g., tobacco coalition, current Breast and Cervical Cancer Services program provider, or other), CPRIT funds may not be used as a match, and the application must explain how this grant complements or leverages existing State and Federal funds. DSHS contractors who also receive CPRIT funds must be in compliance with and fulfill all contractual obligations within CPRIT. CPRIT and DSHS reserve the right to discuss the contractual standing of any contractor receiving funds from both entities.

Collaborations are permitted and encouraged, and collaborators may or may not reside in Texas. However, collaborators who do not reside in Texas are not eligible to receive CPRIT funds. Subcontracting and collaborating organizations may include public, not-for-profit, and for-profit entities. Such entities may be located outside of the State of Texas, but non-Texas-based organizations are not eligible to receive CPRIT funds.

An applicant organization is eligible to receive a grant award only if the applicant certifies that the applicant organization, including the PD, any senior member or key personnel listed on the grant application, and any officer or director of the grant applicant's organization, (or any person related to one or more of these individuals within the second degree of consanguinity or affinity), have not made and will not make a contribution to CPRIT or to any foundation created to benefit CPRIT. An entity is not eligible if the applicant is related to a CPRIT Oversight Committee member.

The applicant must report whether the applicant organization, the PD, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way (whether

slated to receive salary or compensation under the grant award or not), are currently ineligible to receive Federal grant funds or have had a grant terminated for cause within 5 years prior to the submission date of the grant application.

CPRIT grants will be awarded by contract to successful applicants. CPRIT grants are funded on a reimbursement-only basis. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in [Section 7](#). In addition, all statutory provisions and relevant administrative rules can be found at <http://www.cprit.state.tx.us>.

2.5. Funding Information

Applicants may request any amount of funding up to the maximum listed below for each type of project (Table 1). Budget requests for funding will vary depending on the project, and it is anticipated that the majority of projects will request significantly less than the maximum.

Table 1. Summary of Funding Amounts for CCE

Competitive Continuations	Health Behavior Change Through Public Education (PubEd)	Health Behavior Change Through Professional Education (ProfEd)	Health Behavior Change Through Public and Professional Education (PPE)	Evidence-Based Cancer Prevention Services (EBP)
Duration of the project	24 months	24 months	24 months	36 months
Total funding	\$150,000	\$150,000	\$150,000 each component (Public and Professional)	\$1.5 M

Within the Evidence-Based Cancer Prevention Services (EBP) mechanism, the following estimates may be used as a general guide:

- Primary prevention services: \$300,000 to \$500,000
- Screening and early detection services, including clinical services: Up to \$1.5 million (projects requesting the maximum should provide comprehensive services, demonstrate broad-based community collaboration, and serve as many people as possible)
- Survivorship services: \$300,000 to \$500,000

Grant funds may be used to pay for clinical services, navigation services, salary and benefits, project supplies, equipment, costs for outreach and education of populations, and travel of project personnel to project site(s). Equipment requests (\$5,000+ per unit) will receive a case-by-case evaluation and will be carefully scrutinized. Requests for funds to support construction, renovation, or any other infrastructure needs are not appropriate for this mechanism, nor are requests to support lobbying or to attend out-of-State professional meetings. Grantees may request funds for travel for two project staff to attend CPRIT's annual conference.

The budget should be proportional to the number of individuals receiving programs and services, and a significant proportion of funds is expected to be used for program delivery as opposed to program development. In addition, CPRIT seeks to fill gaps in funding rather than replace existing funding, supplant funds that would normally be expended by the applicant's organization, or make up for funding reductions from other sources. CPRIT does not provide support for projects when funds are readily available from other sources. Furthermore, CPRIT funds may not be used for any costs under this award that should be billed to any other funding source.

3. KEY TERMS

People/Professionals Reached: Number of members of the public and/or professionals reached via noninteractive public or professional education and outreach activities, such as mass media efforts, brochure distribution, public service announcements, newsletters, and journals. The category includes individuals who would be reached through activities that are directly funded by CPRIT as well as individuals who would be reached through activities that occur as a direct

consequence of the CPRIT-funded project's leveraging of other resources/funding to implement the CPRIT-funded project.

People/Professionals Served: Number of members of the public and/or professionals served via direct, interactive public or professional education, outreach, training, or clinical service delivery, such as live educational and/or training sessions, vaccine administration, screening, diagnostics, case management services, and physician consults. The category includes individuals who would be served through activities that are directly funded by CPRIT as well as individuals who would be served through activities that occur as a direct consequence of the CPRIT-funded project's leveraging of other resources/funding to implement the CPRIT-funded project (e.g., X people screened for cervical cancer after referral to Y indigent care program as a result of CPRIT-funded navigation services performed by the project).

Goals: Broad statements of general purpose to guide planning. Goals should be few in number and focus on aspects of highest importance to the project.

Objectives: Specific, **measurable**, actionable, realistic, and timely projections for outputs and outcomes Example: "Increase screening service provision in X population from Y percent to Z percent by 20xx." Baseline data for the target population must be included as part of each objective.

Activities: A listing of the "who, what, when, where, and how" for each objective that will be accomplished.

Evidence-Based Program: A program that is validated by some form of documented research or applied evidence. CPRIT's Web site provides links to resources for evidence-based strategies, programs, and clinical recommendations for cancer prevention and control. To access this information, visit <http://www.cprit.state.tx.us/prevention/resources-for-cancer-prevention-and-control>.

4. KEY DATES

RFA

RFA release

December 9, 2013

Application

Online application opens	December 19, 2013, 7 a.m. Central Time
Application due	February 27, 2014, 3 p.m. Central Time
Application review	March–June 2014

Award

Award notification	August 2014
Anticipated start date	August 2014

5. SUBMISSION GUIDELINES

5.1. Online Application Receipt System

Applications must be submitted via the CPRIT Application Receipt System (CARS) (<https://CPRITGrants.org>). **Only applications submitted at this portal will be considered eligible for review.** The PD must create a user account in the system to start and submit an application. The Co-PD, if applicable, must also create a user account to participate in the application. Furthermore, the Authorized Signing Official (a person authorized to sign and submit the application for the organization) and the Grants Contract/Office of Sponsored Projects Official (the individual who will manage the grant contract if an award is made) also must create a user account in CARS. Submission of an application is considered an acceptance of the terms and conditions of the RFA. Detailed instructions for submitting an application in the Instructions for Applicants document which will be posted on CARS beginning December 19, 2013.

5.1.1. Submission Deadline Extension

The submission deadline may be extended for one or more grant applications upon a showing of good cause. All requests for extension of the submission deadline must be submitted via e-mail to the CPRIT HelpDesk. Submission deadline extensions, including the reason for the extension, will be documented as part of the grant review process records.

5.2. Application Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. Submissions that are missing one or more components or do not meet the eligibility requirements listed in [Section 2.4](#) will be administratively withdrawn

without review. Refer to the Instructions for Applicants document for detailed information and guidance on application components.

5.2.1. Abstract and Significance (5,000 characters)

Clearly explain the problem(s) to be addressed and the approach(es) to the solution. The abstract and significance statement should clearly and succinctly address how the application is responsive to this RFA. In the event that the project is funded, the abstract will be made public; therefore, no proprietary information should be included in this statement. Initial compliance decisions are based upon review of this statement.

The required abstract format is as follows (use headings as outlined below):

- **Need:** Include a description of need in the specific service area. Include rates (e.g., incidence of targeted cancer, mortality, and screening) in the service area compared to overall Texas rates. Describe barriers, plans to overcome these barriers, and the target population to be served.
- **Overall Project Strategy:** Describe the project and how it will address the identified need. Clearly explain what the project is and what it will specifically do. For example, summarize the services to be provided, the process/system for delivery of services and outreach to the targeted population, components of the project, and related factors.
- **Specific Goals:** State specifically the overall goals of the proposed project; include the estimated overall numbers of people (public and/or professionals) to be reached and people (public and/or professionals) to be served.
- **Significance and Impact:** Explain how the proposed project, if successful, will have a unique and major impact on cancer prevention and control for the population proposed to be served and for the State of Texas in general.

5.2.2. Goals and Objectives (download template)

Goals and objectives must be completed for the initial funded project and for the proposed continuation/expansion project. Enter the goals and objectives for the initial funded project in the Goals and Objectives template form. Enter the goals and objectives for the proposed continuation/expansion project in the CARS text fields. List specific goals and **measurable**

objectives for each year of the project. Provide baseline and results for the initial funded project and baseline and method(s) of measurement for the proposed continuation/expansion project.

5.2.3. Project Timeline

Provide a project timeline for project activities that includes deliverables and dates.

5.2.4. Project Plan (15 pages maximum; fewer pages permissible)

The required Project Plan format follows. Applicants must use the format outlined below (Table 2). Applications not following the required format will be administratively withdrawn.

The project plan must include information for both the initial funded project and the proposed continuation/expansion project within each of the four major sections listed below: Introduction, Project Components, Sustainability, and Dissemination. Within each of the major sections, the initial project must be described, followed by a description of the proposed continuation/expansion project. Each section must be clearly labeled and formatted.

Table 2. Project Plan components

PROJECT PLAN COMPONENTS	
INITIAL PROJECT	PROPOSED CONTINUATION/EXPANSION PROJECT
SECTION I: Introduction Describe the evidence-based intervention. If applicable, describe how it was adapted for the target population. Goals and Objectives will be completed separately in CARS and need not be provided in the project plan (section 5.2.2). However, if desired, goals and objectives may be fully repeated or briefly summarized here.	SECTION I: Introduction Present the rationale for the project continuation/expansion and describe how results will be improved and/or expanded over the initial project. Goals and Objectives will be completed separately in CARS and need not be provided in the project plan (section 5.2.2). However, if desired, goals and objectives may be fully repeated or briefly summarized here.
SECTION II: Project Components Briefly describe each of the following components of the initial project.	SECTION II: Project Components Briefly describe each of the following components of the proposed project.
Target population	Target population
Geographic region served	Geographic region served
Roles of key collaborators on the project	Roles of key collaborators on the project
Procedures that ensured access to treatment for evidence-based cancer prevention projects or to preventive services for education projects	Procedures that ensure access to treatment for evidence-based cancer prevention projects or to preventive services for education projects
Major system changes implemented during or as a result of project	Planned systems changes to be implemented during or as a result of project
Summary of key challenges or barriers encountered and strategies used to overcome them	Description of the impact on ultimate outcome measures (e.g., reduction of cancer incidence, mortality, and morbidity) and interim outcome measures (e.g., increase in the proportion of individuals receiving cancer screening, increase in the number of individuals demonstrating personal health behavior change);description of the plan for outcome measurements, including data collection and management methods, statistical analyses, and anticipated results

PROJECT PLAN COMPONENTS	
INITIAL PROJECT	PROPOSED CONTINUATION/EXPANSION PROJECT
SECTION III: Sustainability Describe ongoing efforts toward sustainability.	SECTION III: Organizational Capacity and Sustainability Describe the organization and its track record for providing services. Include information on the organization's financial stability and viability. A sustainability plan describing the continuation of the proposed intervention after CPRIT funding has ended must be included.
SECTION IV: Dissemination Describe any dissemination of project results to date. Describe how the project lends itself to further dissemination to other communities.	SECTION IV: Dissemination Describe how the project lends itself to further dissemination to other communities and/or organizations or expansion in the same communities. Describe plans for dissemination of project results. Dissemination of positive and negative project results and outcomes, including barriers encountered and successes achieved, is critical to building the evidence base for cancer prevention and control efforts.

5.2.5. People/Professionals Reached and Served (complete online)

Provide the estimated overall number of people/professionals to be reached and people/professionals to be served by the funded project. Provide an itemized list of activities/services, with estimates, that led to the calculation of the overall estimates provided. Refer to [Section 3](#) for definitions of people/professionals reached and people/professionals served.

5.2.6. References

Provide a concise and relevant list of references cited for the application. The successful applicant will provide referenced evidence of need and literature support for the proposed education and outreach methods.

5.2.7. CPRIT Grants Summary (download template)

Provide a description of the progress or final results of all CPRIT-funded projects, except for the initial funded project that is the basis for this CCE application, regardless of their connection to

this application. Progress for the initial project will be detailed in the Goals and Objectives template form (see [section 5.2.2](#)) and need not be repeated here.

This form must be completed if the organization, PD, or Co-PD has previously received CPRIT funding. Applications that are missing this document and have a PD and/or Co-PD with previous or current CPRIT funds will be administratively withdrawn prior to peer review.

5.2.8. Budget and Justification (complete online)

Provide a brief outline and detailed justification of the budget for the entire proposed period of support, including salaries and benefits, travel, equipment, supplies, contractual expenses, education and outreach expenses, and other expenses. CPRIT funds will be distributed on a reimbursement basis (see the Instructions for Applicants document for budget guidance). It is expected that the competitive renewals will not need a period of startup and that infrastructure will be already established.

Applications requesting more than the maximum allowed cost (total costs) as specified in [Section 2.5](#) will be administratively withdrawn.

- **Cost per Person Served:** The cost per person served will be automatically calculated from the total cost of the project divided by the total number of people (both public and professionals) served (refer to [Section 3](#)).
- **Personnel:** The individual salary cap for CPRIT awards is \$200,000 per year.
- **Travel:** PDs and related project staff are expected to attend CPRIT's annual conference. CPRIT funds may be used to send up to two people to the conference.
- **Equipment:** Equipment requests (\$5,000+ per unit) will be carefully evaluated on a case-by-case basis and must be specifically approved by CPRIT if the project is funded. Justification must be provided for why funding for this equipment cannot be found elsewhere; CPRIT funding should not supplant existing funds. A sustainability plan must be submitted for both the equipment and delivery of corresponding services as a result of the equipment purchase. Cost sharing of equipment purchases is strongly encouraged.
- **Services Costs:** CPRIT reimburses for services using Medicare reimbursement rates.
- **Other Expenses:**

Incentives: Use of incentives or positive rewards to change or elicit behavior is allowed; however, incentives may only be used based on strong evidence of their effectiveness for the purpose and in the target population identified by the applicant. CPRIT will not fund cash incentives. The maximum dollar value allowed for an incentive per person, per activity or session, is \$25.

Indirect Costs: It is CPRIT's policy **not** to allow recovery of indirect costs for prevention programs.

Costs Not Related to Cancer Prevention and Control: CPRIT does not allow recovery of any costs for services not related to cancer (e.g., health physicals, HIV testing).

5.2.9. Current and Pending Support and Sources of Funding (download template)

Applicants must identify by name all sources of contributing funding for the proposed project, including a capitalization table that reflects private investors, if any. This information is used to identify any conflicts of interest for reviewers. In addition, the applicant should list all current and pending awards/grants from State, Federal, nonprofit, and other sources that would extend or complement the proposed project. This allows the applicant to demonstrate how other funds would be leveraged to implement the proposed work. Using the template provided in the online application receipt system (CARS), provide the funding source, amount, status (pending or awarded), duration, and a two-line summary of the use of the funds for each current or pending award/grant.

5.2.10. Biographical Sketches (download template)

The designated PD will be responsible for the overall performance of the funded project and must have relevant education and management experience. The PD/Co-PD(s) must provide a biographical sketch that describes his or her education and training, professional experience, awards and honors, and publications and/or involvement in programs relevant to cancer prevention and/or service delivery.

The evaluation of the project must be headed by a professional who has demonstrated expertise in the field (e.g., qualitative or quantitative statistics). CPRIT encourages applicants to involve such a designated professional early in the planning and preparation of the application. The

applicant may choose to contract for these services if needed; the project budget should reflect these services. The evaluation professional must provide a biographical sketch.

Up to three additional biographical sketches for key personnel may be provided. Each biographical sketch must not exceed two pages.

5.2.11. Collaborating Organizations (complete online)

List all key participating organizations that will partner with the applicant organization to provide one or more components essential to the success of the program (e.g., evaluation, clinical services, recruitment to screening, etc.).

5.2.12. Letters of Commitment

Applicants should provide letters of commitment and/or memorandums of understanding from community organizations, key faculty, or any other component essential to the success of the program. For example, if the goal is to provide education to rural, community-based professionals, the applicant should obtain letters of commitment demonstrating the role of these professionals in providing access to navigation and/or preventive services. These letters must be included and uploaded in the application; do not send any letters directly to the CPRIT office.

Applications that are missing one or more of these components, exceed the specified page, word, or budget limits, or that do not meet the eligibility requirements listed above will be administratively rejected without review.

6. APPLICATION REVIEW

6.1. Review Process Overview

All eligible applications will be reviewed using a two-stage peer review process: (1) evaluation of applications by peer review panels and (2) prioritization of grant applications by the Prevention Review Council. In the first stage, applications will be evaluated by an independent review panel using the criteria listed below. In the second stage, applications judged to be meritorious by review panels will be evaluated by the Prevention Review Council and recommended for funding based on comparisons with applications from all of the review panels and programmatic priorities. Programmatic considerations may include, but are not limited to, geographic distribution, cancer type, population served, and type of program or service. As

emphasized in [Section 2.3.2](#) of this announcement, at the programmatic level of review priority will be given to proposed projects that target geographic regions of the State or population subgroups that are not well represented in the current CPRIT Prevention project portfolio.

Recommendations from the Prevention Review Council are forwarded to the CPRIT Program Integration Committee, which will consider factors including program priorities set by the Oversight Committee, portfolio balance across programs, and available funding.

The CPRIT Oversight Committee will vote to approve each grant award recommendation made by the Program Integration Committee. The grant award recommendations will be presented at an open meeting of the Oversight Committee and must be approved by two-thirds of the Oversight Committee members present and eligible to vote. The review process is described more fully in CPRIT's Administrative Rules, Chapter 703, Sections 703.6–703.8.

Each stage of application review is conducted confidentially and all panel members, Program Integration Committee members, CPRIT employees, and Oversight Committee members with access to grant application information are required to sign nondisclosure statements regarding the contents of the applications.

Individuals directly involved with the review process operate under strict conflict of interest prohibitions. All peer review panel members and Prevention Review Council members will be non-Texas residents. An applicant will be notified regarding the peer review panel assigned to review the grant application. Peer review panel members are listed by panel on CPRIT's Web site. **By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed Conflict of Interest as set forth in CPRIT's Administrative Rules, Chapter 703, Section 703.9(b).**

Communication regarding the substance of a pending application is prohibited between the grant applicant (or someone on the grant applicant's behalf) and the following individuals—an Oversight Committee member, a Program Integration Committee member, a peer review panel member, or a Prevention Review Council member. Applicants should note that both CPRIT's Chief Executive Officer and Chief Prevention Officer are members of the Program Integration Committee. The prohibition on communication begins on the first day that grant applications for

the particular grant mechanism are accepted by the Institute and extends until the grant applicant receives notice regarding a final decision on the grant application. The prohibition on communication does not apply to the time period when pre-applications or letters of interest are accepted. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant application from further consideration for a grant award.

6.2. Review Criteria

Peer review of applications will be based on primary (scored) criteria and secondary (unscored) criteria, identified below. Review panels consisting of experts in the field as well as consumer advocates will evaluate and score each primary criterion and subsequently assign an overall score that reflects an overall assessment of the application. The overall assessment will not be an average of the scores of individual criteria; rather, it will reflect the reviewers' overall impression of the application and responsiveness to the RFA priorities.

6.2.1. Primary Evaluation Criteria

The project will be evaluated on the basis of the following primary criteria. Concerns with any of these criteria potentially indicate a major flaw in the significance and/or design of the proposed project.

Impact

- Do the proposed services address an important problem or need in cancer prevention and control? Will the proposed outcomes have a significant impact on cancer incidence, morbidity, and/or mortality?
- Will the project reach and serve an appropriate number of people based on the budget allocated to providing services and the cost of providing services?
- Are the goals and priorities of the project responsive to the RFA?
- Does the proposed continuation/expansion project build on its initial results (baseline) and continue to demonstrate creativity, ingenuity, resourcefulness, or imagination? Does it go beyond the initial project to address what the applicant has learned or explore new partnerships, new audiences, or improvements to systems?
- Does the program address known gaps in prevention services and avoid duplication of effort?

Previous Project Performance

- Does the proposed continuation project demonstrate a high likelihood of success based on the initial project's results and outcomes?
- Has the applicant sufficiently described results and findings of the currently or previously funded application? This may include, but is not limited to, the following components:
 - Negative results and/or barriers and strategies for overcoming them
 - Organizational infrastructure built and systems improved during the funded project
 - Demonstrated ability to meet goals, objectives, and timelines or adequate justification for not meeting them
 - Demonstrated results, including behavior change for participants

Project Strategy and Feasibility

- Does the proposed project provide prevention interventions or services specified in the RFA?
- Are the overall program approach and strategy clearly described and supported by established theory and practice? Are the proposed objectives and activities feasible within the duration of the award? Has the applicant convincingly demonstrated the short- and long-term impacts of the project?
- Is the program design supported by established theory and practice as well as evidence-based interventions? If the applicant is adapting an evidence-based intervention in a population where it has not been tried/tested, are plans described to adapt it?
- Are possible barriers addressed and approaches for overcoming them proposed?
- Are the target population and culturally appropriate methods to reach the target population clearly described? Are barriers for the population clearly described, and are plans to provide culturally appropriate education to overcome these barriers clearly addressed?
- If applicable, does the application demonstrate the availability of resources and expertise to provide case management, including followup for abnormal results and access to treatment? Has the applicant clearly described plans to ensure access to treatment services for patients diagnosed with cancer as a result of the program?
- Does the program leverage partners and resources to maximize the reach of the services proposed? For example, does the program negotiate for low-cost or pro bono services or in-

kind support, including staffing? Does the program leverage and complement other State, Federal, and nonprofit grants?

Outcomes Evaluation

- Are specific goals and measurable objectives for each year of the project listed for both the initial project and the proposed continuation project? Does the applicant provide the baseline and results or method(s) of measurement?
- Are the proposed outcome measures appropriate for the services provided, and are the expected changes clinically significant?
- Does the application provide a clear and appropriate plan for data collection and management, statistical analyses, and interpretation of results to follow, measure, and report on the project's outcomes?
- If an evidence-based intervention is being adapted in a population where it has not been tried/tested are plans for evaluation of barriers, effectiveness and fidelity to the model described?
- Is the qualitative analysis of planned policy or system changes described?

Organizational Capacity

- Do the organization and its collaborators/partners demonstrate the ability to provide the proposed preventive services? Does the described role of each collaborating organization make it clear that each organization adds value to the project, and do all collaborating organizations demonstrate commitment to work together to implement the project?
- Have the appropriate personnel been recruited to implement, evaluate, and complete the project? Is the appropriate infrastructure already in place?
- Does the applicant provide evidence of compelling project progress of the already funded project? If not, has the applicant addressed obstacles and strategies to overcome those obstacles?

Sustainability

Eventual financial sustainability of a project is desirable and projects should describe the steps they are taking towards that end. Continuation/expansion applications should demonstrate less need for startup time and infrastructure.

- Is the organization structurally and financially stable and viable?
- Are there feasible plans to sustain some or all of the project beyond the funded timeframe of this award?
- Are there feasible plans to integrate the program into existing and sustainable systems?

Elements contributing to organizational project sustainability may include some or all of the following:

- Developing ownership, administrative networks, and formal engagements with stakeholders
- Enhancing system capacity and developing processes for each practice/location to incorporate services into its structure beyond project funding
- Identifying and training of diverse resources (human, financial, material, and technological)

6.2.2. Secondary Evaluation Criteria

Secondary criteria contribute to the overall score assigned to the application. Lack of information or clarity in regard to these criteria may result in a lower overall score. Secondary evaluation criteria include:

Budget

- Is the budget appropriate and reasonable for the scope and services of the proposed work?
- Is the cost per person served appropriate and reasonable?
- Is the proportion of the funds allocated for direct services reasonable?
- Is the project a good investment of Texas public funds?

Dissemination and Scalability (Expansion)

- Does the applicant clearly describe how the project lends itself to dissemination to or adaptation and application by other communities and/or organizations in the State or expansion in the same communities?

Dissemination of positive and negative project results and outcomes, including barriers encountered and successes achieved, is critical to building the evidence base for cancer

prevention and control efforts in the State. Dissemination methods can include, but are not limited to, presentations, publications, abstract submissions, professional journal articles, etc.

7. AWARD ADMINISTRATION

Texas law requires that CPRIT grant awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to institutions or organizations, not to individuals. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT's electronic signature policy as set forth in Chapter 701, Section 701.25.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and intellectual property rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at <http://www.cprit.state.tx.us>. Applicants are advised to review CPRIT's Administrative Rules regarding contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in Chapter 703, Sections 703.10, 703.12.

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements set forth in CPRIT's Administrative Rules, Chapter 703, Section 703.20.

CPRIT requires the PD of the award to submit quarterly, annual, and final progress reports. These reports summarize the progress made toward project goals and address plans for the upcoming year and performance during the previous year(s). In addition, quarterly fiscal reporting and reporting on selected metrics will be required per the instructions to award recipients. Failure to provide timely and complete reports may waive reimbursement of grant award costs, and may result in the termination of the award contract.

8. CONTACT INFORMATION

8.1. HelpDesk

HelpDesk support is available for questions regarding user registration and online submission of applications. Queries submitted via e-mail will be answered within 1 business day. HelpDesk staff are not in a position to answer questions regarding the scope and focus of applications. Before contacting the HelpDesk, please refer to the Instructions for Applicants document (posted by December 19, 2013), which provides a step-by-step guide to using CARS.

Dates of operation: December 19, 2013 to February 27, 2014 (excluding public holidays)

Hours of operation: Monday, Tuesday, Thursday, Friday, 7 a.m. to 4 p.m. Central Time
Wednesday, 8 a.m. to 4 p.m. Central Time

Tel: 866-941-7146

E-mail: Help@CPRITGrants.org

8.2. Program Questions

Questions regarding the CPRIT Prevention program, including questions regarding this or any other funding opportunity, should be directed to the CPRIT Prevention Program Office.

Tel: 512-305-8422

E-mail: Help@CPRITGrants.org

Web site: www.cprit.state.tx.us

9. CONFERENCE CALLS TO ANSWER APPLICANT QUESTIONS

CPRIT will host a Webinar to provide an overview of this RFA and a demonstration of CARS. A programmatic and technical question and answer session will be included. Applicants should sign up for CPRIT's electronic mailing list at <http://www.cprit.state.tx.us> to ensure that they will receive notification of this Webinar.

10. RESOURCES

Cancer Statistics

The Texas Cancer Registry

Cancer incidence (cases) and mortality (deaths) in Texas

Web site: <http://www.dshs.state.tx.us/tcr>

E-mail: CancerData@dshs.state.tx.us

Tel: 800-252-8059

CPRIT, Texas Cancer Registry

Priority cancers for CPRIT's prevention program: Breast, cervical, and colorectal

- [Breast Cancer in Texas: A Closer Look \(1/4/10\)](#)
http://www.cprit.state.tx.us/images/uploads/report_breastc_a_closer_look.pdf
- [Cervical Cancer in Texas, 2010](#)
http://www.cprit.state.tx.us/images/uploads/cervical_cancer_in_texas_tcr_2010_low.pdf
- [Colorectal Cancer in Texas, 2010](#)
http://www.cprit.state.tx.us/images/uploads/colorectal_cancer_in_texas_tcr_2010_low.pdf

Evidence-Based Strategies, Programs, and Clinical Recommendations

The Community Guide

Resources by topic, including specific cancers, tobacco, and worksite programs

<http://www.thecommunityguide.org/index.html>

Cancer Control P.L.A.N.E.T.

Resources by topic, including specific cancers, tobacco, diet/nutrition, and survivorship

<http://cancercontrolplanet.cancer.gov>

Agency for Healthcare Research and Quality

Clinical recommendations for screening, counseling, etc.

Guide to Clinical Preventive Services, 2012: Recommendations of the U.S. Preventive Services Task Force. AHRQ Publication No. 12-05154, October 2012. Agency for Healthcare Research and Quality, Rockville, MD. <http://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/guide/>

Making Health Communication Programs Work—National Cancer Institute®

Effective communication tools for public education and outreach programs

<http://www.cancer.gov/pinkbook>

11. REFERENCES

1. <http://www.cdc.gov/vaccines/vpd-vac/hpv/vac-faqs.htm>
2. Texas Cancer Registry, Cancer Epidemiology and Surveillance Branch, Texas Department of State Health Services, 1100 W. 49th Street, Austin, TX, 78756
3. <http://www.dshs.state.tx.us/tcr/default.shtm> or 512-458-7523
4. <http://cancercontrolplanet.cancer.gov/survivorship.html>
5. Moore DE. A Framework for Outcomes Evaluation in the Continuing Professional Development of Physicians. In: Davis D, Barnes BE, Fox R, eds. The Continuing Professional Development of Physicians: From Research to Practice. Chicago, Ill: American Medical Association; 2003.
6. Centers for Disease Control and Prevention. Distinguishing Public Health Research and Public Health Nonresearch. <http://www.cdc.gov/od/science/integrity/docs/cdc-policy-distinguishing-public-health-research-nonresearch.pdf>.

APPENDIX A Defining Cancer Prevention and Control Programs and Cancer Prevention/Intervention Research for CPRIT Grants

Statute

By Texas statute, 90 percent of dollars available to CPRIT are awarded through CPRIT's Research Program. The CPRIT Prevention Program may award up to 10 percent (but not more) of dollars available to CPRIT.

Purpose of CPRIT Prevention Program

Grants funded under the Prevention Program are intended to fund prevention strategies, programs, and services that have a demonstrated evidence base and are culturally appropriate for the target population. An evidence-based strategy is a program or service that is validated by some form of documented research or applied evidence. Links to resources for evidence-based strategies, programs, and clinical recommendations can be found on CPRIT's Web site at <http://www.cprit.state.tx.us/prevention/resources-for-cancer-prevention-and-control>.

Based upon the above, the Prevention Program will focus on funding:

- Delivery of evidence-based, culturally appropriate education and outreach to the public and to healthcare professionals
- Delivery of evidence-based preventive services
- Adoption and implementation of policy and systems change to address barriers and promote prevention

Eligible projects include:

- Primary prevention (e.g., vaccine-conferred immunity, tobacco control, healthy diet, prevention of alcohol misuse, physical activity, sun protection)
- Early detection/screening (focus on breast, cervical, and/or colorectal cancers)
- Survivorship services (e.g., physical rehabilitation/therapy, psychosocial interventions, navigation services, palliative care)

The Prevention Program seeks to fund innovative ways of delivering evidence-based programs and services that (1) go beyond simply increasing the number of persons educated or trained to demonstrating and supporting sustainable behavior change and (2) go beyond delivering early

detection/screening services to improving systems and cost efficiencies by addressing needed systems and policy change or improvements. Projects should demonstrate measurable public health impact in ways that exceed current performance in a given service area.

The amount of funds available for the CPRIT Prevention Program is approximately \$30 million per year. To ensure that the prevention funds go toward the delivery of programs and clinical services to the public, a distinction between prevention research (funded under the Research Program) and the delivery of evidence-based prevention services to the public (funded under the Prevention Program) must be made. The Prevention Program does not accept or review prevention research applications. Organizations seeking funding for prevention research should consider submitting to CPRIT's Research Program.

Prevention/Intervention Research Versus Prevention Programs and Services

The Centers for Disease Control makes the following distinction between public health research and non-research:

“The major difference between research and non-research lies in the purpose of the activity. The purpose of research is to generate or contribute to generalizable knowledge. The primary intent of non-research in public health is to prevent or control disease or injury and improve health, or to improve a public health program or service.”⁶

CPRIT makes the following distinctions between prevention/intervention research and prevention programs and services.

A project is appropriate for the Prevention Program if:

- The intervention is evidence based.
- The intervention offers a program or service to the public and strives to reach and serve as many people as possible. Cost per person served will be highly variable depending on the project, but the majority of the budget should be for direct program or service delivery. Refer to each RFA; some RFAs, such as those focusing on policy/systems change, may cover only activities to address barriers and may not pay for the delivery of the service being evaluated.

- Evaluation is conducted under real-world (rather than controlled) circumstances, in real time, and with regular personnel conducting the interventions, usually without rigid protocols (also may be described as effectiveness research in contrast to efficacy research). Evaluation and reporting of outcomes are critical components of CPRIT-funded prevention projects and must be guided by a professional with demonstrated expertise and experience in the field. Applicants should budget accordingly for this activity.
- The purpose of the evaluation is to assess the success of the project in achieving its objectives (changing behavior, increasing screening rates, and increasing detection of cancers). CPRIT recognizes that, in many cases, evidence-based practices have been developed but not implemented in all populations or all service settings. For applications proposing to evaluate such projects, other forms of evidence (e.g., preliminary evaluation or pilot project data) that the proposed service is appropriate for the population and has a high likelihood of success must be provided. For example, the project may compare evidence-based strategies or evaluate implementation in a new population, but the main objective of the project should be to deliver a program or service to the public that will have a measureable impact on public health. CPRIT strongly encourages award recipients to submit the results and findings from their funded projects for publication in appropriate journals.

A project is appropriate for the Research Program if:

- The primary intent is to generate or contribute to generalizable knowledge.
- The project is conducted using highly controlled, usually randomized designs (also may be described as efficacy research).

What Kinds of Prevention/Intervention Research Will Be Eligible for the Research Program?

There is no restriction on the type of research that can be supported by CPRIT's Research Program except that the research must be relevant to cancer. Applications will be evaluated based on their significance and importance, their feasibility, the qualifications of the investigator(s), and related factors.

Types of prevention research include, **but are not limited to:**

- Preclinical and clinical research
- Health services research
- Behavioral research
- Intervention research
- Community-based participatory research
- Disease or behavioral surveillance systems research

Third Party Observer Report

CPRIT Prevention Peer Review Panel Observation Report

Report #2014-10

Panel Name: Prevention Peer Review Panel A – FY 14
Cycle 1

Panel Date: May 5-6, 2014

Report Date: May 6, 2014

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized its out-sourced internal audit provider to function as a neutral third-party observer.

Introduction

The subject of this report is the Prevention Peer Review Panel A review of prevention program applications. The meeting was chaired by Lawrence Green and held in person on May 5, 2014 and May 6, 2014 in Dallas, TX.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.

Observation Results Summary

Internal Audit participated in the Prevention Peer Review meeting held in person and chaired by Lawrence Green on May 5, 2014 and May 6, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Eleven prevention program applications were discussed and evaluated by the Prevention Peer Review to determine which grants would receive CPRIT funding.
- Ten panel reviewers, two advocate reviewers, six CPRIT staff members, and three SRA employees were present for the Panel meeting in person. Two panel reviewers joined the meeting via phone.

- Five conflicts of interest were identified prior to or during the meeting. The panel member with the conflict either left the room or logged off of the teleconference and did not participate in the review of the conflicted applications.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the peer review panel's discussion of scientific, technical or programmatic aspects of the applications.

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Prevention Peer Review Panel Observation Report

Report #2014-11

Panel Name: Prevention Peer Review Panel B – FY 14
Cycle 1

Panel Date: May 6-7, 2014

Report Date: May 7, 2014

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized its out-sourced internal audit provider to function as a neutral third-party observer.

Introduction

The subject of this report is the Prevention Peer Review Panel B review of prevention program applications. The meeting was chaired by Nancy Lee and held in person on May 6, 2014 and May 7, 2014 in Dallas, TX.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.

Observation Results Summary

Internal Audit participated in the Prevention Peer Review meeting held in person and chaired by Lawrence Green on May 5, 2014 and May 6, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Twelve prevention program applications were discussed and evaluated by the Prevention Peer Review to determine which grants would receive CPRIT funding.

- Ten panel reviewers, two advocate reviewers, six CPRIT staff members, and three SRA employees were present for the Panel meeting in person. Two panel reviewers and one CPRIT staff joined the meeting via phone.
- No conflicts of interest were identified prior to or during the meeting.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the peer review panel's discussion of scientific, technical or programmatic aspects of the applications.

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Prevention Peer Review Panel Observation Report

Report #2014-21

Panel Name: Prevention Review Council – Prevention
Program Applications

Panel Date: June 27, 2014

Report Date: July 7, 2014

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized its out-sourced internal audit provider to function as a neutral third-party observer.

Introduction

The subject of this report is the Prevention Review Council review of prevention program applications. The meeting was chaired by Lawrence Green and held in person on June 27, 2014.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The Council discussion is focused on the established scoring criteria.

Observation Results Summary

Internal Audit participated in the Prevention Review Council meeting held in person and chaired by Lawrence Green on June 27, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Seventeen prevention program applications were included within the application listing submitted to the Prevention Review Council for their review and approval.
- Three council members and four CPRIT staff members were present for the Council meeting in-person. Two SRA employees joined the meeting via phone.

- Two conflict of interest were identified prior to or during the meeting. The council member with the conflict of interests either left the room or logged off of the teleconference and did not participate in the review of the conflicted applications.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The Council members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the Council's discussion of scientific, technical or programmatic aspects of the applications.

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

De-Identified Overall Evaluation Scores

Competitive Continuation/Expansion Projects

Application ID	Final Overall Score
PP140205*	1.8
PP140033*	2.0
PP140049*	2.1
PP140164*	2.6
PP140210*	2.8
PP140026*	3.0
PP140028*	3.1
PP140182*	3.1
PP140171*	3.3
hh1	3.3
hh2	3.4
hh3	3.8
hh4	3.8
hh5	4.0
hh6	5.0
hh7	5.3
hh8	5.8

*=Recommended for Funding

Final Overall Evaluation Scores and Rank Order Scores

William Rice, M.D.
Oversight Committee Chair
Cancer Prevention and Research Institute of Texas
Via email to Bill.Rice@stdavids.com

Wayne R. Roberts
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cprit.state.tx.us

Dear Mr. Roberts and Dr. Rice,

On behalf of the Prevention Review Council (PRC), I am pleased to provide the PRC's recommendations for CPRIT Prevention grant awards. The applicants on the attached list submitted proposals in response to CPRIT requests for applications (RFA) released for the first review cycle of FY2014. Each recommendation reflects 50+ hours of individual review and panel discussion of the applicants' proposals as well as the PRC's programmatic review.

The projects are numerically ranked in the order the PRC recommends the applications be funded. Recommended funding amounts and the overall evaluation score are stated for each grant application. The PRC did not make changes to the funding amount, goals, timelines, or project objectives requested by the applicants. The Prevention program had \$18,228,345 in available funding for the remainder of the fiscal year. The PRC is recommending awards totaling \$17,568,470.

Our recommendations met the PRC's standards for grant award funding. In addition to meeting standards for quality and potential to impact public health, these projects meet the following standards: 1. are evidence-based; 2. deliver programs or services to underserved populations; and 3. focus on primary, secondary or tertiary prevention.

Sincerely,

Stephen W. Wyatt, DMD, MPH
Chair, CPRIT Prevention Review Council

App ID	Mechanism	Title	PD	Organization	Total Requested Funding	Score	Numerical Ranking Score	Recommended Funding
PP140208	EBP	Increasing HPV Vaccinations in Harris and Jefferson Counties Using Combined Evidence-Based Approaches in a Federally Qualified Health Center	Megdal, Tina	Legacy Community Health Services	\$1,500,000	1.7	1	\$1,500,000
PP140205	CCEEBP	Eliminating Cancer Disparities in Medically Underserved Immigrant and Refugee Populations in Houston Texas	Caracostis, Andrea	Asian American Health Coalition of Greater Houston, Inc., dba Hope Clinic	\$1,496,840	1.8	2	\$1,496,840
PP140033	CCEEBP	Access to Breast and Cervical Care for West Texas (ABC24WT)	Layeequr Rahman, Rakhshanda	Texas Tech University Health Sciences Center	\$1,499,670	2.0	3	\$1,499,670
PP140183	EBP	Multi-component Interventions to Increase HPV Vaccination in a Network of Pediatric Clinics	Vernon, Sally W	The University of Texas Health Science Center at Houston	\$1,495,388	2.0	3	\$1,495,388
PP140049	CCEPubEd	Educating Hispanic adolescents and their families on cervical cancer prevention and HPV vaccination in community and clinic settings	Morales-Campos, Daisy Y	The University of Texas Health Science Center at San Antonio	\$149,985	2.1	5	\$149,985
PP140176	EBP	SMS Cessation Service for Young Adult Smokers in South Texas	Ramirez, Amelie G	The University of Texas Health Science Center at San Antonio	\$1,400,045	2.1	5	\$1,400,045
PP140211	EBP	Tiempo de vacunarte! Time to get vaccinated!	Penaranda, Eribeth K	Texas Tech University Health Sciences Center at El Paso	\$1,499,195	2.3	7	\$1,499,195
PP140018	EBP	Improving Access to Colorectal Cancer Screening in East Texas	Sauter, Edward	The University of Texas Health Center at Tyler	\$1,269,216	2.4	8	\$1,269,216
PP140164	CCEEBP	ACCION 2: Against Colorectal Cancer in our Neighborhoods: El Paso and Hudspeth County	Shokar, Navkiran K	Texas Tech University Health Sciences Center at El Paso	\$1,499,438	2.6	9	\$1,499,438
PP140209	EBP	Building a Healthy Temple Cancer Primary Prevention Program amongst Hispanics	He, Meizi	The University of Texas at San Antonio	\$573,095	2.8	10	\$573,095
PP140210	CCEProfEd	Cancer genomics training program for a competent Texas health education workforce	Chen, Lei-Shih	Texas A&M University	\$149,991	2.8	10	\$149,991
PP140026	CCEEBP	Bridging Access to Breast Healthcare Services	Letman, Vanessa L	The Bridge Breast Network	\$1,497,357	3.0	12	\$1,497,357
PP140028	CCEEBP	Empowering the Medically Underserved Through a Community Network for Cancer Prevention	Jibaja-Weiss, Maria L	Baylor College of Medicine	\$1,499,234	3.1	13	\$1,499,234
PP140182	CCEEBP	Population Based Screening for Hereditary Breast and Ovarian Cancer Syndrome and the Lynch syndrome in	Argenbright, Keith E	The University of Texas Southwestern Medical Center	\$1,499,872	3.1	13	\$1,499,872
PP140171	CCEEBP	Navigating Rural Highways II: Expanding Access to Breast Cancer Screening and the Care Continuum for Underserved Texas Women (NRH II)	Joseph, Bernice	The Rose	\$539,144	3.3	15	\$539,144
				Total Requested	\$17,568,470		Total Recommended	\$17,568,470
							Total Available	\$18,228,345
							Running Total Available	\$659,875



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CEO Affidavit Supporting Information

FY 2014 – Cycle 1
Evidence-Based Cancer Prevention Services

Request for Applications



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**REQUEST FOR
APPLICATIONS
RFA P-14-EBP-1**

Evidence-Based Cancer Prevention Services

**Please also refer to the “Instructions for Applicants” document, which will be
posted December 19, 2013**

Application Receipt Opening Date: December 19, 2013
Application Receipt Closing Date: February 27, 2014

FY 2014

Fiscal Year Award Period

September 1, 2013–August 31, 2014

TABLE OF CONTENTS

1. ABOUT CPRIT	5
2. FUNDING OPPORTUNITY DESCRIPTION	5
2.1. SUMMARY	5
2.2. PROGRAM OBJECTIVES	6
2.3. AWARD DESCRIPTION	6
2.3.1. <i>Required Services</i>	8
2.3.2. <i>Priority Areas</i>	9
2.3.3. <i>Specific Areas of Interest</i>	10
2.3.4. <i>Outcome Metrics</i>	11
2.4. ELIGIBILITY	12
2.4.1. <i>Applicant Organization</i>	12
2.4.2. <i>Resubmission</i>	14
2.4.3. <i>Continuation/Expansion Applications</i>	14
2.5. FUNDING INFORMATION	15
3. KEY TERMS	15
4. KEY DATES	17
5. SUBMISSION GUIDELINES	17
5.1. ONLINE APPLICATION RECEIPT SYSTEM	17
5.1.1. <i>Submission Deadline Extension</i>	17
5.2. APPLICATION COMPONENTS	18
5.2.1. <i>Abstract and Significance (5,000 characters)</i>	18
5.2.2. <i>Goals and Objectives</i>	19
5.2.3. <i>Project Timeline</i>	19
5.2.4. <i>Project Plan (15 pages maximum; fewer pages permissible)</i>	19
5.2.5. <i>People/Professionals Reached and Served (complete online)</i>	21
5.2.6. <i>References</i>	21
5.2.7. <i>Resubmission Summary (if applicable; download template)</i>	21
5.2.8. <i>CPRIT Grants Summary (download template)</i>	21
5.2.9. <i>Budget and Justification (complete online)</i>	22
5.2.10. <i>Current and Pending Support and Sources of Funding (download template)</i>	23
5.2.11. <i>Biographical Sketches (download template)</i>	23

5.2.12.	<i>Collaborating Organizations (complete online)</i>	24
5.2.13.	<i>Letters of Commitment</i>	24
6.	APPLICATION REVIEW	24
6.1.	REVIEW PROCESS OVERVIEW	24
6.2.	REVIEW CRITERIA.....	26
6.2.1.	<i>Primary Evaluation Criteria</i>	26
6.2.2.	<i>Secondary Evaluation Criteria</i>	29
7.	AWARD ADMINISTRATION	29
8.	CONTACT INFORMATION	30
8.1.	HELPDESK	30
8.2.	PROGRAM QUESTIONS	31
9.	CONFERENCE CALLS TO ANSWER APPLICANT QUESTIONS	31
10.	RESOURCES	32
11.	REFERENCES	33
APPENDIX A	DEFINING CANCER PREVENTION AND CONTROL PROGRAMS AND CANCER PREVENTION/INTERVENTION RESEARCH FOR CPRIT GRANTS	34

RFA VERSION HISTORY

Rev 12/9/13 RFA release

1. ABOUT CPRIT

The State of Texas has established the Cancer Prevention and Research Institute of Texas (CPRIT), which may issue up to \$3 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to:

- Create and expedite innovation in the area of cancer research and in enhancing the potential for a medical or scientific breakthrough in the prevention of or cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the State of Texas; and
- Develop and implement the Texas Cancer Plan.

2. FUNDING OPPORTUNITY DESCRIPTION

2.1. Summary

The ultimate goals of the CPRIT Prevention Program are to reduce overall cancer incidence and mortality and to improve the lives of individuals who have survived or are living with cancer. The ability to reduce cancer death rates depends in part on the application of currently available evidence-based technologies and strategies. CPRIT will foster the primary, secondary, and tertiary prevention of cancer in Texas by providing financial support for a wide variety of evidence-based services relevant to prevention through risk reduction, early detection, and survivorship.

The **Evidence-Based Cancer Prevention Services (EBP)** award mechanism seeks to fund programs that greatly challenge the status quo in cancer prevention and control services. The proposed program should be designed to reach and serve as many people as possible. Partnerships with other organizations that can support and leverage resources are strongly encouraged. A coordinated submission of a collaborative partnership program in which all partners have a substantial role in the proposed project is preferred.

2.2. Program Objectives

CPRIT seeks to fund projects that will:

- Address multiple components of the cancer prevention and control continuum (e.g., provision of screening and navigation services in conjunction with outreach and education of the target population as well as healthcare provider education);
- Offer effective and efficient systems of delivery of prevention services based on the existing body of knowledge about and evidence for cancer prevention in ways that far exceed current performance in a given service area (e.g., partnering with other organizations to overcome barriers in order to make delivery systems more efficient and accessible to the target population);
- Offer systems and/or policy changes that are sustainable over time (e.g., development of processes such as reminder systems to increase screening rates and adoption of worksite policies supporting screening);
- Provide tailored, culturally appropriate outreach and accurate information on early detection and prevention to the public and healthcare professionals that result in a health impact that can be measured;
- Deliver evidence-based survivorship services aimed at reducing the morbidity associated with cancer diagnosis and treatment.

2.3. Award Description

This RFA solicits applications for projects up to 36 months in duration that will deliver evidence-based services in at least one of the following cancer prevention and control areas. For this cycle, CPRIT is accepting new applications **limited to** vaccine-conferred immunity, tobacco cessation and control, screening and early detection for breast, cervical, and/or colorectal cancer, or survivorship services. CPRIT is not accepting applications for computerized tomography (CT) screening for lung cancer at this time. At programmatic review (see [Section 6.1](#)), priority will be given to applications addressing geographic areas and subpopulations not well served by other CPRIT projects (see [Section 2.3.2](#)). CPRIT's service grants are intended to fund prevention programs and services that have a demonstrated evidence base and are culturally appropriate for the target population. An evidence-based service is a program or service that is validated by documented evidence. CPRIT's Web site provides links to resources for evidence-based

strategies, programs, and clinical recommendations for cancer prevention and control. To access this information, visit <http://www.cpr.it.state.tx.us/prevention/resources-for-cancer-prevention-and-control>.

CPRIT recognizes that evidence-based services have been developed but not implemented in all populations or service settings. In such cases, other forms of evidence (e.g., preliminary evaluation or pilot project data) that the proposed service is appropriate for the population and has a high likelihood of success must be provided. In addition, the applicant must describe plans to adapt and evaluate the implementation of the program for the specific audience or situation.

Comprehensive projects are preferred and encouraged. Comprehensive projects would include a continuum of services and systems and/or policy changes and would comprise all or some of the following: Public and/or professional education and training, patient support of behavior modification, outreach, delivery of clinical services, and follow-up navigation. These projects would provide education, outreach, and clinical services that are based on scientific evidence of their effectiveness in prevention of cancer. However, CPRIT seeks to fund innovative ways of delivering evidence-based programs and services (e.g., by addressing needed systems change, addressing cost efficiencies, or forming new partnerships) in order to increase service delivery beyond the current baseline.

This RFA encourages traditional and nontraditional partnerships as well as leveraging of existing resources and dollars from other sources. The creation of integrated programs of a collaborative nature based on the concept of the “community of solution,” in which a variety of existing community entities contribute and mobilize their resources collectively to solve a community problem, is preferred. The applicant should coordinate and describe a collaborative partnership program in which all partners have a substantial role in the proposed project. Letters of commitment describing their role in the partnership are required from all partners.

CPRIT expects measurable outcomes of supported activities, such as a significant increase over baseline (for the proposed service area) in the provision of evidence-based services, changes in provider practice, systems changes, and cost effectiveness. Applicants must demonstrate how these outcomes will ultimately impact incidence, mortality, morbidity, or quality of life.

Under this RFA, CPRIT **will not** consider:

- **Projects focusing solely on systems and/or policy change or solely on education and/or outreach** that do not include the delivery of services (see [Section 2.3.1](#)). To be considered under this mechanism, the project must deliver a service.
- **Projects focusing solely on case management/patient navigation services.** Applicants seeking to provide case management/patient navigation services to help individuals obtain primary prevention services, screening services, or survivorship services but that do not plan to deliver the actual clinical service are not eligible under this mechanism. Furthermore, while navigation to the point of treatment of cancer is required when cancer is discovered through a CPRIT-funded project, applications seeking funds to provide coordination of care while an individual is in treatment are not allowed under this RFA.
- **Projects utilizing State Quitline services.** CPRIT does not entertain applications that seek to restore or expand Department of State Health Services (DSHS) Quitline services that have been reduced from previous funding levels by State agencies. Applicants proposing the utilization of Quitline services should communicate with the Tobacco Prevention and Control program prior to submitting a CPRIT grant application to discuss the services currently offered by DSHS.
- **Projects involving prevention/intervention research.** Research will not be funded through this award mechanism. However, this award mechanism expects rigorous evaluation that will build understanding of and capacity to deliver effective programs through dissemination of findings, particularly from efforts to innovate and adapt evidence-based programs for target populations. Applicants interested in research should review CPRIT's research RFAs (available at <http://www.cprit.state.tx.us>). Refer to [Appendix A](#) for guidance in defining prevention research and cancer prevention and control programs.

2.3.1. Required Services

CPRIT requires applicants to deliver **evidence-based** clinical services limited to one or more of the following cancer prevention and control areas (see [Section 2.3.3](#) for areas of interest):

- Delivery of vaccines that reduce the risk of cancer
- Tobacco cessation interventions

- Screening and early detection services at the following anatomic sites for which there is strong evidence of effectiveness—breast, cervical, and/or colorectal cancers
- Survivorship services (e.g., physical rehabilitation/therapy, psychosocial interventions, navigation services, palliative care services)

In addition to other primary prevention and screening/early detection services, CPRIT considers counseling services (e.g., tobacco cessation, survivorship, exercise and nutrition) when done on a one-on-one basis or in small groups as clinical services.

Although applicants are required to provide clinical services in one or more of the areas listed above, they are also required to propose comprehensive projects within that area or provide a continuum of services across prevention areas that would increase desired outcomes (e.g., provide colorectal cancer screening services in conjunction with outreach and education of the target population and provide navigation services for follow-up care, if needed). The proportion of the budget allocated to providing direct services will be a consideration when applications are evaluated.

This mechanism **will fund** case management/patient navigation if it is paired with the actual delivery of a clinical service (e.g., human papillomavirus [HPV] vaccination, screening). Applicants offering screening services must ensure that there is access to treatment services for patients with cancers that are detected as a result of the program and must describe access to treatment services in their application.

2.3.2. Priority Areas

Types of Cancer: Applications addressing any cancer type(s) (e.g., cancers impacted through vaccine-conferred immunity; tobacco cessation and control; screening and early detection for breast, cervical, and/or colorectal cancers) that are responsive to this RFA will be considered for funding.

Target Populations: Priority populations are subgroups that are disproportionately affected by cancer. Priority populations include, but are not limited to, the following:

- Underinsured and uninsured individuals
- Geographically or culturally isolated populations

- Medically unserved or underserved populations
- Populations with low health literacy skills
- Geographic regions of the State with higher prevalence of cancer risk factors (e.g., obesity, tobacco use, alcohol misuse, unhealthy eating, sedentary lifestyle)
- Racial, ethnic, and cultural minority populations
- Any other populations with low screening rates, high incidence rates, and high mortality rates, focusing on individuals who are significantly out of compliance with nationally recommended screening guidelines:
 - Individuals never before screened for colorectal cancer
 - Women never before screened for cervical cancer or who have not been screened in the past 5 years
 - Women never before screened for breast cancer or who have not been screened in the past 5 years

Geographic and Population Priority

For applications submitted in response to this announcement, at the programmatic level of review conducted by Prevention Review Council (see [Section 6.1](#)), priority will be given to projects that target geographic regions of the State and population subgroups that are not adequately covered by the current CPRIT Prevention project portfolio. Potential applicants should go to <http://www.cpr.it.state.tx.us/prevention/resources-for-cancer-prevention-and-control/> to review the geographic distribution of currently funded projects. For information on population subgroups in a specific geographic area, applicants should review the funded grant abstracts on CPRIT's Web site.

2.3.3. Specific Areas of Interest

CPRIT has identified the following areas of interest for this cycle of awards. CPRIT is particularly interested and will give priority consideration to projects that propose to increase screening and detection of colorectal cancer, cervical cancer, or breast cancer, specifically:

Colorectal Cancer

- Increasing screening/detection rates in North and East Texas. The highest rates of cancer incidence and mortality are found in East and North Texas.^{[1,2](#)}

- Decreasing disparities in racial/ethnic populations and rural communities (African Americans have the highest incidence and mortality rates, followed by non-Hispanic Whites and Hispanics.)^{1,2}
- Decreasing incidence and mortality rates in rural counties. Incidence and mortality rates are higher in rural counties compared with urban counties.^{1,2}

Cervical Cancer

- Increasing screening/detection rates for women in Texas-Mexico border counties; women in these counties have a 31-percent higher cervical cancer mortality rate than women in nonborder counties.^{1,2}
- Decreasing disparities in racial/ethnic populations. Hispanics have the highest incidence rates, while African Americans have the highest mortality rates.^{1,2}
- Increasing access to and delivery of the HPV vaccine.³

Breast Cancer

- Increasing screening/detection rates in rural and medically underserved areas of the State.
- Reaching women never before screened or who have not been screened in the last 5 years, if addressing breast cancer in urban areas.

For more information about breast, cervical, and colorectal cancer in Texas, visit CPRIT's Web site at <http://www.cprit.state.tx.us/prevention/resources-for-cancer-prevention-and-control> or visit the Texas Cancer Registry site at <http://www.dshs.state.tx.us/tcr>. Clinical services (e.g., HPV vaccination; screenings for breast, cervical, and colorectal cancer) should be evidence based; therefore, the age of the target population and frequency of screening plans for provision of clinical services described in the application must comply with established and current national guidelines (e.g., U.S. Preventive Services Task Force, American Cancer Society).

2.3.4. Outcome Metrics

The applicant is required to describe final outcome measures for the project. The ultimate goals of this award are to reduce overall cancer incidence and mortality and to improve the lives of individuals who have survived cancer or who are living with cancer. Interim measures that are associated with these goals should be identified and will serve as a measure of program

effectiveness and public health impact. Applicants are required to clearly describe their assessment and evaluation methodology and to provide baseline data describing how funds from the CPRIT grant will improve outcomes over baseline. In the case where no baseline data exist for the target population, the applicant must present clear plans to collect the data necessary to establish a baseline at the beginning of the proposed project. Similarly, applicants with previously or currently funded CPRIT projects are required to use the Grants Summary Form to provide a summary of the project results and to indicate how the current application builds on the previous work or addresses new areas of cancer prevention and control services.

Outcome measures (as appropriate for each project) should include, **but are not limited to**, the following:

- Percentage increase over baseline in provision of age- and risk-appropriate, comprehensive preventive services to eligible men and women in a defined service area; for example:
 - Completion of all required doses of vaccine
 - Number of people quitting tobacco use and sustaining healthy behavior
 - Percentage increase over baseline in cancers detected
 - Percentage increase in early-stage cancer diagnoses in a defined service area
- Percentage of people reporting sustained behavior change
- Qualitative analysis of policy change and/or lasting systems change

Note: In some cases, the baseline may be zero if the service has not been provided. If this is the case, the application should include an explanation and describe plans to collect the data necessary to establish a baseline.

2.4. Eligibility

2.4.1. Applicant Organization

The applicant must be a Texas-based entity, such as a community-based organization, health institution, government organization, public or private company, college or university, or academic health institution.

The designated Program Director (PD) will be responsible for the overall performance of the funded project. The PD must have relevant education and management experience and must reside in Texas during the project performance time.

The evaluation of the project must be headed by a professional who has demonstrated expertise in the field (e.g., qualitative or quantitative statistics) and who resides in Texas during the time that the project is conducted.

The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application was submitted.

The applicant may submit more than one application, but each application must be for distinctly different services without overlap in the services provided. Applicants who do not meet this criterion will have all applications administratively withdrawn without peer review.

If the applicant or a partner is an existing DSHS contractor (e.g., tobacco coalition, current Breast and Cervical Cancer Services program provider, or other), CPRIT funds may not be used as a match, and the application must explain how this grant complements or leverages existing State and Federal funds. DSHS contractors who also receive CPRIT funds must be in compliance with and fulfill all contractual obligations within CPRIT. CPRIT and DSHS reserve the right to discuss the contractual standing of any contractor receiving funds from both entities.

Collaborations are permitted and encouraged, and collaborators may or may not reside in Texas. However, collaborators who do not reside in Texas are not eligible to receive CPRIT funds. Subcontracting and collaborating organizations may include public, not-for-profit, and for-profit entities. Such entities may be located outside of the State of Texas, but non-Texas-based organizations are not eligible to receive CPRIT funds.

An applicant organization is eligible to receive a grant award only if the applicant certifies that the applicant organization, including the PD, any senior member or key personnel listed on the grant application, and any officer or director of the grant applicant's organization (or any person related to one or more of these individuals within the second degree of consanguinity or affinity), have not made and will not make a contribution to CPRIT or to any foundation created to benefit

CPRIT. An entity is not eligible if the applicant is related to a CPRIT Oversight Committee member.

The applicant must report whether the applicant organization, the PD, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, (whether slated to receive salary or compensation under the grant award or not), are currently ineligible to receive Federal grant funds or have had a grant terminated for cause within 5 years prior to the submission date of the grant application.

CPRIT grants will be awarded by contract to successful applicants. CPRIT grants are funded on a reimbursement-only basis. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in [Section 7](#). In addition, all statutory provisions and relevant administrative rules can be found at <http://www.cprit.state.tx.us>.

2.4.2. Resubmission

An application previously submitted to CPRIT but not awarded funding **may be resubmitted one time**. All resubmitted applications should be carefully reconstructed; a simple revision of the prior application with editorial or technical changes is not sufficient, and applicants are advised not to direct reviewers to modest changes. Applicants preparing a resubmission must complete the Resubmission Summary Form in addition to a full application to describe the approach to the resubmission and how reviewers' comments were addressed. Any subsequent resubmission of the project needs to be substantially changed in order to be eligible for consideration. Applications that are not substantially changed will be administratively withdrawn.

2.4.3. Continuation/Expansion Applications

Applications for continuation/expansion of a currently or previously funded CPRIT project must be submitted under a separate RFA (see the Competitive Continuation/Expansion RFA). Applications for continuation/expansion submitted in response to this RFA will be administratively withdrawn. All applicants submitting **new** projects under this RFA who have

been previously funded by CPRIT must complete the CPRIT Grants Summary Form in addition to a full application and provide information on the impact and progress of **any** previously awarded CPRIT grant(s).

2.5. Funding Information

Applicants may request any amount of funding up to a maximum of \$1.5 million in total funding over a maximum of 36 months. Budget requests for funding will vary depending on the project, and it is anticipated that the majority of projects will request significantly less than the maximum.

Grant funds may be used to pay for clinical services, navigation services, salary and benefits, project supplies, equipment, costs for outreach and education of populations, and travel of project personnel to project site(s). Equipment requests (\$5,000+ per unit) will receive a case-by-case evaluation and will be carefully scrutinized. Requests for funds to support construction, renovation, or any other infrastructure needs are not appropriate for this mechanism, nor are requests to support lobbying or to attend out-of-State professional meetings. Grantees may request funds for travel for two project staff to attend CPRIT's conference.

The budget should be proportional to the number of individuals receiving programs and services, and a significant proportion of funds is expected to be used for program delivery as opposed to program development. In addition, CPRIT seeks to fill gaps in funding rather than replace existing funding, supplant funds that would normally be expended by the applicant's organization, or make up for funding reductions from other sources. CPRIT does not provide support for projects when funds are readily available from other sources. Furthermore, CPRIT funds may not be used for any costs under this award that should be billed to any other funding source.

3. KEY TERMS

People/Professionals Reached: Number of members of the public and/or professionals reached via noninteractive public or professional education and outreach activities, such as mass media efforts, brochure distribution, public service announcements, newsletters, and journals. This category includes individuals who would be reached through activities that are directly funded

by CPRIT as well as individuals who would be reached through activities that occur as a direct consequence of the CPRIT-funded project's leveraging of other resources/funding to implement the CPRIT-funded project.

People/Professionals Served: Number of members of the public and/or professionals served via direct, interactive public or professional education, outreach, training, or clinical service delivery, such as live educational and/or training sessions, vaccine administration, screening, diagnostics, case management services, and physician consults. This category includes individuals who would be served through activities that are directly funded by CPRIT as well as individuals who would be served through activities that occur as a direct consequence of the CPRIT-funded project's leveraging of other resources/funding to implement the CPRIT-funded project (e.g., X people screened for cervical cancer after referral to Y indigent care program as a result of CPRIT-funded navigation services performed by the project).

Goals: Broad statements of general purpose to guide planning. Goals should be few in number and focus on aspects of highest importance to the project.

Objectives: Specific, **measurable**, actionable, realistic, and timely projections for outputs and outcomes Example: "Increase screening service provision in X population from Y percent to Z percent by 20xx." Baseline data for the target population must be included as part of each objective.

Activities: A listing of the "who, what, when, where, and how" for each objective that will be accomplished.

Evidence-Based Program: A program that is validated by some form of documented research or applied evidence. CPRIT's Web site provides links to resources for evidence-based strategies, programs, and clinical recommendations for cancer prevention and control. To access this information, visit <http://www.cprit.state.tx.us/prevention/resources-for-cancer-prevention-and-control>.

4. KEY DATES

RFA

RFA release December 9, 2013

Application

Online application opens December 19, 2013, 7 a.m. Central Time

Application due February 27, 2014, 3 p.m. Central Time

Application review March–June 2014

Award

Award notification August 2014

Anticipated start date August 2014

5. SUBMISSION GUIDELINES

5.1. Online Application Receipt System

Applications must be submitted via the CPRIT Application Receipt System (CARS) (<https://CPRITGrants.org>). **Only applications submitted at this portal will be considered eligible for review.** The PD must create a user account in the system to start and submit an application. The Co-PD, if applicable, must also create a user account to participate in the application. Furthermore, the Authorized Signing Official (a person authorized to sign and submit the application for the organization, and the Grants Contract/Office of Sponsored Projects Official, the individual who will manage the grant contract if an award is made, also must create a user account in CARS. Submission of an application is considered an acceptance of the terms and conditions of the RFA. Detailed instructions for submitting an application are in the Instructions for Applicants document which will be posted on CARS beginning December 19, 2013.

5.1.1. Submission Deadline Extension

The submission deadline may be extended for one or more grant applications upon a showing of good cause. All requests for extension of the submission deadline must be submitted via e-mail to the CPRIT HelpDesk. Submission deadline extensions, including the reason for the extension, will be documented as part of the grant review process records.

5.2. Application Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. Submissions that are missing one or more components or do not meet the eligibility requirements listed in [Section 2.4](#) will be administratively withdrawn without review. Refer to the Instructions for Applicants document for detailed information and guidance on application components.

5.2.1. Abstract and Significance (5,000 characters)

Clearly explain the problem(s) to be addressed and the approach(es) to the solution. The abstract and significance statement should clearly and succinctly address how the application is responsive to this RFA. In the event that the project is funded, the abstract will be made public; therefore no proprietary information should be included in this statement. Initial compliance decisions are based in part upon review of this statement.

The required abstract format is as follows (use headings as outlined below):

- **Need:** Include a description of need in the specific service area. Include rates (e.g., incidence of targeted cancer, mortality, and screening) in the service area compared to overall Texas rates. Describe barriers, plans to overcome these barriers, and the target population to be served.
- **Overall Project Strategy:** Describe the project and how it will address the identified need. Clearly explain what the project is and what it will specifically do. For example, summarize the services to be provided, the process/system for delivery of services and outreach to the targeted population, components of the project, and related factors.
- **Specific Goals:** State specifically the overall goals of the proposed project; include the estimated overall numbers of people (public and/or professionals) reached and people (public and/or professionals) served.
- **Innovation:** Describe the creative components of the proposed project. How does it differ from or improve upon the current program or services being provided?
- **Significance and Impact:** Explain how the proposed project, if successful, will have a unique and major impact on cancer prevention and control for the population proposed to be served and for the State of Texas in general.

5.2.2. Goals and Objectives

List specific goals and **measurable** objectives for each year of the project. Provide baseline and method(s) of measurement.

5.2.3. Project Timeline

Provide a project timeline for project activities that includes deliverables and dates.

5.2.4. Project Plan (15 pages maximum; fewer pages permissible)

The required project plan format follows. Applicants must use the headings outlined below.

Applications not following the required format will be administratively withdrawn.

Background: Briefly present the rationale behind the proposed service, emphasizing the critical barriers to current service delivery that will be addressed. Identify the evidence-based service to be implemented for the target population. If evidence-based strategies have not been developed for the specific population or service setting proposed, provide other forms of evidence (e.g., preliminary evaluation or pilot project data) that the proposed service is appropriate for the population and has a high likelihood of success. Baseline data (e.g., screening and detection rates, stage at diagnosis) for the target population and target service area are required where applicable. Inclusion of results of previously funded projects (CPRIT and non-CPRIT funded) is encouraged to provide background and/or baseline. Reviewers will be aware of national and State statistics, and these should be used only to compare rates for the proposed service area. Because reviewers are non-Texans, describe the geographic region of the State that the project will serve; maps are appreciated.

Goals and Objectives (optional): Goals and Objectives will be entered in separate fields in CARS and need not be provided in the project plan. However, if desired, goals and objectives may be fully repeated or briefly summarized here.

Components of the Project: Clearly describe the need, delivery method, and evidence base (provide references) for the services as well as anticipated results. Describe why this project is nonduplicative or unique. Applicants must clearly describe plans to ensure access to preventive services (e.g., navigation to screenings, vaccine, survivorship services). Describe creative components of the proposed project. Clearly demonstrate the ability to provide the proposed

service, and describe how results will be improved over baseline. Clearly demonstrate the ability to reach the target population.

Evaluation Strategy: Describe the impact on ultimate outcome measures (e.g., reduction of cancer incidence, mortality, and morbidity) and interim outcome measures (e.g., increase in the proportion of individuals receiving cancer screening, increase in the number of individuals demonstrating personal health behavior change) as outlined in [Section 2.3.4](#). Describe the plan for outcome measurements, including data collection and management methods, statistical analyses, and anticipated results. Evaluation and reporting of outcomes are critical components of this RFA and must be headed by a professional who has demonstrated expertise in the field of program evaluation, intervention science, cancer screening, and/or behavioral risk reduction. If needed, applicants may want to consider seeking expertise at Texas-based academic cancer centers, schools/programs of public health, prevention research centers, or the like. Applicants should budget accordingly for the evaluation activity and should involve that professional in the conceptualization and planning of the evaluation of the program during grant application preparation to ensure, among other things, that the evaluation plan is linked to the proposed goals and objectives.

Organizational Capacity and Sustainability: Describe the organization and its track record for providing services. Include information on the organization's financial stability and viability. To ensure access to preventive services and reporting of services outcomes, applicants should demonstrate that they have provider partnerships and agreements (via memorandums of understanding) or commitments (via letters of commitment) in place. A sustainability plan describing the continuation of the proposed program or service after CPRIT funding has ended must be included.

Elements of organizational project sustainability may include, but are not limited to, the following:

- Developing ownership, administrative networks, and formal engagements with stakeholders
- Enhancing system capacity and developing processes for each practice/location to incorporate services into its structure beyond project funding

- Identifying and training of diverse resources (human, financial, material, and technological)

Dissemination and Scalability (Expansion): Describe how the project lends itself to dissemination to or application by other communities and/or organizations in the State or expansion in the same communities. Describe plans for dissemination of positive and negative project results and outcomes. Dissemination of project results and outcomes, including barriers encountered and successes achieved, is critical to building the evidence base for cancer prevention and control efforts in the State. Dissemination methods may include, but are not limited to, presentations, publications, abstract submissions, and professional journal articles, etc.

5.2.5. People/Professionals Reached and Served (complete online)

Provide the estimated overall number of people/professionals to be reached and people/professionals to be served by the funded project. Provide an itemized list of activities/services, with estimates, that led to the calculation of the overall estimates provided. Refer to [Section 3](#) for definitions of people/professionals reached and people/professionals served.

5.2.6. References

Provide a concise and relevant list of references cited for the application. The successful applicant will provide referenced evidence of need and literature support for the proposed services delivery.

5.2.7. Resubmission Summary (if applicable; download template)

Describe the approach to the resubmission and how reviewers' comments were addressed. Refer to [Section 2.4.2](#) for information regarding resubmissions.

5.2.8. CPRIT Grants Summary (download template)

Provide a description of the progress or final results of **any** CPRIT-funded projects, regardless of their connection to this application. This form must be completed if the organization, PD, or Co-PD has previously received CPRIT funding. Applications that are missing this document and for which CPRIT records show a PD and/or Co-PD with previous or current CPRIT funds will be

administratively withdrawn prior to peer review. If no previous CPRIT funding has been received, indicate not applicable or “N/A” on the form and upload the document.

5.2.9. Budget and Justification (complete online)

Provide a brief outline and detailed justification of the budget for the entire proposed period of support, including salaries and benefits, travel, equipment, supplies, contractual expenses, services delivery, and other expenses. CPRIT funds will be distributed on a reimbursement basis; see the Instructions for Applicants document for budget guidance.

Applications requesting more than the maximum allowed cost (total costs) as specified in [Section 2.5](#) will be administratively withdrawn.

- **Cost Per Person Served:** The cost per person served will be automatically calculated from the total cost of the project divided by the total number of people (both public and professionals) served (refer to [Section 3](#)). A significant proportion of funds is expected to be used for program delivery as opposed to program development and organizational infrastructure.
- **Personnel:** The individual salary cap for CPRIT awards is \$200,000 per year.
- **Travel:** PDs and related project staff are expected to attend CPRIT’s conference. CPRIT funds may be used to send up to two people to the conference.
- **Equipment:** Equipment requests (\$5,000+ per unit) will be carefully evaluated on a case-by-case basis and must be specifically approved by CPRIT if the project is funded. Justification must be provided for why funding for this equipment cannot be found elsewhere; CPRIT funding should not supplant existing funds. A sustainability plan must be submitted for both the equipment and delivery of corresponding services as a result of the equipment purchase. Cost sharing of equipment purchases is strongly encouraged.
- **Services Costs:** CPRIT reimburses for services using Medicare reimbursement rates.
- **Other Expenses**
 - Incentives:** Use of incentives or positive rewards to change or elicit behavior is allowed; however, incentives may only be used based on strong evidence of their effectiveness for the purpose and in the target population identified by the applicant. CPRIT will not fund

cash incentives. The maximum dollar value allowed for an incentive per person, per activity or session, is \$25.

Indirect Costs: It is CPRIT's policy not to allow recovery of indirect costs for prevention programs.

Costs Not Related to Cancer Prevention and Control: CPRIT does not allow recovery of any costs for services not related to cancer (e.g., health physicals, HIV testing).

5.2.10. Current and Pending Support and Sources of Funding (download template)

Applicants must identify by name all sources of contributing funding for the proposed project, including a capitalization table that reflects private investors, if any. This information is used to identify any conflicts of interest for reviewers. In addition, the applicant should list all current and pending awards/grants from State, Federal, nonprofit, and other sources that would extend or complement the proposed project. This allows the applicant to demonstrate how other funds would be leveraged to implement the proposed work. Using the template provided in the online application receipt system (CARS), provide the funding source, amount, status (pending or awarded), duration, and a two-line summary of the use of the funds for each current or pending award/grant.

5.2.11. Biographical Sketches (download template)

The designated PD will be responsible for the overall performance of the funded project and must have relevant education and management experience. The PD/Co-PD(s) must provide a biographical sketch that describes his or her education and training, professional experience, awards and honors, and publications and/or involvement in programs relevant to cancer prevention and/or service delivery.

The evaluation of the project must be headed by a professional who has demonstrated expertise in the field (e.g., qualitative or quantitative statistics). CPRIT encourages applicants to involve such a designated professional early in the planning and preparation of the application. The applicant may choose to contract for these services if needed; the project budget should reflect these services. The evaluation professional must provide a biographical sketch.

Up to three additional biographical sketches for key personnel may be provided. Each biographical sketch must not exceed two pages.

5.2.12. Collaborating Organizations (complete online)

List all key participating organizations that will partner with the applicant organization to provide one or more components essential to the success of the program (e.g., evaluation, clinical services, recruitment to screening, etc.).

5.2.13. Letters of Commitment

Applicants should provide letters of commitment and/or memorandums of understanding from community organizations, key faculty, or any other component essential to the success of the program. These letters must be included and uploaded in the application; do not send any letters directly to the CPRIT office.

Applications that are missing one or more of these components, exceed the specified page, word, or budget limits, or that do not meet the eligibility requirements listed above will be administratively rejected without review.

6. APPLICATION REVIEW

6.1. Review Process Overview

All eligible applications will be reviewed using a two-stage peer review process: (1) evaluation of applications by peer review panels and (2) prioritization of grant applications by the Prevention Review Council. In the first stage, applications will be evaluated by an independent review panel using the criteria listed below. In the second stage, applications judged to be meritorious by review panels will be evaluated by the Prevention Review Council and recommended for funding based on comparisons with applications from all of the review panels and programmatic priorities. Programmatic considerations may include, but are not limited to, geographic distribution, cancer type, population served, and type of program or service. The order of scores may be disregarded in favor of programmatic considerations. As emphasized in [Section 2.3.3](#) of this announcement, at the programmatic level of review priority will be given to proposed projects that target geographic regions of the State or population subgroups that are not well represented in the current CPRIT Prevention project portfolio.

Recommendations from the Prevention Review Council are forwarded to the CPRIT Program Integration Committee, which will consider factors including program priorities set by the Oversight Committee, portfolio balance across programs, and available funding.

The CPRIT Oversight Committee will vote to approve each grant award recommendation made by the Program Integration Committee. The grant award recommendations will be presented at an open meeting of the Oversight Committee and must be approved by two-thirds of the Oversight Committee members present and eligible to vote. The review process is described more fully in CPRIT's Administrative Rules, Chapter 703, Sections 703.6–703.8.

Each stage of application review is conducted confidentially, and all panel members, Program Integration Committee members, CPRIT employees, and Oversight Committee members with access to grant application information are required to sign nondisclosure statements regarding the contents of the applications.

Individuals directly involved with the review process operate under strict conflict of interest prohibitions. All peer review panel members and Prevention Review Council members will be non-Texas residents. An applicant will be notified regarding the peer review panel assigned to review the grant application. Peer review panel members are listed by panel on CPRIT's Web site. **By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed Conflict of Interest as set forth in CPRIT's Administrative Rules, Chapter 703, Section 703.9(b).**

Communication regarding the substance of a pending application is prohibited between the grant applicant (or someone on the grant applicant's behalf) and the following individuals—an Oversight Committee member, a Program Integration Committee member, a peer review panel member, or a Prevention Review Council member. Applicants should note that both CPRIT's Chief Executive Officer and Chief Prevention Officer are members of the Program Integration Committee. The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by the Institute and extends until the grant applicant receives notice regarding a final decision on the grant application. The prohibition on communication does not apply to the time period when pre-applications or letters of interest are

accepted. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant application from further consideration for a grant award.

6.2. Review Criteria

Peer review of applications will be based on primary (scored) criteria and secondary (unscored) criteria, identified below. Review panels consisting of experts in the field as well as consumer advocates will evaluate and score each primary criterion and subsequently assign an overall score that reflects an overall assessment of the application. The overall assessment will not be an average of the scores of individual criteria; rather, it will reflect the reviewers' overall impression of the application and responsiveness to the RFA priorities.

6.2.1. Primary Evaluation Criteria

The project will be evaluated on the basis of the following primary criteria. Concerns with any of these criteria potentially indicate a major flaw in the significance and/or design of the proposed project. Additionally, resubmission applications will be evaluated on the application's responsiveness to reviewers' previous comments.

Impact and Innovation

- Do the proposed services address an important problem or need in cancer prevention and control? Do the proposed project strategies support desired outcomes in cancer incidence, morbidity, and/or mortality? Are the goals and priorities of the project responsive to the RFA?
- Does the proposed project demonstrate creativity, ingenuity, resourcefulness, or imagination? Does it take evidence-based interventions and apply them in innovative ways, going beyond "doing what has always been done" to explore new partnerships, new audiences, or improvements to systems?
- Does the program address adaptation, if applicable, of the evidence-based intervention to the target population?
- Does the program address known gaps in prevention services and avoid duplication of effort?

- If applicable, have collaborative partners demonstrated that the collaborative effort will provide a greater impact on cancer prevention and control than each individual organization's effort separately?
- Will the project reach and serve an appropriate number of people based on the budget allocated to providing services and the cost of providing services?

Project Strategy and Feasibility

- Does the proposed project provide services specified in the RFA?
- Are the overall program approach and strategy clearly described and supported by established theory and practice? Are the proposed objectives and activities feasible within the duration of the award? Has the applicant convincingly demonstrated the short- and long-term impacts of the project?
- Is the program design supported by established theory and practice as well as evidence-based interventions?
- Are possible barriers addressed and approaches for overcoming them proposed?
- Are the target population and culturally appropriate methods to reach the target population clearly described? Are barriers for the population clearly described, and are plans to provide culturally appropriate education to overcome these barriers clearly addressed?
- If applicable, does the application demonstrate the availability of resources and expertise to provide case management, including followup for abnormal results and access to treatment? Has the applicant clearly described plans to ensure access to treatment services for patients diagnosed with cancer as a result of the program?
- Does the program leverage partners and resources to maximize the reach of the services proposed? For example, does the program negotiate for low-cost or pro bono services or in-kind support, including staffing? Does the program leverage and complement other State, Federal, and nonprofit grants?

Organizational Capacity

- Do the organization and its collaborators/partners demonstrate the ability to provide the proposed preventive services? Does the described role of each collaborating organization

make it clear that each organization adds value to the project, and do all collaborating organizations demonstrate commitment to work together to implement the project?

- Have the appropriate personnel been recruited to implement, evaluate, and complete the project?

Sustainability

Eventual financial sustainability of a project is desirable and projects should describe the steps they are taking towards that end.

- Is the organization structurally and financially stable and viable?
- Are there feasible plans to sustain some or all of the project beyond the funded timeframe of this award?
- Are there feasible plans to integrate the program into existing and sustainable systems?

Elements contributing to organizational project sustainability may include some or all of the following:

- Developing ownership, administrative networks, and formal engagements with stakeholders
- Enhancing system capacity and developing processes for each practice/location to incorporate services into its structure beyond project funding
- Identifying and training of diverse resources (human, financial, material, and technological)

Outcomes Evaluation

- Are specific goals and measurable objectives for each year of the project provided?
- Are the proposed outcome measures appropriate for the services provided, and are the expected changes clinically significant?
- Does the application provide a clear and appropriate plan for data collection and management, statistical analyses, and interpretation of results to follow, measure, and report on the project's outcomes?
- Are clear baseline data provided for the target population, or are clear plans included to collect baseline data at the beginning of the proposed project?

- If an evidence-based intervention is being adapted in a population where it has not been tried/tested, are plans for evaluation of barriers, effectiveness, and fidelity to the model described?
- Is the qualitative analysis of planned policy or system changes described?

6.2.2. Secondary Evaluation Criteria

Secondary criteria contribute to the overall score assigned to the application. Lack of information or clarity in regard to these criteria may result in a lower overall score. Secondary evaluation criteria include:

Budget

- Is the budget appropriate and reasonable for the scope and services of the proposed work?
- Is the cost per person served appropriate and reasonable?
- Is the proportion of the funds allocated for direct services reasonable?
- Is the project a good investment of Texas public funds?

Dissemination and Scalability

Dissemination of positive and negative project results and outcomes, including barriers encountered and successes achieved, is critical to building the evidence base for cancer prevention and control efforts in the State. Dissemination methods can include, but are not limited to, presentations, publications, abstract submissions, and professional journal articles, etc.

- Are plans for dissemination of the project's results (both positive and negative) clearly described?

While scalability of programs is desirable, some programs may have unique resources and may not lend themselves to replication by others. However, some components of the project may lend themselves to modification and replication.

- Does the program lend itself to scalability/expansion by others in the State? If so, does the application describe a plan for doing so?

7. AWARD ADMINISTRATION

Texas law requires that CPRIT grant awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to institutions or organizations, not to individuals. Award

contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT's electronic signature policy as set forth in Chapter 701, Section 701.25.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and intellectual property rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at <http://www.cprit.state.tx.us>. Applicants are advised to review CPRIT's Administrative Rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in Chapter 703, Sections 703.10, 703.12.

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements set forth in CPRIT's Administrative Rules, Chapter 703, Section 703.20.

CPRIT requires the PD of the award to submit quarterly, annual, and final progress reports. These reports summarize the progress made toward project goals and address plans for the upcoming year and performance during the previous year(s). In addition, quarterly fiscal reporting and reporting on selected metrics will be required per the instructions to award recipients. Failure to provide timely and complete reports may waive reimbursement of grant award costs, and may result in the termination of the award contract.

8. CONTACT INFORMATION

8.1. HelpDesk

HelpDesk support is available for questions regarding user registration and online submission of applications. Queries submitted via e-mail will be answered within 1 business day. HelpDesk staff are not in a position to answer questions regarding the scope and focus of applications.

Before contacting the HelpDesk, please refer to the Instructions for Applicants document (posted by December 19, 2013), which provides a step-by-step guide to using CARS.

Dates of operation: December 19, 2013 to February 27, 2014 (excluding public holidays)

Hours of operation: Monday, Tuesday, Thursday, Friday, 7 a.m. to 4 p.m. Central Time
Wednesday, 8 a.m. to 4 p.m. Central Time

Tel: 866-941-7146

E-mail: Help@CPRITGrants.org

8.2. Program Questions

Questions regarding the CPRIT Prevention program, including questions regarding this or any other funding opportunity, should be directed to the CPRIT Prevention Program Office.

Tel: 512-305-8422

E-mail: Help@CPRITGrants.org

Web site: www.cprit.state.tx.us

9. CONFERENCE CALLS TO ANSWER APPLICANT QUESTIONS

CPRIT will host a Webinar to provide an overview of this RFA and a demonstration of CARS. A programmatic and technical question and answer session will be included. Applicants should sign up for CPRIT's electronic mailing list at <http://www.cprit.state.tx.us> to ensure that they will receive notification of this Webinar.

10. RESOURCES

Cancer Statistics

The Texas Cancer Registry

Cancer incidence (cases) and mortality (deaths) in Texas

Web site: <http://www.dshs.state.tx.us/tcr>

E-mail: CancerData@dshs.state.tx.us

Tel: 800-252-8059

CPRIT, Texas Cancer Registry

- Priority cancers for CPRIT's Prevention program: Breast, cervical, and colorectal
- [Breast Cancer in Texas: A Closer Look \(1/4/10\)](#)
http://www.cprit.state.tx.us/images/uploads/report_breastc_a_closer_look.pdf
- [Cervical Cancer in Texas, 2010](#)
http://www.cprit.state.tx.us/images/uploads/cervical_cancer_in_texas_tcr_2010_low.pdf
- [Colorectal Cancer in Texas, 2010](#)
http://www.cprit.state.tx.us/images/uploads/colorectal_cancer_in_texas_tcr_2010_low.pdf

Evidence-Based Strategies, Programs, and Clinical Recommendations

The Community Guide

Resources by topic, including specific cancers, tobacco, and worksite programs

<http://www.thecommunityguide.org/index.html>

Cancer Control P.L.A.N.E.T.

Resources by topic, including specific cancers, tobacco, diet/nutrition, and survivorship

<http://cancercontrolplanet.cancer.gov>

Agency for Healthcare Research and Quality

Clinical recommendations for screening, counseling, etc.

Guide to Clinical Preventive Services, 2012: Recommendations of the U.S. Preventive Services Task Force. AHRQ Publication No. 12-05154, October 2012. Agency for Healthcare Research and Quality, Rockville, MD. <http://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/guide/>

Making Health Communication Programs Work—National Cancer Institute®

Effective communication tools for public education and outreach programs

<http://www.cancer.gov/pinkbook>

11. REFERENCES

1. Texas Cancer Registry, Cancer Epidemiology and Surveillance Branch, Texas Department of State Health Services, 1100 W. 49th Street, Austin, TX 78756
2. <http://www.dshs.state.tx.us/tcr/default.shtm> or 512-458-7523
3. <http://www.cdc.gov/vaccines/vpd-vac/hpv/vac-faqs.htm>
4. Centers for Disease Control and Prevention. Distinguishing Public Health Research and Public Health Nonresearch. <http://www.cdc.gov/od/science/integrity/docs/cdc-policy-distinguishing-public-health-research-nonresearch.pdf>.

APPENDIX A Defining Cancer Prevention and Control Programs and Cancer Prevention/Intervention Research for CPRIT Grants

Statute

By Texas statute, 90 percent of dollars available to CPRIT are awarded through CPRIT's Cancer Research Program. The CPRIT Prevention Program may award up to 10 percent (but not more) of dollars available to CPRIT.

Purpose of the CPRIT Prevention Program

Grants funded under the Prevention Program are intended to fund prevention strategies, programs, and services that have a demonstrated evidence base and are culturally appropriate for the target population. An evidence-based strategy is a program or service that is validated by some form of documented research or applied evidence. Links to resources for evidence-based strategies, programs, and clinical recommendations can be found on CPRIT's Web site at <http://www.cprit.state.tx.us/prevention/resources-for-cancer-prevention-and-control>.

Based upon the above, the Prevention Program will focus on funding:

- Delivery of evidence-based, culturally appropriate education and outreach to the public and to healthcare professionals
- Delivery of evidence-based preventive services
- Adoption and implementation of policy and systems change to address barriers and promote prevention

Eligible projects include:

- Primary prevention (e.g., vaccine-conferred immunity, tobacco control, healthy diet, prevention of alcohol misuse, physical activity, sun protection)
- Early detection/screening (focus on breast, cervical, and/or colorectal cancers)
- Survivorship services (e.g., physical rehabilitation/therapy, psychosocial interventions, navigation services, palliative care)

The Prevention Program seeks to fund innovative ways of delivering evidence-based programs and services that (1) go beyond simply increasing the number of persons educated or trained to

demonstrating and supporting sustainable behavior change and (2) go beyond delivering early detection/screening services to improving systems and cost efficiencies by addressing needed systems and policy change or improvements. Projects should demonstrate measurable public health impact in ways that exceed current performance in a given service area.

The amount of funds available for the CPRIT Prevention Program is approximately \$30 million per year. To ensure that the prevention funds go toward the delivery of programs and clinical services to the public, a distinction between prevention research (funded under the Research Program) and the delivery of evidence-based prevention services to the public (funded under the Prevention Program) must be made. The Prevention Program does not accept or review prevention research applications. Organizations seeking funding for prevention research should consider submitting to CPRIT's Research Program.

Prevention/Intervention Research Versus Prevention Programs and Services

The Centers for Disease Control makes the following distinction between public health research and non-research:

“The major difference between research and nonresearch lies in the purpose of the activity. The purpose of research is to generate or contribute to generalizable knowledge. The purpose of nonresearch in public health is to prevent or control disease or injury and improve health, or to improve a public health program or service.”⁴

CPRIT makes the following distinction between prevention/intervention research and prevention programs and services. A project is appropriate for the Prevention Program if:

- The intervention is evidence based.
- The intervention offers a program or service to the public and strives to reach and serve as many people as possible. Cost per person served will be highly variable depending on the project, but the majority of the budget should be for direct program or service delivery. Refer to each RFA; some RFAs, such as those focusing on policy/systems change, may cover only activities to address barriers and may not pay for the delivery of the service being evaluated.

- Evaluation is conducted under real-world (rather than controlled) circumstances, in real time, and with regular personnel conducting the interventions, usually without rigid protocols. The project may be described as effectiveness research in contrast to efficacy research. Evaluation and reporting of outcomes are critical components of CPRIT-funded prevention projects and must be guided by a professional with demonstrated expertise and experience in the field. Applicants should budget accordingly for this activity.
- The purpose of the evaluation is to assess the success of the project in achieving its objectives (changing behavior, increasing screening rates, and increasing detection of cancers). CPRIT recognizes that, in many cases, evidence-based practices have been developed but not implemented in all populations or all service settings. For applications proposing to evaluate such projects, other forms of evidence (e.g., preliminary evaluation or pilot project data) that the proposed service is appropriate for the population and has a high likelihood of success must be provided. For example, the project may compare evidence-based strategies or evaluate implementation in a new population, but the main objective of the project should be to deliver a program or service to the public that will have a measureable impact on public health. CPRIT strongly encourages award recipients to submit the results and findings from their funded projects for publication in appropriate journals.

A project is appropriate for the Research Program if:

- The primary intent is to generate or contribute to generalizable knowledge.
- The project is conducted using highly controlled, usually randomized designs. The project may be described as efficacy research.

What Kinds of Prevention Research Will Be Eligible for the Research Program?

There is no restriction on the type of research that can be supported by CPRIT's Research Program except that the research must be relevant to cancer. Applications will be evaluated based on their significance and importance, their feasibility, the qualifications of the investigator(s), and related factors.

Types of prevention research include, **but are not limited to:**

- Preclinical and clinical research
- Health services research
- Behavioral research
- Intervention research
- Community-based participatory research
- Disease or behavioral surveillance systems research

Third Party Observer Report

CPRIT Prevention Peer Review Panel Observation Report

Report #2014-10

Panel Name: Prevention Peer Review Panel A – FY 14
Cycle 1

Panel Date: May 5-6, 2014

Report Date: May 6, 2014

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized its out-sourced internal audit provider to function as a neutral third-party observer.

Introduction

The subject of this report is the Prevention Peer Review Panel A review of prevention program applications. The meeting was chaired by Lawrence Green and held in person on May 5, 2014 and May 6, 2014 in Dallas, TX.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.

Observation Results Summary

Internal Audit participated in the Prevention Peer Review meeting held in person and chaired by Lawrence Green on May 5, 2014 and May 6, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Eleven prevention program applications were discussed and evaluated by the Prevention Peer Review to determine which grants would receive CPRIT funding.
- Ten panel reviewers, two advocate reviewers, six CPRIT staff members, and three SRA employees were present for the Panel meeting in person. Two panel reviewers joined the meeting via phone.

- Five conflicts of interest were identified prior to or during the meeting. The panel member with the conflict either left the room or logged off of the teleconference and did not participate in the review of the conflicted applications.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the peer review panel's discussion of scientific, technical or programmatic aspects of the applications.

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Prevention Peer Review Panel Observation Report

Report #2014-11

Panel Name: Prevention Peer Review Panel B – FY 14
Cycle 1

Panel Date: May 6-7, 2014

Report Date: May 7, 2014

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized its out-sourced internal audit provider to function as a neutral third-party observer.

Introduction

The subject of this report is the Prevention Peer Review Panel B review of prevention program applications. The meeting was chaired by Nancy Lee and held in person on May 6, 2014 and May 7, 2014 in Dallas, TX.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.

Observation Results Summary

Internal Audit participated in the Prevention Peer Review meeting held in person and chaired by Lawrence Green on May 5, 2014 and May 6, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Twelve prevention program applications were discussed and evaluated by the Prevention Peer Review to determine which grants would receive CPRIT funding.

- Ten panel reviewers, two advocate reviewers, six CPRIT staff members, and three SRA employees were present for the Panel meeting in person. Two panel reviewers and one CPRIT staff joined the meeting via phone.
- No conflicts of interest were identified prior to or during the meeting.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the peer review panel's discussion of scientific, technical or programmatic aspects of the applications.

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Prevention Peer Review Panel Observation Report

Report #2014-21

Panel Name: Prevention Review Council – Prevention
Program Applications

Panel Date: June 27, 2014

Report Date: July 7, 2014

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized its out-sourced internal audit provider to function as a neutral third-party observer.

Introduction

The subject of this report is the Prevention Review Council review of prevention program applications. The meeting was chaired by Lawrence Green and held in person on June 27, 2014.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The Council discussion is focused on the established scoring criteria.

Observation Results Summary

Internal Audit participated in the Prevention Review Council meeting held in person and chaired by Lawrence Green on June 27, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Seventeen prevention program applications were included within the application listing submitted to the Prevention Review Council for their review and approval.
- Three council members and four CPRIT staff members were present for the Council meeting in-person. Two SRA employees joined the meeting via phone.

- Two conflict of interest were identified prior to or during the meeting. The council member with the conflict of interests either left the room or logged off of the teleconference and did not participate in the review of the conflicted applications.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The Council members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the Council's discussion of scientific, technical or programmatic aspects of the applications.

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

De-Identified Overall Evaluation Scores

Evidence-Based Cancer Prevention Studies

Application ID	Final Overall Score
PP140208*	1.7
PP140183*	2.0
PP140176*	2.1
ff1	2.2
PP140211*	2.3
PP140018*	2.4
PP140209*	2.8
ff2	3.3
ff3	3.8
ff4	4.0
ff5	4.0
ff6	4.5
ff7	4.5
ff8	4.5
ff9	4.5
gg1	4.8
gg2	4.8
gg3	4.8
gg4	5.0
gg5	5.8
gg6	7.0

*=Recommended for Funding

Final Overall Evaluation Scores and Rank Order Scores

William Rice, M.D.
Oversight Committee Chair
Cancer Prevention and Research Institute of Texas
Via email to Bill.Rice@stdavids.com

Wayne R. Roberts
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cprit.state.tx.us

Dear Mr. Roberts and Dr. Rice,

On behalf of the Prevention Review Council (PRC), I am pleased to provide the PRC's recommendations for CPRIT Prevention grant awards. The applicants on the attached list submitted proposals in response to CPRIT requests for applications (RFA) released for the first review cycle of FY2014. Each recommendation reflects 50+ hours of individual review and panel discussion of the applicants' proposals as well as the PRC's programmatic review.

The projects are numerically ranked in the order the PRC recommends the applications be funded. Recommended funding amounts and the overall evaluation score are stated for each grant application. The PRC did not make changes to the funding amount, goals, timelines, or project objectives requested by the applicants. The Prevention program had \$18,228,345 in available funding for the remainder of the fiscal year. The PRC is recommending awards totaling \$17,568,470.

Our recommendations met the PRC's standards for grant award funding. In addition to meeting standards for quality and potential to impact public health, these projects meet the following standards: 1. are evidence-based; 2. deliver programs or services to underserved populations; and 3. focus on primary, secondary or tertiary prevention.

Sincerely,

Stephen W. Wyatt, DMD, MPH
Chair, CPRIT Prevention Review Council

App ID	Mechanism	Title	PD	Organization	Total Requested Funding	Score	Numerical Ranking Score	Recommended Funding
PP140208	EBP	Increasing HPV Vaccinations in Harris and Jefferson Counties Using Combined Evidence-Based Approaches in a Federally Qualified Health Center	Megdal, Tina	Legacy Community Health Services	\$1,500,000	1.7	1	\$1,500,000
PP140205	CCEEBP	Eliminating Cancer Disparities in Medically Underserved Immigrant and Refugee Populations in Houston Texas	Caracostis, Andrea	Asian American Health Coalition of Greater Houston, Inc., dba Hope Clinic	\$1,496,840	1.8	2	\$1,496,840
PP140033	CCEEBP	Access to Breast and Cervical Care for West Texas (ABC24WT)	Layeequr Rahman, Rakhshanda	Texas Tech University Health Sciences Center	\$1,499,670	2.0	3	\$1,499,670
PP140183	EBP	Multi-component Interventions to Increase HPV Vaccination in a Network of Pediatric Clinics	Vernon, Sally W	The University of Texas Health Science Center at Houston	\$1,495,388	2.0	3	\$1,495,388
PP140049	CCEPubEd	Educating Hispanic adolescents and their families on cervical cancer prevention and HPV vaccination in community and clinic settings	Morales-Campos, Daisy Y	The University of Texas Health Science Center at San Antonio	\$149,985	2.1	5	\$149,985
PP140176	EBP	SMS Cessation Service for Young Adult Smokers in South Texas	Ramirez, Amelie G	The University of Texas Health Science Center at San Antonio	\$1,400,045	2.1	5	\$1,400,045
PP140211	EBP	Tiempo de vacunarte! Time to get vaccinated!	Penaranda, Eribeth K	Texas Tech University Health Sciences Center at El Paso	\$1,499,195	2.3	7	\$1,499,195
PP140018	EBP	Improving Access to Colorectal Cancer Screening in East Texas	Sauter, Edward	The University of Texas Health Center at Tyler	\$1,269,216	2.4	8	\$1,269,216
PP140164	CCEEBP	ACCION 2: Against Colorectal Cancer in our Neighborhoods: El Paso and Hudspeth County	Shokar, Navkiran K	Texas Tech University Health Sciences Center at El Paso	\$1,499,438	2.6	9	\$1,499,438
PP140209	EBP	Building a Healthy Temple Cancer Primary Prevention Program amongst Hispanics	He, Meizi	The University of Texas at San Antonio	\$573,095	2.8	10	\$573,095
PP140210	CCEProfEd	Cancer genomics training program for a competent Texas health education workforce	Chen, Lei-Shih	Texas A&M University	\$149,991	2.8	10	\$149,991
PP140026	CCEEBP	Bridging Access to Breast Healthcare Services	Letman, Vanessa L	The Bridge Breast Network	\$1,497,357	3.0	12	\$1,497,357
PP140028	CCEEBP	Empowering the Medically Underserved Through a Community Network for Cancer Prevention	Jibaja-Weiss, Maria L	Baylor College of Medicine	\$1,499,234	3.1	13	\$1,499,234
PP140182	CCEEBP	Population Based Screening for Hereditary Breast and Ovarian Cancer Syndrome and the Lynch syndrome in	Argenbright, Keith E	The University of Texas Southwestern Medical Center	\$1,499,872	3.1	13	\$1,499,872
PP140171	CCEEBP	Navigating Rural Highways II: Expanding Access to Breast Cancer Screening and the Care Continuum for Underserved Texas Women (NRH II)	Joseph, Bernice	The Rose	\$539,144	3.3	15	\$539,144
				Total Requested	\$17,568,470		Total Recommended	\$17,568,470
							Total Available	\$18,228,345
							Running Total Available	\$659,875



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application PP140018
Evidence Based Cancer Prevention Services

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Evidence Based Cancer Prevention Services* Request for Applications (RFA). CPRIT received 22 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to Panel B for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT’s grant review processes were followed by the review panel evaluating the applications in this grant cycle

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that one application that was not recommended for a grant award received a more favorable score than other applications that were recommended for funding. I have conferred with the Chief Prevention Officer and reviewed the Prevention Review Council's written critique for the project that was not funded. According to the notice sent to the applicant, the Prevention Review Council did not recommend the application for funding because the project was not deemed to fit within the intended scope of the Evidence-Based Cancer Prevention Services Request for Applications (RFA), as the proposed project deals with the education and coordination of care during cancer treatment. This is inconsistent with guidance given on page 8 of the RFA, which states, "Under this RFA, CPRIT will not consider....**Projects focusing solely on case management/patient navigation services.** Applicants seeking to provide case management/patient navigation services to help individuals obtain primary prevention services, screening services, or survivorship services but that do not plan to deliver the actual clinical service are not eligible under this mechanism. Furthermore, while navigation to the point of treatment of cancer is required when cancer is discovered through a CPRIT-funded project, **applications seeking funds to provide coordination of care while an individual is in treatment are not allowed under this RFA.**" (emphasis added)

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

This statement is true."

Wayne R. Roberts

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.

Sandra Reyes

Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Prevention
AWARD MECHANISM Evidence-Based Cancer Prevention Services (EBP)
APPLICATION ID PP140018
APPLICATION TITLE Improving Access to Colorectal Cancer Screening in East Texas
APPLICANT NAME Sauter, Edward
ORGANIZATION The University of Texas Health Center at Tyler
PANEL NAME Panel B 14.1 (B 14.1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/03/14
	CPRIT Application Receipt System (CARS) opened	12/19/13	07/03/14
	CPRIT Application Receipt System (CARS) closed	02/27/14	07/03/14
	Date application submitted	02/26/14	07/03/14
	Method of submission	CARS	07/03/14
	Within receipt period	YES	07/03/14
	Appeal to submit application after CARS closed	N/A	07/03/14
	Appeal for late application submission accepted	N/A	07/03/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/03/14
	Donation(s) made to CPRIT/foundation	NO	07/03/14
	Assigned to primary reviewers	04/03/14	07/03/14
	Applicant notified of review panel assignment	04/23/14	07/03/14
	Primary Reviewer 1 COI signed	03/24/14	07/03/14
	Primary (Advocate) Reviewer 2 COI signed	03/20/14	07/03/14
	Primary Reviewer 3 COI signed	03/19/14	07/03/14
	Primary Reviewer 4 COI signed	03/28/14	07/03/14
3. Peer Review: On-Site Meeting	Primary Reviewer 1 critique submitted	04/11/14	07/03/14
	Primary (Advocate) Reviewer 2 critique submitted	04/08/14	07/03/14
	Primary Reviewer 3 critique submitted	04/28/14	07/03/14
	Primary Reviewer 4 critique submitted	04/29/14	07/03/14
	COI indicated by non-primary reviewer	NONE	07/03/14
	COI recused from participation	N/A	07/03/14
	Discussed at On-Site Meeting	YES	07/03/14
	Peer Review: On-Site Meeting	05/06/14-05/07/14	07/03/14
	Post review statements signed	05/12/14	07/03/14
	Third Party Observer Report	05/07/14	07/03/14
	Score report delivered to CPO	05/12/14	07/03/14
4. Final PRC Recommendation	COI indicated by PRC member	NONE	06/27/14
	COI recused from participation	N/A	06/27/14
	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/08/14
	PRC Chair Notification to PIC and OC	07/03/14	07/03/14
5. PIC Review	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
6. Oversight Committee Approval	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

identity of attesting party retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application PP140026
Competitive Continuation/Expansion Projects

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Competitive Continuation/Expansion Projects* Request for Applications (RFA). CPRIT received 17 applications for this RFA. The application was assigned to Panel A for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT’s grant review processes were followed by the review panel evaluating the applications in this grant cycle

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that one application not recommended for funding received the same final score as an application, PP140171, which is recommended for funding. I conferred with CPRIT's Chief Prevention Officer about this issue. Dr. Garcia explained that the application not recommended for funding did not move forward to the full peer review panel discussion. The decision was based upon the application's initial overall evaluation score, consistent with TAC 703.6(b)(4). PP140171 moved forward for discussion by the full peer review panel based upon its initial overall evaluation score. Although the final evaluation score for PP140171 was higher than its initial score, the peer review panel recommended the application for an award based upon the totality of factors. I am satisfied that the review panel followed CPRIT's review process in creating the list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

This statement is true."

Wayne R. Roberts

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.

Sandra Reyes
Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Prevention
AWARD MECHANISM Competitive Continuation/Expansion (CCE)
APPLICATION ID PP140026
APPLICATION TITLE Bridging Access to Breast Healthcare Services
APPLICANT NAME Letman, Vanessa
ORGANIZATION The Bridge Breast Network
PANEL NAME Panel A 14.1 (A 14.1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/01/14
	CPRIT Application Receipt System (CARS) opened	12/19/13	07/01/14
	CPRIT Application Receipt System (CARS) closed	02/27/14	07/01/14
	Date application submitted	02/27/14	07/01/14
	Method of submission	CARS	07/01/14
	Within receipt period	YES	07/01/14
	Appeal to submit application after CARS closed	N/A	07/01/14
	Appeal for late application submission accepted	N/A	07/01/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/01/14
	Donation(s) made to CPRIT/foundation	NO	07/01/14
	Assigned to primary reviewers	04/03/14	07/01/14
	Applicant notified of review panel assignment	04/23/14	07/01/14
	Primary Reviewer 1 COI signed	03/21/14	07/01/14
	Primary (Advocate) Reviewer 2 COI signed	03/20/14	07/01/14
	Primary Reviewer 3 COI signed	03/19/14	07/01/14
	Primary Reviewer 4 COI signed	04/07/14	07/01/14
3. Peer Review: On-Site Meeting	Primary Reviewer 1 critique submitted	04/22/14	07/01/14
	Primary (Advocate) Reviewer 2 critique submitted	04/30/14	07/01/14
	Primary Reviewer 3 critique submitted	04/30/14	07/01/14
	Primary Reviewer 4 critique submitted	04/29/14	07/01/14
	COI indicated by non-primary reviewer	NONE	07/01/14
	COI recused from participation	N/A	07/01/14
	Discussed at On-Site Meeting	YES	07/01/14
	Peer Review: On-Site Meeting	05/05/14-05/06/14	07/01/14
	Post review statements signed	05/12/14	07/01/14
	Third Party Observer Report	05/06/14	07/01/14
	Score report delivered to CPO	05/12/14	07/01/14
4. Final PRC Recommendation	COI indicated by PRC member	NONE	06/27/14
	COI recused from participation	N/A	06/27/14
	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/08/14
	PRC Chair Notification to PIC and OC	07/03/14	07/03/14
5. PIC Review	COI Indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
6. Oversight Committee Approval	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

identity of attesting party retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application PP140028
Competitive Continuation/Expansion Projects

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Competitive Continuation/Expansion Projects* Request for Applications (RFA). CPRIT received 17 applications for this RFA. The application was assigned to Panel B for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that one application not recommended for funding received the same final score as an application, PP140171, which is recommended for funding. I conferred with CPRIT's Chief Prevention Officer about this issue. Dr. Garcia explained that the application not recommended for funding did not move forward to the full peer review panel discussion. The decision was based upon the application's initial overall evaluation score, consistent with TAC 703.6(b)(4). PP140171 moved forward for discussion by the full peer review panel based upon its initial overall evaluation score. Although the final evaluation score for PP140171 was higher than its initial score, the peer review panel recommended the application for an award based upon the totality of factors. I am satisfied that the review panel followed CPRIT's review process in creating the list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

This statement is true."

Wayne R. Roberts

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.

Sandra Reyes
Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Prevention
AWARD MECHANISM Competitive Continuation/Expansion (CCE)
APPLICATION ID PP140028
APPLICATION TITLE Empowering the Medically Underserved Through a Community Network for Cancer Prevention
APPLICANT NAME Jibaja-Weiss, Maria
ORGANIZATION Baylor College of Medicine
PANEL NAME Panel B 14.1 (B 14.1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/03/14
	CPRIT Application Receipt System (CARS) opened	12/19/13	07/03/14
	CPRIT Application Receipt System (CARS) closed	02/27/14	07/03/14
	Date application submitted	02/26/14	07/03/14
	Method of submission	CARS	07/03/14
	Within receipt period	YES	07/03/14
	Appeal to submit application after CARS closed	N/A	07/03/14
	Appeal for late application submission accepted	N/A	07/03/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/03/14
	Donation(s) made to CPRIT/foundation	NO	07/03/14
	Assigned to primary reviewers	04/03/14	07/03/14
	Applicant notified of review panel assignment	04/23/14	07/03/14
	Primary Reviewer 1 COI signed	03/24/14	07/03/14
	Primary (Advocate) Reviewer 2 COI signed	03/20/14	07/03/14
	Primary Reviewer 3 COI signed	03/24/14	07/03/14
	Primary Reviewer 4 COI signed	03/24/14	07/03/14
3. Peer Review: On-Site Meeting	Primary Reviewer 1 critique submitted	04/14/14	07/03/14
	Primary (Advocate) Reviewer 2 critique submitted	04/29/14	07/03/14
	Primary Reviewer 3 critique submitted	04/28/14	07/03/14
	Primary Reviewer 4 critique submitted	04/28/14	07/03/14
	COI indicated by non-primary reviewer	NONE	07/03/14
	COI recused from participation	N/A	07/03/14
	Discussed at On-Site Meeting	YES	07/03/14
	Peer Review: On-Site Meeting	05/06/14-05/07/14	07/03/14
	Post review statements signed	05/12/14	07/03/14
	Third Party Observer Report	05/07/14	07/03/14
	Score report delivered to CPO	05/12/14	07/03/14
4. Final PRC Recommendation	COI indicated by PRC member	NONE	06/27/14
	COI recused from participation	N/A	06/27/14
	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/08/14
	PRC Chair Notification to PIC and OC	07/03/14	07/03/14
5. PIC Review	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
6. Oversight Committee Approval	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

identity of attesting party retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application PP140033
Competitive Continuation/Expansion Projects

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Competitive Continuation/Expansion Projects* Request for Applications (RFA). CPRIT received 17 applications for this RFA. The application was assigned to Panel B for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that one application not recommended for funding received the same final score as an application, PP140171, which is recommended for funding. I conferred with CPRIT's Chief Prevention Officer about this issue. Dr. Garcia explained that the application not recommended for funding did not move forward to the full peer review panel discussion. The decision was based upon the application's initial overall evaluation score, consistent with TAC 703.6(b)(4). PP140171 moved forward for discussion by the full peer review panel based upon its initial overall evaluation score. Although the final evaluation score for PP140171 was higher than its initial score, the peer review panel recommended the application for an award based upon the totality of factors. I am satisfied that the review panel followed CPRIT's review process in creating the list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

This statement is true."

Wayne R. Roberts

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.

Sandra Reyes

Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Prevention
AWARD MECHANISM Competitive Continuation/Expansion (CCE)
APPLICATION ID PP140033
APPLICATION TITLE Access to Breast and Cervical Care for West Texas (ABC24WT)
APPLICANT NAME Layeequr Rahman, Rakhshanda
ORGANIZATION Texas Tech University Health Sciences Center
PANEL NAME Panel B 14.1 (B 14.1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/03/14
	CPRIT Application Receipt System (CARS) opened	12/19/13	07/03/14
	CPRIT Application Receipt System (CARS) closed	02/27/14	07/03/14
	Date application submitted	02/25/14	07/03/14
	Method of submission	CARS	07/03/14
	Within receipt period	YES	07/03/14
	Appeal to submit application after CARS closed	N/A	07/03/14
	Appeal for late application submission accepted	N/A	07/03/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/03/14
	Donation(s) made to CPRIT/foundation	NO	07/03/14
	Assigned to primary reviewers	04/03/14	07/03/14
	Applicant notified of review panel assignment	04/23/14	07/03/14
	Primary Reviewer 1 COI signed	03/28/14	07/03/14
	Primary (Advocate) Reviewer 2 COI signed	03/20/14	07/03/14
	Primary Reviewer 3 COI signed	03/20/14	07/03/14
	Primary Reviewer 4 COI signed	03/25/14	07/03/14
3. Peer Review: On-Site Meeting	Primary Reviewer 1 critique submitted	04/29/14	07/03/14
	Primary (Advocate) Reviewer 2 critique submitted	04/28/14	07/03/14
	Primary Reviewer 3 critique submitted	04/11/14	07/03/14
	Primary Reviewer 4 critique submitted	04/24/14	07/03/14
	COI indicated by non-primary reviewer	NONE	07/03/14
	COI recused from participation	N/A	07/03/14
	Discussed at On-Site Meeting	YES	07/03/14
	Peer Review: On-Site Meeting	05/06/14-05/07/14	07/03/14
	Post review statements signed	05/12/14	07/03/14
	Third Party Observer Report	05/07/14	07/03/14
4. Final PRC Recommendation	Score report delivered to CPO	05/12/14	07/03/14
	COI indicated by PRC member	NONE	06/27/14
	COI recused from participation	N/A	06/27/14
	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/08/14
5. PIC Review	PRC Chair Notification to PIC and OC	07/03/14	07/03/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
6. Oversight Committee Approval	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

identity of attesting party retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application PP140049
Competitive Continuation/Expansion Projects**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Competitive Continuation/Expansion Projects* Request for Applications (RFA). CPRIT received 17 applications for this RFA. The application was assigned to Panel A for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that one application not recommended for funding received the same final score as an application, PP140171, which is recommended for funding. I conferred with CPRIT's Chief Prevention Officer about this issue. Dr. Garcia explained that the application not recommended for funding did not move forward to the full peer review panel discussion. The decision was based upon the application's initial overall evaluation score, consistent with TAC 703.6(b)(4). PP140171 moved forward for discussion by the full peer review panel based upon its initial overall evaluation score. Although the final evaluation score for PP140171 was higher than its initial score, the peer review panel recommended the application for an award based upon the totality of factors. I am satisfied that the review panel followed CPRIT's review process in creating the list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

This statement is true."

Wayne R. Roberts
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.

Sandra Reyes
Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Prevention
AWARD MECHANISM Competitive Continuation/Expansion (CCE)
APPLICATION ID PP140049
APPLICATION TITLE Educating Hispanic adolescents and their families on cervical cancer prevention and HPV vaccination in community and clinic settings
APPLICANT NAME Morales-Campos, Daisy
ORGANIZATION The University of Texas Health Science Center at San Antonio
PANEL NAME Panel A 14.1 (A 14.1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/01/14
	CPRIT Application Receipt System (CARS) opened	12/19/13	07/01/14
	CPRIT Application Receipt System (CARS) closed	02/27/14	07/01/14
	Date application submitted	02/27/14	07/01/14
	Method of submission	CARS	07/01/14
	Within receipt period	YES	07/01/14
	Appeal to submit application after CARS closed	N/A	07/01/14
	Appeal for late application submission accepted	N/A	07/01/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/01/14
	Donation(s) made to CPRIT/foundation	NO	07/01/14
	Assigned to primary reviewers	04/03/14	07/01/14
	Applicant notified of review panel assignment	04/23/14	07/01/14
	Primary Reviewer 1 COI signed	04/02/14	07/01/14
	Primary (Advocate) Reviewer 2 COI signed	03/20/14	07/01/14
	Primary Reviewer 3 COI signed	03/19/14	07/01/14
	Primary Reviewer 4 COI signed	03/19/14	07/01/14
3. Peer Review: On-Site Meeting	Primary Reviewer 1 critique submitted	04/29/14	07/01/14
	Primary (Advocate) Reviewer 2 critique submitted	04/30/14	07/01/14
	Primary Reviewer 3 critique submitted	04/29/14	07/01/14
	Primary Reviewer 4 critique submitted	04/29/14	07/01/14
	COI indicated by non-primary reviewer	Green, Lawrence	07/01/14
	COI recused from participation	YES	07/01/14
	COI indicated by non-primary reviewer	Vanderpool, Robin	07/01/14
	COI recused from participation	YES	07/01/14
	Discussed at On-Site Meeting	YES	07/01/14
	Peer Review: On-Site Meeting	05/05/14-05/06/14	07/01/14
	Post review statements signed	05/12/14	07/01/14
	Third Party Observer Report	05/06/14	07/01/14
4. Final PRC Recommendation	Score report delivered to CPO	05/12/14	07/01/14
	COI indicated by PRC member	L. Green	06/27/14
	COI recused from participation	YES	06/27/14
	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/08/14
5. PIC Review	PRC Chair Notification to PIC and OC	07/03/14	07/03/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
6. Oversight Committee Approval	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

identity of attesting party retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application PP140164
Competitive Continuation/Expansion Projects**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Competitive Continuation/Expansion Projects* Request for Applications (RFA). CPRIT received 17 applications for this RFA. The application was assigned to Panel B for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that one application not recommended for funding received the same final score as an application, PP140171, which is recommended for funding. I conferred with CPRIT's Chief Prevention Officer about this issue. Dr. Garcia explained that the application not recommended for funding did not move forward to the full peer review panel discussion. The decision was based upon the application's initial overall evaluation score, consistent with TAC 703.6(b)(4). PP140171 moved forward for discussion by the full peer review panel based upon its initial overall evaluation score. Although the final evaluation score for PP140171 was higher than its initial score, the peer review panel recommended the application for an award based upon the totality of factors. I am satisfied that the review panel followed CPRIT's review process in creating the list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

This statement is true."

Wayne R. Roberts

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.

Sandra Reyes
Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Prevention
AWARD MECHANISM Competitive Continuation/Expansion (CCE)
APPLICATION ID PP140164
APPLICATION TITLE ACCION 2: Against Colorectal Cancer in our Neighborhoods: El Paso and Hudspeth County
APPLICANT NAME Shokar, Navkiran
ORGANIZATION Texas Tech University Health Sciences Center at El Paso
PANEL NAME Panel B 14.1 (B 14.1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/03/14
	CPRIT Application Receipt System (CARS) opened	12/19/13	07/03/14
	CPRIT Application Receipt System (CARS) closed	02/27/14	07/03/14
	Date application submitted	02/27/14	07/03/14
	Method of submission	CARS	07/03/14
	Within receipt period	YES	07/03/14
	Appeal to submit application after CARS closed	N/A	07/03/14
	Appeal for late application submission accepted	N/A	07/03/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/03/14
	Donation(s) made to CPRIT/foundation	NO	07/03/14
	Assigned to primary reviewers	04/03/14	07/03/14
	Applicant notified of review panel assignment	04/23/14	07/03/14
	Primary Reviewer 1 COI signed	03/23/14	07/03/14
	Primary (Advocate) Reviewer 2 COI signed	03/20/14	07/03/14
	Primary Reviewer 3 COI signed	03/24/14	07/03/14
3. Peer Review: On-Site Meeting	Primary Reviewer 4 COI signed	03/24/14	07/03/14
	Primary Reviewer 1 critique submitted	04/24/14	07/03/14
	Primary (Advocate) Reviewer 2 critique submitted	04/29/14	07/03/14
	Primary Reviewer 3 critique submitted	04/15/14	07/03/14
	Primary Reviewer 4 critique submitted	04/29/14	07/03/14
	COI indicated by non-primary reviewer	NONE	07/03/14
	COI recused from participation	N/A	07/03/14
	Discussed at On-Site Meeting	YES	07/03/14
	Peer Review: On-Site Meeting	05/06/14-05/07/14	07/03/14
	Post review statements signed	05/12/14	07/03/14
4. Final PRC Recommendation	Third Party Observer Report	05/07/14	07/03/14
	Score report delivered to CPO	05/12/14	07/03/14
	COI indicated by PRC member	NONE	06/27/14
	COI recused from participation	N/A	06/27/14
	Third Party Observer Report	07/07/14	07/08/14
5. PIC Review	Recommended for grant award	YES	07/08/14
	PRC Chair Notification to PIC and OC	07/03/14	07/03/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
6. Oversight Committee Approval	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

identity of attesting party retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application PP140171
Competitive Continuation/Expansion Projects**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Competitive Continuation/Expansion Projects* Request for Applications (RFA). CPRIT received 17 applications for this RFA. The application was assigned to Panel A for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that one application not recommended for funding received the same final score as an application, PP140171, which is recommended for funding. I conferred with CPRIT's Chief Prevention Officer about this issue. Dr. Garcia explained that the application not recommended for funding did not move forward to the full peer review panel discussion. The decision was based upon the application's initial overall evaluation score, consistent with TAC 703.6(b)(4). PP140171 moved forward for discussion by the full peer review panel based upon its initial overall evaluation score. Although the final evaluation score for PP140171 was higher than its initial score, the peer review panel recommended the application for an award based upon the totality of factors. I am satisfied that the review panel followed CPRIT's review process in creating the list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

This statement is true."

Wayne R. Roberts
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.

Sandra Reyes
Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Prevention
AWARD MECHANISM Competitive Continuation/Expansion (CCE)
APPLICATION ID PP140171
APPLICATION TITLE Navigating Rural Highways II: Expanding Access to Breast Cancer Screening and the Care Continuum for Underserved Texas Women (NRH II)
APPLICANT NAME Joseph, Bernice
ORGANIZATION The Rose
PANEL NAME Panel A 14.1 (A 14.1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/01/14
	CPRIT Application Receipt System (CARS) opened	12/19/13	07/01/14
	CPRIT Application Receipt System (CARS) closed	02/27/14	07/01/14
	Date application submitted	02/27/14	07/01/14
	Method of submission	CARS	07/01/14
	Within receipt period	YES	07/01/14
	Appeal to submit application after CARS closed	N/A	07/01/14
	Appeal for late application submission accepted	N/A	07/01/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/01/14
	Donation(s) made to CPRIT/foundation	NO	07/01/14
	Assigned to primary reviewers	04/03/14	07/01/14
	Applicant notified of review panel assignment	04/23/14	07/01/14
	Primary Reviewer 1 COI signed	03/28/14	07/01/14
	Primary (Advocate) Reviewer 2 COI signed	03/20/14	07/01/14
	Primary Reviewer 3 COI signed	03/28/14	07/01/14
	Primary Reviewer 4 COI signed	03/19/14	07/01/14
3. Peer Review: On-Site Meeting	Primary Reviewer 1 critique submitted	04/27/14	07/01/14
	Primary (Advocate) Reviewer 2 critique submitted	04/30/14	07/01/14
	Primary Reviewer 3 critique submitted	04/08/14	07/01/14
	Primary Reviewer 4 critique submitted	04/30/14	07/01/14
	COI indicated by non-primary reviewer	NONE	07/01/14
	COI recused from participation	N/A	07/01/14
	Discussed at On-Site Meeting	YES	07/01/14
	Peer Review: On-Site Meeting	05/05/14-05/06/14	07/01/14
	Post review statements signed	05/12/14	07/01/14
	Third Party Observer Report	05/06/14	07/01/14
4. Final PRC Recommendation	Score report delivered to CPO	05/12/14	07/01/14
	COI indicated by PRC member	NONE	06/27/14
	COI recused from participation	N/A	06/27/14
	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/08/14
5. PIC Review	PRC Chair Notification to PIC and OC	07/03/14	07/03/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
6. Oversight Committee Approval	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

identity of attesting party retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application PP140176
Evidence Based Cancer Prevention Services

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Evidence Based Cancer Prevention Services* Request for Applications (RFA). CPRIT received 22 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to Panel A for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT’s grant review processes were followed by the review panel evaluating the applications in this grant cycle

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that one application that was not recommended for a grant award received a more favorable score than other applications that were recommended for funding. I have conferred with the Chief Prevention Officer and reviewed the Prevention Review Council's written critique for the project that was not funded. According to the notice sent to the applicant, the Prevention Review Council did not recommend the application for funding because the project was not deemed to fit within the intended scope of the Evidence-Based Cancer Prevention Services Request for Applications (RFA), as the proposed project deals with the education and coordination of care during cancer treatment. This is inconsistent with guidance given on page 8 of the RFA, which states, "Under this RFA, CPRIT will not consider....**Projects focusing solely on case management/patient navigation services.** Applicants seeking to provide case management/patient navigation services to help individuals obtain primary prevention services, screening services, or survivorship services but that do not plan to deliver the actual clinical service are not eligible under this mechanism. Furthermore, while navigation to the point of treatment of cancer is required when cancer is discovered through a CPRIT-funded project, **applications seeking funds to provide coordination of care while an individual is in treatment are not allowed under this RFA.**" (emphasis added)

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

This statement is true."

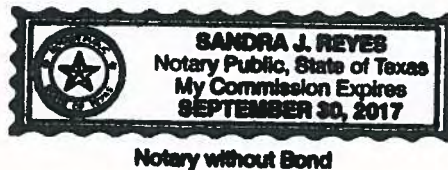
Wayne R. Roberts

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.

Sandra Reyes
Sandra Reyes
Notary Public, State of Texas



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Prevention
AWARD MECHANISM Evidence-Based Cancer Prevention Services (EBP)
APPLICATION ID PP140176
APPLICATION TITLE SMS Cessation Service for Young Adult Smokers in South Texas
APPLICANT NAME Ramirez, Amelie
ORGANIZATION The University of Texas Health Science Center at San Antonio
PANEL NAME Panel A 14.1 (A 14.1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/01/14
	CPRIT Application Receipt System (CARS) opened	12/19/13	07/01/14
	CPRIT Application Receipt System (CARS) closed	02/27/14	07/01/14
	Date application submitted	02/27/14	07/01/14
	Method of submission	CARS	07/01/14
	Within receipt period	YES	07/01/14
	Appeal to submit application after CARS closed	N/A	07/01/14
	Appeal for late application submission accepted	N/A	07/01/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/01/14
	Donation(s) made to CPRIT/foundation	NO	07/01/14
	Assigned to primary reviewers	04/03/14	07/01/14
	Applicant notified of review panel assignment	04/23/14	07/01/14
	Primary Reviewer 1 COI signed	03/19/14	07/01/14
	Primary (Advocate) Reviewer 2 COI signed	03/20/14	07/01/14
	Primary Reviewer 3 COI signed	03/21/14	07/01/14
	Primary Reviewer 4 COI signed	03/28/14	07/01/14
3. Peer Review: On-Site Meeting	Primary Reviewer 1 critique submitted	04/28/14	07/01/14
	Primary (Advocate) Reviewer 2 critique submitted	04/30/14	07/01/14
	Primary Reviewer 3 critique submitted	04/20/14	07/01/14
	Primary Reviewer 4 critique submitted	04/12/14	07/01/14
	COI indicated by non-primary reviewer	Green, Lawrence	07/01/14
	COI recused from participation	YES	07/01/14
	COI indicated by non-primary reviewer	Plescia, Marcus	07/01/14
	COI recused from participation	YES	07/01/14
	Discussed at On-Site Meeting	YES	07/01/14
	Peer Review: On-Site Meeting	05/05/14-05/06/14	07/01/14
	Post review statements signed	05/12/14	07/01/14
	Third Party Observer Report	05/06/14	07/01/14
4. Final PRC Recommendation	Score report delivered to CPO	05/12/14	07/01/14
	COI indicated by PRC member	L. GREEN	06/27/14
	COI recused from participation	YES	06/27/14
	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/08/14
5. PIC Review	PRC Chair Notification to PIC and OC	07/03/14	07/03/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/14/15	07/15/14
6. Oversight Committee Approval	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

identity of attesting party retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application PP140182
Competitive Continuation/Expansion Projects**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Competitive Continuation/Expansion Projects* Request for Applications (RFA). CPRIT received 17 applications for this RFA. The application was assigned to Panel B for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that one application not recommended for funding received the same final score as an application, PP140171, which is recommended for funding. I conferred with CPRIT's Chief Prevention Officer about this issue. Dr. Garcia explained that the application not recommended for funding did not move forward to the full peer review panel discussion. The decision was based upon the application's initial overall evaluation score, consistent with TAC 703.6(b)(4). PP140171 moved forward for discussion by the full peer review panel based upon its initial overall evaluation score. Although the final evaluation score for PP140171 was higher than its initial score, the peer review panel recommended the application for an award based upon the totality of factors. I am satisfied that the review panel followed CPRIT's review process in creating the list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

This statement is true."

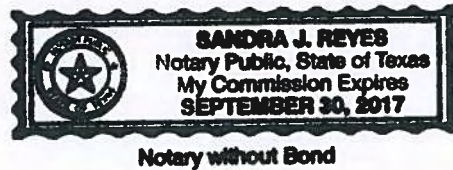
Wayne R. Roberts

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.

Sandra Reyes
Sandra Reyes
Notary Public, State of Texas



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Prevention
AWARD MECHANISM Competitive Continuation/Expansion (CCE)
APPLICATION ID PP140182
APPLICATION TITLE Population Based Screening for Hereditary Breast and Ovarian Cancer Syndrome and the Lynch syndrome in the Underserved
APPLICANT NAME Argenbright, Keith
ORGANIZATION The University of Texas Southwestern Medical Center
PANEL NAME Panel B 14.1 (B 14.1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/03/14
	CPRIT Application Receipt System (CARS) opened	12/19/13	07/03/14
	CPRIT Application Receipt System (CARS) closed	02/27/14	07/03/14
	Date application submitted	02/27/14	07/03/14
	Method of submission	CARS	07/03/14
	Within receipt period	YES	07/03/14
	Appeal to submit application after CARS closed	N/A	07/03/14
	Appeal for late application submission accepted	N/A	07/03/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/03/14
	Donation(s) made to CPRIT/foundation	NO	07/03/14
	Assigned to primary reviewers	04/03/14	07/03/14
	Applicant notified of review panel assignment	04/23/14	07/03/14
	Primary Reviewer 1 COI signed	03/27/14	07/03/14
	Primary (Advocate) Reviewer 2 COI signed	03/20/14	07/03/14
	Primary Reviewer 3 COI signed	03/26/14	07/03/14
3. Peer Review: On-Site Meeting	Primary Reviewer 4 COI signed	03/23/14	07/03/14
	Primary Reviewer 1 critique submitted	04/27/14	07/03/14
	Primary (Advocate) Reviewer 2 critique submitted	04/28/14	07/03/14
	Primary Reviewer 3 critique submitted	04/29/14	07/03/14
	Primary Reviewer 4 critique submitted	04/24/14	07/03/14
	COI indicated by non-primary reviewer	NONE	07/03/14
	COI recused from participation	N/A	07/03/14
	Discussed at On-Site Meeting	YES	07/03/14
	Peer Review: On-Site Meeting	05/06/14-05/07/14	07/03/14
	Post review statements signed	05/12/14	07/03/14
	Third Party Observer Report	05/07/14	07/03/14
4. Final PRC Recommendation	Score report delivered to CPO	05/12/14	07/03/14
	COI Indicated by PRC member	NONE	06/27/14
	COI recused from participation	N/A	06/27/14
	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/08/14
5. PIC Review	PRC Chair Notification to PIC and OC	07/03/14	07/03/14
	COI Indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
6. Oversight Committee Approval	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

identity of attesting party retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application PP140183
Evidence Based Cancer Prevention Services**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Evidence Based Cancer Prevention Services* Request for Applications (RFA). CPRIT received 22 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to Panel A for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that one application that was not recommended for a grant award received a more favorable score than other applications that were recommended for funding. I have conferred with the Chief Prevention Officer and reviewed the Prevention Review Council's written critique for the project that was not funded. According to the notice sent to the applicant, the Prevention Review Council did not recommend the application for funding because the project was not deemed to fit within the intended scope of the Evidence-Based Cancer Prevention Services Request for Applications (RFA), as the proposed project deals with the education and coordination of care during cancer treatment. This is inconsistent with guidance given on page 8 of the RFA, which states, "Under this RFA, CPRIT will not consider....**Projects focusing solely on case management/patient navigation services.** Applicants seeking to provide case management/patient navigation services to help individuals obtain primary prevention services, screening services, or survivorship services but that do not plan to deliver the actual clinical service are not eligible under this mechanism. Furthermore, while navigation to the point of treatment of cancer is required when cancer is discovered through a CPRIT-funded project, **applications seeking funds to provide coordination of care while an individual is in treatment are not allowed under this RFA.**" (emphasis added)

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

This statement is true."

Wayne R. Roberts

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.

Sandra Reyes
Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Prevention
AWARD MECHANISM Evidence-Based Cancer Prevention Services (EBP)
APPLICATION ID PP140183
APPLICATION TITLE Multi-component Interventions to Increase HPV Vaccination in a Network of Pediatric Clinics
APPLICANT NAME Vernon, Sally
ORGANIZATION The University of Texas Health Science Center at Houston
PANEL NAME Panel A 14.1 (A 14.1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/01/14
	CPRIT Application Receipt System (CARS) opened	12/19/13	07/01/14
	CPRIT Application Receipt System (CARS) closed	02/27/14	07/01/14
	Date application submitted	02/27/14	07/01/14
	Method of submission	CARS	07/01/14
	Within receipt period	YES	07/01/14
	Appeal to submit application after CARS closed	N/A	07/01/14
	Appeal for late application submission accepted	N/A	07/01/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/01/14
	Donation(s) made to CPRIT/foundation	NO	07/01/14
	Assigned to primary reviewers	04/03/14	07/01/14
	Applicant notified of review panel assignment	04/23/14	07/01/14
	Primary Reviewer 1 COI signed	03/19/14	07/01/14
	Primary (Advocate) Reviewer 2 COI signed	03/19/14	07/01/14
	Primary Reviewer 3 COI signed	03/19/14	07/01/14
	Primary Reviewer 4 COI signed	03/19/14	07/01/14
3. Peer Review: On-Site Meeting	Primary Reviewer 1 critique submitted	04/29/14	07/01/14
	Primary (Advocate) Reviewer 2 critique submitted	04/30/14	07/01/14
	Primary Reviewer 3 critique submitted	04/26/14	07/01/14
	Primary Reviewer 4 critique submitted	04/27/14	07/01/14
	COI indicated by non-primary reviewer	Vanderpool, Robin	07/01/14
	COI recused from participation	YES	07/01/14
	Discussed at On-Site Meeting	YES	07/01/14
	Peer Review: On-Site Meeting	05/05/14-05/06/14	07/01/14
	Post review statements signed	05/12/14	07/01/14
	Third Party Observer Report	05/06/14	07/01/14
4. Final PRC Recommendation	Score report delivered to CPO	05/12/14	07/01/14
	COI indicated by PRC member	NONE	06/27/14
	COI recused from participation	N/A	06/27/14
	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/08/14
5. PIC Review	PRC Chair Notification to PIC and OC	07/03/14	07/03/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
6. Oversight Committee Approval	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
7. Advance Authority	Advance authority approved by Oversight Committee	YES/NO	

identity of attesting party retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application PP140205
Competitive Continuation/Expansion Projects

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Competitive Continuation/Expansion Projects* Request for Applications (RFA). CPRIT received 17 applications for this RFA. The application was assigned to Panel B for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT’s grant review processes were followed by the review panel evaluating the applications in this grant cycle

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that one application not recommended for funding received the same final score as an application, PP140171, which is recommended for funding. I conferred with CPRIT's Chief Prevention Officer about this issue. Dr. Garcia explained that the application not recommended for funding did not move forward to the full peer review panel discussion. The decision was based upon the application's initial overall evaluation score, consistent with TAC 703.6(b)(4). PP140171 moved forward for discussion by the full peer review panel based upon its initial overall evaluation score. Although the final evaluation score for PP140171 was higher than its initial score, the peer review panel recommended the application for an award based upon the totality of factors. I am satisfied that the review panel followed CPRIT's review process in creating the list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

This statement is true."

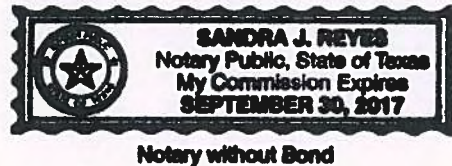
Wayne R. Roberts

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.

Sandra Reyes
Sandra Reyes
Notary Public, State of Texas



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Prevention
AWARD MECHANISM Competitive Continuation/Expansion (CCE)
APPLICATION ID PP140205
APPLICATION TITLE Eliminating Cancer Disparities in Medically Underserved Immigrant and Refugee Populations in Houston Texas
APPLICANT NAME Caracostis, Andrea
ORGANIZATION Asian American Health Coalition of Greater Houston, Inc., dba Hope Clinic
PANEL NAME Panel B 14.1 (B 14.1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/03/14
	CPRIT Application Receipt System (CARS) opened	12/19/13	07/03/14
	CPRIT Application Receipt System (CARS) closed	02/27/14	07/03/14
	Date application submitted	02/27/14	07/03/14
	Method of submission	CARS	07/03/14
	Within receipt period	YES	07/03/14
	Appeal to submit application after CARS closed	N/A	07/03/14
	Appeal for late application submission accepted	N/A	07/03/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/03/14
	Donation(s) made to CPRIT/foundation	NO	07/03/14
	Assigned to primary reviewers	04/03/14	07/03/14
	Applicant notified of review panel assignment	04/23/14	07/03/14
	Primary Reviewer 1 COI signed	03/25/14	07/03/14
	Primary (Advocate) Reviewer 2 COI signed	03/20/14	07/03/14
	Primary Reviewer 3 COI signed	03/23/14	07/03/14
3. Peer Review: On-Site Meeting	Primary Reviewer 4 COI signed	03/25/14	07/03/14
	Primary Reviewer 1 critique submitted	05/03/14	07/03/14
	Primary (Advocate) Reviewer 2 critique submitted	04/29/14	07/03/14
	Primary Reviewer 3 critique submitted	05/02/14	07/03/14
	Primary Reviewer 4 critique submitted	04/26/14	07/03/14
	COI indicated by non-primary reviewer	NONE	07/03/14
	COI recused from participation	N/A	07/03/14
	Discussed at On-Site Meeting	YES	07/03/14
	Peer Review: On-Site Meeting	05/06/14-05/07/14	07/03/14
	Post review statements signed	05/12/14	07/03/14
	Third Party Observer Report	05/07/14	07/03/14
	Score report delivered to CPO	05/12/14	07/03/14
4. Final PRC Recommendation	COI indicated by PRC member	NONE	06/27/14
	COI recused from participation	N/A	06/27/14
	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/08/14
	PRC Chair Notification to PIC and OC	07/03/14	07/03/14
5. PIC Review	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
6. Oversight Committee Approval	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

identity of attesting party retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application PP140208
Evidence Based Cancer Prevention Services

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Evidence Based Cancer Prevention Services* Request for Applications (RFA). CPRIT received 22 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to Panel A for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT’s grant review processes were followed by the review panel evaluating the applications in this grant cycle

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that one application that was not recommended for a grant award received a more favorable score than other applications that were recommended for funding. I have conferred with the Chief Prevention Officer and reviewed the Prevention Review Council's written critique for the project that was not funded. According to the notice sent to the applicant, the Prevention Review Council did not recommend the application for funding because the project was not deemed to fit within the intended scope of the Evidence-Based Cancer Prevention Services Request for Applications (RFA), as the proposed project deals with the education and coordination of care during cancer treatment. This is inconsistent with guidance given on page 8 of the RFA, which states, "Under this RFA, CPRIT will not consider....**Projects focusing solely on case management/patient navigation services.** Applicants seeking to provide case management/patient navigation services to help individuals obtain primary prevention services, screening services, or survivorship services but that do not plan to deliver the actual clinical service are not eligible under this mechanism. Furthermore, while navigation to the point of treatment of cancer is required when cancer is discovered through a CPRIT-funded project, **applications seeking funds to provide coordination of care while an individual is in treatment are not allowed under this RFA.**" (emphasis added)

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

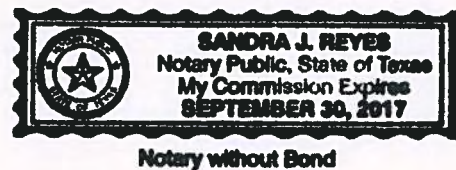
This statement is true."

Wayne R. Roberts
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.

Sandra Reyes
Sandra Reyes
Notary Public, State of Texas



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Prevention
AWARD MECHANISM Evidence-Based Cancer Prevention Services (EBP)
APPLICATION ID PP140208
APPLICATION TITLE Increasing HPV Vaccinations in Harris and Jefferson Counties Using Combined Evidence-Based Approaches in a Federally Qualified Health Center
APPLICANT NAME Megdal, Tina
ORGANIZATION Legacy Community Health Services
PANEL NAME Panel A 14.1 (A 14.1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/01/14
	CPRIT Application Receipt System (CARS) opened	12/19/13	07/01/14
	CPRIT Application Receipt System (CARS) closed	02/27/14	07/01/14
	Date application submitted	02/27/14	07/01/14
	Method of submission	CARS	07/01/14
	Within receipt period	YES	07/01/14
	Appeal to submit application after CARS closed	N/A	07/01/14
	Appeal for late application submission accepted	N/A	07/01/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/01/14
	Donation(s) made to CPRIT/foundation	NO	07/01/14
	Assigned to primary reviewers	04/03/14	07/01/14
	Applicant notified of review panel assignment	04/23/14	07/01/14
	Primary Reviewer 1 COI signed	04/02/14	07/01/14
	Primary (Advocate) Reviewer 2 COI signed	03/20/14	07/01/14
	Primary Reviewer 3 COI signed	03/19/14	07/01/14
3. Peer Review: On-Site Meeting	Primary Reviewer 4 COI signed	03/28/14	07/01/14
	Primary Reviewer 1 critique submitted	04/25/14	07/01/14
	Primary (Advocate) Reviewer 2 critique submitted	04/30/14	07/01/14
	Primary Reviewer 3 critique submitted	04/30/14	07/01/14
	Primary Reviewer 4 critique submitted	04/28/14	07/01/14
	COI indicated by non-primary reviewer	NONE	07/01/14
	COI recused from participation	N/A	07/01/14
	Discussed at On-Site Meeting	YES	07/01/14
	Peer Review: On-Site Meeting	05/05/14-05/06/14	07/01/14
	Post review statements signed	05/12/14	07/01/14
	Third Party Observer Report	05/06/14	07/01/14
4. Final PRC Recommendation	Score report delivered to CPO	05/12/14	07/01/14
	COI indicated by PRC member	NONE	06/27/14
	COI recused from participation	N/A	06/27/14
	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/08/14
5. PIC Review	PRC Chair Notification to PIC and OC	07/03/14	07/03/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
6. Oversight Committee Approval	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

identity of attesting party retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application PP140209
Evidence Based Cancer Prevention Services

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Evidence Based Cancer Prevention Services* Request for Applications (RFA). CPRIT received 22 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to Panel B for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT’s grant review processes were followed by the review panel evaluating the applications in this grant cycle

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that one application that was not recommended for a grant award received a more favorable score than other applications that were recommended for funding. I have conferred with the Chief Prevention Officer and reviewed the Prevention Review Council's written critique for the project that was not funded. According to the notice sent to the applicant, the Prevention Review Council did not recommend the application for funding because the project was not deemed to fit within the intended scope of the Evidence-Based Cancer Prevention Services Request for Applications (RFA), as the proposed project deals with the education and coordination of care during cancer treatment. This is inconsistent with guidance given on page 8 of the RFA, which states, "Under this RFA, CPRIT will not consider....**Projects focusing solely on case management/patient navigation services.** Applicants seeking to provide case management/patient navigation services to help individuals obtain primary prevention services, screening services, or survivorship services but that do not plan to deliver the actual clinical service are not eligible under this mechanism. Furthermore, while navigation to the point of treatment of cancer is required when cancer is discovered through a CPRIT-funded project, **applications seeking funds to provide coordination of care while an individual is in treatment are not allowed under this RFA.**" (emphasis added)

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

This statement is true."

Wayne R. Roberts

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.

[Signature]

Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Prevention
AWARD MECHANISM Evidence-Based Cancer Prevention Services (EBP)
APPLICATION ID PP140209
APPLICATION TITLE Building a Healthy Temple Cancer Primary Prevention Program amongst Hispanics
APPLICANT NAME He, Meizi
ORGANIZATION The University of Texas at San Antonio
PANEL NAME Panel B 14.1 (B 14.1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/03/14
	CPRIT Application Receipt System (CARS) opened	12/19/13	07/03/14
	CPRIT Application Receipt System (CARS) closed	02/27/14	07/03/14
	Date application submitted	02/27/14	07/03/14
	Method of submission	CARS	07/03/14
	Within receipt period	YES	07/03/14
	Appeal to submit application after CARS closed	N/A	07/03/14
	Appeal for late application submission accepted	N/A	07/03/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/03/14
	Donation(s) made to CPRIT/foundation	NO	07/03/14
	Assigned to primary reviewers	04/03/14	07/03/14
	Applicant notified of review panel assignment	04/23/14	07/03/14
	Primary Reviewer 1 COI signed	03/20/14	07/03/14
	Primary (Advocate) Reviewer 2 COI signed	03/20/14	07/03/14
	Primary Reviewer 3 COI signed	03/28/14	07/03/14
	Primary Reviewer 4 COI signed	03/23/14	07/03/14
3. Peer Review: On-Site Meeting	Primary Reviewer 1 critique submitted	04/29/14	07/03/14
	Primary (Advocate) Reviewer 2 critique submitted	04/28/14	07/03/14
	Primary Reviewer 3 critique submitted	04/29/14	07/03/14
	Primary Reviewer 4 critique submitted	04/24/14	07/03/14
	COI indicated by non-primary reviewer	Green, Lawrence	07/03/14
	COI recused from participation	YES	07/03/14
	Discussed at On-Site Meeting	YES	07/03/14
	Peer Review: On-Site Meeting	05/06/14-05/07/14	07/03/14
	Post review statements signed	05/12/14	07/03/14
	Third Party Observer Report	05/07/14	07/03/14
	Score report delivered to CPO	05/12/14	07/03/14
4. Final PRC Recommendation	COI indicated by PRC member	NONE	06/27/14
	COI recused from participation	N/A	06/27/14
	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/08/14
	PRC Chair Notification to PIC and OC	07/03/14	07/03/14
5. PIC Review	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
6. Oversight Committee Approval	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

identity of attesting party retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application PP140210
Competitive Continuation/Expansion Projects

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Competitive Continuation/Expansion Projects* Request for Applications (RFA). CPRIT received 17 applications for this RFA. The application was assigned to Panel A for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that one application not recommended for funding received the same final score as an application, PP140171, which is recommended for funding. I conferred with CPRIT's Chief Prevention Officer about this issue. Dr. Garcia explained that the application not recommended for funding did not move forward to the full peer review panel discussion. The decision was based upon the application's initial overall evaluation score, consistent with TAC 703.6(b)(4). PP140171 moved forward for discussion by the full peer review panel based upon its initial overall evaluation score. Although the final evaluation score for PP140171 was higher than its initial score, the peer review panel recommended the application for an award based upon the totality of factors. I am satisfied that the review panel followed CPRIT's review process in creating the list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

This statement is true.”

Wayne R. Roberts
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.

Sandra Reyes
Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Prevention
AWARD MECHANISM Competitive Continuation/Expansion (CCE)
APPLICATION ID PP140210

APPLICATION TITLE Cancer genomics training program for a competent Texas health education workforce

APPLICANT NAME Chen, Lei-Shih
ORGANIZATION Texas A&M University
PANEL NAME Panel A 14.1 (A 14.1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/01/14
	CPRIT Application Receipt System (CARS) opened	12/19/13	07/01/14
	CPRIT Application Receipt System (CARS) closed	02/27/14	07/01/14
	Date application submitted	02/27/14	07/01/14
	Method of submission	CARS	07/01/14
	Within receipt period	YES	07/01/14
	Appeal to submit application after CARS closed	N/A	07/01/14
	Appeal for late application submission accepted	N/A	07/01/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/01/14
	Donation(s) made to CPRIT/foundation	NO	07/01/14
	Assigned to primary reviewers	04/03/14	07/01/14
	Applicant notified of review panel assignment	04/23/14	07/01/14
	Primary Reviewer 1 COI signed	03/19/14	07/01/14
	Primary (Advocate) Reviewer 2 COI signed	03/20/14	07/01/14
	Primary Reviewer 3 COI signed	03/21/14	07/01/14
	Primary Reviewer 4 COI signed	04/07/14	07/01/14
3. Peer Review: On-Site Meeting	Primary Reviewer 1 critique submitted	04/26/14	07/01/14
	Primary (Advocate) Reviewer 2 critique submitted	04/30/14	07/01/14
	Primary Reviewer 3 critique submitted	04/18/14	07/01/14
	Primary Reviewer 4 critique submitted	04/29/14	07/01/14
	COI indicated by non-primary reviewer	NONE	07/01/14
	COI recused from participation	N/A	07/01/14
	Discussed at On-Site Meeting	YES	07/01/14
	Peer Review: On-Site Meeting	05/05/14-05/06/14	07/01/14
	Post review statements signed	05/12/14	07/01/14
	Third Party Observer Report	05/06/14	07/01/14
4. Final PRC Recommendation	Score report delivered to CPO	05/12/14	07/01/14
	COI indicated by PRC member	NONE	06/27/14
	COI recused from participation	N/A	06/27/14
	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/08/14
5. PIC Review	PRC Chair Notification to PIC and OC	07/03/14	07/03/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
6. Oversight Committee Approval	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

identity of attesting party retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application PP140211
Evidence Based Cancer Prevention Services**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Evidence Based Cancer Prevention Services* Request for Applications (RFA). CPRIT received 22 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to Panel A for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT’s grant review processes were followed by the review panel evaluating the applications in this grant cycle

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that one application that was not recommended for a grant award received a more favorable score than other applications that were recommended for funding. I have conferred with the Chief Prevention Officer and reviewed the Prevention Review Council's written critique for the project that was not funded. According to the notice sent to the applicant, the Prevention Review Council did not recommend the application for funding because the project was not deemed to fit within the intended scope of the Evidence-Based Cancer Prevention Services Request for Applications (RFA), as the proposed project deals with the education and coordination of care during cancer treatment. This is inconsistent with guidance given on page 8 of the RFA, which states, "Under this RFA, CPRIT will not consider....**Projects focusing solely on case management/patient navigation services.** Applicants seeking to provide case management/patient navigation services to help individuals obtain primary prevention services, screening services, or survivorship services but that do not plan to deliver the actual clinical service are not eligible under this mechanism. Furthermore, while navigation to the point of treatment of cancer is required when cancer is discovered through a CPRIT-funded project, **applications seeking funds to provide coordination of care while an individual is in treatment are not allowed under this RFA.**" (emphasis added)

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

This statement is true."

Wayne R. Roberts

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.

Sandra Reyes

Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Prevention
AWARD MECHANISM Evidence-Based Cancer Prevention Services (EBP)
APPLICATION ID PP140211

APPLICATION TITLE Tiempo de Vacunarte! Time to Get Vaccinated!

APPLICANT NAME Penaranda, Eribeth
ORGANIZATION Texas Tech University Health Sciences Center at El Paso
PANEL NAME Panel A 14.1 (A 14.1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/01/14
	CPRIT Application Receipt System (CARS) opened	12/19/13	07/01/14
	CPRIT Application Receipt System (CARS) closed	02/27/14	07/01/14
	Date application submitted	02/27/14	07/01/14
	Method of submission	CARS	07/01/14
	Within receipt period	YES	07/01/14
	Appeal to submit application after CARS closed	N/A	07/01/14
	Appeal for late application submission accepted	N/A	07/01/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/01/14
	Donation(s) made to CPRIT/foundation	NO	07/01/14
	Assigned to primary reviewers	04/03/14	07/01/14
	Applicant notified of review panel assignment	04/23/14	07/01/14
	Primary Reviewer 1 COI signed	03/19/14	07/01/14
	Primary (Advocate) Reviewer 2 COI signed	03/19/14	07/01/14
	Primary Reviewer 3 COI signed	03/28/14	07/01/14
3. Peer Review: On-Site Meeting	Primary Reviewer 4 COI signed	03/28/14	07/01/14
	Primary Reviewer 1 critique submitted	04/29/14	07/01/14
	Primary (Advocate) Reviewer 2 critique submitted	04/30/14	07/01/14
	Primary Reviewer 3 critique submitted	04/29/14	07/01/14
	Primary Reviewer 4 critique submitted	04/15/14	07/01/14
	COI indicated by non-primary reviewer	NONE	07/01/14
	COI recused from participation	N/A	07/01/14
	Discussed at On-Site Meeting	YES	07/01/14
	Peer Review: On-Site Meeting	05/05/14-05/06/14	07/01/14
	Post review statements signed	05/12/14	07/01/14
	Third Party Observer Report	05/06/14	07/01/14
4. Final PRC Recommendation	Score report delivered to CPO	05/12/14	07/01/14
	COI indicated by PRC member	NONE	06/27/14
	COI recused from participation	N/A	06/27/14
	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/08/14
5. PIC Review	PRC Chair Notification to PIC and OC	07/03/14	07/03/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
6. Oversight Committee Approval	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

identity of attesting party retained by CPRIT



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: MARGARET KRIPKE, PH.D., CHIEF SCIENTIFIC OFFICER
SUBJECT: UPDATE OF RESEARCH ACTIVITIES
DATE: AUGUST 20, 2014

Research Grants

The Scientific Review Panels evaluated 483 responses to an RFA for Individual Investigator Research Awards (IIRA) and 100 responses to an RFA for High Impact-High Reward (HIHR) grants during the period from May 28-June 10, 2014. Of these, 61 IIRA applications (13%) and 15 HIHR applications (15%) were recommended for consideration by the Scientific Review Council (SRC). The SRC met on June 24, 2014, by conference call and accepted the recommendations of the review panels to fund the 76 grants, at a total amount of \$54,665,415. The recommendation was considered and approved by the Program Integration Committee (PIC) on July 15, 2015, and the Oversight Committee will vote on these recommendations in this meeting.

The Scientific Review Council (SRC) also evaluated responses to RFAs for the Recruitment of Established Investigators, Rising Stars, and First Time–Tenure Track Faculty on July 11, 2014, and its recommendation was forwarded to the Program Integration Committee and the Oversight Committee for approval. Sixteen applications were reviewed by the SRC, and 8 were recommended for funding for a total of \$22M. The recommendation was approved by the PIC on July 15, 2014, and the Oversight Committee will vote on these recommendations later in this meeting.

The chairs of the scientific research peer review panels have begun assigning applications to panel members to begin the reviews of more than 400 applications submitted in response to three RFAs on June 26, 2014. In addition to the traditional, untargeted IIRA, applications were submitted for two targeted IIRA RFAs: one for childhood and adolescent cancer and another for cancer prevention and early detection research. Included among the submissions are 57 applications for the targeted childhood cancer IIRA and 66 applications for the targeted prevention/early detection research IIRA. These applications will be considered at peer review meetings to be held in Dallas between October 27 and November 11, 2014.

RFAs for Multi-Investigator Research Awards, Core Facility Support Awards, and another round of High Impact/High Risk Awards opened in mid-July. The closing date for these RFAs is November 17, 2014, with peer review scheduled for March, 2015. Additionally, RFAs for the recruitment

mechanisms are open continuously, and starting in September, 2014, will be reviewed monthly by the SRC.

Research Grant Funding Cycles

<u>Grant Mechanism</u>	<u>Post</u>	<u>Close</u>	<u>Peer Review</u>	<u>OC Approval</u>
(14.1) IIRA, HIHR	12/13	2/14	6/14	8/14
(15.1) IIRA, IIRAP, IIRACCA	3/14	6/14	10/14	2/15
(15.2) CFSA, MIRA, HIHR	7/14	11/14	3/15	5/15
(16.1) IIRA, RTA, other?*	3/15	6/15	10/15	2/16
(16.2) HIHR, other?*	7/15	11/15	3/16	5/16

*Proposed; dates subject to change

(Recruitment Awards are open continuously and reviewed monthly by the SRC. Recommended applications are brought to each OC meeting, with a possible extra meeting in March or April of each year.)

Research Subcommittee

The Oversight Committee's Research Subcommittee met on August 11, 2014, to discuss new nominations to peer review panels, the research awards mentioned above, the University Advisory Committee charter and white paper, and the program priorities project.

Nominations for Peer Review Panels

The Scientific Research office presented an additional 4 peer review panelists and 14 advocate reviewers to the Nominations Subcommittee for recommendation on August 15, 2014. Oversight Committee members will consider these recommendations today for approval. These individuals have stellar records of achievement in their areas of expertise and will enhance our already illustrious review panels.

Meeting of the University Advisory Committee

The University Advisory Committee met on June 27, 2014, in Houston, with a follow up call on July 8, 2014, to discuss the CPRIT program priorities project. The committee worked diligently to produce a white paper containing recommendations to the Oversight Committee for priorities for the Research and Product Development Programs. They also approved the UAC charter, which is before you today for approval. The UAC recommendations were captured in a document titled, "Program Priorities for CPRIT: An Academic Perspective. A Whitepaper submitted to the CPRIT Oversight Committee by the CPRIT University Advisory Committee", which was submitted to the Scientific Research Office on August 6, 2014. This document will be considered by the Oversight Committee in conjunction with its September 3, 2014 retreat to consider inter- and intra-program priorities.

**Conflicts of Interest for Scientific Research Cycle 14.1 (Individual Investigator Research Awards, High-Impact/High-Risk Research Awards) and Recruitment Cycle 14.2 Applications
(Scientific Research Cycle 14.1 and Recruitment Cycle 14.2 Awards Announced at August 2014 Oversight Committee Meeting)**

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC. COI information used for this table was collected by SRA International, CPRIT's third party grant administrator, and by CPRIT.

Grant ID	Applicant	Institution	Conflict Noted
Applications considered by the PIC and Oversight Committee			
RR140061	Fitz, John	The University of Texas Southwestern Medical Center	Gambhir, Sanjiv Sam; Montgomery, Will; Mitchell, Amy
RR140071	Dmitrovsky, Ethan	The University of Texas M.D. Anderson Cancer Center	Montgomery, Will; Mitchell, Amy
RR140072	Gonzalez-Scarano, Francisco	The University of Texas Health Science Center at San Antonio	Montgomery, Will; Mitchell, Amy
RR140073	Carson, Daniel	Rice University	Montgomery, Will; Mitchell, Amy
RR140077	Dmitrovsky, Ethan	The University of Texas M.D. Anderson Cancer Center	Montgomery, Will; Mitchell, Amy
RR140081	McLendon, George	Rice University	Montgomery, Will; Mitchell, Amy
RR140082	Fitz, John	The University of Texas Southwestern Medical Center	Montgomery, Will; Mitchell, Amy
RR140084	Fitz, John	The University of Texas Southwestern Medical Center	Montgomery, Will; Mitchell, Amy
RP140001	Goodell, Margaret	Baylor College of Medicine	Mitchell, Amy
RP140132	Zhang, David	Rice University	Montgomery, Will; Mitchell, Amy
RP140140	Gao, Jinming	The University of Texas Southwestern Medical Center	Montgomery, Will; Mitchell, Amy
RP140141	Ward, Elizabeth	The University of Texas Southwestern Medical Center	Montgomery, Will; Mitchell, Amy

* = Not Discussed

Grant ID	Applicant	Institution	Conflict Noted
RP140143	Cobb, Melanie	The University of Texas Southwestern Medical Center	Montgomery, Will; Mitchell, Amy
RP140152	MacMillan, John	The University of Texas Southwestern Medical Center	Montgomery, Will; Mitchell, Amy
RP140179	Lacorazza, Daniel	Baylor College of Medicine	Mitchell, Amy
RP140181pe/RP140181	Marchetti, Dario	Baylor College of Medicine	Costello, Joseph; Mitchell, Amy
RP140216	Scott, Kenneth	Baylor College of Medicine	Mitchell, Amy
RP140218pe/RP140218	Konopleva, Marina	The University of Texas M.D. Anderson Cancer Center	Mullighan, Charles; DiPersio, John; Montgomery, Will; Mitchell, Amy
RP140222	Johnson, David	The University of Texas M.D. Anderson Cancer Center	Wahl, Geoffrey; Montgomery, Will; Mitchell, Amy
RP140223	Anderson, Matthew	Baylor College of Medicine	Mitchell, Amy
RP140224	Shureiqi, Imad	The University of Texas M.D. Anderson Cancer Center	Wahl, Geoffrey; Montgomery, Will; Mitchell, Amy
RP140233pe/RP140233	Westover, Kenneth	The University of Texas Southwestern Medical Center	Balk, Steven; Ritz, Jerome; Montgomery, Will; Mitchell, Amy
RP140244	Sun, Shao-Cong	The University of Texas M.D. Anderson Cancer Center	Montgomery, Will; Mitchell, Amy
RP140252	Chan, Keith	Baylor College of Medicine	Mitchell, Amy
RP140258	Lupo, Philip	Baylor College of Medicine	Mitchell, Amy
RP140262pe/RP140262	Cinciripini, Paul	The University of Texas M.D. Anderson Cancer Center	Brandon, Thomas; Montgomery, Will; Mitchell, Amy
RP140271	Flores, Elsa	The University of Texas M.D. Anderson Cancer Center	Pure, Ellen; Montgomery, Will; Mitchell, Amy
RP140285	Mason, Ralph	The University of Texas Southwestern Medical Center	Montgomery, Will; Mitchell, Amy
RP140298	Vanapalli, Siva	Texas Tech University	Mitchell, Amy
RP140315	Zu, Youli	The Methodist Hospital Research Institute	Montgomery, Will; Mitchell, Amy
RP140320	Zhong, Qing	The University of Texas Southwestern Medical Center	Montgomery, Will; Mitchell, Amy
RP140323	Shi, Xiaobing	The University of Texas M.D. Anderson Cancer Center	Wahl, Geoffrey; Montgomery, Will; Mitchell, Amy
RP140328	Matouschek, Andreas	The University of Texas at Austin	Montgomery, Will; Mitchell, Amy

* = Not Discussed

Grant ID	Applicant	Institution	Conflict Noted
RP140329	Curran, Michael	The University of Texas M.D. Anderson Cancer Center	Montgomery, Will; Mitchell, Amy
RP140350	Amirian, E Susan	Baylor College of Medicine	Kushi, Lawrence; Martinez, Maria; Petersen, Gloria; Mitchell, Amy
RP140367	Chiang, Cheng-Ming	The University of Texas Southwestern Medical Center	Montgomery, Will; Mitchell, Amy
RP140399	Pinney, Kevin	Baylor University	Mitchell, Amy
RP140402	Zhang, Chengcheng	The University of Texas Southwestern Medical Center	Montgomery, Will; Mitchell, Amy
RP140408	Lin, Hui-Kuan	The University of Texas M.D. Anderson Cancer Center	Wahl, Geoffrey; Montgomery, Will; Mitchell, Amy
RP140411	McCarty, Joseph	The University of Texas M.D. Anderson Cancer Center	Wahl, Geoffrey; Montgomery, Will; Mitchell, Amy
RP140412	Scherer, Philipp	The University of Texas Southwestern Medical Center	Montgomery, Will; Mitchell, Amy
RP140429	Bast, Robert	The University of Texas M.D. Anderson Cancer Center	Wahl, Geoffrey; Montgomery, Will; Mitchell, Amy
RP140430	Grosshans, David	The University of Texas M.D. Anderson Cancer Center	Montgomery, Will; Mitchell, Amy
RP140435	Boyer, Thomas	The University of Texas Health Science Center at San Antonio	Montgomery, Will; Mitchell, Amy
RP140449	Orth, Kim	The University of Texas Southwestern Medical Center	Montgomery, Will; Mitchell, Amy
RP140452	Aguiar, Ricardo	The University of Texas Health Science Center at San Antonio	Montgomery, Will; Mitchell, Amy
RP140456	Ira, Grzegorz	Baylor College of Medicine	Mitchell, Amy
RP140462	Liang, Han	The University of Texas M.D. Anderson Cancer Center	Montgomery, Will; Mitchell, Amy
RP140464	William, William	The University of Texas M.D. Anderson Cancer Center	Montgomery, Will; Mitchell, Amy
RP140468	Cooper, Laurence	The University of Texas M.D. Anderson Cancer Center	Montgomery, Will; Mitchell, Amy
RP140469	Song, Yongcheng	Baylor College of Medicine	Mitchell, Amy

* = Not Discussed

Grant ID	Applicant	Institution	Conflict Noted
RP140473	Dahia, Patricia	The University of Texas Health Science Center at San Antonio	Montgomery, Will; Mitchell, Amy
RP140478	Morales, Jorge	Texas Tech University	Mitchell, Duane; Mitchell, Amy
RP140479	Rosenthal, Gil	Texas A&M University	Montgomery, Will; Mitchell, Amy
RP140482	Dondossola, Elenora	The University of Texas M.D. Anderson Cancer Center	Montgomery, Will; Mitchell, Amy
RP140500	Garcia-Manero, Guillermo	The University of Texas M.D. Anderson Cancer Center	Montgomery, Will; Mitchell, Amy
RP140515	Maru, Dipen	The University of Texas M.D. Anderson Cancer Center	Montgomery, Will; Mitchell, Amy
RP140515	Vidyasagar, Mathukumalli	The University of Texas at Dallas	Montgomery, Will; Mitchell, Amy
RP140522	Overwijk, Willem	The University of Texas M.D. Anderson Cancer Center	Montgomery, Will; Mitchell, Amy
RP140542	McConkey, David	The University of Texas M.D. Anderson Cancer Center	Montgomery, Will; Mitchell, Amy
RP140544	Zheng, Jie	The University of Texas at Dallas	Montgomery, Will; Mitchell, Amy
RP140553	Rosenberg, Susan	Baylor College of Medicine	Mitchell, Amy
RP140556	Gu, Jian	The University of Texas M.D. Anderson Cancer Center	Montgomery, Will; Mitchell, Amy
RP140563	Park, Jae-Il	The University of Texas M.D. Anderson Cancer Center	Montgomery, Will; Mitchell, Amy
RP140594	Rao, Manjeet	The University of Texas Health Science Center at San Antonio	Montgomery, Will; Mitchell, Amy
RP140597pe/RP140597	Orlowski, Robert	The University of Texas M.D. Anderson Cancer Center	Lawlor, Elizabeth; Wahl, Geoffrey; Montgomery, Will; Mitchell, Amy
RP140606pe/RP140606	Verhaak, Roeland	The University of Texas M.D. Anderson Cancer Center	Basilion, James; Montgomery, Will; Mitchell, Amy
RP140609	Klopp, Ann	The University of Texas M.D. Anderson Cancer Center	Montgomery, Will; Mitchell, Amy
RP140612	DePinho, Ronald	The University of Texas M.D. Anderson Cancer Center	Montgomery, Will; Mitchell, Amy

* = Not Discussed

Grant ID	Applicant	Institution	Conflict Noted
RP140616pe/RP140616	Rowley, David	Baylor College of Medicine	DeClerck, Yves; Mitchell, Amy
RP140648	Dalby, Kevin	The University of Texas at Austin	Montgomery, Will; Mitchell, Amy
RP140649	Dalby, Kevin	The University of Texas at Austin	Montgomery, Will; Mitchell, Amy
RP140655	Tu, Benjamin	The University of Texas Southwestern Medical Center	Montgomery, Will; Mitchell, Amy
RP140661	Zhang, Xuewu	The University of Texas Southwestern Medical Center	Montgomery, Will; Mitchell, Amy
RP140664	Georgiou, George	The University of Texas at Austin	Montgomery, Will; Mitchell, Amy
RP140672	Scaglioni, Pier Paolo	The University of Texas Southwestern Medical Center	Montgomery, Will; Mitchell, Amy
RP140678	Woo, Jung	Scout & White Healthcare	Mitchell, Amy
RP140685pe/RP140685	Mahalingam, Devalingam	The University of Texas Health Science Center at San Antonio	Abu-Khalaf, Maysa; Montgomery, Will; Mitchell, Amy
RP140767pe/RP140767	Jiao, Li	Baylor College of Medicine	Mucci, Lorelai; Martinez, Maria; Mitchell, Amy
RP140781	McIntyre, Peter	Texas A&M University	Montgomery, Will; Mitchell, Amy
RP140784pe/RP140784	Goel, Ajay	Baylor Research Institute	Petersen, Gloria; Mitchell, Amy
RP140800	Wagner, Eric	The University of Texas Health Science Center at Houston	Montgomery, Will; Mitchell, Amy
RP140840	Vanapalli, Siva	Texas Tech University	Mitchell, Amy
RP140842	Sullivan, Christopher	The University of Texas at Austin	Montgomery, Will; Mitchell, Amy
Applications Not Recommended for PIC or Oversight Committee Consideration			
RR140075	Gorenstein, David G.	The University of Texas Health Science Center at Houston	Gambhir, Sanjiv Sam
RP140157pe/ RP140157*	Tsai, Kenneth	The University of Texas M. D. Anderson Cancer Center	Haigis, Kevin
RP140169pe/ RP140169*	Bibb, James	The University of Texas Southwestern Medical Center	Hank, Jacquelyn
RP140371pe/ RP140371*	Yang, Jianhua	Baylor College of Medicine	Hank, Jacquelyn
RP140387pe	Zage, Peter	Baylor College of Medicine	Hank, Jacquelyn; Hunter, Kent
RP140446pe	Shiio, Yuzuru	The University of Texas	Hunter, Kent; Schiffman, Joshua

* = Not Discussed

Grant ID	Applicant	Institution	Conflict Noted
		Health Science Center at San Antonio	
RP140446	Shiio, Yuzuru	The University of Texas Health Science Center at San Antonio	Hunter, Kent
RP140538*	Li, Xiao-Nan	Baylor College of Medicine	Hank, Jacquelyn; Wechsler-Reya, Robert
RP140702*	Shiio, Yuzuru	The University of Texas Health Science Center at San Antonio	Hunter, Kent
RP140727	Threadgill, David	Texas A&M University	Hunter, Kent
RP140182*	Bast, Robert	The University of Texas MD Anderson Cancer Center	Tomkinson, Alan
RP140437	Boothman, David	The University of Texas Southwestern Medical Center	Manley, James
RP140635	Das, Kumuda	Texas Tech University Health Sciences Center	Kast, W. Martin
RP140147	Li, Lei	The University of Texas MD Anderson Cancer Center	Wahl, Geoffrey
RP140324*	Schmid, Sandra	The University of Texas Southwestern Medical Center	Courtneidge, Sara
RP140503pe	Karbowniczek, Magdalena	Texas Tech University Health Sciences Center	Haigis, Kevin; Hunter, Kent; Rauscher, III, Frank
RP140530pe	Lin, Xia	Baylor College of Medicine	McMahon, Martin
RP140532pe	Vasudevan, Sanjeev	Baylor College of Medicine	Hank, Jacquelyn
RP140581pe	Petros, Robby	University of North Texas	Williams, Bart
RP140843pe	Webb, Paul	The Methodist Hospital Research Institute	McMahon, Martin
RP140450pe	Davis, Anthony	The University of Texas Southwestern Medical Center	Chazin, Walter; Tomkinson, Alan
RP140536pe	Lee, Mong-Hong	The University of Texas M. D. Anderson Cancer Center	Wrana, Jeffrey
RP140340pe/ RP140340*	Kim, Chongwoo	The University of Texas Health Science Center at San Antonio	Bernstein, Bradley; Roberts, Charles
RP140365	Xia, Yang	The University of Texas Health Science Center at Houston	Brelinsky, Steven
RP140379	Lin, Xin	The University of Texas M. D. Anderson Cancer Center	Wahl, Geoffrey

* = Not Discussed

Grant ID	Applicant	Institution	Conflict Noted
RP140409	Jackson, James	The University of Texas M. D. Anderson Cancer Center	Wahl, Geoffrey
RP140398pe	Lee, Ju-Seog	The University of Texas M. D. Anderson Cancer Center	Laird, Peter
RP140484pe/ RP140484*	Kurie, Jonathan	The University of Texas M. D. Anderson Cancer Center	Belinsky, Steven
RP104521*	Song, Yongcheng	Baylor College of Medicine	Carpten, John; Wahl, Geoffrey
RP140525pe/ RP140525	Lee, Min Gyu	The University of Texas M. D. Anderson Cancer Center	Belinsky, Steven
RP140525	Lee, Min Gyu	The University of Texas M. D. Anderson Cancer Center	Wahl, Geoffrey
RP140638	Zhang, Shuxing	The University of Texas M. D. Anderson Cancer Center	Wahl, Geoffrey
RP140734*	Li, Yi	Baylor College of Medicine	Greene, Geoffrey
RP140255pe/ RP140255	Daniel-MacDougall, Carrie	The University of Texas M. D. Anderson Cancer Center	Mayne, Susan
RP140280*	Beretta, Laura	The University of Texas M. D. Anderson Cancer Center	Li, Christopher; Petersen, Gloria
RP140322*	Yem, Laising	Baylor College of Medicine	Martinez, Maria
RP140310pe	Beretta, Laura	The University of Texas M. D. Anderson Cancer Center	Barlow, William; Kristal, Alan; Li, Christopher
RP140518pe/ RP140518*	Kaseb, Ahmed	The University of Texas M. D. Anderson Cancer Center	Petersen, Gloria
RP140384	Mani, Sendurai	The University of Texas M. D. Anderson Cancer Center	Martinez, Maria; Petersen, Gloria; Parker, Alexander
RP140448*	Hu, Ye	The Methodist Hospital Research Institute	Fridley, Brooke; Petersen, Gloria
RP140603pe	Symmans, William	The University of Texas M. D. Anderson Cancer Center	Mucci, Lorelei
RP140630pe	Huang, Tim	The University of Texas Health Science Center at San Antonio	Kristal, Alan
RP140687pe	Vernon, Sally	The University of Texas Southwestern Medical Center	Barlow, William
RP140687	Vernon, Sally	The University of Texas Southwestern Medical Center	Kushi, Lawrence
RP140765pe/ RP140765*	Singal, Amit	The University of Texas Southwestern Medical Center	Kushi, Lawrence
RP140765*	Singal, Amit	The University of Texas Southwestern Medical Center	Barlow, William

* = Not Discussed

Grant ID	Applicant	Institution	Conflict Noted
RP140161pe/ RP140161	Hannan, Raquibul	The University of Texas Southwestern Medical Center	Koong, Albert
RP140576	Chang, Jenny	The Methodist Hospital Research Institute	LaRusso, Patricia
RP140589pe	Hong, David	The University of Texas M. D. Anderson Cancer Center	Hochster, Howard
RP140276pe	Shao, Yiping	The University of Texas M. D. Anderson Cancer Center	Berbeco, Ross
RP140286pe/ RP140286	Schellingerhout, Dawid	The University of Texas M. D. Anderson Cancer Center	Berbeco, Ross
RP140547pe	Wong, Stephen	The Methodist Hospital Research Institute	Cai, Weibo
RP140201	Ge, Woo-Ping	The University of Texas Southwestern Medical Center	Liu, Jonathan
RP140811*	Feng, Yusheng	The University of Texas at San Antonio	Pomper, Martin
RP140674pe/ RP140674	Jo, Javier	Texas Engineering Experiment Station	Sutcliffe, Julie

* = Not Discussed



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CEO Affidavit Supporting Information

FY 2014 – Cycle 1
High-Impact/High-Risk Research Award

Request for Applications



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA R-14-HIHR-1

High Impact/High-Risk Research Awards

**Please also refer to the Instructions for Applicants document,
which will be posted December 23, 2013**

Applications for this award mechanism are subject to institutional limits. Applicants are advised to consult with their institution's Office of Research and Sponsored Programs (or equivalent).

Application Receipt Opening Date: December 23, 2013
Application Receipt Closing Date: February 3, 2014

FY 2014

Fiscal Year Award Period

September 1, 2013–August 31, 2014

TABLE OF CONTENTS

1. ABOUT CPRIT	5
2. RATIONALE	5
3. RESEARCH OBJECTIVES	6
4. FUNDING INFORMATION	6
5. ELIGIBILITY	7
6. RESUBMISSION POLICY	8
7. RESPONDING TO THIS RFA	8
7.1. APPLICATION SUBMISSION GUIDELINES	8
7.1.1. Submission Deadline Extension	9
7.2. APPLICATION COMPONENTS	9
7.2.1. Abstract and Significance (5,000 characters)	9
7.2.2. Layperson's Summary (2,000 characters)	9
7.2.3. Goals and Objectives	10
7.2.4. Timeline (One page)	10
7.2.5. Resubmission Summary (One page)	10
7.2.6. Research Plan (Four pages)	10
7.2.7. Vertebrate Animals and/or Human Subjects (One page)	11
7.2.8. Publications/References	11
7.2.9. Budget and Justification	11
7.2.10. Biographical Sketches (Two pages each)	12
7.2.11. Current and Pending Support	12
7.2.12. Institutional/Collaborator Support and/or Other Certification (Two pages)	12
7.2.13. Previous Summary Statement	12
7.2.14. Institutional Limits	12
8. APPLICATION REVIEW	13
8.1. REVIEW PROCESS OVERVIEW	13
8.2. CONFIDENTIALITY OF REVIEW	14
8.3. REVIEW CRITERIA	15
8.3.1. Primary Criteria	15
8.3.2. Secondary Criteria	16
9. KEY DATES	16
10. AWARD ADMINISTRATION	17

11. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS.....	18
12. CONTACT INFORMATION.....	18
12.1. HELPDESK	18
12.2. SCIENTIFIC AND PROGRAMMATIC QUESTIONS	18

RFA VERSION HISTORY

Rev 12/9/13 RFA release

1. ABOUT CPRIT

The State of Texas has established the Cancer Prevention and Research Institute of Texas (CPRIT), which may issue up to \$3 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature and the citizens of Texas to:

- Create and expedite innovation in the area of cancer research and product or service development, thereby enhancing the potential for a medical or scientific breakthrough in the prevention, treatment, and possible cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the State of Texas; and
- Continue to develop and implement the Texas Cancer Plan by promoting the development and coordination of effective and efficient statewide public and private policies, programs, and services related to cancer and by encouraging cooperative, comprehensive, and complementary planning among the public, private, and volunteer sectors involved in cancer prevention, detection, treatment, and research.

CPRIT furthers cancer research in Texas by providing financial support for a wide variety of projects relevant to cancer research.

2. RATIONALE

CPRIT High-Impact/High-Risk (HIHR) Research Awards seek to provide short-term funding to explore the feasibility of high-risk projects that, if successful, would contribute major new insights into the etiology, diagnosis, treatment, or prevention of cancers. Because HIHR Research Awards are designed to support new ideas, preliminary data are not required. Using this mechanism, CPRIT intends to support innovative, developmental projects that focus on exceptionally promising topics that are not yet sufficiently mature to compete successfully for more conventional funding. The HIHR Research Awards are expected to provide the foundation for individual or multiple investigator awards upon completion. Applicants must explain why more conventional sources of support are not available for the proposed research and how short-term funding will lead to strong applications for additional support. Applications that might be

described as “mini-R01s” will not be competitive. **The goal of this award mechanism is to fund uncommonly great ideas that merit the opportunity to acquire preliminary data. There should be reasons for the idea to be plausible, but CPRIT acknowledges that most of the selected projects will ultimately fail to meet their primary goals. The rare proposals that succeed will be of sufficient importance to justify this program.** Applications may address any research topic related to cancer biology, causation, prevention, detection, screening, or treatment.

3. RESEARCH OBJECTIVES

Areas of interest include laboratory research, translational studies, population-based and/or clinical investigations. In that cancers arise from a large number of derangements of basic molecular and cellular functions, which, in turn, cause many alterations in basic biological processes, almost any aspect of biology may be relevant to cancer research, more or less directly. The *degree of relevance* to cancer research will be an important criterion for evaluation of projects for funding by CPRIT ([Section 8.3.1](#)). For example, are alterations in the process in question *primarily* responsible for oncogenesis or secondary manifestations of malignant transformation? Will understanding the process or interfering with it offer selective and useful insight into prevention, diagnosis, or treatment of cancer? *Successful applicants for funding from CPRIT will have addressed these questions satisfactorily.*

4. FUNDING INFORMATION

Applicants may request a total of \$200,000 for a period of up to 24 months (2 years), inclusive of both direct and indirect costs. Because of the nature of this funding mechanism, renewal applications will not be accepted. Follow-on applications will not be funded until the time requested for the HIHR Research Award has passed. Award funds may be used to pay for salary and benefits, research supplies, equipment, and clinical costs. Requests for funds for travel to scientific meetings are not appropriate for this funding mechanism, nor are requests for funds to support construction and/or renovation. State law limits the amount of award funding that may be spent on indirect costs to no more than 5 percent of the total award amount.

5. ELIGIBILITY

- The applicant must be a Texas-based entity. Any not-for-profit institution or organization that conducts research is eligible to apply for funding under this award mechanism.
A public or private company is also eligible for funding under this award mechanism.
- The Principal Investigator (PI) must have a doctoral degree, including M.D., Ph.D., D.D.S., D.M.D., Dr.P.H., D.O., D.V.M., or equivalent, and reside in Texas for the period of the time that the research that is the subject of the grant is conducted.
- A PI may submit only one new or resubmission application under this RFA during this funding cycle.
- One Co-PI may be included.
- Collaborations are permitted and encouraged, and collaborators may or may not reside in Texas. However, collaborators who do not reside in Texas are not eligible to receive CPRIT funds. Collaborators should have specific and well-defined roles. Subcontracting and collaborating organizations may include public, not-for-profit, and for-profit entities. Such entities may be located outside of the State of Texas, but non-Texas-based organizations are not eligible to receive CPRIT funds.
- An applicant is eligible to receive a grant award only if the applicant certifies that the applicant institution or organization, including the PI, any senior member or key personnel listed on the grant application, and any officer or director of the grant applicant's institution or organization (or any person related to one or more of these individuals within the second degree of consanguinity or affinity), have not made and will not make a contribution to CPRIT or to any foundation specifically created to benefit CPRIT.
- An applicant is not eligible to receive a CPRIT grant award if the applicant PI, any senior member or key personnel listed on the grant application, and any officer or director of the grant applicant's institution or organization is related to a CPRIT Oversight Committee member.
- The applicant must report whether the applicant institution or organization, the PI, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, whether or not those individuals are slated to receive salary or compensation under the grant award, are currently ineligible to receive Federal grant

funds or have had a grant terminated for cause within 5 years prior to the submission date of the grant application.

- CPRIT grants will be awarded by contract to successful applicants. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in [Section 10](#) and [Section 11](#). All statutory provisions and relevant administrative rules can be found at www.cpritis.state.tx.us.

6. RESUBMISSION POLICY

An application previously submitted to CPRIT but not funded may be resubmitted once and must follow all resubmission guidelines. More than one resubmission is not permitted. This policy is in effect for all applications submitted to date. See [Section 7.2.5](#).

7. RESPONDING TO THIS RFA

7.1. Application Submission Guidelines

Applications must be submitted via the CPRIT Application Receipt System (CARS) (<https://CPRITGrants.org>). Only applications submitted through this portal will be considered eligible for evaluation. The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application was submitted. The PI must create a user account in the system to start and submit an application. The Co-PI, if applicable, must also create a user account to participate in the application. Furthermore, the Authorized Signing Official (ASO) (a person authorized to sign and submit the application for the organization) and the Grants Contract/Office of Sponsored Projects Official (the individual who will manage the grant contract if an award is made) also must create a user account in CARS. Applications will be accepted beginning at 7 a.m. Central Time on December 23, 2013 and must be submitted by 3 p.m. Central Time on February 3, 2014. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

7.1.1. Submission Deadline Extension

The submission deadline may be extended for one or more grant applications upon a showing of good cause. All requests for extension of the submission deadline must be submitted via e-mail to the CPRIT HelpDesk. Submission deadline extensions, including the reason for the extension, will be documented as part of the grant review process records.

7.2. Application Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. Please refer to the *Instructions for Applicants* document for details that will be available when the application receipt system opens. Submissions that are missing one or more components or that do not meet the eligibility requirements listed in [Section 5](#) will be administratively withdrawn without review.

7.2.1. Abstract and Significance (5,000 characters)

Clearly explain the question or problem to be addressed and the approach to its answer or solution. The specific aims of the application must be obvious from the abstract, although they need not be restated verbatim from the Research Plan. Clearly address how the proposed project, if successful, will have a major impact on the field of cancer research or on the care of patients with cancer. Summarize how the proposed research creates new paradigms or challenges existing ones.

7.2.2. Layperson's Summary (2,000 characters)

Provide a layperson's summary of the proposed work. Describe, in simple, nontechnical terms, the overall goals of the proposed work, the type(s) of cancer addressed, the potential significance of the results, and the impact of the work on advancing the field of cancer prevention research, early diagnosis or treatment. The information provided in this summary will be made publicly available by CPRIT, particularly if the application is recommended for funding. Do not include any proprietary information in the Layperson's Summary. The Layperson's Summary will also be used by advocate reviewers ([Section 8.1](#)) in evaluating the significance and impact of the proposed work.

7.2.3. Goals and Objectives

List specific goals and objectives for each year of the project. These goals and objectives will also be used, during the submission and evaluation of progress reports and assessment of project success.

7.2.4. Timeline (One page)

Provide an outline of anticipated major milestones to be tracked. Timelines will be reviewed for reasonableness and adherence to timelines will be a criterion for continued support of successful applications. If the application is approved for funding, this section will be included in the award contract. Applicants are advised not to include information that they consider confidential or proprietary when preparing this section.

7.2.5. Resubmission Summary (One page)

Applicants preparing a resubmission must describe the approach to the resubmission. If a summary statement was prepared for the original application review, applicants are advised to address all noted concerns.

Note: An application previously submitted to CPRIT but not funded may be resubmitted once after careful consideration of the reasons for lack of prior success. Applications that received overall numerical scores of 5 or higher are likely to need considerable attention. Applicants may prepare a fresh Research Plan or modify the original Research Plan and mark the changes. However, all resubmitted applications should be carefully reconstructed; a simple revision of the prior application with editorial or technical changes is not sufficient, and applicants are advised not to direct reviewers to such modest changes.

7.2.6. Research Plan (Four pages)

Background: Present the rationale behind the proposed project, emphasizing the pressing problem in cancer research that will be addressed. Preliminary data are not required, but strong reasoning and literature support will obviously enhance the application.

Hypothesis and Specific Aims: Concisely state the hypothesis and/or specific aims to be tested or addressed by the research described in the application.

Research Strategy: Describe the experimental design, including methods, anticipated results, potential problems or pitfalls, and alternative approaches. Preliminary data that support the proposed hypothesis are encouraged but not required.

7.2.7. Vertebrate Animals and/or Human Subjects (One page)

If vertebrate animals will be used, provide an outline of the appropriate protocols that will be followed. If human subjects or human biological samples will be used, provide a plan for recruitment of subjects or acquisition of samples that will meet the time constraints of this award mechanism.

7.2.8. Publications/References

Provide a concise and relevant list of publications/references cited for the application.

7.2.9. Budget and Justification

Provide a compelling justification of the budget for the entire proposed period of support, including salaries and benefits, supplies, equipment, patient care costs, animal care costs, and other expenses. Applications requesting more than \$200,000 (total costs) over a maximum period of 24 months (2 years) will be administratively withdrawn.

In preparing the requested budget, applicants should be aware of the following:

- Major equipment purchases are discouraged for this funding mechanism. Equipment having a useful life of more than 1 year and an acquisition cost of \$5,000 or more per unit must be specifically approved by CPRIT. An applicant does not need to seek this approval prior to submitting the application.
- Texas law limits the amount of grant funds that may be spent on indirect costs to no more than 5 percent of the total award amount (5.263 percent of the direct costs). Guidance regarding indirect cost recovery can be found in CPRIT's Administrative Rules, which are available at www.cprit.state.tx.us. So-called grants management and facilities fees (e.g., sponsored programs fees; grants and contracts fees; electricity, gas and water; custodial fees; maintenance fees; etc.) may not be requested. Applications that include such budgetary items will be rejected administratively and returned without review.

7.2.10. Biographical Sketches (Two pages each)

Applicants should provide a biographical sketch that describes their education and training, professional experience, awards and honors, and publications relevant to cancer research.

A biographical sketch must be provided for the PI and, if applicable, the Co-PI (as required by the online application receipt system). Up to two additional biographical sketches for key personnel may be provided. Each biographical sketch must not exceed two pages.

7.2.11. Current and Pending Support

Describe the funding source and duration of all current and pending support for all personnel who have included a biographical sketch with the application. For each award, provide the title, a two-line summary of the goal of the project and, if relevant, a statement of overlap with the current application. At a minimum, current and pending support of the PI and, if applicable, the Co-PI must be provided.

7.2.12. Institutional/Collaborator Support and/or Other Certification (Two pages)

Applicants may provide letters of institutional support, collaborator support, and/or other certification documentation relevant to the proposed project. A maximum of two pages may be provided.

7.2.13. Previous Summary Statement

If the application is being resubmitted, the summary statement of the original application review, if previously prepared, will be automatically appended to the resubmission. The applicant is not responsible for providing this document.

Applications that are missing one or more of these components, exceed the specified page, word, or budget limits, or that do not meet the eligibility requirements listed above will be administratively rejected without review.

7.2.14. Institutional Limits

Because a large number of submissions is anticipated, and to ensure timely and high-quality review of the most innovative and cutting-edge research with the greatest potential for advancement of cancer research, CPRIT is imposing a limit on the number of HIHR Research Award applications that may be submitted by an institution during this review cycle. The limit on the number of applications may seem restrictive, but experience indicates that truly innovative

ideas that are appropriate for this award mechanism are uncommon. CPRIT expects institutions to initiate an internal review process and only authorize submission of the appropriate number of applications that have been judged rigorously to be responsive to this RFA. Institutional limits (which need not be fully used) are as follows: University of Texas M. D. Anderson Cancer Center, 10; Baylor College of Medicine, 10; University of Texas Southwestern Medical Center, 10; University of Texas Health Science Center at San Antonio, 5; University of Texas Health Science Center at Houston, 5; University of Texas at Austin, 5; University of Texas Medical Branch, 5; Texas A&M University, 5; Texas A&M University Health Science Center, 5; Texas Tech University, 5; Texas Tech University Health Sciences Center (combined campuses), 5; all others, 2 each.

8. APPLICATION REVIEW

8.1. Review Process Overview

All eligible applications will be evaluated using a two-stage peer review process: (1) Peer review and (2) prioritization of grant applications by the CPRIT Scientific Review Council. In the first stage, applications will be evaluated by an independent peer review panel consisting of scientific experts as well as advocate reviewers, using the criteria listed below. In the second stage, applications judged to be most meritorious by the peer review panels will be evaluated and recommended for funding by the CPRIT Scientific Review Council based on comparisons with applications from all of the peer review panels and programmatic priorities. Applications approved by the Scientific Review Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review. The PIC will consider factors including program priorities set by the Oversight Committee, portfolio balance across programs, and available funding. The CPRIT Oversight Committee will vote to approve each grant award recommendation made by the PIC. The grant award recommendations will be presented at an open meeting of the Oversight Committee and must be approved by two-thirds of the Oversight Committee members present and eligible to vote. The review process is described more fully in CPRIT's Administrative Rules, Chapter 703, Sections 703.6–703.8.

8.2. Confidentiality of Review

Each stage of application review is conducted confidentially, and all CPRIT Scientific Peer Review Panel members, Scientific Review Council members, Program Integration Committee members, CPRIT employees, and Oversight Committee members with access to grant application information are required to sign nondisclosure statements regarding the contents of the applications. All technological and scientific information included in the application is protected from public disclosure pursuant to Health and Safety Code §102.262(b).

Individuals directly involved with the review process operate under strict conflict of interest prohibitions. All CPRIT Scientific Peer Review Panel members and Scientific Review Council members are non-Texas residents. An applicant will be notified regarding the peer review panel assigned to review the grant application. Peer review panel members are listed by panel on CPRIT's Web site. **By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed Conflict of Interest as set forth in CPRIT's Administrative Rules, Chapter 703, Section 703.9.**

Communication regarding the substance of a pending application is prohibited between the grant applicant (or someone on the grant applicant's behalf) and the following individuals—an Oversight Committee member, a Program Integration Committee member, a Scientific Review Panel member or a Scientific Review Council member. Applicants should note that the CPRIT Program Integration Committee is comprised of the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention Officer, the Chief Product Development Officer, and the Commissioner of State Health Services. The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. The prohibition on communication does not apply to the time period when pre-applications or letters of interest are accepted. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant applicant from further consideration for a grant award.

8.3. Review Criteria

Peer review of applications will be based on primary scored criteria and secondary unscored criteria, listed below. Review committees will evaluate and score each primary criterion and subsequently assign a global score that reflects an overall assessment of the application. **The overall assessment will not be an average of the scores of individual criteria; rather, it will reflect the reviewers' overall impression of the application. Evaluation of the scientific merit of each application is within the sole discretion of the peer reviewers.**

8.3.1. Primary Criteria

Primary criteria will evaluate the scientific merit and potential impact of the proposed work contained in the application. Concerns with any of these criteria potentially indicate a major flaw in the significance and/or design of the proposed study. Primary criteria include:

Significance and Impact: Is the application clearly responsive to the RFA and specifically to the HIHR Research Award mechanism? What is the innovative potential of the project? Does the applicant propose new paradigms or challenge existing ones? Does the project develop state-of-the-art technologies, methods, tools, or resources for cancer research or address important under- or unexplored areas? If the research project is successful, will it lead to truly substantial advances in the field rather than add modest increments of insight? Responsive applications will be highly speculative or exploratory; they need not be based on preliminary data but must have the potential for high scientific payoff because of exceptionally promising ideas.

Research Plan: Is the proposed work presented as a self-contained research project? Does the proposed research have a clearly defined hypothesis or goal that is supported by a sound scientific rationale? Are the methods appropriate, and are potential experimental obstacles and unexpected results discussed?

Applicant Investigator: Does the applicant investigator demonstrate the required creativity, expertise, experience, and accomplishments to make a significant contribution to the research? Applicants' credentials will be evaluated in a career stage-specific fashion. Have early career stage investigators received excellent training, and do their accomplishments to date offer great promise for a successful career? Has the applicant devoted a sufficient amount of his or her time (percentage effort) to this project?

Relevance: Does the proposed research have a high degree of relevance to cancer? This will be an important criterion for evaluation of projects for CPRIT support.

8.3.2. Secondary Criteria

Secondary criteria contribute to the global score assigned to the application. Concerns with these criteria potentially question the feasibility of the proposed research. Secondary criteria include:

Research Environment: Does the research team have the needed expertise, facilities, and resources to accomplish all aspects of the proposed research? Are the levels of effort of the key personnel appropriate? Is there evidence of institutional support of the research team and the project?

Vertebrate Animals and/or Human Subjects: If vertebrate animals and/or human subjects are included in the proposed research, certification of approval by the institutional IACUC and/or IRB, as appropriate, will be required before funding can occur.

Budget and Duration: Are the budget and the duration appropriate for the proposed work?

9. KEY DATES

RFA

RFA release	December 9, 2013
-------------	------------------

Application

Online application opens	December 23, 2013, 7 a.m. Central Time
Application due	February 3, 2014, 3 p.m. Central Time
Application review	May/June 2014

Award

Award notification	August 2014
Anticipated start date	August 2014

10. AWARD ADMINISTRATION

Texas law requires that CPRIT grant awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to institutions or organizations, not to individuals. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT's electronic signature policy as set forth in Chapter 701, Section 701.25.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and intellectual property rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.state.tx.us. Applicants are advised to review CPRIT's Administrative Rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in Chapter 703, Sections 703.10, 703.12.

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements set forth in CPRIT's Administrative Rules, Chapter 703, Section 703.20.

CPRIT requires award recipients to submit an annual progress report. These reports summarize the progress made toward the research goals and address plans for the upcoming year. In addition, fiscal reporting, human studies reporting, and vertebrate animal use reporting will be required as appropriate. Continuation of funding is contingent upon the timely receipt of these reports. Failure to provide timely and complete reports may waive reimbursement of grant award costs, and may result in the termination of award contract. Forms and instructions will be made available at www.cprit.state.tx.us.

11. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas law requires that prior to disbursement of CPRIT grant funds, the award recipient must demonstrate that it has an amount of funds equal to one-half of the CPRIT funding dedicated to the research that is the subject of the award. The demonstration of available matching funds must be made at the time the award contract is executed and annually thereafter, not when the application is submitted. Grant applicants are advised to consult CPRIT's Administrative Rules, Chapter 703, Section 703.11 for specific requirements regarding the demonstration of available funding.

12. CONTACT INFORMATION

12.1. HelpDesk

HelpDesk support is available for questions regarding user registration and online submission of applications. Queries submitted via e-mail will be answered within 1 business day. HelpDesk staff are not in a position to answer questions regarding scientific aspects of applications.

Dates of operation: December 9, 2013 – February 3, 2014 (excluding public holidays)

Hours of operation: Monday, Tuesday, Thursday, Friday, 7 a.m. to 4 p.m. Central Time
Wednesday, 8 a.m. to 4 p.m. Central Time

Tel: 866-941-7146

E-mail: Help@CPRITGrants.org

12.2. Scientific and Programmatic Questions

Questions regarding the CPRIT program, including questions regarding this or any other funding opportunity, should be directed to the CPRIT Research Program Director.

Tel: 512-305-8491

E-mail: Help@CPRITGrants.org

Web site: www.cprit.state.tx.us

Third Party Observer Report

CPRIT Basic Cancer Research-1 Review Panel Observation Report

Report #2014-15

Panel Name: Basic Cancer Research-1 Panel Review Meeting

Panel Date: May 31, 2014

Report Date: June 12, 2014

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized its out-sourced internal audit provider to function as a neutral third-party observer.

Introduction

The subject of this report is the Basic Cancer Research-1 Panel review of the High-Impact/High-Risk Research Awards (HIHRRRA) and of the Individual Investigator Research Awards (IIRA) applications. The meeting was chaired by Tom Curran and held in-person on May 31, 2014.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.

Observation Results Summary

Internal Audit participated in the Basic Cancer Research-1 Panel review of the High-Impact/High-Risk Research Awards (HIHRRRA) and of the Individual Investigator Research Awards (IIRA) applications held in-person and chaired by Tom Curran on May 31, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Ten HIHRRRA applications and fifteen IIRA applications were discussed and evaluated by the Basic Cancer Research-1 Panel to determine which grants would receive CPRIT funding.
- Eighteen panel members, two advocate reviewers, four CPRIT staff members, and three SRA employees were present for the in-person panel review meeting.

- Two conflicts of interest were identified prior to or during the meeting. The panel member with the conflict of interest left the room and did not participate in the review of the conflicted applications.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the peer review panel's discussion of scientific, technical or programmatic aspects of the applications.

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Research Panel Review Report

Report #2014-17

Panel Name: Basic Cancer Research – Part 2 Panel Review Meeting

Panel Date: June 4, 2014 - June 5, 2014

Report Date: June 12, 2014

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized its out-sourced internal audit provider to function as a neutral third-party observer.

Introduction

The subject of this report is the Basic Cancer Research Panel Review (Part 2) chaired by Carol Prives and held in-person on June 4, 2014 and June 5, 2014.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the discussion if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.

Observation Results Summary

Internal Audit participated in the Basic Cancer Research Panel Review (Part 2) meeting held in-person on June 4, 2014 and June 5, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Twenty-six out of forty-eight basic cancer research pre-screened applications were discussed and evaluated by the Basic Cancer Research Panel to determine which grants would be brought forth for further review. A cut-off is determined by the chair, and the applications discussed were based on their initial scores. However, the panel had the ability to champion an application, if requested.
- Sixteen panel members, two advocate reviewers, four CPRIT staff members, and six SRA employees were present for the in-person panel meeting.

- One conflict of interest was identified prior to the meeting. One conflict of interest was identified during the meeting. The panel members with the conflict of interest left the room and did not participate in the review of the conflicted application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the peer review panel's discussion of scientific, technical or programmatic aspects of the applications.

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Cancer Prevention Research Review Panel Observation Report

Report #2014-16

Panel Name: Cancer Prevention Research Panel Review Meeting

Panel Date: June 3, 2014 – June 4, 2014

Report Date: June 12, 2014

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized its out-sourced internal audit provider to function as a neutral third-party observer.

Introduction

The subject of this report is the Cancer Prevention Research Panel review of the High-Impact/High-Risk Research Awards (HIHRRA) and of the Individual Investigator Research Awards (IIRA) applications. The meeting was chaired by Tom Sellers and held in-person on June 3, 2014 and June 4, 2014.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.

Observation Results Summary

Internal Audit participated in the Cancer Prevention Research Panel review of the High-Impact/High-Risk Research Awards (HIHRRA) and of the Individual Investigator Research Awards (IIRA) applications held in-person and chaired by Tom Sellers on June 3, 2014 and June 4, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Two HIHRRA applications and twenty-three IIRA applications were discussed and evaluated by the Cancer Prevention Research Panel to determine which grants would receive CPRIT funding.
- Eighteen panel members, two advocate reviewers, three CPRIT staff members, and three SRA employees were present for the in-person panel review meeting.

- Twelve conflicts of interest were identified prior to or during the meeting. The panel members with the conflicts of interest left the room and did not participate in the review of the conflicted applications.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the peer review panel's discussion of scientific, technical or programmatic aspects of the applications.

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Scientific Research Cancer Biology Review Panel Observation Report

Report #2014-13

Panel Name: Scientific Research Cancer Biology Panel Review Meeting

Panel Date: May 28, 2014 – May 29, 2014

Report Date: June 12, 2014

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized its out-sourced internal audit provider to function as a neutral third-party observer.

Introduction

The subject of this report is the Scientific Research Cancer Biology Panel review of the High-Impact/High-Risk Research Awards (HIHRRRA) and of the Individual Investigator Research Awards (IIRA) applications. The meeting was chaired by Peter Jones and held in-person on May 28, 2014 and May 29, 2014.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.

Observation Results Summary

Internal Audit participated in the Scientific Research Cancer Biology Panel review of the High-Impact/High-Risk Research Awards (HIHRRRA) and of the Individual Investigator Research Awards (IIRA) applications held in-person and chaired by Peter Jones on May 28, 2014 and May 29, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Three HIRRA applications and twenty-seven IIRA applications were discussed and evaluated by the Scientific Research Cancer Biology Panel to determine which grants would receive CPRIT funding.
- Sixteen panel members, two advocate reviewers, four CPRIT staff members, and five SRA employees were present for the in-person panel review meeting.
- Sixteen conflicts of interest were identified prior to or during the meeting. The panel members with the conflicts of interest left the room and did not participate in the review of the conflicted applications.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the peer review panel's discussion of scientific, technical or programmatic aspects of the applications.

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Imaging Technology and Informatics Review Panel Observation Report

Report #2014-14

Panel Name: Scientific Research Imaging Technology and Informatics
Panel Review Meeting

Panel Date: May 29, 2014 – May 30, 2014

Report Date: May 30, 2014

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized its out-sourced internal audit provider to function as a neutral third-party observer.

Introduction

The subject of this report is the Scientific Research Imaging Technology and Informatics Panel review of the High-Impact/High-Risk Research Awards (HIHRRRA) and of the Individual Investigator Research Awards (IIRA) applications. The meeting was chaired by Sam Gambhir and held in-person on May 29, 2014 and May 30, 2014.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.

Observation Results Summary

Internal Audit participated in the Scientific Research Imaging Technology and Informatics Panel review of the High-Impact/High-Risk Research Awards (HIHRRRA) and of the Individual Investigator Research Awards (IIRA) applications held in-person and chaired by Sam Gambhir on May 29, 2014 and May 30, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Five HHHRA applications and nineteen IIRA applications were discussed and evaluated by the Scientific Research Imaging Technology and Informatics Panel to determine which grants would receive CPRIT funding.
- Eighteen panel members, two advocate reviewers, five CPRIT staff members, and four SRA employees were present for the in-person panel review meeting.
- Five conflicts of interest were identified prior to or during the meeting. The panel members with the conflicts of interest left the room and did not participate in the review of the conflicted applications.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the peer review panel's discussion of scientific, technical or programmatic aspects of the applications.

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Translational Cancer Research Review Panel Observation Report

Report #2014-18

Panel Name: Translational Cancer Research Panel Review Meeting

Panel Date: June 6, 2014

Report Date: June 12, 2014

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized its out-sourced internal audit provider to function as a neutral third-party observer.

Introduction

The subject of this report is the Translational Cancer Research Panel review of the High-Impact/High-Risk Research Awards (HIHRRRA) and of the Individual Investigator Research Awards (IIRA) applications. The meeting was chaired by Richard O'Reilly and held in-person on June 6, 2014.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.

Observation Results Summary

Internal Audit participated in the Translational Cancer Research Panel review of the High-Impact/High-Risk Research Awards (HIHRRRA) and of the Individual Investigator Research Awards (IIRA) applications held in-person and chaired by Richard O'Reilly on June 6, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Six HHRRA applications and nineteen IIRA applications were discussed and evaluated by the Translational Cancer Research Panel to determine which grants would receive CPRIT funding.
- Sixteen panel members, two advocate reviewers, two CPRIT staff members, and three SRA employees were present for the in-person panel review meeting.
- Four conflicts of interest were identified prior to or during the meeting. The panel members with the conflicts of interest left the room and did not participate in the review of the conflicted applications.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the peer review panel's discussion of scientific, technical or programmatic aspects of the applications.

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Clinical and Translational Cancer Research Review Panel Observation Report

Report #2014-19

Panel Name: Clinical and Translational Cancer Research Panel Review Meeting

Panel Date: June 10, 2014

Report Date: June 12, 2014

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized its out-sourced internal audit provider to function as a neutral third-party observer.

Introduction

The subject of this report is the Clinical and Translational Cancer Research Panel review of the High-Impact/High-Risk Research Awards (HIHRRRA) and of the Individual Investigator Research Awards (IIRA) applications. The meeting was chaired by Margaret Tempero and held over the phone on June 10, 2014.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.

Observation Results Summary

Internal Audit participated in the Clinical and Translational Cancer Research Panel review of the High-Impact/High-Risk Research Awards (HIHRRRA) and of the Individual Investigator Research Awards (IIRA) applications held over the phone and chaired by Margaret Tempero on June 10, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- One HHRRA applications and sixteen IIRA applications were discussed and evaluated by the Clinical and Translational Cancer Research Panel to determine which grants would receive CPRIT funding.
- Fifteen panel members, two advocate reviewers, three CPRIT staff members, and two SRA employees were present for the in-person panel review meeting.
- Three conflicts of interest were identified prior to or during the meeting. One of the conflicted panel member did not attend the meeting and the other panel members with conflicts of interest left the room and did not participate in the review of the conflicted applications.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the peer review panel's discussion of scientific, technical or programmatic aspects of the applications.

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Scientific Review Council Observation Report

Report #2014-20

Panel Name: Scientific Review Council Meeting – High-Impact/High-Risk Research Awards & Individual Investigator Research Awards

Panel Date: June 24, 2014

Report Date: July 7, 2014

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized its out-sourced internal audit provider to function as a neutral third-party observer.

Introduction

The subject of this report is the Scientific Review Council review of High-Impact/High-Risk Research Awards (HIHRRRA) and Individual Investigator Research Awards (IIRA). The meeting was chaired by Richard Kolodner and held over the phone on June 24, 2014.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.

Observation Results Summary

Internal Audit participated in the Scientific Review Council meeting held telephonically and chaired by Richard Kolodner on January 31, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Seventy-six research applications were included within the application listing submitted to the Scientific Review Council for their review and approval.

- Six council members, two CPRIT staff members, and one SRA employees were present for the Council meeting over the phone.
- No conflict of interest was identified prior to or during the call.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The Council members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the peer review panel's discussion of scientific, technical or programmatic aspects of the applications.

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

De-Identified Overall Evaluation Scores

High-Impact/High-Risk Research Award

Application ID	Mechanism	Final Overall Score
RP140350*	HIHR	1.6
RP140664*	HIHR	2
RP140329*	HIHR	2.1
RP140840*	HIHR	2.2
RP140449*	HIHR	2.4
RP140223*	HIHR	2.5
RP140649*	HIHR	2.5
RP140216*	HIHR	2.7
RP140478*	HIHR	2.7
RP140320*	HIHR	2.9
RP140678*	HIHR	2.9
RP140479*	HIHR	3.1
RP140435*	HIHR	3.1
RP140781*	HIHR	3.3
RP140328*	HIHR	3.5
r4	HIHR	3.5
r5	HIHR	3.7
r6	HIHR	3.7
r7	HIHR	3.7
r8	HIHR	3.7
r9	HIHR	3.7
s1	HIHR	3.7
s2	HIHR	3.7
s3	HIHR	3.7
s4	HIHR	3.8
s5	HIHR	3.9
s6	HIHR	4
s7	HIHR	4
s8	HIHR	4
s9	HIHR	4
t1	HIHR	4
t2	HIHR	4
t3	HIHR	4
t4	HIHR	4

*=Recommended for Funding

t5	HIHR	4
t6	HIHR	4
t7	HIHR	4.1
t8	HIHR	4.1
t9	HIHR	4.3
u1	HIHR	4.3
u2	HIHR	4.3
u3	HIHR	4.3
u4	HIHR	4.3
u5	HIHR	4.3
u6	HIHR	4.3
u7	HIHR	4.3
u8	HIHR	4.4
u9	HIHR	4.4
v1	HIHR	4.5
v2	HIHR	4.6
v3	HIHR	4.6
v4	HIHR	4.6
v5	HIHR	4.7
v6	HIHR	4.7
v7	HIHR	4.7
v8	HIHR	4.7
v9	HIHR	4.7
w1	HIHR	4.9
w2	HIHR	4.9
w3	HIHR	5
w4	HIHR	5
w5	HIHR	5
w6	HIHR	5
w7	HIHR	5
w8	HIHR	5
w9	HIHR	5
x1	HIHR	5
x2	HIHR	5
x3	HIHR	5
x4	HIHR	5
x5	HIHR	5
x6	HIHR	5
x7	HIHR	5
x8	HIHR	5

*=Recommended for Funding

x9	HIHR	5
y1	HIHR	5.1
y2	HIHR	5.1
y3	HIHR	5.2
y4	HIHR	5.3
y5	HIHR	5.3
y6	HIHR	5.3
y7	HIHR	5.3
y8	HIHR	5.3
y9	HIHR	5.3
z1	HIHR	5.5
z2	HIHR	5.7
z3	HIHR	5.7
z4	HIHR	5.7
z5	HIHR	5.7
z6	HIHR	5.7
z7	HIHR	5.7
z8	HIHR	5.7
z9	HIHR	5.7
aa1	HIHR	5.7
aa2	HIHR	5.7
aa3	HIHR	6
aa4	HIHR	6.7
aa5	HIHR	6.7
aa6	HIHR	7
aa7	HIHR	7.7

*=Recommended for Funding

Final Overall Evaluation Scores and Rank Order Scores

Ludwig Institute for
Cancer Research Ltd

June 24, 2014

**Richard D. Kolodner
Ph.D.**

Head, Laboratory of
Cancer Genetics
San Diego Branch

Senior Advisor on Academic
Affairs
New York Office

Distinguished Professor of
Medicine, University of
California San Diego

rkolodner@ucsd.edu

San Diego Branch
Univ of California San Diego
CMM-East / Rm 3058
9500 Gilman Dr - MC 0669
La Jolla, CA 92093-0669

T 858 534 7804
F 858 534 7750

New York Office
28th Floor
666 Third Avenue
New York, NY 10017

T 212 450 1500
F 212 450 1555

William Rice, M.D.
Oversight Committee Chair
Cancer Prevention and Research Institute of Texas
Via email to Bill.Rice@stdavids.com

Wayne R. Roberts
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cprit.state.tx.us

Dear Dr. Rice and Mr. Roberts,

The Scientific Review Council (SRC) is pleased to submit this list of research grant recommendations for the **Individual Investigator Research Awards (IIRA) and High-Impact/High-Risk Research Awards (HIHR)**. The SRC met on Tuesday, June 24, 2014 to consider the applications recommended by the peer review panels following their meetings that were held between May 26 and June 11, 2014. The projects on the attached list are numerically ranked in the order the SRC recommends the applications be funded. Recommended funding amounts and the overall evaluation score are stated for each grant application. The SRC accepted the recommendations of the peer review panels concerning adjustments to three grant applications. These adjustments are listed at the end of the list of recommended projects.

These recommendations meet the SRC's standards for grant award funding. These standards include selecting innovative research projects addressing critically important questions that will significantly advance knowledge of the causes, prevention, and/or treatment of cancer, and exceptional potential for achieving future impact in basic, translational, population-based, or clinical research.

Sincerely yours,



Richard D. Kolodner
Chair, Scientific Review Council

Attachment

Rank	App ID	Award Mechanism	Organization	Application Title	Budget	Meeting Overall Score
1	RP140244	IIRA	The University of Texas M. D. Anderson Cancer Center	Regulation of MDM2-mediated oncogenesis and anti-tumor immunity by USP15	\$870,156	1.0
2	RP140412	IIRA	The University of Texas Southwestern Medical Center	Endotrophin and the Obesity/Cancer Nexus: Role in Growth and Chemoresistance	\$899,997	1.1
3	RP140597	IIRA	The University of Texas M. D. Anderson Cancer Center	Role of TJP1 in Sensitivity and Resistance to Proteasome Inhibitors in Myeloma	\$900,000	1.3
4	RP140655	IIRA	The University of Texas Southwestern Medical Center	Evaluation of the role of tumor suppressor candidate NPRL2 in cell growth control	\$596,265	1.4
5	RP140350	HIHR	Baylor College of Medicine	Integrated Human Herpesvirus 6 as a Novel Heritable Risk Factor for Glioma	\$199,298	1.6
6	RP140606	IIRA	The University of Texas M. D. Anderson Cancer Center	Optimizing therapy for glioblastoma through genomic profiling of treatment failure	\$900,000	1.6
7	RP140672	IIRA	The University of Texas Southwestern Medical Center	Mutant KRAS reprograms lipid metabolism exposing beta-oxidation as a novel therapeutic target in lung cancer lung cancer	\$687,759	1.9
8	RP140402	IIRA	The University of Texas Southwestern Medical Center	Novel targets for acute myeloid leukemia treatment	\$900,000	1.9
9*	RP140464	IIRA	The University of Texas M. D. Anderson Cancer Center	Next Generation Sequencing and Transcriptome Profiling of Oral Potentially Malignant Lesions to Identify Markers of Cancer Risk and Targets for Chemoprevention	\$900,000	1.9
10	RP140612	IIRA	The University of Texas M. D. Anderson Cancer Center	Collateral Genomic Deletions As Targetable Vulnerabilities in Cancer	\$900,000	2.0
11	RP140469	IIRA	Baylor College of Medicine	Novel Small Molecule Probes Targeting IDH Mutated Glioma	\$695,527	2.0
12	RP140323	IIRA	The University of Texas M. D. Anderson Cancer Center	Role of a novel histone variant-specific epigenetic reader ZMYND11 in breast cancer	\$899,534	2.0
13	RP140408	IIRA	The University of Texas M. D. Anderson Cancer Center	Identificaion of a novel mechanism of mTORC1 and autophagy regulation for cancer therapy.	\$900,000	2.0
14	RP140462	IIRA	The University of Texas M. D. Anderson Cancer Center	Systematic Investigation of Clinically Relevant Expressed Pseudogenes in Cancer	\$870,539	2.0
15	RP140132	IIRA	Rice University	Towards Point-of-Care Nucleic Acid Cancer Diagnostics	\$900,000	2.0
16	RP140517	IIRA	The University of Texas at Dallas	Optimal Biomarkers for Personalized Cancer Therapy: A Network-Based Approach	\$490,689	2.0
17	RP140285	IIRA	The University of Texas Southwestern Medical Center	Noninvasive Identification of Prostate Tumor Hypoxia as a Prognostic Biomarker of Radiation Response	\$895,820	2.0
18	RP140664	HIHR	The University of Texas at Austin	Development of therapeutic antibodies having both Fc[gamma] and Fc[Alpha] effector functions and displaying potent cancer cell killing.	\$200,000	2.0
19	RP140329	HIHR	The University of Texas M. D. Anderson Cancer Center	Opening the central nervous system to immunotherapy by blocking TREK1	\$198,957	2.1
20	RP140181	IIRA	Baylor College of Medicine	Mechanisms of CTC Biomarkers in Breast Cancer Brain Metastasis	\$899,968	2.1
21	RP140252	IIRA	Baylor College of Medicine	Investigating and preclinical targeting molecular drivers of muscle-invasive bladder cancer	\$827,451	2.1
22	RP140262	IIRA	The University of Texas M. D. Anderson Cancer Center	Intrinsic Reward Sensitivity & Smoking Cessation with Varenicline or Patch NRT	\$899,505	2.1

23	RP140784	IIRA	Baylor Research Institute	Next Generation Sequencing-Based Approaches for the Development of Epigenetic Biomarkers for Predicting Therapeutic Outcome in Patients with Colorectal Cancer	\$886,982	2.1
24	RP140556	IIRA	The University of Texas M. D. Anderson Cancer Center	DNA methylation and telomere length in peripheral blood as predictors of aggressive prostate cancer	\$898,721	2.1
25	RP140298	IIRA	Texas Tech University	Engineering microfluidic devices for multimodal mechanical phenotyping of tumor cells in flow	\$674,465	2.1
26	RP140152	IIRA	The University of Texas Southwestern Medical Center	Natural Product for Treatment of Non-Small Cell Lung Cancer	\$772,368	2.1
27	RP140218	IIRA	The University of Texas M. D. Anderson Cancer Center	Inhibiting Oxidative Phosphorylation: A Novel Strategy in Leukemia	\$826,744	2.1
28	RP140522	IIRA	The University of Texas M. D. Anderson Cancer Center	Reversing vaccination-induced impairment of anti-CTLA-4-based cancer therapy.	\$899,991	2.1
29	RP140233	IIRA	The University of Texas Southwestern Medical Center	Structure-guided Kinase Inhibitor Design for Cancer Therapy	\$900,000	2.1
30	RP140648	IIRA	The University of Texas at Austin	New Therapeutic Strategies for Metastatic Melanoma	\$900,000	2.2
31	RP140452	IIRA	The University of Texas Health Science Center at San Antonio	Inactivating mutation of D2HGDH establishes a novel link between metabolism, alpha-KG dependent dioxygenases and epigenetic reprogramming in B cell lymphoma	\$854,740	2.2
32	RP140840	HIHR	Texas Tech University	New Technology for Ultra High Throughput Enumeration of Circulating Tumor Cells	\$199,993	2.2
33**	RP140001	IIRA	Baylor College of Medicine	Role of DNA METHYLTRANSFERASE 3A in Hematologic Malignancies	\$900,000	2.3
34	RP140468	IIRA	The University of Texas M. D. Anderson Cancer Center	TARGETING OF CHRONIC LYMPHOCYTIC LEUKEMIA BY DESIGNER T CELLS	\$900,000	2.3
35	RP140449	HIHR	The University of Texas Southwestern Medical Center	A new Cancer Target: AMPylation machinery	\$200,000	2.4
36	RP140271	IIRA	The University of Texas M. D. Anderson Cancer Center	Targeting p53 in cancer through manipulation of p63 and p73	\$900,000	2.4
37	RP140140	IIRA	The University of Texas Southwestern Medical Center	Turn ON the Tumor Contrast for Surgical Resection of Head and Neck Cancers	\$900,000	2.4
38	RP140482	IIRA	The University of Texas M. D. Anderson Cancer Center	Preclinical Intravital Microscopy of Prostate Cancer Lesions in Bone: Identification and Eradication of Survival Niches by Combination Therapy	\$256,061	2.4
39	RP140141	IIRA	The University of Texas Southwestern Medical Center	Targeting HER2 for cancer therapy	\$892,989	2.4
40	RP140179	IIRA	Baylor College of Medicine	Targeting self-renewal in leukemic stem cells through the inactivation of KLF4	\$813,789	2.5
41	RP140430	IIRA	The University of Texas M. D. Anderson Cancer Center	Synaptic Mechanisms of Cognitive Decline after Cranial Radiation	\$836,557	2.5
42	RP140563	IIRA	The University of Texas M. D. Anderson Cancer Center	PAF, a Novel Wnt Signaling Regulator, in Colorectal Cancer	\$900,000	2.5
43	RP140223	HIHR	Baylor College of Medicine	Viral MicroRNAs in Ovarian Cancer Growth and Metastasis	\$199,995	2.5
44	RP140224	IIRA	The University of Texas M. D. Anderson Cancer Center	PPAR-delta Regulation of Wnt/B-catenin to Drive Colon Cancer	\$890,003	2.5
45	RP140315	IIRA	The Methodist Hospital Research Institute	Accurate and High Throughput Detection of Breast and Ovarian Cancer Cells in Whole Blood	\$900,000	2.5

46	RP140649	HIHR	The University of Texas at Austin	Realizing Personalized and Precision Medicine for Melanoma: A Rapid Assay for Measuring ERK Activity	\$200,000	2.5
47	RP140222	IIRA	The University of Texas M. D. Anderson Cancer Center	Direct Roles for RB and E2F1 in DNA Repair	\$900,000	2.6
48	RP140685	IIRA	The University of Texas Health Science Center at San Antonio	Modulation of autophagy: Phase II study of vorinostat plus hydroxychloroquine vs. regorafenib in refractory metastatic colorectal cancer (mCRC)	\$825,285	2.6
49	RP140500	IIRA	The University of Texas M. D. Anderson Cancer Center	Realizing Personalized and Precision Medicine for Melanoma: A Rapid Assay for Measuring ERK Activity	\$900,000	2.6
50	RP140216	HIHR	Baylor College of Medicine	Context-Specific In Vivo Screening for KRAS-Associated Gene Aberration Drivers Using Genetically Engineered Mouse Models of Lung Cancer	\$199,715	2.7
51	RP140842	IIRA	The University of Texas at Austin	Determining the Functional Role of microRNAs in Viral Tumorigenesis.	\$604,624	2.7
52	RP140478	HIHR	Texas Tech University	Computational Chemistry Determination of DNA Damage Mechanisms in Proton Cancer Therapy to Optimize Its Clinical Use	\$200,000	2.7
53	RP140544	IIRA	The University of Texas at Dallas	Mapping Acidic Tumor Microenvironment with Renal Clearable pH Nanoindicators	\$900,000	2.7
54***	RP140456	IIRA	Baylor College of Medicine	Role of DNA2 Nuclease in Cellular Tolerance of Replication Stress and Telomere Maintenance - Implications for Cancer Biology and Anticancer Therapy	\$746,531	2.8
55	RP140515	IIRA	The University of Texas M. D. Anderson Cancer Center	CDK Inhibitors as Adjunctive to 5-FU and/or Radiation in Esophageal Adenocarcinoma- Assessment of Efficacy and Predictive Biomarkers	\$882,133	2.8
56	RP140399	IIRA	Baylor University	Targeting Hypoxia in Breast Cancer with Highly Potent Small-Molecule Anticancer Prodrugs	\$900,000	2.8
57	RP140320	HIHR	The University of Texas Southwestern Medical Center	DISSECTING A Necrotic Signaling Pathway in Human Cancer Cells	\$200,000	2.9
58	RP140661	IIRA	The University of Texas Southwestern Medical Center	Analyses of the regulatory mechanisms of tankyrase and its role in tumorigenesis	\$876,751	2.9
59	RP140367	IIRA	The University of Texas Southwestern Medical Center	Targeting BRD4 in Breast Cancer	\$900,000	2.9
60	RP140678	HIHR	Scott & White Healthcare	Novel, humanized single-chain CD123xCD3 bispecific antibodies for eliminating leukemia stem cells and leukemic cells	\$199,959	2.9
61	RP140800	IIRA	The University of Texas Health Science Center at Houston	The Role of Alternative Polyadenylation in Glioblastoma Tumor Progression	\$848,491	3.0
62	RP140473	IIRA	The University of Texas Health Science Center at San Antonio	Investigation of the tumor suppressor TMEM127 on lysosome function and lipid metabolism	\$881,146	3.0
63	RP140542	IIRA	The University of Texas M. D. Anderson Cancer Center	Biology and Therapy of Basal Bladder Cancers	\$865,587	3.0
64	RP140594	IIRA	The University of Texas Health Science Center at San Antonio	microRNAs: safe and effective therapeutic adjuvants for treating drug resistant breast cancers	\$900,000	3.0
65	RP140479	HIHR	Texas A&M University	Screening for melanoma genes using natural hybrid incompatibilities	\$199,993	3.1
66	RP140435	HIHR	The University of Texas Health Science Center at San Antonio	SHH/GLI3 signaling axis as a therapeutic target in castration resistant prostate cancer	\$200,000	3.1

67	RP140553	IIRA	Baylor College of Medicine	Translational Discovery of Resistance Genes and Cancer Gene Functions	\$900,000	3.1
68	RP140616	IIRA	Baylor College of Medicine	Tenascin-C and Metastatic Prostate Cancer Progression	\$827,806	3.1
69	RP140429	IIRA	The University of Texas M. D. Anderson Cancer Center	The Role of DIRAS3 (ARHI) in Initiating Autophagy and Tumor Dormancy	\$900,000	3.1
70	RP140411	IIRA	The University of Texas M. D. Anderson Cancer Center	Targeting Tumor Cell Invasion in Glioblastoma	\$900,000	3.1
71	RP140258	IIRA	Baylor College of Medicine	The Intersection between Childhood Cancer and Congenital Anomalies: Identifying Novel Cancer Predisposition Syndromes	\$874,964	3.1
72	RP140781	HIHR	Texas A&M University	High-Field Open MRI: Cost-Effective Screening for Early Detection of Breast Cancer	\$200,000	3.3
73	RP140328	HIHR	The University of Texas at Austin	Synthetic protein degradation agents to clear oncogenic proteins from cells	\$199,852	3.5
74	RP140143	IIRA	The University of Texas Southwestern Medical Center	Dependence of small cell lung cancer on the basic helix-loop-helix transcription factors Ascl1 and NeuroD1	\$900,000	3.5
75	RP140767	IIRA	Baylor College of Medicine	Toll-like receptors, gut microbiota, and risk of colorectal adenoma	\$899,131	3.5
76	RP140609	IIRA	The University of Texas M. D. Anderson Cancer Center	A missing link between obesity and cancer: Adipose derived stem cells	\$610,704	3.5

*RP140464- Budget will be adjusted down during contracting to accommodate a change in the Scope of Work (removal of specific Aim 4) as recommended by the peer review panel. The total amount requested was \$900,000.

**RP140001 - Budget was reduced from \$1,167,880 to \$900,000. The RFA stated that requests in excess of the allowable amount must be well justified. In the opinion of the peer review panel, the request was not well justified.

***RP140456 - Budget was reduced from \$900,000 to \$746,531. The peer review panel recommended the deletion of x-ray crystallography work, resulting in a total reduction of \$120,000 (\$40,000 annually for three years).

**Ludwig Institute for
Cancer Research Ltd**

July 10, 2014

**Richard D. Kolodner
Ph.D.**

Head, Laboratory of
Cancer Genetics
San Diego Branch

Senior Advisor on Academic
Affairs
New York Office

Distinguished Professor of
Medicine, University of
California San Diego

rkolodner@ucsd.edu

San Diego Branch
Univ of California San Diego
CMM-East / Rm 3058
9500 Gilman Dr - MC 0669
La Jolla, CA 92093-0669

T 858 534 7804
F 858 534 7750

New York Office
28th Floor
666 Third Avenue
New York, NY 10017

T 212 450 1500
F 212 450 1555

William Rice, M.D.
Oversight Committee Chair
Cancer Prevention and Research Institute of Texas
Via email to Bill.Rice@stdavids.com

Wayne R. Roberts
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cpr.it.state.tx.us

Dear Dr. Rice and Mr. Roberts,

It has come to my attention that there were minor errors with three applications in the list of research grants recommended for the Individual Investigator Research Awards (IIRA) and High-Impact/High-Risk Research Awards (HIHR) that was provided on June 24, 2014. Below is a description of the errors:

RP140132 - The online scoring system, P²RMIS, rounded the score up from 1.9 to 2.0.

RP140462 - The online scoring system, P²RMIS, rounded the score up from 1.9 to 2.0.

RP140500 - The title of the application was listed as "Realizing Personalized and Precision Medicine for Melanoma: A Rapid Assay for Measuring ERK Activity", but should have been listed as "Toward the Cure of Myelodysplastic Syndrome: Interfering with Innate Immunity Alterations in Human and Mouse Systems".

These errors do not change the positive recommendation of the Scientific Research Council for the award of these three projects.

Sincerely yours,



Richard D. Kolodner
Chair, CPRIT Scientific Review Council



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CEO Affidavit Supporting Information

FY 2014 – Cycle 1
Individual Investigator Research Award

Request for Applications



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA R-14-IIRA-1

Individual Investigator Research Awards

**Please also refer to the Instructions for Applicants document,
which will be posted December 23, 2013**

Application Receipt Opening Date: December 23, 2013
Application Receipt Closing Date: February 3, 2014

FY 2014

Fiscal Year Award Period

September 1, 2013–August 31, 2014

TABLE OF CONTENTS

1. ABOUT CPRIT	5
2. RATIONALE	5
3. RESEARCH OBJECTIVES	6
4. FUNDING INFORMATION	7
5. ELIGIBILITY	7
6. RESUBMISSION POLICY	8
7. RENEWAL POLICY	9
8. RESPONDING TO THIS RFA	9
8.1. APPLICATION SUBMISSION GUIDELINES	9
8.1.1. Submission Deadline Extension	9
8.2. APPLICATION COMPONENTS	9
8.2.1. Abstract and Significance (5,000 characters).....	10
8.2.2. Layperson's Summary (2,000 characters)	10
8.2.3. Goals and Objectives	10
8.2.4. Timeline (One page).....	11
8.2.5. Resubmission Summary (One page).....	11
8.2.6. Renewal Summary (Two pages)	11
8.2.7. Research Plan (Ten pages)	11
8.2.8. Vertebrate Animals and/or Human Subjects (One page).....	12
8.2.9. Publications/References	12
8.2.10. Budget and Justification	12
8.2.11. Biographical Sketches (Two pages each)	13
8.2.12. Current and Pending Support.....	13
8.2.13. Institutional/Collaborator Support and/or Other Certification (Four pages).....	13
8.2.14. Previous Summary Statement	14
9. APPLICATION REVIEW	14
9.1. PRELIMINARY EVALUATION.....	14
9.2. FULL PEER REVIEW	14
9.3. CONFIDENTIALITY OF REVIEW	15
9.4. REVIEW CRITERIA.....	16
9.4.1. Primary Criteria.....	16
9.4.2. Secondary Criteria.....	17

10. KEY DATES.....	18
11. AWARD ADMINISTRATION.....	18
12. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS.....	19
13. CONTACT INFORMATION.....	19
13.1. HELPDESK	19
13.2. SCIENTIFIC AND PROGRAMMATIC QUESTIONS	20

RFA VERSION HISTORY

Rev 12/9/13 RFA release

1. ABOUT CPRIT

The State of Texas has established the Cancer Prevention and Research Institute of Texas (CPRIT), which may issue up to \$3 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature and the citizens of Texas to:

- Create and expedite innovation in the area of cancer research and product or service development, thereby enhancing the potential for a medical or scientific breakthrough in the prevention, treatment, and possible cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the State of Texas; and
- Continue to develop and implement the Texas Cancer Plan by promoting the development and coordination of effective and efficient statewide public and private policies, programs, and services related to cancer and by encouraging cooperative, comprehensive, and complementary planning among the public, private, and volunteer sectors involved in cancer prevention, detection, treatment, and research.

CPRIT furthers cancer research in Texas by providing financial support for a wide variety of projects relevant to cancer research.

2. RATIONALE

The goals of the CPRIT Research Grants Program are to support the discovery of new information about cancer that can lead to prevention, early detection, and cures, and to translate new and existing discoveries into practical advances in cancer diagnosis and treatment. CPRIT encourages applications that seek new fundamental knowledge about cancer and cancer development, as well as those attempting to develop state-of-the-art technologies, tools, and/or resources for cancer research, including those with potential commercialization opportunities. This award allows experienced or early career-stage cancer researchers the opportunity to explore new methods and approaches for investigating a question of importance that has been inadequately addressed or for which there may be an absence of an established paradigm or technical framework. CPRIT will look with special favor on new approaches to be taken or new

areas of investigation to be explored by established investigators and on supporting the research programs of the most promising investigators at the beginning of their research careers. Applicants need not be trained specifically in cancer research. Indeed, CPRIT strongly encourages investigators from other fields, including the mathematical, physical, chemical, and engineering sciences, to bring their expertise to bear on the exceptionally challenging problems posed by cancer. CPRIT expects outcomes of supported activities to directly and indirectly benefit subsequent cancer research efforts, cancer public health policy, or the continuum of cancer care—from prevention to treatment and cure. To fulfill this vision, applications may address any topic or issue related to cancer biology, causation, prevention, detection or screening, treatment, or cure. Successful applicants should be working in a research environment capable of supporting potentially high-impact studies. Access to a clinical environment and interaction with translational cancer physician-scientists are highly desirable.

3. RESEARCH OBJECTIVES

CPRIT will foster cancer research in Texas by providing financial support for a wide variety of projects relevant to cancer research. This Request for Applications (RFA) solicits applications for innovative research projects addressing critically important questions that will significantly advance knowledge of the causes, prevention, and/or treatment of cancer. The goal of awards made in response to this RFA is to fund exceptionally innovative research projects with great potential impact that are directed by a single investigator. Areas of interest include laboratory research, translational studies, and/or clinical investigations. In that cancers arise from a large number of derangements of basic molecular and cellular functions and, in turn, cause many alterations in basic biological processes, almost any aspect of biology may be relevant to cancer research, more or less directly. The *degree of relevance* to cancer research will be an important criterion for evaluation of projects for funding by CPRIT ([Section 9.4.1](#)). For example, are alterations in the process in question *primarily* responsible for oncogenesis or secondary manifestations of malignant transformation? Will understanding the process or interfering with it offer selective and useful insight into prevention, diagnosis, or treatment of cancer? *Successful applicants for funding from CPRIT will have addressed these questions satisfactorily.*

4. FUNDING INFORMATION

Applicants may request a maximum of \$300,000 in total costs per year for up to 3 years for research. Exceptions to these limits may be requested if extremely well justified (see [Section 8.2.10](#)). Applications funded in this cycle will be eligible for competitive renewal. Funds may be used for salary and fringe benefits, research supplies, equipment, subject participation costs, and travel to scientific/technical meetings or collaborating institutions. Requests for funds to support construction and/or renovation will not be approved under this funding mechanism. State law limits the amount of award funding that may be spent on indirect costs to no more than 5 percent of the total award amount.

5. ELIGIBILITY

- The applicant must be a Texas-based entity. Any not-for-profit institution or organization that conducts research is eligible to apply for funding under this award mechanism. A public or private company is not eligible for funding under this award mechanism; these entities must use the appropriate award mechanism(s) under CPRIT's Product Development Program.
- The Principal Investigator (PI) must have a doctoral degree, including M.D., Ph.D., D.D.S., D.M.D., Dr.P.H., D.O., D.V.M., or equivalent, and must reside in Texas during the time the research that is the subject of the grant is conducted.
- A PI may submit only one new or resubmission application under this RFA during this funding cycle. If submitting a renewal application, a PI may submit both a new or resubmission application and a renewal application under this RFA during this funding cycle.
- Because this award mechanism is intended to support research directed by a single investigator, only one Co-PI may be included.
- Collaborations are permitted and encouraged, and collaborators may or may not reside in Texas. However, collaborators who do not reside in Texas are not eligible to receive CPRIT funds. Collaborators should have specific and well-defined roles. Subcontracting and collaborating organizations may include public, not-for-profit, and for-profit entities. Such entities may be located outside of the State of Texas, but non-Texas-based organizations are not eligible to receive CPRIT funds.

- An applicant is eligible to receive a grant award only if the applicant certifies that the applicant institution or organization, including the PI, any senior member or key personnel listed on the grant application, and any officer or director of the grant applicant's institution or organization (or any person related to one or more of these individuals within the second degree of consanguinity or affinity), have not made and will not make a contribution to CPRIT or to any foundation specifically created to benefit CPRIT.
- An applicant is not eligible to receive a CPRIT grant award if the applicant PI, any senior member or key personnel listed on the grant application, and any officer or director of the grant applicant's organization or institution is related to a CPRIT Oversight Committee member.
- The applicant must report whether the applicant institution or organization, the PI, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, whether or not those individuals are slated to receive salary or compensation under the grant award, are currently ineligible to receive Federal grant funds or have had a grant terminated for cause within 5 years prior to the submission date of the grant application.
- CPRIT grants will be awarded by contract to successful applicants. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in [Section 11](#) and [Section 12](#). All statutory provisions and relevant administrative rules can be found at www.cprit.state.tx.us.

6. RESUBMISSION POLICY

An application previously submitted to CPRIT but not funded may be resubmitted once and must follow all resubmission guidelines. More than one resubmission is not permitted. This policy is in effect for all applications submitted to date. See [Section 8.2.5](#).

7. RENEWAL POLICY

An application funded by CPRIT under this mechanism may be submitted for a competitive renewal. This policy is in effect for all awards submitted to date. See [Section 8.2.6](#).

8. RESPONDING TO THIS RFA

8.1. Application Submission Guidelines

Applications must be submitted via the CPRIT Application Receipt System (CARS) (<https://CPRITGrants.org>). **Only applications submitted through this portal will be considered eligible for evaluation.** The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application was submitted. The PI must create a user account in the system to start and submit an application. The Co-PI, if applicable, must also create a user account to participate in the application. Furthermore, the Authorized Signing Official (ASO) (a person authorized to sign and submit the application for the organization) and the Grants Contract/Office of Sponsored Projects Official (the individual who will manage the grant contract if an award is made) also must create a user account in CARS. Applications will be accepted beginning at 7 a.m. Central Time on December 23, 2013 and must be submitted by 3 p.m. Central Time on February 3, 2014. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

8.1.1. Submission Deadline Extension

The submission deadline may be extended for one or more grant applications upon a showing of good cause. All requests for extension of the submission deadline must be submitted via e-mail to the CPRIT HelpDesk. Submission deadline extensions, including the reason for the extension, will be documented as part of the grant review process records.

8.2. Application Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. Please refer to the *Instructions for Applicants* document for details that will be available when the application receipt system opens. Submissions that are missing one or more components or do not meet the eligibility requirements listed in [Section 5](#) will be administratively withdrawn without review.

8.2.1. Abstract and Significance (5,000 characters)

Clearly explain the question or problem to be addressed and the approach to its answer or solution. The specific aims of the application must be obvious from the abstract, although they need not be restated verbatim from the Research Plan. Clearly address how the proposed project, if successful, will have a major impact on cancer. Summarize how the proposed research creates new paradigms or challenges existing ones. Indicate whether this research plan represents a new direction for the PI.

Note: It is the responsibility of the applicant to capture CPRIT's attention primarily with the Abstract and Significance statement alone. Therefore, applicants are advised to prepare this section wisely. Applicants should not waste this valuable space by stating obvious facts (e.g., that cancer is a significant problem; that better diagnostic and therapeutic approaches are needed urgently; that the type of cancer of interest to the PI is important, vexing, or deadly; etc.).

Based on this statement (and the Budget and Justification and Biographical Sketches), applications that are judged to offer only modest contributions to the field of cancer research or that do not sufficiently capture the reviewers' interest may be excluded from further peer review (see [Section 9.1](#)).

8.2.2. Layperson's Summary (2,000 characters)

Provide a layperson's summary of the proposed work. Describe, in simple, nontechnical terms, the overall goals of the proposed work, the type(s) of cancer addressed, the potential significance of the results, and the impact of the work on advancing the field of cancer research, early diagnosis, prevention or treatment. The information provided in this summary will be made publicly available by CPRIT, particularly if the application is recommended for funding. Do not include any proprietary information in the Layperson's Summary. The Layperson's Summary will also be used by advocate reviewers ([Section 9.2](#)) in evaluating the significance and impact of the proposed work.

8.2.3. Goals and Objectives

List specific goals and objectives for each year of the project. These goals and objectives will also be used during the submission and evaluation of progress reports and assessment of project success.

8.2.4. Timeline (One page)

Provide an outline of anticipated major milestones to be tracked. Timelines will be reviewed for reasonableness, and adherence to timelines will be a criterion for continued support of successful applications. If the application is approved for funding, this section will be included in the award contract. Applicants are advised not to include information that they consider confidential or proprietary when preparing this section.

8.2.5. Resubmission Summary (One page)

Applicants preparing a resubmission must describe the approach to the resubmission. If a summary statement was prepared for the original application review, applicants are advised to address all noted concerns.

Note: An application previously submitted to CPRIT but not funded may be resubmitted once after careful consideration of the reasons for lack of prior success. Applications that received overall numerical scores of 5 or higher are likely to need considerable attention. Applicants may prepare a fresh Research Plan or modify the original Research Plan and mark the changes. However, all resubmitted applications should be carefully reconstructed; a simple revision of the prior application with editorial or technical changes is not sufficient, and applicants are advised not to direct reviewers to such modest changes.

8.2.6. Renewal Summary (Two pages)

Applicants preparing a renewal must describe and demonstrate that appropriate/adequate progress has been made on the current funded award to warrant further funding. Publications and manuscripts in press that have resulted from work performed during the initial funded period should be listed in the renewal summary.

8.2.7. Research Plan (Ten pages)

Background: Present the rationale behind the proposed project, emphasizing the pressing problem in cancer research that will be addressed.

Hypothesis and Specific Aims: Concisely state the hypothesis and/or specific aims to be tested or addressed by the research described in the application.

Research Strategy: Describe the experimental design, including methods, anticipated results, potential problems or pitfalls, and alternative approaches. Preliminary data that support the proposed hypothesis are encouraged but not required.

8.2.8. Vertebrate Animals and/or Human Subjects (One page)

If vertebrate animals will be used, provide an outline of the appropriate protocols that will be followed. If human subjects or human biological samples will be used, provide a plan for recruitment of subjects or acquisition of samples that will meet the time constraints of this award mechanism.

8.2.9. Publications/References

Provide a concise and relevant list of publications/references cited for the application.

8.2.10. Budget and Justification

Provide a compelling justification of the budget for the entire proposed period of support, including salaries and benefits, supplies, equipment, patient care costs, animal care costs, and other expenses. Applicants are advised not to interpret the maximum allowable request under this award as a suggestion that they should expand their anticipated budget to this level. Reasonable budgets clearly work in favor of the applicant.

However, if there is a highly specific and defensible need to request more than the maximum amount in any year(s) of the proposed budget, include a special and clearly labeled section in the budget justification that explains the request. Poorly justified requests of this type will likely have a negative impact on the overall evaluation of the application.

In preparing the requested budget, applicants should be aware of the following:

- Equipment having a useful life of more than 1 year and an acquisition cost of \$5,000 or more per unit must be specifically approved by CPRIT. An applicant does not need to seek this approval prior to submitting the application.
- Texas law limits the amount of grant funds that may be spent on indirect costs to no more than 5 percent of the total award amount (5.263 percent of the direct costs). Guidance regarding indirect cost recovery can be found in CPRIT's Administrative Rules, which are available at www.cpritis.state.tx.us. So-called grants management and facilities fees (e.g., sponsored programs fees; grants and contracts fees; electricity, gas and water;

custodial fees; maintenance fees; etc.) may not be requested. Applications that include such budgetary items will be rejected administratively and returned without review.

- The annual salary (also referred to as direct salary or institutional base salary) that an individual may receive under a CPRIT award for FY 2014 and FY 2015 is \$200,000; CPRIT FY 2014 is from September 1, 2013 through August 31, 2014 and FY 2015 is from September 1, 2014 through August 31, 2015. Salary does not include fringe benefits and/or facilities and administrative (F&A) costs, also referred to as indirect costs. An individual's institutional base salary is the annual compensation that the applicant organization pays for an individual's appointment, whether that individual's time is spent on research, teaching, patient care, or other activities. Base salary excludes any income that an individual may be permitted to earn outside of his or her duties to the applicant organization.

8.2.11. Biographical Sketches (Two pages each)

Applicants should provide a biographical sketch that describes their education and training, professional experience, awards and honors, and publications relevant to cancer research.

A biographical sketch must be provided for the PI and, if applicable, the Co-PI (as required by the online application receipt system). Up to two additional biographical sketches for key personnel may be provided. Each biographical sketch must not exceed two pages.

8.2.12. Current and Pending Support

Describe the funding source and duration of all current and pending support for all personnel who have included a biographical sketch with the application. For each award, provide the title, a two-line summary of the goal of the project and, if relevant, a statement of overlap with the current application. At a minimum, current and pending support of the PI and, if applicable, the Co-PI must be provided.

8.2.13. Institutional/Collaborator Support and/or Other Certification (Four pages)

Applicants may provide letters of institutional support, collaborator support, and/or other certification documentation relevant to the proposed project. A maximum of four pages may be provided.

8.2.14. Previous Summary Statement

If the application is being resubmitted, the summary statement of the original application review, if previously prepared, will be automatically appended to the resubmission. The applicant is not responsible for providing this document.

Applications that are missing one or more of these components, exceed the specified page, word, or budget limits, or that do not meet the eligibility requirements listed above will be administratively rejected without review.

9. APPLICATION REVIEW

9.1. Preliminary Evaluation

To ensure the timely and thorough review of only the most innovative and cutting-edge research with the greatest potential for advancement of cancer research, all eligible applications may be preliminarily evaluated by CPRIT Scientific Research Program panel members for scientific merit and impact.

This preliminary evaluation will be based on a subset of material presented in the application—namely Abstract and Significance, Budget and Justification, and Biographical Sketches. Applications that do not sufficiently capture the reviewers’ interest at this stage will not be considered for further review. Such applications will have been judged to offer only modest contributions to the field of cancer research and will be excluded from further peer review.

The applicant will be notified of the decision to disapprove the application after the preliminary evaluation stage has concluded. Due to the volume of applications to be reviewed, comments made by reviewers at the preliminary evaluation stage may not be provided to applicants. The preliminary evaluation process will be used only when the number of applications exceeds the capacity of the review panels to conduct a full peer review of all received applications.

9.2. Full Peer Review

Applications that pass preliminary evaluation will undergo further review using a two-stage peer review process: (1) Full peer review, and (2) prioritization of grant applications by the CPRIT Scientific Review Council. In the first stage, applications will be evaluated by an independent peer review panel consisting of scientific experts as well as advocate reviewers using the criteria

listed below. In the second stage, applications judged to be most meritorious by the peer review panels will be evaluated and recommended for funding by the CPRIT Scientific Review Council based on comparisons with applications from all of the peer review panels and programmatic priorities. Applications approved by Scientific Review Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review. The PIC will consider factors including program priorities set by the Oversight Committee, portfolio balance across programs, and available funding. The CPRIT Oversight Committee will vote to approve each grant award recommendation made by the PIC. The grant award recommendations will be presented at an open meeting of the Oversight Committee and must be approved by two-thirds of the Oversight Committee members present and eligible to vote. The review process is described more fully in CPRIT's Administrative Rules, Chapter 703, Sections 703.6–703.8.

9.3. Confidentiality of Review

Each stage of application review is conducted confidentially, and all CPRIT Scientific Peer Review Panel members, Scientific Review Council members, Program Integration Committee members, CPRIT employees, and Oversight Committee members with access to grant application information are required to sign nondisclosure statements regarding the contents of the applications. All technological and scientific information included in the application is protected from public disclosure pursuant to Health and Safety Code §102.262(b).

Individuals directly involved with the review process operate under strict conflict of interest prohibitions. All CPRIT Scientific Peer Review Panel members, and Scientific Review Council members are non-Texas residents.

An applicant will be notified regarding the peer review panel assigned to review the grant application. Peer review panel members are listed by panel on CPRIT's Web site. **By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed Conflict of Interest as set forth in CPRIT's Administrative Rules, Chapter 703, Section 703.9.**

Communication regarding the substance of a pending application is prohibited between the grant applicant (or someone on the grant applicant's behalf) and the following individuals: an Oversight Committee Member, a Program Integration Committee Member, a Scientific Review Panel member, or a Scientific Review Council member. Applicants should note that the CPRIT

Program Integration Committee is comprised of the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention Officer, the Chief Product Development Officer, and the Commissioner of State Health Services. The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. The prohibition on communication does not apply to the time period when pre-applications or letters of interest are accepted. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant application from further consideration for a grant award.

9.4. Review Criteria

Full peer review of applications will be based on primary scored criteria and secondary unscored criteria, listed below. Review committees will evaluate and score each primary criterion and subsequently assign a global score that reflects an overall assessment of the application. **The overall assessment will not be an average of the scores of individual criteria; rather, it will reflect the reviewers' overall impression of the application. Evaluation of the scientific merit of each application is within the sole discretion of the peer reviewers.**

9.4.1. Primary Criteria

Primary criteria will evaluate the scientific merit and potential impact of the proposed work contained in the application. Concerns with any of these criteria potentially indicate a major flaw in the significance and/or design of the proposed study. Primary criteria include:

Significance and Impact: Will the results of this research, if successful, significantly change the research of others or the opportunities for better cancer prevention, diagnosis or treatment for patients? Is the application innovative? Does the applicant propose new paradigms or challenge existing ones? Does the project develop state-of-the-art technologies, methods, tools, or resources for cancer research or address important under- or unexplored areas? If the research project is successful, will it lead to truly substantial advances in the field rather than add modest increments of insight? Projects that modestly extend current lines of research will not be considered for this award. Projects that represent straightforward extensions of ongoing work, especially work traditionally funded by other mechanisms, will not be competitive.

Research Plan: Is the proposed work presented as a self-contained research project? Does the proposed research have a clearly defined hypothesis or goal that is supported by sufficient preliminary data and/or scientific rationale? Are the methods appropriate, and are potential experimental obstacles and unexpected results discussed?

Applicant Investigator: Does the applicant investigator demonstrate the required creativity and expertise to make a significant contribution to the research? Applicants' credentials will be evaluated in a career stage-specific fashion. Have early career stage investigators received excellent training, and do their accomplishments to date offer great promise for a successful career? Has the applicant devoted a sufficient amount of his or her time (percentage effort) to this project?

Relevance: Does the proposed research have a high degree of relevance to cancer research? This will be an important criterion for evaluation of projects for CPRIT support.

9.4.2. Secondary Criteria

Secondary criteria contribute to the global score assigned to the application. Concerns with these criteria potentially question the feasibility of the proposed research.

Secondary criteria include:

Research Environment: Does the research team have the needed expertise, facilities, and resources to accomplish all aspects of the proposed research? Are the levels of effort of the key personnel appropriate? Is there evidence of institutional support of the research team and the project?

Vertebrate Animals and/or Human Subjects: If vertebrate animals and/or human subjects are included in the proposed research, certification of approval by the institutional IACUC and/or IRB, as appropriate, will be required before funding can occur.

Budget: Is the budget appropriate for the proposed work?

Duration: Is the stated duration appropriate for the proposed work?

10. KEY DATES

RFA

RFA release December 9, 2013

Application

Online application opens December 23, 2013, 7 a.m. Central Time

Application due February 3, 2014, 3 p.m. Central Time

Application review May/June 2014

Award

Award notification August 2014

Anticipated start date August 2014

11. AWARD ADMINISTRATION

Texas law requires that CPRIT grant awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to institutions or organizations, not to individuals. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT's electronic signature policy as set forth in Chapter 701, Section 701.25.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and intellectual property rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.state.tx.us. Applicants are advised to review CPRIT's administrative rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in Chapter 703, Sections 703.10, 703.12.

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements set forth in CPRIT's Administrative Rules, Chapter 703, Section 703.20.

CPRIT requires award recipients to submit an annual progress report. These reports summarize the progress made toward the research goals and address plans for the upcoming year. In addition, fiscal reporting, human studies reporting, and vertebrate animal use reporting will be required as appropriate. Continuation of funding is contingent upon the timely receipt of these reports. Failure to provide timely and complete reports may waive reimbursement of grant award costs, and may result in the termination of award contract. Forms and instructions will be made available at www.cpritchestates.tx.us.

12. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas law requires that prior to disbursement of CPRIT grant funds, the award recipient must demonstrate that it has an amount of funds equal to one-half of the CPRIT funding dedicated to the research that is the subject of the award. The demonstration of available matching funds must be made at the time the award contract is executed, and annually thereafter, not when the application is submitted. Grant applicants are advised to consult CPRIT's Administrative Rules, Chapter 703, Section 703.11, for specific requirements regarding demonstration of available funding.

13. CONTACT INFORMATION

13.1. HelpDesk

HelpDesk support is available for questions regarding user registration and online submission of applications. Queries submitted via e-mail will be answered within 1 business day. HelpDesk staff are not in a position to answer questions regarding scientific aspects of applications.

Dates of operation: December 9, 2013 – February 3, 2014 (excluding public holidays)

Hours of operation: Monday, Tuesday, Thursday, Friday, 7 a.m. to 4 p.m. Central Time
Wednesday, 8 a.m. to 4 p.m. Central Time

Tel: 866-941-7146

E-mail: Help@CPRITGrants.org

13.2. Scientific and Programmatic Questions

Questions regarding the CPRIT program, including questions regarding this or any other funding opportunity, should be directed to the CPRIT Research Program Director.

Tel: 512-305-8491

E-mail: Help@CPRITGrants.org

Web site: www.cprit.state.tx.us

Third Party Observer Report

CPRIT Basic Cancer Research-1 Review Panel Observation Report

Report #2014-15

Panel Name: Basic Cancer Research-1 Panel Review Meeting

Panel Date: May 31, 2014

Report Date: June 12, 2014

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized its out-sourced internal audit provider to function as a neutral third-party observer.

Introduction

The subject of this report is the Basic Cancer Research-1 Panel review of the High-Impact/High-Risk Research Awards (HIHRRA) and of the Individual Investigator Research Awards (IIRA) applications. The meeting was chaired by Tom Curran and held in-person on May 31, 2014.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.

Observation Results Summary

Internal Audit participated in the Basic Cancer Research-1 Panel review of the High-Impact/High-Risk Research Awards (HIHRRA) and of the Individual Investigator Research Awards (IIRA) applications held in-person and chaired by Tom Curran on May 31, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Ten HIHRRA applications and fifteen IIRA applications were discussed and evaluated by the Basic Cancer Research-1 Panel to determine which grants would receive CPRIT funding.
- Eighteen panel members, two advocate reviewers, four CPRIT staff members, and three SRA employees were present for the in-person panel review meeting.

- Two conflicts of interest were identified prior to or during the meeting. The panel member with the conflict of interest left the room and did not participate in the review of the conflicted applications.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the peer review panel's discussion of scientific, technical or programmatic aspects of the applications.

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Research Panel Review Report

Report #2014-17

Panel Name: Basic Cancer Research – Part 2 Panel Review Meeting

Panel Date: June 4, 2014 - June 5, 2014

Report Date: June 12, 2014

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized its out-sourced internal audit provider to function as a neutral third-party observer.

Introduction

The subject of this report is the Basic Cancer Research Panel Review (Part 2) chaired by Carol Prives and held in-person on June 4, 2014 and June 5, 2014.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the discussion if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.

Observation Results Summary

Internal Audit participated in the Basic Cancer Research Panel Review (Part 2) meeting held in-person on June 4, 2014 and June 5, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Twenty-six out of forty-eight basic cancer research pre-screened applications were discussed and evaluated by the Basic Cancer Research Panel to determine which grants would be brought forth for further review. A cut-off is determined by the chair, and the applications discussed were based on their initial scores. However, the panel had the ability to champion an application, if requested.
- Sixteen panel members, two advocate reviewers, four CPRIT staff members, and six SRA employees were present for the in-person panel meeting.

- One conflict of interest was identified prior to the meeting. One conflict of interest was identified during the meeting. The panel members with the conflict of interest left the room and did not participate in the review of the conflicted application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the peer review panel's discussion of scientific, technical or programmatic aspects of the applications.

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Cancer Prevention Research Review Panel Observation Report

Report #2014-16

Panel Name: Cancer Prevention Research Panel Review Meeting

Panel Date: June 3, 2014 – June 4, 2014

Report Date: June 12, 2014

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized its out-sourced internal audit provider to function as a neutral third-party observer.

Introduction

The subject of this report is the Cancer Prevention Research Panel review of the High-Impact/High-Risk Research Awards (HIHRRA) and of the Individual Investigator Research Awards (IIRA) applications. The meeting was chaired by Tom Sellers and held in-person on June 3, 2014 and June 4, 2014.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.

Observation Results Summary

Internal Audit participated in the Cancer Prevention Research Panel review of the High-Impact/High-Risk Research Awards (HIHRRA) and of the Individual Investigator Research Awards (IIRA) applications held in-person and chaired by Tom Sellers on June 3, 2014 and June 4, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Two HIHRRA applications and twenty-three IIRA applications were discussed and evaluated by the Cancer Prevention Research Panel to determine which grants would receive CPRIT funding.
- Eighteen panel members, two advocate reviewers, three CPRIT staff members, and three SRA employees were present for the in-person panel review meeting.

- Twelve conflicts of interest were identified prior to or during the meeting. The panel members with the conflicts of interest left the room and did not participate in the review of the conflicted applications.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the peer review panel's discussion of scientific, technical or programmatic aspects of the applications.

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Scientific Research Cancer Biology Review Panel Observation Report

Report #2014-13

Panel Name: Scientific Research Cancer Biology Panel Review Meeting

Panel Date: May 28, 2014 – May 29, 2014

Report Date: June 12, 2014

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized its out-sourced internal audit provider to function as a neutral third-party observer.

Introduction

The subject of this report is the Scientific Research Cancer Biology Panel review of the High-Impact/High-Risk Research Awards (HIHRRRA) and of the Individual Investigator Research Awards (IIRA) applications. The meeting was chaired by Peter Jones and held in-person on May 28, 2014 and May 29, 2014.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.

Observation Results Summary

Internal Audit participated in the Scientific Research Cancer Biology Panel review of the High-Impact/High-Risk Research Awards (HIHRRRA) and of the Individual Investigator Research Awards (IIRA) applications held in-person and chaired by Peter Jones on May 28, 2014 and May 29, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Three HIRRA applications and twenty-seven IIRA applications were discussed and evaluated by the Scientific Research Cancer Biology Panel to determine which grants would receive CPRIT funding.
- Sixteen panel members, two advocate reviewers, four CPRIT staff members, and five SRA employees were present for the in-person panel review meeting.
- Sixteen conflicts of interest were identified prior to or during the meeting. The panel members with the conflicts of interest left the room and did not participate in the review of the conflicted applications.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the peer review panel's discussion of scientific, technical or programmatic aspects of the applications.

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Imaging Technology and Informatics Review Panel Observation Report

Report #2014-14

Panel Name: Scientific Research Imaging Technology and Informatics
Panel Review Meeting

Panel Date: May 29, 2014 – May 30, 2014

Report Date: May 30, 2014

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized its out-sourced internal audit provider to function as a neutral third-party observer.

Introduction

The subject of this report is the Scientific Research Imaging Technology and Informatics Panel review of the High-Impact/High-Risk Research Awards (HIHRRRA) and of the Individual Investigator Research Awards (IIRA) applications. The meeting was chaired by Sam Gambhir and held in-person on May 29, 2014 and May 30, 2014.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.

Observation Results Summary

Internal Audit participated in the Scientific Research Imaging Technology and Informatics Panel review of the High-Impact/High-Risk Research Awards (HIHRRRA) and of the Individual Investigator Research Awards (IIRA) applications held in-person and chaired by Sam Gambhir on May 29, 2014 and May 30, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Five HIRRA applications and nineteen IIRA applications were discussed and evaluated by the Scientific Research Imaging Technology and Informatics Panel to determine which grants would receive CPRIT funding.
- Eighteen panel members, two advocate reviewers, five CPRIT staff members, and four SRA employees were present for the in-person panel review meeting.
- Five conflicts of interest were identified prior to or during the meeting. The panel members with the conflicts of interest left the room and did not participate in the review of the conflicted applications.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the peer review panel's discussion of scientific, technical or programmatic aspects of the applications.

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Translational Cancer Research Review Panel Observation Report

Report #2014-18

Panel Name: Translational Cancer Research Panel Review Meeting

Panel Date: June 6, 2014

Report Date: June 12, 2014

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized its out-sourced internal audit provider to function as a neutral third-party observer.

Introduction

The subject of this report is the Translational Cancer Research Panel review of the High-Impact/High-Risk Research Awards (HIHRRRA) and of the Individual Investigator Research Awards (IIRA) applications. The meeting was chaired by Richard O'Reilly and held in-person on June 6, 2014.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.

Observation Results Summary

Internal Audit participated in the Translational Cancer Research Panel review of the High-Impact/High-Risk Research Awards (HIHRRRA) and of the Individual Investigator Research Awards (IIRA) applications held in-person and chaired by Richard O'Reilly on June 6, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Six HHRRA applications and nineteen IIRA applications were discussed and evaluated by the Translational Cancer Research Panel to determine which grants would receive CPRIT funding.
- Sixteen panel members, two advocate reviewers, two CPRIT staff members, and three SRA employees were present for the in-person panel review meeting.
- Four conflicts of interest were identified prior to or during the meeting. The panel members with the conflicts of interest left the room and did not participate in the review of the conflicted applications.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the peer review panel's discussion of scientific, technical or programmatic aspects of the applications.

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Clinical and Translational Cancer Research Review Panel Observation Report

Report #2014-19

Panel Name: Clinical and Translational Cancer Research Panel Review Meeting

Panel Date: June 10, 2014

Report Date: June 12, 2014

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized its out-sourced internal audit provider to function as a neutral third-party observer.

Introduction

The subject of this report is the Clinical and Translational Cancer Research Panel review of the High-Impact/High-Risk Research Awards (HIHRRRA) and of the Individual Investigator Research Awards (IIRA) applications. The meeting was chaired by Margaret Tempero and held over the phone on June 10, 2014.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.

Observation Results Summary

Internal Audit participated in the Clinical and Translational Cancer Research Panel review of the High-Impact/High-Risk Research Awards (HIHRRRA) and of the Individual Investigator Research Awards (IIRA) applications held over the phone and chaired by Margaret Tempero on June 10, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- One HHRRA applications and sixteen IIRA applications were discussed and evaluated by the Clinical and Translational Cancer Research Panel to determine which grants would receive CPRIT funding.
- Fifteen panel members, two advocate reviewers, three CPRIT staff members, and two SRA employees were present for the in-person panel review meeting.
- Three conflicts of interest were identified prior to or during the meeting. One of the conflicted panel member did not attend the meeting and the other panel members with conflicts of interest left the room and did not participate in the review of the conflicted applications.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the peer review panel's discussion of scientific, technical or programmatic aspects of the applications.

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Scientific Review Council Observation Report

Report #2014-20

Panel Name: Scientific Review Council Meeting – High-Impact/High-Risk Research Awards & Individual Investigator Research Awards

Panel Date: June 24, 2014

Report Date: July 7, 2014

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized its out-sourced internal audit provider to function as a neutral third-party observer.

Introduction

The subject of this report is the Scientific Review Council review of High-Impact/High-Risk Research Awards (HIHRRRA) and Individual Investigator Research Awards (IIRA). The meeting was chaired by Richard Kolodner and held over the phone on June 24, 2014.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.

Observation Results Summary

Internal Audit participated in the Scientific Review Council meeting held telephonically and chaired by Richard Kolodner on January 31, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Seventy-six research applications were included within the application listing submitted to the Scientific Review Council for their review and approval.

- Six council members, two CPRIT staff members, and one SRA employees were present for the Council meeting over the phone.
- No conflict of interest was identified prior to or during the call.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The Council members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the peer review panel's discussion of scientific, technical or programmatic aspects of the applications.

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

De-Identified Overall Evaluation Scores

Individual Investigator Research Award—Final Scores for Preliminary Evaluations

Application ID	Mechanism	Final Overall Score
aaa1	IIRA PreE	3.3
aaa2	IIRA PreE	3.3
aaa3	IIRA PreE	3.3
aaa4	IIRA PreE	3.3
aaa5	IIRA PreE	3.3
aaa6	IIRA PreE	3.3
aaa7	IIRA PreE	3.3
aaa8	IIRA PreE	3.3
aaa9	IIRA PreE	3.3
bbb1	IIRA PreE	3.3
bbb2	IIRA PreE	3.7
bbb3	IIRA PreE	3.7
bbb4	IIRA PreE	3.7
bbb5	IIRA PreE	3.7
bbb6	IIRA PreE	3.7
bbb7	IIRA PreE	3.7
bbb8	IIRA PreE	3.7
bbb9	IIRA PreE	3.7
ccc1	IIRA PreE	3.7
ccc2	IIRA PreE	3.7
ccc3	IIRA PreE	3.7
ccc4	IIRA PreE	3.7
ccc5	IIRA PreE	3.7
ccc6	IIRA PreE	3.7
ccc7	IIRA PreE	3.7
ccc8	IIRA PreE	3.7
ccc9	IIRA PreE	3.7
ddd1	IIRA PreE	3.7
ddd2	IIRA PreE	3.7
ddd3	IIRA PreE	3.7
ddd4	IIRA PreE	3.7
ddd5	IIRA PreE	3.7
ddd6	IIRA PreE	3.7

ddd7	IIRA PreE	3.7
ddd8	IIRA PreE	3.7
ddd9	IIRA PreE	3.7
eee1	IIRA PreE	3.7
eee2	IIRA PreE	3.7
eee3	IIRA PreE	3.7
eee4	IIRA PreE	3.7
eee5	IIRA PreE	3.7
eee6	IIRA PreE	3.7
eee7	IIRA PreE	3.7
eee8	IIRA PreE	3.7
eee9	IIRA PreE	4
fff1	IIRA PreE	4
fff2	IIRA PreE	4
fff3	IIRA PreE	4
fff4	IIRA PreE	4
fff5	IIRA PreE	4
fff6	IIRA PreE	4
fff7	IIRA PreE	4
fff8	IIRA PreE	4
fff9	IIRA PreE	4
ggg1	IIRA PreE	4
ggg2	IIRA PreE	4
ggg3	IIRA PreE	4
ggg4	IIRA PreE	4
ggg5	IIRA PreE	4
ggg6	IIRA PreE	4
ggg7	IIRA PreE	4
ggg8	IIRA PreE	4
ggg9	IIRA PreE	4
hhh1	IIRA PreE	4
hhh2	IIRA PreE	4
hhh3	IIRA PreE	4
hhh4	IIRA PreE	4
hhh5	IIRA PreE	4
hhh6	IIRA PreE	4
hhh7	IIRA PreE	4
hhh8	IIRA PreE	4
hhh9	IIRA PreE	4
iii1	IIRA PreE	4

iii2	IIRA PreE	4
iii3	IIRA PreE	4
iii4	IIRA PreE	4
iii5	IIRA PreE	4.3
iii6	IIRA PreE	4.3
iii7	IIRA PreE	4.3
iii9	IIRA PreE	4.3
jjj1	IIRA PreE	4.3
jjj2	IIRA PreE	4.3
jjj3	IIRA PreE	4.3
jjj4	IIRA PreE	4.3
jjj5	IIRA PreE	4.3
jjj6	IIRA PreE	4.3
jjj7	IIRA PreE	4.3
jjj8	IIRA PreE	4.3
jjj9	IIRA PreE	4.3
III1	IIRA PreE	4.3
III2	IIRA PreE	4.3
III3	IIRA PreE	4.3
III4	IIRA PreE	4.3
III5	IIRA PreE	4.3
III6	IIRA PreE	4.3
III7	IIRA PreE	4.3
III8	IIRA PreE	4.3
III9	IIRA PreE	4.3
mmm1	IIRA PreE	4.3
mmm2	IIRA PreE	4.3
mmm3	IIRA PreE	4.3
mmm4	IIRA PreE	4.3
mmm5	IIRA PreE	4.3
mmm6	IIRA PreE	4.3
mmm7	IIRA PreE	4.3
mmm8	IIRA PreE	4.3
mmm9	IIRA PreE	4.3
nnn1	IIRA PreE	4.3
nnn2	IIRA PreE	4.3
nnn3	IIRA PreE	4.3
nnn4	IIRA PreE	4.3
nnn5	IIRA PreE	4.3
nnn6	IIRA PreE	4.3

nnn7	IIRA PreE	4.3
nnn8	IIRA PreE	4.7
nnn9	IIRA PreE	4.7
ooo1	IIRA PreE	4.7
ooo2	IIRA PreE	4.7
ooo3	IIRA PreE	4.7
ooo4	IIRA PreE	4.7
ooo5	IIRA PreE	4.7
ooo6	IIRA PreE	4.7
ooo7	IIRA PreE	4.7
ooo8	IIRA PreE	4.7
ooo9	IIRA PreE	4.7
ppp1	IIRA PreE	4.7
ppp2	IIRA PreE	4.7
ppp3	IIRA PreE	4.7
ppp4	IIRA PreE	4.7
ppp5	IIRA PreE	4.7
ppp6	IIRA PreE	4.7
ppp7	IIRA PreE	4.7
ppp8	IIRA PreE	4.7
ppp9	IIRA PreE	4.7
qqq1	IIRA PreE	4.7
qqq2	IIRA PreE	4.7
qqq3	IIRA PreE	4.7
qqq4	IIRA PreE	4.7
qqq5	IIRA PreE	4.7
qqq6	IIRA PreE	4.7
qqq7	IIRA PreE	4.7
qqq8	IIRA PreE	4.7
qqq9	IIRA PreE	4.7
rrr1	IIRA PreE	4.7
rrr2	IIRA PreE	4.7
rrr3	IIRA PreE	5
rrr4	IIRA PreE	5
rrr5	IIRA PreE	5
rrr6	IIRA PreE	5
rrr7	IIRA PreE	5
rrr8	IIRA PreE	5
rrr8	IIRA PreE	5
sss1	IIRA PreE	5

sss2	IIRA PreE	5
sss3	IIRA PreE	5
sss4	IIRA PreE	5
sss5	IIRA PreE	5
sss6	IIRA PreE	5
sss7	IIRA PreE	5
sss8	IIRA PreE	5
sss9	IIRA PreE	5
ttt1	IIRA PreE	5
ttt2	IIRA PreE	5
ttt3	IIRA PreE	5
ttt4	IIRA PreE	5
ttt5	IIRA PreE	5
ttt6	IIRA PreE	5
ttt7	IIRA PreE	5
ttt8	IIRA PreE	5
ttt9	IIRA PreE	5
uuu1	IIRA PreE	5
uuu2	IIRA PreE	5
uuu3	IIRA PreE	5
uuu4	IIRA PreE	5
uuu5	IIRA PreE	5
uuu6	IIRA PreE	5
uuu7	IIRA PreE	5
uuu8	IIRA PreE	5
uuu9	IIRA PreE	5
vvv1	IIRA PreE	5
vvv2	IIRA PreE	5
vvv3	IIRA PreE	5
vvv4	IIRA PreE	5
vvv5	IIRA PreE	5
vvv6	IIRA PreE	5
vvv7	IIRA PreE	5
vvv8	IIRA PreE	5
vvv9	IIRA PreE	5.3
www1	IIRA PreE	5.3
www2	IIRA PreE	5.3
www3	IIRA PreE	5.3
www4	IIRA PreE	5.3
www5	IIRA PreE	5.3

www6	IIRA PreE	5.3
www7	IIRA PreE	5.3
www8	IIRA PreE	5.3
www9	IIRA PreE	5.3
xxx1	IIRA PreE	5.3
xxx2	IIRA PreE	5.3
xxx3	IIRA PreE	5.3
xxx4	IIRA PreE	5.3
xxx5	IIRA PreE	5.3
xxx6	IIRA PreE	5.3
xxx7	IIRA PreE	5.3
xxx8	IIRA PreE	5.3
xxx9	IIRA PreE	5.3
yyy1	IIRA PreE	5.3
yyy2	IIRA PreE	5.3
yyy3	IIRA PreE	5.5
yyy4	IIRA PreE	5.5
yyy5	IIRA PreE	5.5
yyy6	IIRA PreE	5.5
yyy7	IIRA PreE	5.5
yyy8	IIRA PreE	5.7
yyy9	IIRA PreE	5.7
zzz1	IIRA PreE	5.7
zzz2	IIRA PreE	5.7
zzz3	IIRA PreE	5.7
zzz4	IIRA PreE	5.7
zzz5	IIRA PreE	5.7
zzz6	IIRA PreE	5.7
zzz7	IIRA PreE	5.7
zzz8	IIRA PreE	5.7
zzz9	IIRA PreE	5.7
aaaa1	IIRA PreE	5.7
aaaa2	IIRA PreE	5.7
aaaa3	IIRA PreE	5.7
aaaa4	IIRA PreE	5.7
aaaa5	IIRA PreE	5.7
aaaa6	IIRA PreE	5.7
aaaa7	IIRA PreE	5.7
aaaa8	IIRA PreE	5.7
aaaa9	IIRA PreE	5.7

bbbb1	IIRA PreE	6
bbbb2	IIRA PreE	6
bbbb3	IIRA PreE	6
bbbb4	IIRA PreE	6
bbbb5	IIRA PreE	6
bbbb6	IIRA PreE	6
bbbb7	IIRA PreE	6
bbbb8	IIRA PreE	6
bbbb9	IIRA PreE	6
cccc1	IIRA PreE	6
cccc2	IIRA PreE	6
cccc3	IIRA PreE	6
cccc4	IIRA PreE	6
cccc5	IIRA PreE	6
cccc6	IIRA PreE	6
cccc7	IIRA PreE	6.3
cccc8	IIRA PreE	6.3
cccc9	IIRA PreE	6.3
dddd1	IIRA PreE	6.3
dddd2	IIRA PreE	6.3
dddd3	IIRA PreE	6.3
dddd4	IIRA PreE	6.3
dddd5	IIRA PreE	6.3
dddd6	IIRA PreE	6.3
dddd7	IIRA PreE	6.3
dddd8	IIRA PreE	6.7
dddd9	IIRA PreE	6.7
eeee1	IIRA PreE	6.7
eeee2	IIRA PreE	6.7
eeee3	IIRA PreE	6.7
eeee4	IIRA PreE	7
eeee5	IIRA PreE	7.3

Individual Investigator Research Award—Final Scores for Fully Reviewed Applications

Application ID	Mechanism	Overall Score
RP140244*	IIRA	1
RP140412*	IIRA	1.1
RP140597*	IIRA	1.3
RP140655*	IIRA	1.4
RP140606*	IIRA	1.6
RP140402*	IIRA	1.9
RP140672*	IIRA	1.9
RP140462*	IIRA	1.9
RP140464*	IIRA	1.9
RP140132*	IIRA	1.9
RP140469*	IIRA	2
RP140612*	IIRA	2
RP140323*	IIRA	2
RP140408*	IIRA	2
RP140285*	IIRA	2
RP140517*	IIRA	2
RP140181*	IIRA	2.1
RP140252*	IIRA	2.1
RP140262*	IIRA	2.1
RP140784*	IIRA	2.1
RP140556*	IIRA	2.1
RP140298*	IIRA	2.1
RP140152*	IIRA	2.1
RP140218*	IIRA	2.1
RP140233*	IIRA	2.1
RP140522*	IIRA	2.1
RP140648*	IIRA	2.2
RP140452*	IIRA	2.2
RP140001*	IIRA	2.3
RP140468*	IIRA	2.3
RP140271*	IIRA	2.4
RP140140*	IIRA	2.4
RP140482*	IIRA	2.4
RP140141*	IIRA	2.4

*=Recommended for Funding

RP140179*	IIRA	2.5
RP140430*	IIRA	2.5
RP140563*	IIRA	2.5
RP140224*	IIRA	2.5
RP140315*	IIRA	2.5
RP140222*	IIRA	2.6
RP140685*	IIRA	2.6
RP140500*	IIRA	2.6
RP140842*	IIRA	2.7
RP140544*	IIRA	2.7
RP140456*	IIRA	2.8
RP140515*	IIRA	2.8
RP140399*	IIRA	2.8
RP140367*	IIRA	2.9
RP140661*	IIRA	2.9
RP140800*	IIRA	3
RP140473*	IIRA	3
RP140542*	IIRA	3
RP140594*	IIRA	3
RP140553*	IIRA	3.1
RP140411*	IIRA	3.1
RP140429*	IIRA	3.1
RP140616*	IIRA	3.1
RP140258*	IIRA	3.1
a1	IIRA	3.3
a2	IIRA	3.3
a3	IIRA	3.3
a4	IIRA	3.4
a5	IIRA	3.4
a6	IIRA	3.4
a7	IIRA	3.4
RP140143*	IIRA	3.5
a8	IIRA	3.5
a9	IIRA	3.5
RP140609*	IIRA	3.5
b1	IIRA	3.5
RP140767*	IIRA	3.5
b2	IIRA	3.5
b3	IIRA	3.6
b4	IIRA	3.6

*=Recommended for Funding

b5	IIRA	3.6
b6	IIRA	3.6
b7	IIRA	3.7
b8	IIRA	3.7
b9	IIRA	3.7
c1	IIRA	3.7
c2	IIRA	3.7
c3	IIRA	3.7
c4	IIRA	3.7
c5	IIRA	3.7
c6	IIRA	3.7
c7	IIRA	3.7
c8	IIRA	3.8
c9	IIRA	3.8
d1	IIRA	3.8
d2	IIRA	3.8
d3	IIRA	3.8
d4	IIRA	3.8
d5	IIRA	3.9
d6	IIRA	3.9
d7	IIRA	3.9
d8	IIRA	3.9
d9	IIRA	4
e1	IIRA	4
e2	IIRA	4
e3	IIRA	4
e4	IIRA	4
e5	IIRA	4
e6	IIRA	4
e7	IIRA	4
e8	IIRA	4
e9	IIRA	4
f1	IIRA	4
f2	IIRA	4
f3	IIRA	4
f4	IIRA	4
f5	IIRA	4
f6	IIRA	4
f7	IIRA	4
f8	IIRA	4

*=Recommended for Funding

f9	IIRA	4
g1	IIRA	4
g2	IIRA	4
g3	IIRA	4
g4	IIRA	4
g5	IIRA	4
g6	IIRA	4.1
g7	IIRA	4.1
g8	IIRA	4.1
g9	IIRA	4.1
h1	IIRA	4.1
h2	IIRA	4.1
h3	IIRA	4.1
h4	IIRA	4.2
h5	IIRA	4.2
h6	IIRA	4.2
h7	IIRA	4.2
h8	IIRA	4.2
h9	IIRA	4.2
i1	IIRA	4.2
i2	IIRA	4.2
i3	IIRA	4.2
i4	IIRA	4.2
i5	IIRA	4.3
i6	IIRA	4.3
i7	IIRA	4.3
i8	IIRA	4.3
i9	IIRA	4.3
j1	IIRA	4.3
j2	IIRA	4.3
j3	IIRA	4.3
j4	IIRA	4.3
j5	IIRA	4.3
j6	IIRA	4.3
j7	IIRA	4.3
j8	IIRA	4.3
j9	IIRA	4.3
k1	IIRA	4.3
k2	IIRA	4.3
k3	IIRA	4.3

*=Recommended for Funding

k4	IIRA	4.3
k5	IIRA	4.3
k6	IIRA	4.3
k7	IIRA	4.3
k8	IIRA	4.3
k9	IIRA	4.3
l1	IIRA	4.3
l2	IIRA	4.3
l3	IIRA	4.3
l4	IIRA	4.3
l5	IIRA	4.3
l6	IIRA	4.3
l7	IIRA	4.3
l8	IIRA	4.5
l9	IIRA	4.5
m1	IIRA	4.6
m2	IIRA	4.6
m3	IIRA	4.6
m4	IIRA	4.6
m5	IIRA	4.6
m6	IIRA	4.6
m7	IIRA	4.7
m8	IIRA	4.7
m9	IIRA	4.7
n1	IIRA	4.7
n2	IIRA	4.7
n3	IIRA	4.7
n4	IIRA	4.7
n5	IIRA	4.7
n6	IIRA	4.7
n7	IIRA	4.7
n8	IIRA	4.7
n9	IIRA	4.8
o1	IIRA	4.8
o2	IIRA	4.9
o3	IIRA	4.9
o4	IIRA	4.9
o5	IIRA	4.9
o6	IIRA	5
o7	IIRA	5

*=Recommended for Funding

o8	IIRA	5
o9	IIRA	5
p1	IIRA	5
p2	IIRA	5
p3	IIRA	5
p4	IIRA	5.1
p5	IIRA	5.1
p6	IIRA	5.1
p7	IIRA	5.2
p8	IIRA	5.3
p9	IIRA	5.3
q1	IIRA	5.3
q2	IIRA	5.3
q3	IIRA	5.3
q4	IIRA	5.3
q5	IIRA	5.4
q6	IIRA	5.4
q7	IIRA	5.5
q8	IIRA	5.7
q9	IIRA	5.7
r1	IIRA	5.7
r2	IIRA	6
r3	IIRA	6

*=Recommended for Funding

Final Overall Evaluation Scores and Rank Order Scores

Ludwig Institute for
Cancer Research Ltd

June 24, 2014

**Richard D. Kolodner
Ph.D.**

Head, Laboratory of
Cancer Genetics
San Diego Branch

Senior Advisor on Academic
Affairs
New York Office

Distinguished Professor of
Medicine, University of
California San Diego

rkolodner@ucsd.edu

San Diego Branch
Univ of California San Diego
CMM-East / Rm 3058
9500 Gilman Dr - MC 0669
La Jolla, CA 92093-0669

T 858 534 7804
F 858 534 7750

New York Office
28th Floor
666 Third Avenue
New York, NY 10017

T 212 450 1500
F 212 450 1555

William Rice, M.D.
Oversight Committee Chair
Cancer Prevention and Research Institute of Texas
Via email to Bill.Rice@stdavids.com

Wayne R. Roberts
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cprit.state.tx.us

Dear Dr. Rice and Mr. Roberts,

The Scientific Review Council (SRC) is pleased to submit this list of research grant recommendations for the **Individual Investigator Research Awards (IIRA) and High-Impact/High-Risk Research Awards (HIHR)**. The SRC met on Tuesday, June 24, 2014 to consider the applications recommended by the peer review panels following their meetings that were held between May 26 and June 11, 2014. The projects on the attached list are numerically ranked in the order the SRC recommends the applications be funded. Recommended funding amounts and the overall evaluation score are stated for each grant application. The SRC accepted the recommendations of the peer review panels concerning adjustments to three grant applications. These adjustments are listed at the end of the list of recommended projects.

These recommendations meet the SRC's standards for grant award funding. These standards include selecting innovative research projects addressing critically important questions that will significantly advance knowledge of the causes, prevention, and/or treatment of cancer, and exceptional potential for achieving future impact in basic, translational, population-based, or clinical research.

Sincerely yours,



Richard D. Kolodner
Chair, Scientific Review Council

Attachment

Rank	App ID	Award Mechanism	Organization	Application Title	Budget	Meeting Overall Score
1	RP140244	IIRA	The University of Texas M. D. Anderson Cancer Center	Regulation of MDM2-mediated oncogenesis and anti-tumor immunity by USP15	\$870,156	1.0
2	RP140412	IIRA	The University of Texas Southwestern Medical Center	Endotrophin and the Obesity/Cancer Nexus: Role in Growth and Chemoresistance	\$899,997	1.1
3	RP140597	IIRA	The University of Texas M. D. Anderson Cancer Center	Role of TJP1 in Sensitivity and Resistance to Proteasome Inhibitors in Myeloma	\$900,000	1.3
4	RP140655	IIRA	The University of Texas Southwestern Medical Center	Evaluation of the role of tumor suppressor candidate NPRL2 in cell growth control	\$596,265	1.4
5	RP140350	HIHR	Baylor College of Medicine	Integrated Human Herpesvirus 6 as a Novel Heritable Risk Factor for Glioma	\$199,298	1.6
6	RP140606	IIRA	The University of Texas M. D. Anderson Cancer Center	Optimizing therapy for glioblastoma through genomic profiling of treatment failure	\$900,000	1.6
7	RP140672	IIRA	The University of Texas Southwestern Medical Center	Mutant KRAS reprograms lipid metabolism exposing beta-oxidation as a novel therapeutic target in lung cancer lung cancer	\$687,759	1.9
8	RP140402	IIRA	The University of Texas Southwestern Medical Center	Novel targets for acute myeloid leukemia treatment	\$900,000	1.9
9*	RP140464	IIRA	The University of Texas M. D. Anderson Cancer Center	Next Generation Sequencing and Transcriptome Profiling of Oral Potentially Malignant Lesions to Identify Markers of Cancer Risk and Targets for Chemoprevention	\$900,000	1.9
10	RP140612	IIRA	The University of Texas M. D. Anderson Cancer Center	Collateral Genomic Deletions As Targetable Vulnerabilities in Cancer	\$900,000	2.0
11	RP140469	IIRA	Baylor College of Medicine	Novel Small Molecule Probes Targeting IDH Mutated Glioma	\$695,527	2.0
12	RP140323	IIRA	The University of Texas M. D. Anderson Cancer Center	Role of a novel histone variant-specific epigenetic reader ZMYND11 in breast cancer	\$899,534	2.0
13	RP140408	IIRA	The University of Texas M. D. Anderson Cancer Center	Identificaion of a novel mechanism of mTORC1 and autophagy regulation for cancer therapy.	\$900,000	2.0
14	RP140462	IIRA	The University of Texas M. D. Anderson Cancer Center	Systematic Investigation of Clinically Relevant Expressed Pseudogenes in Cancer	\$870,539	2.0
15	RP140132	IIRA	Rice University	Towards Point-of-Care Nucleic Acid Cancer Diagnostics	\$900,000	2.0
16	RP140517	IIRA	The University of Texas at Dallas	Optimal Biomarkers for Personalized Cancer Therapy: A Network-Based Approach	\$490,689	2.0
17	RP140285	IIRA	The University of Texas Southwestern Medical Center	Noninvasive Identification of Prostate Tumor Hypoxia as a Prognostic Biomarker of Radiation Response	\$895,820	2.0
18	RP140664	HIHR	The University of Texas at Austin	Development of therapeutic antibodies having both Fc[gamma] and Fc[Alpha] effector functions and displaying potent cancer cell killing.	\$200,000	2.0
19	RP140329	HIHR	The University of Texas M. D. Anderson Cancer Center	Opening the central nervous system to immunotherapy by blocking TREK1	\$198,957	2.1
20	RP140181	IIRA	Baylor College of Medicine	Mechanisms of CTC Biomarkers in Breast Cancer Brain Metastasis	\$899,968	2.1
21	RP140252	IIRA	Baylor College of Medicine	Investigating and preclinical targeting molecular drivers of muscle-invasive bladder cancer	\$827,451	2.1
22	RP140262	IIRA	The University of Texas M. D. Anderson Cancer Center	Intrinsic Reward Sensitivity & Smoking Cessation with Varenicline or Patch NRT	\$899,505	2.1

23	RP140784	IIRA	Baylor Research Institute	Next Generation Sequencing-Based Approaches for the Development of Epigenetic Biomarkers for Predicting Therapeutic Outcome in Patients with Colorectal Cancer	\$886,982	2.1
24	RP140556	IIRA	The University of Texas M. D. Anderson Cancer Center	DNA methylation and telomere length in peripheral blood as predictors of aggressive prostate cancer	\$898,721	2.1
25	RP140298	IIRA	Texas Tech University	Engineering microfluidic devices for multimodal mechanical phenotyping of tumor cells in flow	\$674,465	2.1
26	RP140152	IIRA	The University of Texas Southwestern Medical Center	Natural Product for Treatment of Non-Small Cell Lung Cancer	\$772,368	2.1
27	RP140218	IIRA	The University of Texas M. D. Anderson Cancer Center	Inhibiting Oxidative Phosphorylation: A Novel Strategy in Leukemia	\$826,744	2.1
28	RP140522	IIRA	The University of Texas M. D. Anderson Cancer Center	Reversing vaccination-induced impairment of anti-CTLA-4-based cancer therapy.	\$899,991	2.1
29	RP140233	IIRA	The University of Texas Southwestern Medical Center	Structure-guided Kinase Inhibitor Design for Cancer Therapy	\$900,000	2.1
30	RP140648	IIRA	The University of Texas at Austin	New Therapeutic Strategies for Metastatic Melanoma	\$900,000	2.2
31	RP140452	IIRA	The University of Texas Health Science Center at San Antonio	Inactivating mutation of D2HGDH establishes a novel link between metabolism, alpha-KG dependent dioxygenases and epigenetic reprogramming in B cell lymphoma	\$854,740	2.2
32	RP140840	HIHR	Texas Tech University	New Technology for Ultra High Throughput Enumeration of Circulating Tumor Cells	\$199,993	2.2
33**	RP140001	IIRA	Baylor College of Medicine	Role of DNA METHYLTRANSFERASE 3A in Hematologic Malignancies	\$900,000	2.3
34	RP140468	IIRA	The University of Texas M. D. Anderson Cancer Center	TARGETING OF CHRONIC LYMPHOCYTIC LEUKEMIA BY DESIGNER T CELLS	\$900,000	2.3
35	RP140449	HIHR	The University of Texas Southwestern Medical Center	A new Cancer Target: AMPylation machinery	\$200,000	2.4
36	RP140271	IIRA	The University of Texas M. D. Anderson Cancer Center	Targeting p53 in cancer through manipulation of p63 and p73	\$900,000	2.4
37	RP140140	IIRA	The University of Texas Southwestern Medical Center	Turn ON the Tumor Contrast for Surgical Resection of Head and Neck Cancers	\$900,000	2.4
38	RP140482	IIRA	The University of Texas M. D. Anderson Cancer Center	Preclinical Intravital Microscopy of Prostate Cancer Lesions in Bone: Identification and Eradication of Survival Niches by Combination Therapy	\$256,061	2.4
39	RP140141	IIRA	The University of Texas Southwestern Medical Center	Targeting HER2 for cancer therapy	\$892,989	2.4
40	RP140179	IIRA	Baylor College of Medicine	Targeting self-renewal in leukemic stem cells through the inactivation of KLF4	\$813,789	2.5
41	RP140430	IIRA	The University of Texas M. D. Anderson Cancer Center	Synaptic Mechanisms of Cognitive Decline after Cranial Radiation	\$836,557	2.5
42	RP140563	IIRA	The University of Texas M. D. Anderson Cancer Center	PAF, a Novel Wnt Signaling Regulator, in Colorectal Cancer	\$900,000	2.5
43	RP140223	HIHR	Baylor College of Medicine	Viral MicroRNAs in Ovarian Cancer Growth and Metastasis	\$199,995	2.5
44	RP140224	IIRA	The University of Texas M. D. Anderson Cancer Center	PPAR-delta Regulation of Wnt/B-catenin to Drive Colon Cancer	\$890,003	2.5
45	RP140315	IIRA	The Methodist Hospital Research Institute	Accurate and High Throughput Detection of Breast and Ovarian Cancer Cells in Whole Blood	\$900,000	2.5

46	RP140649	HIHR	The University of Texas at Austin	Realizing Personalized and Precision Medicine for Melanoma: A Rapid Assay for Measuring ERK Activity	\$200,000	2.5
47	RP140222	IIRA	The University of Texas M. D. Anderson Cancer Center	Direct Roles for RB and E2F1 in DNA Repair	\$900,000	2.6
48	RP140685	IIRA	The University of Texas Health Science Center at San Antonio	Modulation of autophagy: Phase II study of vorinostat plus hydroxychloroquine vs. regorafenib in refractory metastatic colorectal cancer (mCRC)	\$825,285	2.6
49	RP140500	IIRA	The University of Texas M. D. Anderson Cancer Center	Realizing Personalized and Precision Medicine for Melanoma: A Rapid Assay for Measuring ERK Activity	\$900,000	2.6
50	RP140216	HIHR	Baylor College of Medicine	Context-Specific In Vivo Screening for KRAS-Associated Gene Aberration Drivers Using Genetically Engineered Mouse Models of Lung Cancer	\$199,715	2.7
51	RP140842	IIRA	The University of Texas at Austin	Determining the Functional Role of microRNAs in Viral Tumorigenesis.	\$604,624	2.7
52	RP140478	HIHR	Texas Tech University	Computational Chemistry Determination of DNA Damage Mechanisms in Proton Cancer Therapy to Optimize Its Clinical Use	\$200,000	2.7
53	RP140544	IIRA	The University of Texas at Dallas	Mapping Acidic Tumor Microenvironment with Renal Clearable pH Nanoindicators	\$900,000	2.7
54***	RP140456	IIRA	Baylor College of Medicine	Role of DNA2 Nuclease in Cellular Tolerance of Replication Stress and Telomere Maintenance - Implications for Cancer Biology and Anticancer Therapy	\$746,531	2.8
55	RP140515	IIRA	The University of Texas M. D. Anderson Cancer Center	CDK Inhibitors as Adjunctive to 5-FU and/or Radiation in Esophageal Adenocarcinoma- Assessment of Efficacy and Predictive Biomarkers	\$882,133	2.8
56	RP140399	IIRA	Baylor University	Targeting Hypoxia in Breast Cancer with Highly Potent Small-Molecule Anticancer Prodrugs	\$900,000	2.8
57	RP140320	HIHR	The University of Texas Southwestern Medical Center	DISSECTING A Necrotic Signaling Pathway in Human Cancer Cells	\$200,000	2.9
58	RP140661	IIRA	The University of Texas Southwestern Medical Center	Analyses of the regulatory mechanisms of tankyrase and its role in tumorigenesis	\$876,751	2.9
59	RP140367	IIRA	The University of Texas Southwestern Medical Center	Targeting BRD4 in Breast Cancer	\$900,000	2.9
60	RP140678	HIHR	Scott & White Healthcare	Novel, humanized single-chain CD123xCD3 bispecific antibodies for eliminating leukemia stem cells and leukemic cells	\$199,959	2.9
61	RP140800	IIRA	The University of Texas Health Science Center at Houston	The Role of Alternative Polyadenylation in Glioblastoma Tumor Progression	\$848,491	3.0
62	RP140473	IIRA	The University of Texas Health Science Center at San Antonio	Investigation of the tumor suppressor TMEM127 on lysosome function and lipid metabolism	\$881,146	3.0
63	RP140542	IIRA	The University of Texas M. D. Anderson Cancer Center	Biology and Therapy of Basal Bladder Cancers	\$865,587	3.0
64	RP140594	IIRA	The University of Texas Health Science Center at San Antonio	microRNAs: safe and effective therapeutic adjuvants for treating drug resistant breast cancers	\$900,000	3.0
65	RP140479	HIHR	Texas A&M University	Screening for melanoma genes using natural hybrid incompatibilities	\$199,993	3.1
66	RP140435	HIHR	The University of Texas Health Science Center at San Antonio	SHH/GLI3 signaling axis as a therapeutic target in castration resistant prostate cancer	\$200,000	3.1

67	RP140553	IIRA	Baylor College of Medicine	Translational Discovery of Resistance Genes and Cancer Gene Functions	\$900,000	3.1
68	RP140616	IIRA	Baylor College of Medicine	Tenascin-C and Metastatic Prostate Cancer Progression	\$827,806	3.1
69	RP140429	IIRA	The University of Texas M. D. Anderson Cancer Center	The Role of DIRAS3 (ARHI) in Initiating Autophagy and Tumor Dormancy	\$900,000	3.1
70	RP140411	IIRA	The University of Texas M. D. Anderson Cancer Center	Targeting Tumor Cell Invasion in Glioblastoma	\$900,000	3.1
71	RP140258	IIRA	Baylor College of Medicine	The Intersection between Childhood Cancer and Congenital Anomalies: Identifying Novel Cancer Predisposition Syndromes	\$874,964	3.1
72	RP140781	HIHR	Texas A&M University	High-Field Open MRI: Cost-Effective Screening for Early Detection of Breast Cancer	\$200,000	3.3
73	RP140328	HIHR	The University of Texas at Austin	Synthetic protein degradation agents to clear oncogenic proteins from cells	\$199,852	3.5
74	RP140143	IIRA	The University of Texas Southwestern Medical Center	Dependence of small cell lung cancer on the basic helix-loop-helix transcription factors Ascl1 and NeuroD1	\$900,000	3.5
75	RP140767	IIRA	Baylor College of Medicine	Toll-like receptors, gut microbiota, and risk of colorectal adenoma	\$899,131	3.5
76	RP140609	IIRA	The University of Texas M. D. Anderson Cancer Center	A missing link between obesity and cancer: Adipose derived stem cells	\$610,704	3.5

*RP140464- Budget will be adjusted down during contracting to accommodate a change in the Scope of Work (removal of specific Aim 4) as recommended by the peer review panel. The total amount requested was \$900,000.

**RP140001 - Budget was reduced from \$1,167,880 to \$900,000. The RFA stated that requests in excess of the allowable amount must be well justified. In the opinion of the peer review panel, the request was not well justified.

***RP140456 - Budget was reduced from \$900,000 to \$746,531. The peer review panel recommended the deletion of x-ray crystallography work, resulting in a total reduction of \$120,000 (\$40,000 annually for three years).

**Ludwig Institute for
Cancer Research Ltd**

July 10, 2014

**Richard D. Kolodner
Ph.D.**

Head, Laboratory of
Cancer Genetics
San Diego Branch

Senior Advisor on Academic
Affairs
New York Office

Distinguished Professor of
Medicine, University of
California San Diego

rkolodner@ucsd.edu

San Diego Branch
Univ of California San Diego
CMM-East / Rm 3058
9500 Gilman Dr - MC 0669
La Jolla, CA 92093-0669

T 858 534 7804
F 858 534 7750

New York Office
28th Floor
666 Third Avenue
New York, NY 10017

T 212 450 1500
F 212 450 1555

William Rice, M.D.
Oversight Committee Chair
Cancer Prevention and Research Institute of Texas
Via email to Bill.Rice@stdavids.com

Wayne R. Roberts
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cprit.state.tx.us

Dear Dr. Rice and Mr. Roberts,

It has come to my attention that there were minor errors with three applications in the list of research grants recommended for the Individual Investigator Research Awards (IIRA) and High-Impact/High-Risk Research Awards (HIHR) that was provided on June 24, 2014. Below is a description of the errors:

RP140132 - The online scoring system, P²RMIS, rounded the score up from 1.9 to 2.0.

RP140462 - The online scoring system, P²RMIS, rounded the score up from 1.9 to 2.0.

RP140500 - The title of the application was listed as "Realizing Personalized and Precision Medicine for Melanoma: A Rapid Assay for Measuring ERK Activity", but should have been listed as "Toward the Cure of Myelodysplastic Syndrome: Interfering with Innate Immunity Alterations in Human and Mouse Systems".

These errors do not change the positive recommendation of the Scientific Research Council for the award of these three projects.

Sincerely yours,



Richard D. Kolodner
Chair, CPRIT Scientific Review Council



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CEO Affidavit Supporting Information

FY 2014 – Cycle 2
Recruitment of Established Investigator

Request for Applications



**CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS**

REQUEST FOR APPLICATIONS

RFA R-14-REI-1

**Recruitment of
Established Investigators**

**Please also refer to the Instructions for Applicants document,
which will be posted on March 3, 2014.**

Application Receipt Opening Date: March 3, 2014

FY 2014

Fiscal Year Award Period

September 1, 2013–August 31, 2014

TABLE OF CONTENTS

1. ABOUT CPRIT	4
2. RATIONALE	4
3. RECRUITMENT OBJECTIVES.....	5
4. FUNDING INFORMATION	6
5. ELIGIBILITY	7
6. RESPONDING TO THIS RFA	8
6.1. APPLICATION SUBMISSION GUIDELINES	8
6.2. APPLICATION COMPONENTS	9
6.2.1. <i>Summary of Nomination (2,000 characters)</i>	9
6.2.2. <i>Recruitment Activities/Institutional Commitment (two pages)</i>	9
6.2.3. <i>Curriculum Vitae (CV)</i>	10
6.2.4. <i>Summary of Goals and Objectives</i>	10
6.2.5. <i>Research (four pages)</i>	10
6.2.6. <i>Publications</i>	11
6.2.7. <i>Timeline (one page)</i>	11
6.2.8. <i>Current and Pending Support</i>	11
6.2.9. <i>Research Environment (one page)</i>	11
6.2.10. <i>Descriptive Biography (Up to two pages)</i>	12
7. APPLICATION REVIEW	12
7.1. REVIEW PROCESS	12
7.2. CONFIDENTIALITY OF REVIEW	13
7.3. REVIEW CRITERIA	14
8. KEY DATES.....	15
9. AWARD ADMINISTRATION.....	15
10. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS.....	16
11. CONTACT INFORMATION.....	16
11.1. HELPDESK	16
11.2. SCIENTIFIC AND PROGRAMMATIC QUESTIONS	17

RFA VERSION HISTORY

- Rev 1/15/14 RFA release
- Rev 2/21/14 Application Receipt opening date March 3, 2014
- Rev 2/21/14 Revised Section 6.1 Application Submission Guidelines
- Added application receipt opening and closing dates
- Rev 2/21/14 Revised Section 6.2.4 Goals and Objectives
- “Goals and Objectives” changed to “Summary of Goals and Objectives”
- Rev 2/21/14 Revised Section 6.2.7 Timeline
- Added page limit: one page
- Rev 2/21/14 Revised Section 8. Key Dates
- Added Application Receipt and Review Timeline
- Rev 2/23/14 Revised Section 7.1 Review Process
- Revised sentence: “Applications may be submitted continuously in response to this RFA, but will generally be reviewed on a quarterly basis by the CPRIT Scientific Review Council.”

1. ABOUT CPRIT

The State of Texas has established the Cancer Prevention and Research Institute of Texas (CPRIT), which may issue up to \$3 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature and the citizens of Texas to:

- Create and expedite innovation in the area of cancer research and product or service development, thereby enhancing the potential for a medical or scientific breakthrough in the prevention, treatment, and possible cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the State of Texas; and
- Continue to develop and implement the Texas Cancer Plan by promoting the development and coordination of effective and efficient statewide public and private policies, programs, and services related to cancer and by encouraging cooperative, comprehensive, and complementary planning among the public, private, and volunteer sectors involved in cancer prevention, detection, treatment, and research.

CPRIT furthers cancer research in Texas by providing financial support for a wide variety of projects relevant to cancer research.

2. RATIONALE

The aim of this award mechanism is to bolster cancer research in Texas by providing financial support to attract world class research scientists with distinguished professional careers to Texas universities and cancer research institutes to establish research programs that add research talent to the State. This award will support established academic leaders whose body of work has made an outstanding contribution to cancer research. Awards are intended to provide institutions with a competitive edge in recruiting the world's best talent in cancer research, thereby advancing cancer research efforts and promoting economic development in the State of Texas. The recruitment of outstanding scientists will greatly enhance programs of scientific excellence in cancer research and will position Texas as a leader in the fight against cancer.

Applications may address any research topic related to cancer biology, causation, prevention, detection or screening, or treatment.

3. RECRUITMENT OBJECTIVES

The goal of this award mechanism is to recruit exceptional faculty to universities and/or cancer research institutions in the State of Texas. This award honors outstanding senior investigators with proven track records of research accomplishments combined with excellence in leadership and teaching. All candidates should be recognized research or clinical investigators, held in the highest esteem by professional colleagues nationally and internationally, whose contributions have had a significant influence on their discipline and, likely, beyond. They must have clearly established themselves as exemplary faculty members with exceptional accomplishments in teaching and advising and/or basic, translational, population-based, or clinical cancer research activities. It is expected that the candidate will contribute significantly to and have a major impact on the institution's overall cancer research initiative. Candidates will be leaders capable of initiating and developing creative ideas leading to novel solutions related to cancer detection, diagnosis, and/or treatment. They are also expected to maintain and lead a strong research group and have a stellar, high-impact publication portfolio, as well as continue securing external funding. Furthermore, recipients will lead and inspire undergraduate and graduate students interested in pursuing research careers and will engage in collegial and collaborative relationships with others within and beyond their traditional discipline in an effort to expand the boundaries of cancer research.

Funding will be given for exceptional candidates who will continue to develop new research methods and techniques in the life, population-based, physical, engineering, or computational sciences and apply them to solving outstanding problems in cancer research that have been inadequately addressed or for which there may be an absence of an established paradigm or technical framework. Ideal candidates will have specific expertise in cancer-related areas needed to address an institutional priority. Candidates should be at the career level of a full professor or equivalent. This funding mechanism considers expertise, accomplishments, and breadth of experience as vital metrics for guiding CPRIT's investment in that person's originality, insight, and potential for continued contribution.

Unless prohibited by policy, the institution is also expected to bestow on the newly recruited faculty member the prestigious title of “CPRIT Scholar in Cancer Research,” and the faculty member should be encouraged strongly to use this title on letterhead, business cards, and other appropriate documents. The title is to be retained as long as the individual remains in Texas.

4. FUNDING INFORMATION

This is a 5-year award and is not renewable. Grant support will be awarded based upon the breadth and nature of the research program proposed. Grant funds of up to \$6 million (total costs) for the 5-year period may be requested. Exceptions to this limit will be entertained only if there is compelling written justification. The award request may include indirect costs of up to 5 percent of the total award amount (5.263 percent of the direct costs). CPRIT will make every effort to be flexible in the timing for disbursement of funds; recipients will be asked at the beginning of each year for an estimate of their needs for the year. Funds may not be carried over beyond 5 years. In addition, funds for extraordinary equipment needs may be awarded in the first year of the grant if very well justified. **Grant funds may be used for salary support of this candidate but may not be used to construct or renovate laboratory space.** Consistent with the statutory mandate that the recipient institution demonstrate that it has funds equivalent to one-half of the total grant award amount dedicated to the individual recruited, a total institutional commitment of 50 percent of the total award will be required. The institutional commitment can be made on a year-by-year basis and may be fulfilled by demonstrating funds dedicated to salary support and endowment for the individual recruited as well as expenses for research support, laboratory renovation, and/or relocation to Texas. Grant funding from other sources that the recruited individual may bring with him or her to the institution may also be counted toward the amount necessary for the institutional commitment. No annual limit on the number of potential award recipients has been set.

5. ELIGIBILITY

- The applicant must be a Texas-based entity. Any not-for-profit institution that conducts research is eligible to apply for funding under this award mechanism. A public or private company is not eligible for funding under this award mechanism.
- Candidates must be nominated by the president, provost, or appropriate dean of a Texas-based public or private institution of higher education, including academic health institutions. The application must be submitted on behalf of a specific candidate.
- A candidate may be nominated by only one institution. If more than one institution is interested in a given candidate, negotiations as to which institution will nominate him or her must be concluded before the nomination is made.
- Candidates who have already accepted a position at the recruiting institution are not eligible for a recruitment award as an investment by CPRIT is obviously not necessary. Such individuals may, however, apply for other CPRIT grant awards, as appropriate.
- The candidate must have a doctoral degree, including M.D., Ph.D., D.D.S., D.M.D., Dr.P.H., D.O., D.V.M., or equivalent, and reside in Texas for the duration of the appointment. The candidate must devote at least 70 percent time to research activities. Candidates whose major responsibilities are clinical care, teaching or administration are not eligible.
- At the time of the application, the candidate should hold an appointment at the rank of professor (or equivalent) at an accredited academic institution, research institution, industry, government agency, or private foundation not primarily based in Texas. The candidate must not reside in Texas at the time the application is submitted.
- An applicant is eligible to receive a grant award only if the applicant certifies that the applicant institution or organization, including the nominator, any senior member or key personnel listed on the grant application, and any officer or director of the grant applicant's institution or organization (or any person related to one or more of these individuals within the second degree of consanguinity or affinity), have not made and will not make a contribution to CPRIT or to any foundation specifically created to benefit CPRIT. Prior to final approval of an award, the candidate must provide the same certification.

- An applicant is not eligible to receive a CPRIT grant award if the applicant nominator, any senior member or key personnel listed on the grant application, and any officer or director of the grant applicant's institution or organization is related to a CPRIT Oversight Committee member. Prior to final approval of an award, the candidate must provide the same certification.
- The applicant must report whether the applicant institution or organization, the nominator, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, whether or not the individuals will receive salary or compensation under the grant award, are currently ineligible to receive Federal grant funds or have had a grant terminated for cause within 5 years prior to the submission date of the grant application. Prior to final approval of an award, the candidate must provide the same certification.
- CPRIT grants will be awarded by contract to successful applicants. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in [Section 9](#) and [Section 10](#). All statutory provisions and relevant administrative rules can be found at www.cprit.state.tx.us.

6. RESPONDING TO THIS RFA

6.1. Application Submission Guidelines

Applications must be submitted via the CPRIT Application Receipt System (CARS) (<https://CPRITGrants.org>). **Only applications submitted through this portal will be considered eligible for evaluation.** The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application is submitted. Candidates must be nominated by the institution's president, provost, or appropriate dean. The individual submitting the application (nominator) must create a user account in the system to start and submit an application. Furthermore, the Authorized Signing Official (ASO), who is the person authorized to sign and submit the application for the organization, and the Grants Contract/Office of Sponsored Projects Official, who is the individual who will manage the grant contract if an award is made, also must create a user account in CARS.

Applications will be accepted on a continuous basis and reviewed quarterly. To manage the timely review of nominations for each evaluation period, the application receipt system will open and close sequentially. For the most immediate submission period, nominations will be accepted beginning at 7 a.m. Central Time on March 3, 2014 and must be submitted by 3 p.m. Central Time on March 31, 2014. The next submission period will open on April 1, 2014. A complete timeline of review for this fiscal year is provided in [Section 8](#). **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

6.2. Application Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. Please refer to the *Instructions for Applicants* document for details that will be available when the application receipt system opens. Submissions that are missing one or more components or do not meet the eligibility requirements listed in [Section 5](#) will be administratively withdrawn without review.

6.2.1. Summary of Nomination (2,000 characters)

Provide a brief summary of the nomination. Include the candidate's name, organization from which the candidate is being recruited, and also the department and/or entity within the nominator's organization where the candidate will hold the faculty position.

6.2.2. Recruitment Activities/Institutional Commitment (two pages)

Describe the recruitment activities, strategies, and priorities that have led to nomination of this candidate. Describe the institutional commitment to the candidate, including total salary, institutional support of salary, endowment or other support, space, and all other agreements between the institution and the candidate. **The institutional commitment must state the total award amount requested.** Provide a brief job description for the candidate should recruitment be successful. This information should be supplied in the form of a letter signed by the applicant institution's president, provost, or appropriate dean. While scholars may engage in direct patient care activities and/or have some administrative, or teaching duties, at least 70 percent of the candidate's time must be available for research. Breach of this requirement will constitute grounds for discontinuation of funding.

The letter of institutional commitment must demonstrate the organization's commitment to bringing the candidate to Texas. The following guidelines should be used when outlining the institutional match in the letter. This information may be provided as part of paragraph text or as a tabular summary that states the approximate amounts assigned to each item.

- **Start-up Package:** Complete details including salary and fringe benefits, dedicated personnel, amounts for equipment and supplies, and/or infrastructure that will be offered to the candidate as part of the recruitment award.
- **Endowment Equivalents:** The principal of an endowment may not be included as part of the institutional match, but endowment income over the lifetime of the award may be included.
- **Rent:** Amount for recovery of occupying facility space (i.e., “rent”) is not a permitted institutional commitment item.
- **Caliber of Candidate:** The letter should include a description of the caliber of the candidate and justification of nomination of the candidate by the institution.
- **Description of Candidate Duties and Certification** that 70 percent time will be spent on research must be included.

6.2.3. Curriculum Vitae (CV)

Provide a complete CV and list of publications for the candidate.

6.2.4. Summary of Goals and Objectives

List very broad goals and objectives to be achieved during this award. **This section must be completed by the candidate.**

6.2.5. Research (four pages)

Summarize the key elements of the candidate's research accomplishments and provide an overview of the proposed research by outlining the background and rationale, hypotheses and aims, strategies, goals, and projected impact of the focus of the research program. Highlight the innovative aspects of this effort and place it into context with regard to what pressing problem in cancer will be addressed. **This section of the application must be prepared by the candidate. References cited in this section must be included within the stated page limit. Any appropriate citation format is acceptable; official journal abbreviations should be used.**

Candidates for CPRIT Scholar Awards must include the following signed statement at the end of this section. **Applications that do not contain this signed statement will be returned without review.**

“I understand that I do not need to have made a commitment to <*nominating institution*> before this application has been submitted. However, I also understand that only one Texas institution may nominate me for a CPRIT Recruitment Award, and this is the nomination that I have endorsed. Requests to change the recruiting institution during the recruitment process are inappropriate.”

6.2.6. Publications

Provide the five most significant publications that have resulted from the candidate’s research efforts. Publications should be uploaded as PDFs of full-text articles. Only articles that have been published or that have been accepted for publication (“in press”) should be submitted.

6.2.7. Timeline (one page)

Provide a general outline of anticipated major award outcomes to be tracked. Timelines will be reviewed during the evaluation of annual progress reports. If the application is approved for funding, this section will be included in the award contract. Applicants are advised not to include information that they consider confidential or proprietary when preparing this section.

6.2.8. Current and Pending Support

State the funding source, duration, and title of all current and pending research support held by the candidate. If the candidate has no current or pending funding, a document stating this must be submitted.

6.2.9. Research Environment (one page)

Briefly describe the research environment available to support the candidate’s research program, including core facilities, training programs, and collaborative opportunities.

6.2.10. Descriptive Biography (Up to two pages)

Provide a brief descriptive biography of the candidate, including his or her accomplishments, education and training, professional experience, awards and honors, publications relevant to cancer research, and a brief overview of the candidate's goals if selected to receive the award.

This section of the application must be prepared by the candidate. If the application is approved for funding, this section will be made publicly available on CPRIT's Web site.

Candidates are advised not to include information that they consider confidential or proprietary when preparing this section.

Applications that are missing one or more of these components, exceed the specified page, word, or budget limits, or do not meet the eligibility requirements listed above will be administratively withdrawn without review.

7. APPLICATION REVIEW

7.1. Review Process

All eligible applications will be evaluated and scored by the CPRIT Scientific Review Council using the criteria listed in this RFA. Applications may be submitted continuously in response to this RFA, but will generally be reviewed on a quarterly basis by the CPRIT Scientific Review Council. Council members may seek additional ad hoc evaluations of candidates. Scientific Review Council members will discuss applications and provide an individual Overall Evaluation Score that conveys the members' recommendation related to the proposed recruitment.

Applications approved by Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review, prioritization, and recommendation to the CPRIT Oversight Committee for approval and funding. Approval is based on an application receiving a positive vote from at least two-thirds of the members of the Oversight Committee. The review process is described more fully in CPRIT's Administrative Rules, Chapter 703, Sections 703.6–703.8.

The decision of the Scientific Review Council not to recommend an application is final, and such applications may not be resubmitted for a recruitment award. Notification of review decisions are sent to the nominator.

7.2. Confidentiality of Review

Each stage of application review is conducted confidentially, and all CPRIT Scientific Review Council members, Program Integration Committee members, CPRIT employees, and Oversight Committee members with access to grant application information are required to sign nondisclosure statements regarding the contents of the applications. All technological and scientific information included in the application is protected from public disclosure pursuant to Health and Safety Code §102.262(b).

Individuals directly involved with the review process operate under strict conflict of interest prohibitions. All CPRIT Scientific Review Council members are non-Texas residents.

By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed conflict of interest as set forth in CPRIT's Administrative Rules, Chapter 703, Section 703.9.

Communication regarding the substance of a pending application is prohibited between the grant applicant (or someone on the grant applicant's behalf) and the following individuals—an Oversight Committee member, a Program Integration Committee member, or a Scientific Review Council member. Applicants should note that the CPRIT Program Integration Committee is comprised of the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention Officer, the Chief Product Development Officer, and the Commissioner of State Health Services. The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant applicant from further consideration for a grant award.

7.3. Review Criteria

Applications will be assessed based on evaluation of the quality of the candidate and his or her potential for continued superb performance as a cancer researcher. Also of critical importance is the strength of the institutional commitment to the candidate. Recruitment efforts are not likely to be successful unless there is a strong commitment from both CPRIT and the host institution. It is not necessary that a candidate agree to accept the recruitment offer at the time an application is submitted. However, applicant institutions should have some reasonable expectation that recruitment will be successful if an award is granted by CPRIT.

Review criteria will focus on the overall impression of the candidate, his/her proposed research program, and his/her long-term contribution to and impact on the field of cancer research.

Questions to be considered by the reviewers are as follows:

Quality of the Candidate: Has the candidate made significant, transformative, and sustained contributions to basic, translational, clinical or population-based cancer research? Is the candidate an established and nationally and/or internationally recognized leader in the field? Has the candidate demonstrated excellence in leadership and teaching? Has the candidate provided mentorship, inspiration, and/or professional training opportunities to junior scientists and students? Does the candidate have a strong record of research funding? Does the candidate have a publication history in high-impact journals? Does the candidate show evidence of collaborative interaction with others?

Scientific Merit of Proposed Research: Is the research plan comprehensive and well thought out? Does the proposed research program demonstrate innovation, creativity, and feasibility? Will it expand the boundaries of cancer research beyond traditional methodology by incorporating novel and interdisciplinary techniques? Does the research program integrate with and/or increase collaborative research efforts and relationships at the nominating institution?

Relevance of Candidate's Research: Is the proposed research likely to have a significant impact on reducing the burden of cancer in the near term? Does the research contribute to basic, translational, clinical, or population-based cancer research?

Research Environment: Does the institution have the necessary facilities, expertise, and resources to support the candidate’s research program? Is there evidence of strong institutional support? Will the candidate be free of major administrative/clinical responsibilities so that he or she can focus on maintaining and enhancing his or her research program?

8. KEY DATES

RFA

RFA Release January 15, 2014

Application Receipt and Review Timeline

Application Receipt System opens, 7 am CT	Application Receipt System closes, 3 pm CT	Anticipated Application Review	Anticipated Award Notification	Anticipated Award Start Date
March 3, 2014	March 31, 2014	Mid-April 2014	May 21, 2014	June 1, 2014
April 1, 2014	TBD	TBD	TBD	TBD

9. AWARD ADMINISTRATION

Texas law requires that CPRIT grant awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to institutions or organizations, not to individuals. Awards made under this RFA are not transferable to another institution. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT’s electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT’s electronic signature policy as set forth in Chapter 701, Section 701.25.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and intellectual property rights. These contract provisions are specified in CPRIT’s Administrative Rules, which are available at www.cprit.state.tx.us. Applicants are advised to review CPRIT’s Administrative Rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in Chapter 703, Sections 703.10, 703.12.

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements set forth in CPRIT's Administrative Rules, Chapter 703, Section 703.20.

CPRIT requires award recipients to submit an annual progress report. These reports summarize the progress made toward the research goals and address plans for the upcoming year. In addition, fiscal reporting, human studies reporting, and vertebrate animal use reporting will be required as appropriate. Continuation of funding is contingent upon the timely receipt of these reports. Failure to provide timely and complete reports may waive reimbursement of grant award costs, and may result in the termination of the award contract. Forms and instructions will be made available at www.cprit.state.tx.us.

10. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas law requires that prior to disbursement of CPRIT grant funds, the award recipient must demonstrate that it has an amount of funds equal to one-half of the CPRIT funding dedicated to the research that is the subject of the award. The demonstration of available matching funds must be made at the time the award contract is executed and annually thereafter, not when the application is submitted. Grant applicants are advised to consult CPRIT's Administrative Rules, Chapter 703, Section 703.11 for specific requirements regarding the demonstration of available funding.

11. CONTACT INFORMATION

11.1. HelpDesk

HelpDesk support is available for questions regarding user registration and online submission of applications. Queries submitted via e-mail will be answered within 1 business day. HelpDesk staff members are not in a position to answer questions regarding scientific aspects of applications.

Dates of operation:	January 15, 2014 onward (excluding public holidays)
Hours of operation:	Monday, Tuesday, Thursday, Friday, 7 a.m. to 4 p.m. Central Time Wednesday, 8 a.m. to 4 p.m. Central Time
Tel:	866-941-714
E-mail:	Help@CPRITGrants.org

11.2. Scientific and Programmatic Questions

Questions regarding the CPRIT Program, including questions regarding this or other funding opportunities, should be directed to the CPRIT Research Program Director.

Tel: 512-305-8491

E-mail: Help@CPRITGrants.org

Web site: www.cprit.state.tx.us

Third Party Observer Report

CPRIT Scientific Review Council Observation Report

Report #2014-23

Panel Name: Scientific Review Council Meeting – Recruitment Program Applications

Panel Date: July 11, 2014

Report Date: July 12, 2014

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized its out-sourced internal audit provider to function as a neutral third-party observer.

Introduction

The subject of this report is the Scientific Review Council review of recruitment program applications. The meeting was chaired by Richard Kolodner and held over the phone on July 11, 2014.

Panel Observation Objectives and Scope

This third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- Peer review panel discussion is focused on the established scoring criteria.

Observation Results Summary

Internal Audit participated in the Scientific Review Council meeting held telephonically and chaired by Richard Kolodner on July 11, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Thirteen recruitment applications were discussed and evaluated by the Scientific Review Council to determine which grants would receive CPRIT funding.
- Six council members, two CPRIT staff members, and two SRA employees were present for the Council meeting over the phone.

- Two conflicts of interest were identified prior to or during the call. The council member with the conflict of interest left the teleconference and did not participate in the review of the conflicted applications.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The Council members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the peer review panel's discussion of scientific, technical or programmatic aspects of the applications.

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

De-Identified Overall Evaluation Scores

Recruitment of Established Investigators

Application ID	Mechanism	Final Overall Score
RR140081*	REI	2
aa8	REI	3.4
aa9	REI	4.8

*=Recommended for Funding

Final Overall Evaluation Scores and Rank Order Scores

Ludwig Institute for
Cancer Research Ltd

July 11, 2014

Richard D. Kolodner
Ph.D.

Head, Laboratory of
Cancer Genetics
San Diego Branch

Senior Advisor on Academic
Affairs
New York Office

Distinguished Professor of
Medicine, University of
California San Diego

rkolodner@ucsd.edu

San Diego Branch
Univ of California San Diego
CMM-East / Rm 3058
9500 Gilman Dr - MC 0669
La Jolla, CA 92093-0669

T 858 534 7804
F 858 534 7750

New York Office
28th Floor
666 Third Avenue
New York, NY 10017

T 212 450 1500
F 212 450 1555

William Rice, M.D.
Oversight Committee Chair
Cancer Prevention and Research Institute of Texas
Via email to Bill.Rice@stdavids.com

Wayne R. Roberts
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cprit.state.tx.us

Dear Dr. Rice and Mr. Roberts,

The Scientific Review Council (SRC) is pleased to submit its final list of research grant recommendations. The SRC met on Friday, July 11th to consider the applications submitted to CPRIT under the **Recruitment for First-Time, Tenure Track Faculty Members, Recruitment of Established Investigators, and Recruitment of Rising Stars** Request for Applications. The projects on the attached list are numerically ranked in the order the SRC recommends the applications be funded. Recommended funding amounts and the overall evaluation score are stated for each grant application. The SRC did not make changes to the funding amount, goals, timelines, or project objectives requested by the applicant.

These recommendations meet the SRC's standards for grant award funding. These standards include selecting candidates at all career levels that have demonstrated academic excellence, innovation, excellent training, a commitment to cancer research, and exceptional potential for achieving future impact in basic, translational, population-based, or clinical research.

Sincerely yours,



Richard D. Kolodner
Chair, CPRIT Scientific Review Board

Attachment

Rank	Application ID	Nominator Organization	Candidate	Mechanism	Budget Requested	Overall Score
1	RR140082	The University of Texas Southwestern Medical Center	Daniela Nicastro	RRS	\$4,000,000	1.0
2	RR140084	The University of Texas Southwestern Medical Center	David McFadden	RFT	\$2,000,000	1.0
3	RR140071	The University of Texas M. D. Anderson Cancer Center	Yiwen Chen	RFT	\$2,000,000	1.4
4	RR140061	The University of Texas Southwestern Medical Center	Andrew Hsieh	RFT	\$2,000,000	1.5
5	RR140072	The University of Texas Health Science Center at San Antonio	Kexin Xu	RFT	\$2,000,000	1.8
6	RR140081	Rice University	Gang Bao	REI	\$6,000,000	2.0
7	RR140077	The University of Texas M. D. Anderson Cancer Center	George Eisenhoffer	RFT	\$2,000,000	2.2
8	RR140073	Rice University	Aryeh Warmflash	RFT	\$2,000,000	2.2

RFT = Recruitment of First-Time, Tenure-Track Faculty Members

RRS = Recruitment of Rising Stars

REI = Recruitment of Established Investigators



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CEO Affidavit Supporting Information

FY 2014 – Cycle 2

Recruitment of First-Time, Tenure-Track Faculty Member

Request for Applications



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA R-14-RFT-1

**Recruitment of
First-Time Tenure-Track Faculty Members**

**Please also refer to the Instructions for Applicants document,
which will be posted on March 3, 2014.**

Application Receipt Opening Date: March 3, 2014

Fiscal Year Award Period

September 1, 2013–August 31, 2014

TABLE OF CONTENTS

1. ABOUT CPRIT	4
2. RATIONALE	4
3. RECRUITMENT OBJECTIVES.....	5
4. FUNDING INFORMATION	6
5. ELIGIBILITY	6
6. RESPONDING TO THIS RFA	9
6.1. APPLICATION SUBMISSION GUIDELINES	9
6.2. APPLICATION COMPONENTS	9
6.2.1. <i>Summary of Nomination (2,000 characters)</i>	9
6.2.2. <i>Recruitment Activities/Institutional Commitment (three pages)</i>	10
6.2.3. <i>Curriculum Vitae (CV)</i>	11
6.2.4. <i>Summary of Goals and Objectives</i>	11
6.2.5. <i>Research (four pages)</i>	11
6.2.6. <i>Publications</i>	11
6.2.7. <i>Timeline (one page)</i>	12
6.2.8. <i>Current and Pending Support</i>	12
6.2.9. <i>Letters of Recommendation</i>	12
6.2.10. <i>Research Environment (one page)</i>	12
6.2.11. <i>Descriptive Biography (Up to two pages)</i>	12
7. APPLICATION REVIEW.....	13
7.1. REVIEW PROCESS.....	13
7.1.1. <i>Confidentiality of Review</i>	13
7.2. REVIEW CRITERIA.....	14
8. KEY DATES.....	15
9. AWARD ADMINISTRATION.....	16
10. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS.....	17
11. CONTACT INFORMATION.....	17
11.1. HELPDESK	17
11.2. SCIENTIFIC AND PROGRAMMATIC QUESTIONS	17

RFA VERSION HISTORY

- Rev 1/15/14 RFA release
- Rev 2/21/14 Application Receipt opening date March 3, 2014
- Rev 2/21/14 Revised Section 6.1 Application Submission Guidelines
- Added application receipt opening and closing dates
- Rev 2/21/14 Revised Section 6.2.4 Goals and Objectives
- “Goals and Objectives” changed to “Summary of Goals and Objectives”
- Rev 2/21/14 Revised Section 6.2.7 Timeline
- Added page limit: one page
- Rev 2/21/14 Revised Section 8. Key Dates
- Added Application Receipt and Review Timeline
- Rev 2/23/14 Revised Section 7.1 Review Process
- Revised sentence: “Applications may be submitted continuously in response to this RFA, but will generally be reviewed on a quarterly basis by the CPRIT Scientific Review Council.”

1. ABOUT CPRIT

The State of Texas has established the Cancer Prevention and Research Institute of Texas (CPRIT), which may issue up to \$3 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature and the citizens of Texas to:

- Create and expedite innovation in the area of cancer research and product or service development, thereby enhancing the potential for a medical or scientific breakthrough in the prevention, treatment, and possible cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the State of Texas; and
- Continue to develop and implement the Texas Cancer Plan by promoting the development and coordination of effective and efficient statewide public and private policies, programs, and services related to cancer and by encouraging cooperative, comprehensive, and complementary planning among the public, private, and volunteer sectors involved in cancer prevention, detection, treatment, and research.

CPRIT furthers cancer research in Texas by providing financial support for a wide variety of projects relevant to cancer research.

2. RATIONALE

The aim of this award mechanism is to bolster cancer research in Texas by providing financial support to attract very promising investigators who are pursuing their first faculty appointment at the level of assistant professor (first-time, tenure-track faculty members).

These individuals must have demonstrated academic excellence, innovation during predoctoral and/or postdoctoral research training, commitment to pursuing cancer research, and exceptional potential for achieving future impact in basic, translational, population-based, or clinical research. Awards are intended to provide institutions with a competitive edge in recruiting the world's best talent in cancer research, thereby advancing cancer research efforts and promoting economic development in the State of Texas.

The recruitment of outstanding scientists will greatly enhance programs of scientific excellence in cancer research and will position Texas as a leader in the fight against cancer. Applications may address any research topic related to cancer biology, causation, prevention, detection or screening, or treatment.

3. RECRUITMENT OBJECTIVES

The goal of this award mechanism is to recruit exceptional faculty to universities and/or cancer research institutions in the State of Texas. All candidates are expected to have completed their doctoral and fellowship training and to have clearly demonstrated truly superior ability as evidenced by their accomplishments during training, proposed research plan, publication record, and letters of recommendation. This CPRIT-supported initiative is designed to enhance innovative programs of excellence by providing research support for promising, early-stage investigators **seeking their first tenure-track position**. CPRIT will provide start-up funding for newly independent investigators, with the goal of augmenting and expanding the institution's efforts in cancer research. Candidates will be expected to develop research projects within the sponsoring institution. Projects should be appropriate for a newly independent investigator and should foster the development of preliminary data that can be used to prepare applications for future independent research project grants to further both the investigator's research career and the CPRIT mission. The institution will be expected to work with each newly recruited research faculty member to design and execute a faculty career development plan consistent with his or her research emphasis. Relevance to cancer research is an important evaluation criterion for CPRIT funding.

Unless prohibited by policy, the institution is also expected to bestow on the newly recruited faculty member the prestigious title of "CPRIT Scholar in Cancer Research," and the faculty member should be encouraged strongly to use this title on letterhead, business cards, and other appropriate documents. The title is to be retained as long as the individual remains in Texas.

4. FUNDING INFORMATION

This is a 4-year award and is not renewable, although individuals may apply for other future CPRIT funding as appropriate. Grant funds of up to \$2,000,000 (total costs) for the 4-year period may be requested. Funding is to be used by the candidate to support his or her research program. The award request may include indirect costs of up to 5 percent of the total award amount (5.263 percent of the direct costs). CPRIT will make every effort to be flexible in the timing for disbursement of funds; recipients will be asked at the beginning of each year for an estimate of their needs for the year. Funds may not be carried over beyond 4 years. In addition, funds for extraordinary equipment needs may be awarded in the first year of the grant if very well justified. **Grant funds may not be used for salary support of this candidate, or to construct or renovate laboratory space.** Consistent with the statutory mandate that the recipient institution demonstrate that it has funds equivalent to one-half of the total grant award amount dedicated to the individual recruited, a total institutional commitment of 50 percent of the total award will be required. The institutional commitment can be made on a year-by-year basis and may be fulfilled by demonstrating funds dedicated to salary support for the individual recruited as well as expenses for research support, laboratory renovation, and/or relocation to Texas. Grant funding from other sources that the recruited individual may bring with him or her to the institution may also be counted toward the amount necessary for the institutional commitment. No annual limit on the number of potential award recipients has been set.

5. ELIGIBILITY

- The applicant must be a Texas-based entity. Any not-for-profit institution that conducts research is eligible to apply for funding under this award mechanism. A public or private company is not eligible for funding under this award mechanism.
- Candidates must be nominated by the president, provost, or appropriate dean of a Texas-based public or private institution of higher education, including academic health institutions. The application must be submitted on behalf of a specific candidate.
- A candidate may be nominated by only one institution. If more than one institution is interested in a given candidate, negotiations as to which institution will nominate him or her must be concluded before the nomination is made.

- Candidates who have already accepted a position as assistant professor tenure track at the recruiting institution are not eligible for a recruitment award as an investment by CPRIT is obviously not necessary. Such individuals may, however, apply for other CPRIT grant awards, as appropriate.
- The candidate must have a doctoral degree, including M.D., Ph.D., D.D.S., D.M.D., Dr.P.H., D.O., D.V.M., or equivalent, and reside in Texas for the duration of the appointment. The candidate must devote at least 70 percent time to research activities. Candidates whose major responsibilities are clinical care, teaching, or administration are not eligible.
- At the time of the application, the candidate **must not** hold an appointment at the rank of assistant professor or above (or equivalent) at an accredited academic institution, research institution, industry, government agency, or private foundation not primarily based in Texas. Candidates holding non–tenure-track appointments at the rank of assistant professor are not eligible for this award. Examples of such appointments include Research Assistant Professor, Adjunct Research Assistant Professor, Assistant Professor (Non-Tenure Track), etc. The candidate may or may not reside in Texas at the time the application is submitted and may be nominated for a faculty position at the Texas institution where they are completing postdoctoral training.
- Successful candidates will be offered tenure-track academic positions at the rank of assistant professor.
- An applicant is eligible to receive a grant award only if the applicant certifies that the applicant institution or organization, including the nominator, any senior member or key personnel listed on the grant application, and any officer or director of the grant applicant’s institution or organization (or any person related to one or more of these individuals within the second degree of consanguinity or affinity), have not made and will not make a contribution to CPRIT or to any foundation specifically created to benefit CPRIT. Prior to final approval of an award, the candidate must provide the same certification.

- An applicant is not eligible to receive a CPRIT grant award if the applicant nominator, any senior member or key personnel listed on the grant application, and any officer or director of the grant applicant's institution or organization is related to a CPRIT Oversight Committee member. Prior to final approval of an award, the candidate must provide the same certification.
- The applicant must report whether the applicant institution or organization, the nominator, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, whether or not the individuals will receive salary or compensation under the grant award, are currently ineligible to receive Federal grant funds or have had a grant terminated for cause within 5 years prior to the submission date of the grant application. Prior to final approval of an award, the candidate must provide the same certification.
- CPRIT grants will be awarded by contract to successful applicants. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in [Section 9](#) and [Section 10](#). All statutory provisions and relevant administrative rules can be found at www.cprit.state.tx.us.

6. RESPONDING TO THIS RFA

6.1. Application Submission Guidelines

Applications must be submitted via the CPRIT Application Receipt System (CARS) (<https://CPRITGrants.org>). **Only applications submitted through this portal will be considered eligible for evaluation.** The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application is submitted. Candidates must be nominated by the institution's president, provost, or appropriate dean. The individual submitting the application (nominator) must create a user account in the system to start and submit an application. Furthermore, the Authorized Signing Official (ASO), who is the person authorized to sign and submit the application for the organization, and the Grants Contract/Office of Sponsored Projects Official, who is the individual who will manage the grant contract if an award is made, also must create a user account in CARS.

Applications will be accepted on a continuous basis and reviewed quarterly. To manage the timely review of nominations for each evaluation period, the application receipt system will open and close sequentially. For the most immediate submission period, nominations will be accepted beginning at 7 a.m. Central Time on March 3, 2014 and must be submitted by 3 p.m. Central Time on March 31, 2014. The next submission period will open on April 1, 2014. A complete timeline of review for this fiscal year is provided in [Section 8](#). **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

6.2. Application Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. Please refer to the *Instructions for Applicants* document for details that will be available when the application receipt system opens. Submissions that are missing one or more components or do not meet the eligibility requirements listed in [Section 5](#) will be administratively withdrawn without review.

6.2.1. Summary of Nomination (2,000 characters)

Provide a brief summary of the nomination. Include the candidate's name, organization from which the candidate is being recruited, and also the department and/or entity within the nominator's organization where the candidate will hold the faculty position.

6.2.2. Recruitment Activities/Institutional Commitment (three pages)

Describe the recruitment activities, strategies, and priorities that have led to nomination of this candidate. Describe the institutional commitment to the candidate, including total salary, institutional support of salary, endowment or other support, space, and all other agreements between the institution and the candidate. **The institutional commitment must state the total award amount requested.** Provide a brief job description for the candidate should recruitment be successful. This information should be supplied in the form of a letter signed by the applicant institution's president, provost, or appropriate dean. While scholars may engage in direct patient care activities and/or have some administrative or teaching duties, at least 70 percent of the candidate's time must be available for research. Breach of this requirement will constitute grounds for discontinuation of funding.

The letter of institutional commitment must demonstrate the organization's commitment to bringing the candidate to Texas. The following guidelines should be used when outlining the institutional match in the letter. This information may be provided as part of paragraph text or as a tabular summary that states the approximate amounts assigned to each item.

- **Start-up Package:** Complete details including salary and fringe benefits, dedicated personnel, amounts for equipment and supplies, and/or infrastructure that will be offered to the candidate as part of the recruitment award.
- **Rent:** Amount for recovery of occupying facility space (i.e., "rent") is not a permitted institutional commitment item.
- **Caliber of Candidate:** The letter should include a description of the caliber of the candidate and justification for nomination of the candidate by the institution.
- **Description of Candidate Duties and Certification** that 70 percent time will be spent on research must be included.

The letter of institutional commitment must also:

1. Describe how the candidate will be independent and autonomous in developing his or her research program at the institution;
2. Present a plan for mentoring that includes the design and execution of a faculty career development plan for the candidate.

6.2.3. Curriculum Vitae (CV)

Provide a complete CV and list of publications for the candidate.

6.2.4. Summary of Goals and Objectives

List very broad goals and objectives to be achieved during this award. **This section must be completed by the candidate.**

6.2.5. Research (four pages)

Summarize the key elements of the candidate's research accomplishments and provide an overview of the proposed research by outlining the background and rationale, hypotheses and aims, strategies, goals, and projected impact of the focus of the research program. Highlight the innovative aspects of this effort and place it into context with regard to what pressing problem in cancer will be addressed. **This section of the application must be prepared by the candidate. References cited in this section must be included within the stated page limit. Any appropriate citation format is acceptable; official journal abbreviations should be used.**

Candidates for CPRIT Scholar Awards must include the following signed statement at the end of this section. **Applications that do not contain this signed statement will be returned without review.**

"I understand that I do not need to have made a commitment to *<nominating institution>* before this application has been submitted. However, I also understand that only one Texas institution may nominate me for a CPRIT Recruitment Award, and this is the nomination that I have endorsed. Requests to change the recruiting institution during the recruitment process are inappropriate."

6.2.6. Publications

Provide the three most significant publications that have resulted from the candidate's research efforts. Publications should be uploaded as PDFs of full-text articles. Only articles that have been published or that have been accepted for publication ("in press") should be submitted.

6.2.7. Timeline (one page)

Provide a general outline of anticipated major award outcomes to be tracked. Timelines will be reviewed during the evaluation of annual progress reports. If the application is approved for funding, this section will be included in the award contract. Applicants are advised not to include information that they consider confidential or proprietary when preparing this section.

6.2.8. Current and Pending Support

State the funding source, duration, and title of all current and pending research support held by the candidate. If the candidate has no current or pending funding, a document stating this must be submitted.

6.2.9. Letters of Recommendation

Provide three letters of recommendation from individuals who are in a position to detail the candidate's academic and scientific research accomplishments, potential for high-impact research, and ability to make a significant contribution to the field of cancer research.

6.2.10. Research Environment (one page)

Briefly describe the research environment available to support the candidate's research program, including core facilities, training programs, and collaborative opportunities.

6.2.11. Descriptive Biography (Up to two pages)

Provide a brief descriptive biography of the candidate, including his or her accomplishments, education and training, professional experience, awards and honors, publications relevant to cancer research, and a brief overview of the candidate's goals if selected to receive the award. **This section of the application must be prepared by the candidate.** If the application is approved for funding, this section will be made publicly available on CPRIT's Web site. Candidates are advised not to include information that they consider confidential or proprietary when preparing this section.

Applications that are missing one or more of these components, exceed the specified page, word, or budget limits, or do not meet the eligibility requirements listed above will be administratively withdrawn without review.

7. APPLICATION REVIEW

7.1. Review Process

All eligible applications will be evaluated and scored by the CPRIT Scientific Review Council using the criteria listed in this RFA. Applications may be submitted continuously in response to this RFA, but will generally be reviewed on a quarterly basis by the CPRIT Scientific Review Council. Council members may seek additional ad hoc evaluations of candidates. Scientific Review Council members will discuss applications and provide an individual Overall Evaluation Score that conveys the members' recommendation related to the proposed recruitment. Applications approved by Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review, prioritization, and recommendation to the CPRIT Oversight Committee for approval and funding. Approval is based on an application receiving a positive vote from at least two-thirds of the members of the Oversight Committee. The review process is described more fully in CPRIT's Administrative Rules, Chapter 703, Sections 703.6–703.8.

The decision of the Scientific Review Council not to recommend an application is final, and such applications may not be resubmitted for a recruitment award. Notification of review decisions are sent to the nominator.

7.1.1. Confidentiality of Review

Each stage of application review is conducted confidentially, and all CPRIT Scientific Review Council members, Program Integration Committee members, CPRIT employees, and Oversight Committee members with access to grant application information are required to sign nondisclosure statements regarding the contents of the applications. All technological and scientific information included in the application is protected from public disclosure pursuant to Health and Safety Code §102.262(b).

Individuals directly involved with the review process operate under strict conflict of interest prohibitions. All CPRIT Scientific Review Council members are non-Texas residents.

By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed conflict of interest as set forth in CPRIT's Administrative Rules, Chapter 703, Section 703.9.

Communication regarding the substance of a pending application is prohibited between the grant applicant (or someone on the grant applicant's behalf) and the following individuals—an Oversight Committee member, a Program Integration Committee member, or a Scientific Review Council member. Applicants should note that the CPRIT Program Integration Committee is comprised of the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention Officer, the Chief Product Development Officer, and the Commissioner of State Health Services. The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant applicant from further consideration for a grant award.

7.2. Review Criteria

Applications will be assessed based on evaluation of the quality of the candidate and his or her potential for continued superb performance as a cancer researcher. Also of critical importance is the strength of the institutional commitment to the candidate. Recruitment efforts are not likely to be successful unless there is a strong commitment from both CPRIT and the host institution. It is not necessary that a candidate agree to accept the recruitment offer at the time an application is submitted. However, applicant institutions should have some reasonable expectation that recruitment will be successful if an award is granted by CPRIT.

Review criteria will focus on the overall impression of the candidate, his or her proposed research program, and his or her long-term contribution to and impact on the field of cancer research. Questions to be considered by the reviewers are as follows:

Quality of the Candidate: Has the candidate demonstrated academic excellence? Has the candidate received excellent predoctoral and postdoctoral training? Does the candidate show exceptional potential for achieving future impact on basic, translational, clinical, or population-based cancer research in the future? Has the candidate demonstrated a commitment to cancer research? Has the candidate demonstrated independence or the potential of independence?

Scientific Merit of Proposed Research: Is the research plan comprehensive and well thought out? Does the proposed research program demonstrate innovation, creativity, and feasibility? Will it have a significant impact on the field of cancer research? Will the proposed research generate preliminary data that can be used for the preparation of applications for future independent research project grants?

Relevance of Candidate's Research: Is the proposed research likely to have a significant impact on reducing the burden of cancer in the near term? Does the research contribute to basic, translational, clinical, or population-based cancer research?

Letters of Recommendation: Do the letters of recommendation detail the candidate's academic and clinical research accomplishments, potential for high-impact research, and ability to make a significant contribution to the field of cancer research?

Research Environment: Does the institution have the necessary facilities, expertise, and resources to support the candidate's research? Is there evidence of strong institutional support? Will the candidate be free of major administrative/clinical responsibilities so that he or she can focus on growing his or her research? Has the institution identified a mentor who will design and execute a faculty career development plan for the candidate?

8. KEY DATES

RFA

RFA Release January 15, 2014

Application Receipt and Review Timeline

Application Receipt System opens, 7 am CT	Application Receipt System closes, 3 pm CT	Anticipated Application Review	Anticipated Award Notification	Anticipated Award Start Date
March 3, 2014	March 31, 2014	Mid-April 2014	May 21, 2014	June 1, 2014
April 1, 2014	TBD	TBD	TBD	TBD

9. AWARD ADMINISTRATION

Texas law requires that CPRIT grant awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to institutions or organizations, not to individuals. Awards made under this RFA are not transferable to another institution. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT's electronic signature policy as set forth in Chapter 701, Section 701.25.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and intellectual property rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.state.tx.us. Applicants are advised to review CPRIT's Administrative Rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in Chapter 703, Sections 703.10, 703.12.

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements set forth in CPRIT's Administrative Rules, Chapter 703, Section 703.20.

CPRIT requires award recipients to submit an annual progress report. These reports summarize the progress made toward the research goals and address plans for the upcoming year. In addition, fiscal reporting, human studies reporting, and vertebrate animal use reporting will be required as appropriate. Continuation of funding is contingent upon the timely receipt of these reports. Failure to provide timely and complete reports may waive reimbursement of grant award costs, and may result in the termination of the award contract. Forms and instructions will be made available at www.cprit.state.tx.us.

10. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas law requires that prior to disbursement of CPRIT grant funds, the award recipient must demonstrate that it has an amount of funds equal to one-half of the CPRIT funding dedicated to the research that is the subject of the award. The demonstration of available matching funds must be made at the time the award contract is executed and annually thereafter, not when the application is submitted. Grant applicants are advised to consult CPRIT's Administrative Rules, Chapter 703, Section 703.11 for specific requirements regarding the demonstration of available funding.

11. CONTACT INFORMATION

11.1. HelpDesk

HelpDesk support is available for questions regarding user registration and online submission of applications. Queries submitted via e-mail will be answered within 1 business day. HelpDesk staff members are not in a position to answer questions regarding scientific aspects of applications.

Dates of operation:	January 15, 2014 onward (excluding public holidays)
Hours of operation:	Monday, Tuesday, Thursday, Friday, 7 a.m. to 4 p.m. Central Time Wednesday, 8 a.m. to 4 p.m. Central Time
Tel:	866-941-7146
E-mail:	Help@CPRITGrants.org

11.2. Scientific and Programmatic Questions

Questions regarding the CPRIT Program, including questions regarding this or other funding opportunities, should be directed to the CPRIT Research Program Director.

Tel:	512-305-8491
E-mail:	Help@CPRITGrants.org
Web site:	www.cprit.state.tx.us

Third Party Observer Report

CPRIT Scientific Review Council Observation Report

Report #2014-23

Panel Name: Scientific Review Council Meeting – Recruitment Program Applications

Panel Date: July 11, 2014

Report Date: July 12, 2014

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized its out-sourced internal audit provider to function as a neutral third-party observer.

Introduction

The subject of this report is the Scientific Review Council review of recruitment program applications. The meeting was chaired by Richard Kolodner and held over the phone on July 11, 2014.

Panel Observation Objectives and Scope

This third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- Peer review panel discussion is focused on the established scoring criteria.

Observation Results Summary

Internal Audit participated in the Scientific Review Council meeting held telephonically and chaired by Richard Kolodner on July 11, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Thirteen recruitment applications were discussed and evaluated by the Scientific Review Council to determine which grants would receive CPRIT funding.
- Six council members, two CPRIT staff members, and two SRA employees were present for the Council meeting over the phone.

- Two conflicts of interest were identified prior to or during the call. The council member with the conflict of interest left the teleconference and did not participate in the review of the conflicted applications.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The Council members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the peer review panel's discussion of scientific, technical or programmatic aspects of the applications.

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

De-Identified Overall Evaluation Scores

Recruitment of First-Time, Tenure-Track Faculty Members

Application ID	Mechanism	Final Overall Score
RR140084*	RFT	1
RR140071*	RFT	1.4
RR140061*	RFT	1.5
RR140072*	RFT	1.8
RR140073*	RFT	2.2
RR140077*	RFT	2.2
bb1	RFT	4

*=Recommended for Funding

Final Overall Evaluation Scores and Rank Order Scores

Ludwig Institute for
Cancer Research Ltd

July 11, 2014

Richard D. Kolodner
Ph.D.

Head, Laboratory of
Cancer Genetics
San Diego Branch

Senior Advisor on Academic
Affairs
New York Office

Distinguished Professor of
Medicine, University of
California San Diego

rkolodner@ucsd.edu

San Diego Branch
Univ of California San Diego
CMM-East / Rm 3058
9500 Gilman Dr - MC 0669
La Jolla, CA 92093-0669

T 858 534 7804
F 858 534 7750

New York Office
28th Floor
666 Third Avenue
New York, NY 10017

T 212 450 1500
F 212 450 1555

William Rice, M.D.
Oversight Committee Chair
Cancer Prevention and Research Institute of Texas
Via email to Bill.Rice@stdavids.com

Wayne R. Roberts
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cprit.state.tx.us

Dear Dr. Rice and Mr. Roberts,

The Scientific Review Council (SRC) is pleased to submit its final list of research grant recommendations. The SRC met on Friday, July 11th to consider the applications submitted to CPRIT under the **Recruitment for First-Time, Tenure Track Faculty Members, Recruitment of Established Investigators, and Recruitment of Rising Stars** Request for Applications. The projects on the attached list are numerically ranked in the order the SRC recommends the applications be funded. Recommended funding amounts and the overall evaluation score are stated for each grant application. The SRC did not make changes to the funding amount, goals, timelines, or project objectives requested by the applicant.

These recommendations meet the SRC's standards for grant award funding. These standards include selecting candidates at all career levels that have demonstrated academic excellence, innovation, excellent training, a commitment to cancer research, and exceptional potential for achieving future impact in basic, translational, population-based, or clinical research.

Sincerely yours,



Richard D. Kolodner
Chair, CPRIT Scientific Review Board

Attachment

Rank	Application ID	Nominator Organization	Candidate	Mechanism	Budget Requested	Overall Score
1	RR140082	The University of Texas Southwestern Medical Center	Daniela Nicastro	RRS	\$4,000,000	1.0
2	RR140084	The University of Texas Southwestern Medical Center	David McFadden	RFT	\$2,000,000	1.0
3	RR140071	The University of Texas M. D. Anderson Cancer Center	Yiwen Chen	RFT	\$2,000,000	1.4
4	RR140061	The University of Texas Southwestern Medical Center	Andrew Hsieh	RFT	\$2,000,000	1.5
5	RR140072	The University of Texas Health Science Center at San Antonio	Kexin Xu	RFT	\$2,000,000	1.8
6	RR140081	Rice University	Gang Bao	REI	\$6,000,000	2.0
7	RR140077	The University of Texas M. D. Anderson Cancer Center	George Eisenhoffer	RFT	\$2,000,000	2.2
8	RR140073	Rice University	Aryeh Warmflash	RFT	\$2,000,000	2.2

RFT = Recruitment of First-Time, Tenure-Track Faculty Members

RRS = Recruitment of Rising Stars

REI = Recruitment of Established Investigators



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CEO Affidavit Supporting Information

FY 2014 – Cycle 2
Recruitment of Rising Stars

Request for Applications



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA R-14-RRS-1

Recruitment of Rising Stars

**Please also refer to the Instructions for Applicants document,
which will be posted on March 3, 2014.**

Application Receipt Opening Date: March 3, 2014

Fiscal Year Award Period

September 1, 2013–August 31, 2014

TABLE OF CONTENTS

1. ABOUT CPRIT	4
2. RATIONALE	4
3. RECRUITMENT OBJECTIVES.....	5
4. FUNDING INFORMATION	6
5. ELIGIBILITY	6
6. RESPONDING TO THIS RFA	8
6.1. APPLICATION SUBMISSION GUIDELINES	8
6.2. APPLICATION COMPONENTS	9
6.2.1. Summary of Nomination (2,000 characters)	9
6.2.2. Recruitment Activities/Institutional Commitment (two pages).....	9
6.2.3. Curriculum Vitae (CV)	10
6.2.4. Summary of Goals and Objectives	10
6.2.5. Research (four pages)	10
6.2.6. Publications.....	11
6.2.7. Timeline (one page).....	11
6.2.8. Current and Pending Support	11
6.2.9. Research Environment (one page)	11
6.2.10. Descriptive Biography (Up to two pages)	11
7. APPLICATION REVIEW	12
7.1. 7.1. REVIEW PROCESS	12
7.1.1. Confidentiality of Review	12
7.2. REVIEW CRITERIA	13
8. KEY DATES.....	14
9. AWARD ADMINISTRATION.....	15
10. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS.....	16
11. CONTACT INFORMATION.....	16
11.1. HELPDESK	16
11.2. SCIENTIFIC AND PROGRAMMATIC QUESTIONS	16

RFA VERSION HISTORY

- Rev 1/15/14 RFA release
- Rev 2/21/14 Application Receipt opening date March 3, 2014
- Rev 2/21/14 Revised Section 6.1 Application Submission Guidelines
- Added application receipt opening and closing dates
- Rev 2/21/14 Revised Section 6.2.4 Goals and Objectives
- “Goals and Objectives” changed to “Summary of Goals and Objectives”
- Rev 2/21/14 Revised Section 6.2.7 Timeline
- Added page limit: one page
- Rev 2/21/14 Revised Section 8. Key Dates
- Added Application Receipt and Review Timeline
- Rev 2/23/14 Revised Section 7.1 Review Process
- Revised sentence: “Applications may be submitted continuously in response to this RFA, but will generally be reviewed on a quarterly basis by the CPRIT Scientific Review Council.”

1. ABOUT CPRIT

The State of Texas has established the Cancer Prevention and Research Institute of Texas (CPRIT), which may issue up to \$3 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature and the citizens of Texas to:

- Create and expedite innovation in the area of cancer research and product or service development, thereby enhancing the potential for a medical or scientific breakthrough in the prevention, treatment, and possible cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the State of Texas; and
- Continue to develop and implement the Texas Cancer Plan by promoting the development and coordination of effective and efficient statewide public and private policies, programs, and services related to cancer and by encouraging cooperative, comprehensive, and complementary planning among the public, private, and volunteer sectors involved in cancer prevention, detection, treatment, and research.

CPRIT furthers cancer research in Texas by providing financial support for a wide variety of projects relevant to cancer research.

2. RATIONALE

The aim of this award mechanism is to bolster cancer research in Texas by providing financial support to attract individuals whose work has outstanding merit, who show a marked capacity for self-direction, and who demonstrate the promise for continued and enhanced contributions to the field of cancer research (“Rising Stars”). Awards are intended to provide institutions with a competitive edge in recruiting the world’s best talent in cancer research, thereby advancing cancer research efforts and promoting economic development in the State of Texas. The recruitment of outstanding scientists will greatly enhance programs of scientific excellence in cancer research and will position Texas as a leader in the fight against cancer. Applications may address any research topic related to cancer biology, causation, prevention, detection or screening, or treatment.

3. RECRUITMENT OBJECTIVES

The goal of this award mechanism is to recruit exceptional faculty to universities and/or cancer research institutions in the State of Texas. Having already demonstrated extraordinary accomplishments during their initial years of independent research, Rising Stars represent a unique blend of scholastic aptitude, scientific rigor, and commitment to exploring transformational research through the development of creative ideas with high potential. Candidates who have not historically worked in cancer research but are proposing creative hypotheses and research plans for this field are encouraged to apply. Similarly, candidates pursuing original and potentially high-impact basic science programs that have the potential to be translated toward clinical investigations or provide “proof of principle” are also encouraged to apply. It is expected that the candidate will contribute significantly to and have a major impact on the institution’s overall cancer research initiative. Funding will be given for exceptional candidates who will continue to develop new research methods and techniques in the life, population-based, physical, engineering, or computational sciences and apply them to solving outstanding problems in cancer research that have been inadequately addressed or for which there may be an absence of an established paradigm or technical framework.

Ideal candidates will have specific expertise in cancer-related areas needed to address an institutional priority. Candidates are expected to be approximately at the career level of a late assistant/early associate professor or equivalent. This funding mechanism considers expertise, accomplishments, and breadth of experience vital metrics for guiding CPRIT’s investment in that person's originality, insight, and potential for continued contribution.

Unless prohibited by policy, the institution is also expected to bestow on the newly recruited faculty member the prestigious title of “CPRIT Scholar in Cancer Research,” and the faculty member should be encouraged strongly to use this title on letterhead, business cards, and other appropriate documents. The title is to be retained as long as the individual remains in Texas.

4. FUNDING INFORMATION

This is a 5-year award and is not renewable. Grant funds of up to \$4,000,000 (total costs) over a 5-year period may be requested. Exceptions to this limit will be entertained only if there is compelling written justification. Annual allocations of this award are at the discretion of the awardee, as long as the total award does not exceed \$4,000,000. The award request may include indirect costs of up to 5 percent of the total award amount (5.263 percent of the direct costs).

CPRIT will make every effort to be flexible in the timing for disbursement of funds; recipients will be asked at the beginning of each year for an estimate of their needs for the year. Funds may not be carried over beyond 5 years. In addition, funds for extraordinary equipment needs may be awarded in the first year of the grant if very well justified. **Grant funds may be used for salary support of this candidate, but may not be used to construct or renovate laboratory space.**

Consistent with the statutory mandate that the recipient institution demonstrate that it has funds equivalent to one-half of the total grant award amount dedicated to the individual recruited, a total institutional commitment of 50 percent of the total award will be required. The institutional commitment can be made on a year-by-year basis and may be fulfilled by demonstrating funds dedicated to salary support and endowment for the individual recruited as well as expenses for research support, laboratory renovation, and/or relocation to Texas. Grant funding from other sources that the recruited individual may bring with him or her to the institution may also be counted toward the amount necessary for the institutional commitment. No annual limit on the number of potential award recipients has been set.

5. ELIGIBILITY

- The applicant must be a Texas-based entity. Any not-for-profit institution that conducts research is eligible to apply for funding under this award mechanism. A public or private company is not eligible for funding under this award mechanism.
- Candidates must be nominated by the president, provost, or appropriate dean of a Texas-based public or private institution of higher education, including academic health institutions. The application must be submitted on behalf of a specific candidate.
- A candidate may be nominated by only one institution. If more than one institution is interested in a given candidate, negotiations as to which institution will nominate him or her must be concluded before the nomination is made.

- Candidates who have already accepted a position at the recruiting institution are not eligible for a recruitment award as an investment by CPRIT is obviously not necessary. Such individuals may, however, apply for other CPRIT grant awards, as appropriate.
- The candidate must have a doctoral degree, including M.D., Ph.D., D.D.S., D.M.D., Dr.P.H., D.O., D.V.M., or equivalent, and reside in Texas for the duration of the appointment. The candidate must devote at least 70 percent time to research activities. Candidates whose major responsibilities are clinical care, teaching or administration are not eligible.
- At the time of the application, the candidate should hold an appointment at the rank of assistant or associate professor tenure-track or tenured (or equivalent) at an accredited academic institution, research institution, industry, government agency, or private foundation not primarily based in Texas. The candidate must not reside in Texas at the time the application is submitted.
- An applicant is eligible to receive a grant award only if the applicant certifies that the applicant institution or organization, including the nominator, any senior member or key personnel listed on the grant application, and any officer or director of the grant applicant's institution or organization (or any person related to one or more of these individuals within the second degree of consanguinity or affinity), have not made and will not make a contribution to CPRIT or to any foundation specifically created to benefit CPRIT. Prior to final approval of an award, the candidate must provide the same certification.
- An applicant is not eligible to receive a CPRIT grant award if the applicant nominator, any senior member or key personnel listed on the grant application, and any officer or director of the grant applicant's institution or organization is related to a CPRIT Oversight Committee member. Prior to final approval of an award, the candidate must provide the same certification.
- The applicant must report whether the applicant institution or organization, the nominator, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, whether or not the individuals will receive salary or compensation under the grant award, are currently ineligible to receive Federal grant funds or have had a grant terminated for cause within 5 years prior to the submission date of the grant application. Prior to final approval of an award, the candidate must provide the same certification.

- CPRIT grants will be awarded by contract to successful applicants. Certain contractual requirements are mandated by Texas law or by administrative rules. Although applicants need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should make themselves aware of these standards before submitting a grant application. Significant issues addressed by the CPRIT contract are listed in [Section 9](#) and [Section 10](#). All statutory provisions and relevant administrative rules can be found at www.cpr.it.state.tx.us.

6. RESPONDING TO THIS RFA

6.1. Application Submission Guidelines

Applications must be submitted via the CPRIT Application Receipt System (CARS) (<https://CPRITGrants.org>). **Only applications submitted through this portal will be considered eligible for evaluation.** The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application is submitted. Candidates must be nominated by the institution's president, provost, or appropriate dean. The individual submitting the application (nominator) must create a user account in the system to start and submit an application. Furthermore, the Authorized Signing Official (ASO), who is the person authorized to sign and submit the application for the organization, and the Grants Contract/Office of Sponsored Projects Official, who is the individual who will manage the grant contract if an award is made, also must create a user account in CARS. Applications will be accepted on a continuous basis and reviewed quarterly. To manage the timely review of nominations for each evaluation period, the application receipt system will open and close sequentially. For the most immediate submission period, nominations will be accepted beginning at 7 a.m. Central Time on March 3, 2014 and must be submitted by 3 p.m. Central Time on March 31, 2014. The next submission period will open on April 1, 2014. A complete timeline of review for this fiscal year is provided in [Section 8](#). **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

6.2. Application Components

Applicants are advised to follow all instructions to ensure accurate and complete submission of all components of the application. Please refer to the *Instructions for Applicants* document for details that will be available when the application receipt system opens. Submissions that are missing one or more components or do not meet the eligibility requirements listed in [Section 5](#) will be administratively withdrawn without review.

6.2.1. Summary of Nomination (2,000 characters)

Provide a brief summary of the nomination. Include the candidate's name, organization from which the candidate is being recruited, and also the department and/or entity within the nominator's organization where the candidate will hold the faculty position.

6.2.2. Recruitment Activities/Institutional Commitment (two pages)

Describe the recruitment activities, strategies, and priorities that have led to nomination of this candidate. Describe the institutional commitment to the candidate, including total salary, institutional support of salary, endowment or other support, space, and all other agreements between the institution and the candidate. **The institutional commitment must state the total award amount requested.** Provide a brief job description for the candidate should recruitment be successful. This information should be supplied in the form of a letter signed by the applicant institution's president, provost, or appropriate dean. While scholars may engage in direct patient care activities and/or have some administrative, or teaching duties, at least 70 percent of the candidate's time must be available for research. Breach of this requirement will constitute grounds for discontinuation of funding.

The letter of institutional commitment must demonstrate the organization's commitment to bringing the candidate to Texas. The following guidelines should be used when outlining the institutional match in the letter. This information may be provided as part of paragraph text or as a tabular summary that states the approximate amounts assigned to each item.

- **Start-up Package:** Complete details including salary and fringe benefits, dedicated personnel, amounts for equipment and supplies, and/or infrastructure that will be offered to the candidate as part of the recruitment award.

- **Endowment Equivalents:** The principal of an endowment may not be included as part of the institutional match, but endowment income over the lifetime of the award may be included.
- **Rent:** Amount for recovery of occupying facility space (i.e., “rent”) is not a permitted institutional commitment item.
- **Caliber of Candidate:** The letter should include a description of the caliber of the candidate and justification of nomination of the candidate by the institution.
- **Description of Candidate Duties and Certification** that 70 percent time will be spent on research must be included.

6.2.3. Curriculum Vitae (CV)

Provide a complete CV and list of publications for the candidate.

6.2.4. Summary of Goals and Objectives

List very broad goals and objectives to be achieved during this award. **This section must be completed by the candidate.**

6.2.5. Research (four pages)

Summarize the key elements of the candidate’s research accomplishments, and provide an overview of the proposed research by outlining the background and rationale, hypotheses and aims, strategies, goals, and projected impact of the focus of the research program. Highlight the innovative aspects of this effort, and place it into context with regard to what pressing problem in cancer will be addressed. **This section of the application must be prepared by the candidate. References cited in this section must be included within the stated page limit. Any appropriate citation format is acceptable; official journal abbreviations should be used.**

Candidates for CPRIT Scholar Awards must include the following signed statement at the end of this section. **Applications that do not contain this signed statement will be returned without review.**

“I understand that I do not need to have made a commitment to *<nominating institution>* before this application has been submitted. However, I also understand that only one Texas institution may nominate me for a CPRIT Recruitment Award, and this is the nomination that I have endorsed. Requests to change the recruiting institution during the recruitment process are inappropriate.”

6.2.6. Publications

Provide the five most significant publications that have resulted from the candidate’s research efforts. Publications should be uploaded as PDFs of full-text articles. Only articles that have been published or that have been accepted for publication (“in press”) should be submitted.

6.2.7. Timeline (one page)

Provide a general outline of anticipated major award outcomes to be tracked. Timelines will be reviewed during the evaluation of annual progress reports. If the application is approved for funding, this section will be included in the award contract. Applicants are advised not to include information that they consider confidential or proprietary when preparing this section.

6.2.8. Current and Pending Support

State the funding source, duration, and title of all current and pending research support held by the candidate. If the candidate has no current or pending funding, a document stating this must be submitted.

6.2.9. Research Environment (one page)

Briefly describe the research environment available to support the candidate’s research program, including core facilities and training programs, and collaborative opportunities.

6.2.10. Descriptive Biography (Up to two pages)

Provide a brief descriptive biography of the candidate, including his or her accomplishments, education and training, professional experience, awards and honors, publications relevant to cancer research, and a brief overview of the candidate’s goals if selected to receive the award.

This section of the application must be prepared by the candidate. If the application is approved for funding, this section will be made publicly available on CPRIT’s Web site.

Candidates are advised not to include information that they consider confidential or proprietary when preparing this section.

Applications that are missing one or more of these components, exceed the specified page, word, or budget limits, or do not meet the eligibility requirements listed above will be administratively withdrawn without review.

7. APPLICATION REVIEW

7.1. 7.1. Review Process

All eligible applications will be evaluated and scored by the CPRIT Scientific Review Council using the criteria listed in this RFA. Applications may be submitted continuously in response to this RFA, but will generally be reviewed on a quarterly basis by the CPRIT Scientific Review Council. Council members may seek additional ad hoc evaluations of candidates. Scientific Review Council members will discuss applications and provide an individual Overall Evaluation Score that conveys the members' recommendation related to the proposed recruitment.

Applications approved by Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review, prioritization, and recommendation to the CPRIT Oversight Committee for approval and funding. Approval is based on an application receiving a positive vote from at least two-thirds of the members of the Oversight Committee. The review process is described more fully in CPRIT's Administrative Rules, Chapter 703, Sections 703.6–703.8.

The decision of the Scientific Review Council not to recommend an application is final, and such applications may not be resubmitted for a recruitment award. Notification of review decisions are sent to the nominator.

7.1.1. Confidentiality of Review

Each stage of application review is conducted confidentially, and all CPRIT Scientific Review Council members, Program Integration Committee members, CPRIT employees, and Oversight Committee members with access to grant application information are required to sign nondisclosure statements regarding the contents of the applications. All technological and scientific information included in the application is protected from public disclosure pursuant to Health and Safety Code §102.262(b).

Individuals directly involved with the review process operate under strict conflict of interest prohibitions. All CPRIT Scientific Review Council members are non-Texas residents.

By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed conflict of interest as set forth in CPRIT’s Administrative Rules, Chapter 703, Section 703.9.

Communication regarding the substance of a pending application is prohibited between the grant applicant (or someone on the grant applicant’s behalf) and the following individuals—an Oversight Committee member, a Program Integration Committee member, or a Scientific Review Council member. Applicants should note that the CPRIT Program Integration Committee is comprised of the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention Officer, the Chief Product Development Officer, and the Commissioner of State Health Services. The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant applicant from further consideration for a grant award.

7.2. Review Criteria

Applications will be assessed based on evaluation of the quality of the candidate and his or her potential for continued superb performance as a cancer researcher. Also of critical importance is the strength of the institutional commitment to the candidate. Recruitment efforts are not likely to be successful unless there is a strong commitment from both CPRIT and the host institution. It is not necessary that a candidate agree to accept the recruitment offer at the time an application is submitted. However, applicant institutions should have some reasonable expectation that recruitment will be successful if an award is granted by CPRIT.

Review criteria will focus on the overall impression of the candidate, his/her proposed research program, and his/her long-term contribution to and impact on the field of cancer research. Questions to be considered by the reviewers are as follows:

Quality of the Candidate: Has the candidate demonstrated extraordinary accomplishments during his or her initial years of independent research? Does the candidate show promise of making important contributions with significant impact to basic, translational, clinical, or population-based cancer research in the future? Has the candidate demonstrated strong self-direction, motivation, and commitment for transformative cancer research?

Scientific Merit of Proposed Research: Is the research plan comprehensive and well thought out? Does the proposed research program demonstrate innovation, creativity, and feasibility? Will it have a significant impact on the field of cancer research? Will it expand the boundaries of cancer research beyond traditional methodology by incorporating novel and interdisciplinary techniques?

Relevance of Candidate's Research: Is the proposed research likely to have a significant impact on reducing the burden of cancer in the near term? Does the research contribute to basic, translational, clinical, or population-based cancer research?

Research Environment: Does the institution have the necessary facilities, expertise, and resources to support the candidate's research? Is there evidence of strong institutional support? Will the candidate be free of major administrative/clinical responsibilities so that he or she can focus on maintaining and enhancing his or her research program? Will the candidate be provided with adequate professional development opportunities to grow as a leader?

8. KEY DATES

RFA

RFA Release January 15, 2014

Application Receipt and Review Timeline

Application Receipt System opens, 7 am CT	Application Receipt System closes, 3 pm CT	Anticipated Application Review	Anticipated Award Notification	Anticipated Award Start Date
March 3, 2014	March 31, 2014	Mid-April 2014	May 21, 2014	June 1, 2014
April 1, 2014	TBD	TBD	TBD	TBD

9. AWARD ADMINISTRATION

Texas law requires that CPRIT grant awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to institutions or organizations, not to individuals. Awards made under this RFA are not transferable to another institution. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT's electronic signature policy as set forth in Chapter 701, Section 701.25.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and intellectual property rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.state.tx.us. Applicants are advised to review CPRIT's Administrative Rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in Chapter 703, Sections 703.10, 703.12.

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements set forth in CPRIT's Administrative Rules, Chapter 703, Section 703.20.

CPRIT requires award recipients to submit an annual progress report. These reports summarize the progress made toward the research goals and address plans for the upcoming year. In addition, fiscal reporting, human studies reporting, and vertebrate animal use reporting will be required as appropriate. **Continuation of funding is contingent upon the timely receipt of these reports.** Failure to provide timely and complete reports may waive reimbursement of grant award costs, and may result in the termination of the award contract. Forms and instructions will be made available at www.cprit.state.tx.us.

10. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas law requires that prior to disbursement of CPRIT grant funds, the award recipient must demonstrate that it has an amount of funds equal to one-half of the CPRIT funding dedicated to the research that is the subject of the award. The demonstration of available matching funds must be made at the time the award contract is executed and annually thereafter, not when the application is submitted. Grant applicants are advised to consult CPRIT's Administrative Rules, Chapter 703, Section 703.11 for specific requirements regarding the demonstration of available funding.

11. CONTACT INFORMATION

11.1. HelpDesk

HelpDesk support is available for questions regarding user registration and online submission of applications. Queries submitted via e-mail will be answered within 1 business day. HelpDesk staff members are not in a position to answer questions regarding scientific aspects of applications.

Dates of operation: January 15, 2014 onward (excluding public holidays)
Hours of operation: Monday, Tuesday, Thursday, Friday, 7 a.m. to 4 p.m. Central Time
Wednesday, 8 a.m. to 4 p.m. Central Time
Tel: 866-941-7146
E-mail: Help@CPRITGrants.org

11.2. Scientific and Programmatic Questions

Questions regarding the CPRIT Program, including questions regarding this or other funding opportunities, should be directed to the CPRIT Research Program Director.

Tel: 512-305-8491
E-mail: Help@CPRITGrants.org
Web site: www.cprit.state.tx.us

Third Party Observer Report

CPRIT Scientific Review Council Observation Report

Report #2014-23

Panel Name: Scientific Review Council Meeting – Recruitment Program Applications

Panel Date: July 11, 2014

Report Date: July 12, 2014

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized its out-sourced internal audit provider to function as a neutral third-party observer.

Introduction

The subject of this report is the Scientific Review Council review of recruitment program applications. The meeting was chaired by Richard Kolodner and held over the phone on July 11, 2014.

Panel Observation Objectives and Scope

This third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- Peer review panel discussion is focused on the established scoring criteria.

Observation Results Summary

Internal Audit participated in the Scientific Review Council meeting held telephonically and chaired by Richard Kolodner on July 11, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Thirteen recruitment applications were discussed and evaluated by the Scientific Review Council to determine which grants would receive CPRIT funding.
- Six council members, two CPRIT staff members, and two SRA employees were present for the Council meeting over the phone.

- Two conflicts of interest were identified prior to or during the call. The council member with the conflict of interest left the teleconference and did not participate in the review of the conflicted applications.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The Council members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the peer review panel's discussion of scientific, technical or programmatic aspects of the applications.

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

De-Identified Overall Evaluation Scores

Recruitment of Rising Stars

Application ID	Mechanism	Final Overall Score
RR140082*	RRS	1
bb2	RRS	3
bb3	RRS	3.8
bb4	RRS	4
bb5	RRS	4
bb6	RRS	4

*=Recommended for Funding

Final Overall Evaluation Scores and Rank Order Scores

Ludwig Institute for
Cancer Research Ltd

July 11, 2014

Richard D. Kolodner
Ph.D.

Head, Laboratory of
Cancer Genetics
San Diego Branch

Senior Advisor on Academic
Affairs
New York Office

Distinguished Professor of
Medicine, University of
California San Diego

rkolodner@ucsd.edu

San Diego Branch
Univ of California San Diego
CMM-East / Rm 3058
9500 Gilman Dr - MC 0669
La Jolla, CA 92093-0669

T 858 534 7804
F 858 534 7750

New York Office
28th Floor
666 Third Avenue
New York, NY 10017

T 212 450 1500
F 212 450 1555

William Rice, M.D.
Oversight Committee Chair
Cancer Prevention and Research Institute of Texas
Via email to Bill.Rice@stdavids.com

Wayne R. Roberts
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cprit.state.tx.us

Dear Dr. Rice and Mr. Roberts,

The Scientific Review Council (SRC) is pleased to submit its final list of research grant recommendations. The SRC met on Friday, July 11th to consider the applications submitted to CPRIT under the **Recruitment for First-Time, Tenure Track Faculty Members, Recruitment of Established Investigators, and Recruitment of Rising Stars** Request for Applications. The projects on the attached list are numerically ranked in the order the SRC recommends the applications be funded. Recommended funding amounts and the overall evaluation score are stated for each grant application. The SRC did not make changes to the funding amount, goals, timelines, or project objectives requested by the applicant.

These recommendations meet the SRC's standards for grant award funding. These standards include selecting candidates at all career levels that have demonstrated academic excellence, innovation, excellent training, a commitment to cancer research, and exceptional potential for achieving future impact in basic, translational, population-based, or clinical research.

Sincerely yours,



Richard D. Kolodner
Chair, CPRIT Scientific Review Board

Attachment

Rank	Application ID	Nominator Organization	Candidate	Mechanism	Budget Requested	Overall Score
1	RR140082	The University of Texas Southwestern Medical Center	Daniela Nicastro	RRS	\$4,000,000	1.0
2	RR140084	The University of Texas Southwestern Medical Center	David McFadden	RFT	\$2,000,000	1.0
3	RR140071	The University of Texas M. D. Anderson Cancer Center	Yiwen Chen	RFT	\$2,000,000	1.4
4	RR140061	The University of Texas Southwestern Medical Center	Andrew Hsieh	RFT	\$2,000,000	1.5
5	RR140072	The University of Texas Health Science Center at San Antonio	Kexin Xu	RFT	\$2,000,000	1.8
6	RR140081	Rice University	Gang Bao	REI	\$6,000,000	2.0
7	RR140077	The University of Texas M. D. Anderson Cancer Center	George Eisenhoffer	RFT	\$2,000,000	2.2
8	RR140073	Rice University	Aryeh Warmflash	RFT	\$2,000,000	2.2

RFT = Recruitment of First-Time, Tenure-Track Faculty Members

RRS = Recruitment of Rising Stars

REI = Recruitment of Established Investigators



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140001
Individual Investigator Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Basic Cancer Research Panel 1 for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle

- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

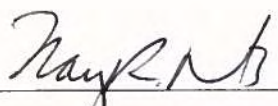
An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.


This statement is true."



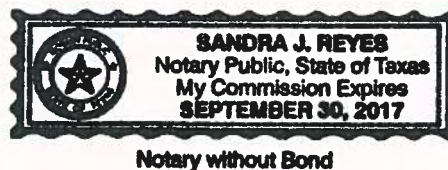
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research
AWARD MECHANISM Individual Investigator Research Awards (IIRA)
APPLICATION ID RP140001
APPLICATION TITLE Role of DNA METHYLTRANSFERASE 3A in Hematologic Malignancies
APPLICANT NAME Goodell, Margaret
ORGANIZATION Baylor College of Medicine
PANEL NAME Basic Cancer Research-1 (BCR-1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	01/31/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	N/A	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	N/A	07/02/14
	Primary Reviewer 2 COI signed	N/A	07/02/14
	Primary Reviewer 3 COI signed	N/A	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 1 critique submitted	N/A	07/02/14
	Primary Reviewer 2 critique submitted	N/A	07/02/14
	Primary Reviewer 3 critique submitted	N/A	07/02/14
	COI indicated by non-primary reviewer	N/A	07/02/14
	Preliminary Evaluation score summary sent to Chair	N/A	07/02/14
	Recommended for full review	N/A	07/02/14
4. Peer Review: On-Site Meeting	Applicant notified of outcome	N/A	07/02/14
	Assigned to primary reviewers	04/18/14	07/02/14
	Primary Reviewer 1 COI signed	04/14/14	07/02/14
	Primary Reviewer 2 COI signed	04/09/14	07/02/14
	Primary Reviewer 3 COI signed	04/10/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/23/14	07/02/14
	Primary Reviewer 1 critique submitted	05/19/14	07/02/14
	Primary Reviewer 2 critique submitted	05/14/14	07/02/14
	Primary Reviewer 3 critique submitted	05/19/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	05/24/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	05/31/14-06/01/14	07/02/14
	Post review statements signed	06/11/14	07/02/14
	Third Party Observer Report	06/12/14	07/02/14
5. Final SRC Recommendation	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRCPDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/02/14
6. PIC Review	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
7. Oversight Committee Approval	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT

Application RR140061

Recruitment of First-Time, Tenure Track Nomination of Andrew Hsieh

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Recruitment of First-Time, Tenure Track Faculty Member* Request for Applications (RFA). CPRIT received seven applications for this RFA. The application was assigned to the Scientific Review Council for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

This statement is true."

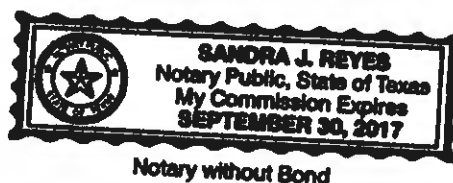
Wayne R. Roberts

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 4th day of August, 2014,
by WAYNE R. ROBERTS.

Sandra Reyes
Sandra Reyes
Notary Public, State of Texas



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 2
PROGRAM Research
AWARD MECHANISM Recruitment of First-Time Faculty Members (RFTFM)
APPLICATION ID RR140061
APPLICATION TITLE Translational Regulation in Prostate Cancer
APPLICANT NAME Fitz, John
ORGANIZATION The University of Texas Southwestern Medical Center
PANEL NAME Recruitment Review Panel - 3 (RRP-3)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	05/16/14	07/22/14
	CPRIT Application Receipt System (CARS) opened	04/01/14	07/22/14
	CPRIT Application Receipt System (CARS) closed	06/11/14	07/22/14
	Date application submitted	05/08/14	07/22/14
	Method of submission	CARS	07/22/14
	Within receipt period	YES	07/22/14
	Appeal to submit application after CARS closed	N/A	07/22/14
	Appeal for late application submission accepted	N/A	07/22/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/22/14
	Donation(s) made to CPRIT/foundation	NO	07/22/14
	Assigned to primary reviewers	06/20/14	07/22/14
	Applicant notified of review panel assignment	N/A	07/22/14
	Primary Reviewer 1 COI signed	06/18/14	07/22/14
	Primary Reviewer 2 COI signed	06/20/14	07/22/14
3. Peer Review: Teleconference Meeting	Primary Reviewer 1 critique submitted	07/08/14	07/22/14
	Primary Reviewer 2 critique submitted	07/09/14	07/22/14
	COI indicated by non-primary reviewer	Gambhir, Sanjiv Sam	07/22/14
	COI recused from participation	YES	07/22/14
	Discussed at Teleconference Meeting	YES	07/22/14
	Peer Review: Teleconference Meeting	07/11/14	07/22/14
	Post review statements signed	07/22/14	07/23/14
	Third Party Observer Report	07/12/14	07/23/14
	Score report delivered to CSO	07/12/14	07/22/14
4. Final SRC Recommendation	COI indicated by SRC member	Gambhir, Sanjiv Sam	07/22/14
	COI recused from participation	N/A	07/22/14
	SRC Meeting	07/11/14	07/22/14
	Third Party Observer Report	07/12/14	07/23/14
	Recommended for grant award	YES	07/23/14
	SRC Chair Notification to PIC and OC	07/11/14	07/23/14
5. PIC Review	COI indicated by PIC member	NONE	07/23/14
	COI recused from participation	N/A	07/23/14
	PIC review meeting	07/15/14	07/23/14
	Recommended for grant award	YES	07/23/14
6. Oversight Committee Approval	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT

Application RR140071

Recruitment of First-Time, Tenure Track Nomination of Yiwen Chen

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Recruitment of First-Time, Tenure Track Faculty Member Request for Applications (RFA)*. CPRIT received seven applications for this RFA. The application was assigned to the Scientific Review Council for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

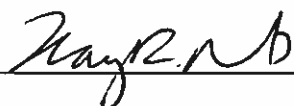
- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.


This statement is true."



Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 4th day of August, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 2
PROGRAM Research
AWARD MECHANISM Recruitment of First-Time Faculty Members (RFTFM)
APPLICATION ID RR140071
APPLICATION TITLE Recruitment of First-time, Tenure-Track Faculty - Dr. Yiwen Chen
APPLICANT NAME Dmitrovsky, Ethan
ORGANIZATION The University of Texas M. D. Anderson Cancer Center
PANEL NAME Recruitment Review Panel - 3 (RRP-3)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	05/16/14	07/22/14
	CPRIT Application Receipt System (CARS) opened	04/01/14	07/22/14
	CPRIT Application Receipt System (CARS) closed	06/11/14	07/22/14
	Date application submitted	06/11/14	07/22/14
	Method of submission	CARS	07/22/14
	Within receipt period	YES	07/22/14
	Appeal to submit application after CARS closed	N/A	07/22/14
	Appeal for late application submission accepted	N/A	07/22/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/22/14
	Donation(s) made to CPRIT/foundation	NO	07/22/14
	Assigned to primary reviewers	06/20/14	07/22/14
	Applicant notified of review panel assignment	N/A	07/22/14
	Primary Reviewer 1 COI signed	06/18/14	07/22/14
	Primary Reviewer 2 COI signed	06/20/14	07/22/14
3. Peer Review: Teleconference Meeting	Primary Reviewer 1 critique submitted	07/08/14	07/22/14
	Primary Reviewer 2 critique submitted	07/09/14	07/22/14
	COI indicated by non-primary reviewer	NONE	07/22/14
	COI recused from participation	N/A	07/22/14
	Discussed at Teleconference Meeting	YES	07/22/14
	Peer Review: Teleconference Meeting	07/11/14	07/22/14
	Post review statements signed	07/22/14	07/23/14
	Third Party Observer Report	07/12/14	07/23/14
4. Final SRC Recommendation	Score report delivered to CSO	07/12/14	07/22/14
	COI indicated by SRC member	NONE	07/22/14
	COI recused from participation	N/A	07/22/14
	SRC Meeting	07/11/14	07/22/14
	Third Party Observer Report	07/12/14	07/23/14
	Recommended for grant award	YES	07/23/14
5. PIC Review	SRC Chair Notification to PIC and OC	07/11/14	07/23/14
	COI indicated by PIC member	NONE	07/23/14
	COI recused from participation	N/A	07/23/14
	PIC review meeting	07/15/14	07/23/14
6. Oversight Committee Approval	Recommended for grant award	YES	07/23/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT

Application RR140072

Recruitment of First-Time, Tenure Track Nomination of Kexin Xu

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Recruitment of First-Time, Tenure Track Faculty Member* Request for Applications (RFA). CPRIT received seven applications for this RFA. The application was assigned to the Scientific Review Council for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT’s grant review processes were followed by the review panel evaluating the applications in this grant cycle

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

This statement is true."



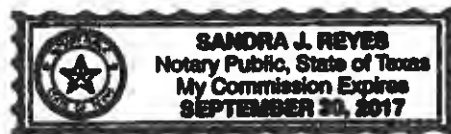
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 4th day of August, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 2
PROGRAM Research
AWARD MECHANISM Recruitment of First-Time Faculty Members (RFTFM)
APPLICATION ID RR140072
APPLICATION TITLE Recruitment of First-Time, Tenure Track Faculty Member
 – Dr. Kexin Xu
APPLICANT NAME Gonzalez-Scarano, Francisco
ORGANIZATION The University of Texas Health Science Center at San Antonio
PANEL NAME Recruitment Review Panel - 3 (RRP-3)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	05/16/14	07/22/14
	CPRIT Application Receipt System (CARS) opened	04/01/14	07/22/14
	CPRIT Application Receipt System (CARS) closed	06/11/14	07/22/14
	Date application submitted	06/09/14	07/22/14
	Method of submission	CARS	07/22/14
	Within receipt period	YES	07/22/14
	Appeal to submit application after CARS closed	N/A	07/22/14
	Appeal for late application submission accepted	N/A	07/22/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/22/14
	Donation(s) made to CPRIT/foundation	NO	07/22/14
	Assigned to primary reviewers	06/20/14	07/22/14
	Applicant notified of review panel assignment	N/A	07/22/14
	Primary Reviewer 1 COI signed	06/17/14	07/22/14
	Primary Reviewer 2 COI signed	06/19/14	07/22/14
3. Peer Review: Teleconference Meeting	Primary Reviewer 1 critique submitted	07/07/14	07/22/14
	Primary Reviewer 2 critique submitted	07/10/14	07/22/14
	COI indicated by non-primary reviewer	NONE	07/22/14
	COI recused from participation	N/A	07/22/14
	Discussed at Teleconference Meeting	YES	07/22/14
	Peer Review: Teleconference Meeting	07/11/14	07/22/14
	Post review statements signed	07/22/14	07/23/14
	Third Party Observer Report	07/12/14	07/23/14
	Score report delivered to CSO	07/12/14	07/22/14
4. Final SRC Recommendation	COI indicated by SRC member	NONE	07/22/14
	COI recused from participation	N/A	07/22/14
	SRC Meeting	07/11/14	07/22/14
	Third Party Observer Report	07/12/14	07/23/14
	Recommended for grant award	YES	07/23/14
	SRC Chair Notification to PIC and OC	07/11/14	07/23/14
5. PIC Review	COI Indicated by PIC member	NONE	07/23/14
	COI recused from participation	N/A	07/23/14
	PIC review meeting	07/15/14	07/23/14
	Recommended for grant award	YES	07/23/14
6. Oversight Committee Approval	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT

Application RR140073

Recruitment of First-Time, Tenure Track Nomination of Aryeh Warmflash

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Recruitment of First-Time, Tenure Track Faculty Member* Request for Applications (RFA). CPRIT received seven applications for this RFA. The application was assigned to the Scientific Review Council for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

This statement is true."



Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 4th day of August, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 2
PROGRAM Research
AWARD MECHANISM Recruitment of First-Time Faculty Members (RFTFM)
APPLICATION ID RR140073
APPLICATION TITLE Recruitment of First-Time, Tenure Track Faculty Member -
 Dr. Aryeh Warmflash
APPLICANT NAME Carson, Daniel
ORGANIZATION Rice University
PANEL NAME Recruitment Review Panel - 3 (RRP-3)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	05/16/14	07/22/14
	CPRIT Application Receipt System (CARS) opened	04/01/14	07/22/14
	CPRIT Application Receipt System (CARS) closed	06/11/14	07/22/14
	Date application submitted	06/10/14	07/22/14
	Method of submission	CARS	07/22/14
	Within receipt period	YES	07/22/14
	Appeal to submit application after CARS closed	N/A	07/22/14
	Appeal for late application submission accepted	N/A	07/22/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/22/14
	Donation(s) made to CPRIT/foundation	NO	07/22/14
	Assigned to primary reviewers	06/20/14	07/22/14
	Applicant notified of review panel assignment	N/A	07/22/14
	Primary Reviewer 1 COI signed	06/19/14	07/22/14
	Primary Reviewer 2 COI signed	06/20/14	07/22/14
3. Peer Review: Teleconference Meeting	Primary Reviewer 1 critique submitted	07/07/14	07/22/14
	Primary Reviewer 2 critique submitted	07/09/14	07/22/14
	COI indicated by non-primary reviewer	NONE	07/22/14
	COI recused from participation	N/A	07/22/14
	Discussed at Teleconference Meeting	YES	07/22/14
	Peer Review: Teleconference Meeting	07/11/14	07/22/14
	Post review statements signed	07/22/14	07/23/14
	Third Party Observer Report	07/12/14	07/23/14
4. Final SRC Recommendation	Score report delivered to CSO	07/12/14	07/22/14
	COI indicated by SRC member	NONE	07/22/14
	COI recused from participation	N/A	07/22/14
	SRC Meeting	07/11/14	07/22/14
	Third Party Observer Report	07/12/14	07/23/14
	Recommended for grant award	YES	07/23/14
5. PIC Review	SRC Chair Notification to PIC and OC	07/11/14	07/23/14
	COI indicated by PIC member	NONE	07/23/14
	COI recused from participation	N/A	07/23/14
	PIC review meeting	07/15/14	07/23/14
6. Oversight Committee Approval	Recommended for grant award	YES	07/23/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT

Application RR140077

Recruitment of First-Time, Tenure Track Nomination of George Eisenhoffer

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Recruitment of First-Time, Tenure Track Faculty Member* Request for Applications (RFA). CPRIT received seven applications for this RFA. The application was assigned to the Scientific Review Council for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

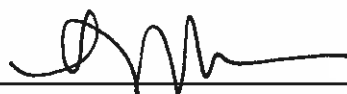
This statement is true."



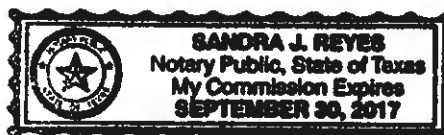
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 4th day of August, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 2
PROGRAM Research
AWARD MECHANISM Recruitment of First-Time Faculty Members (RFTFM)
APPLICATION ID RR140077
APPLICATION TITLE Recruitment of First-Time, Tenure-Track Faculty - George Eisenhoffer
APPLICANT NAME Dmitrovsky, Ethan
ORGANIZATION The University of Texas M. D. Anderson Cancer Center
PANEL NAME Recruitment Review Panel - 3 (RRP-3)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	05/16/14	07/22/14
	CPRIT Application Receipt System (CARS) opened	04/01/14	07/22/14
	CPRIT Application Receipt System (CARS) closed	06/11/14	07/22/14
	Date application submitted	06/10/14	07/22/14
	Method of submission	CARS	07/22/14
	Within receipt period	YES	07/22/14
	Appeal to submit application after CARS closed	N/A	07/22/14
	Appeal for late application submission accepted	N/A	07/22/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/22/14
	Donation(s) made to CPRIT/foundation	NO	07/22/14
	Assigned to primary reviewers	06/20/14	07/22/14
	Applicant notified of review panel assignment	N/A	07/22/14
	Primary Reviewer 1 COI signed	06/20/14	07/22/14
	Primary Reviewer 2 COI signed	06/19/14	07/22/14
3. Peer Review: Teleconference Meeting	Primary Reviewer 1 critique submitted	07/07/14	07/22/14
	Primary Reviewer 2 critique submitted	07/10/14	07/22/14
	COI indicated by non-primary reviewer	NONE	07/22/14
	COI recused from participation	N/A	07/22/14
	Discussed at Teleconference Meeting	YES	07/22/14
	Peer Review: Teleconference Meeting	07/11/14	07/22/14
	Post review statements signed	07/22/14	07/23/14
	Third Party Observer Report	07/12/14	07/23/14
4. Final SRC Recommendation	Score report delivered to CSO	07/12/14	07/22/14
	COI indicated by SRC member	NONE	07/22/14
	COI recused from participation	N/A	07/22/14
	SRC Meeting	07/11/14	07/22/14
	Third Party Observer Report	07/12/14	07/23/14
	Recommended for grant award	YES	07/23/14
5. PIC Review	SRC Chair Notification to PIC and OC	07/11/14	07/23/14
	COI indicated by PIC member	NONE	07/23/14
	COI recused from participation	N/A	07/23/14
	PIC review meeting	07/15/14	07/23/14
6. Oversight Committee Approval	Recommended for grant award	YES	07/23/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT

Application RR140081

Recruitment of Established Investigators Nomination of Gang Bao

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Recruitment of Established Investigators Request for Applications (RFA)*. CPRIT received three applications for this RFA. The application was assigned to the Scientific Review Council for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.


This statement is true."



Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 4th day of August, 2014,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 2
PROGRAM Research
AWARD MECHANISM Recruitment of Established Investigators (REI)
APPLICATION ID RR140081
APPLICATION TITLE Rice University Recruitment of Established Investigator,
 Gang Bao
APPLICANT NAME McLendon, George
ORGANIZATION Rice University
PANEL NAME Recruitment Review Panel - 3 (RRP-3)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	05/16/14	07/22/14
	CPRIT Application Receipt System (CARS) opened	04/01/14	07/22/14
	CPRIT Application Receipt System (CARS) closed	06/11/14	07/22/14
	Date application submitted	06/11/14	07/22/14
	Method of submission	CARS	07/22/14
	Within receipt period	YES	07/22/14
	Appeal to submit application after CARS closed	N/A	07/22/14
	Appeal for late application submission accepted	N/A	07/22/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/22/14
	Donation(s) made to CPRIT/foundation	NO	07/22/14
	Assigned to primary reviewers	06/20/14	07/22/14
	Applicant notified of review panel assignment	N/A	07/22/14
	Primary Reviewer 1 COI signed	06/19/14	07/22/14
	Primary Reviewer 2 COI signed	06/17/14	07/22/14
3. Peer Review: Teleconference Meeting	Primary Reviewer 1 critique submitted	07/10/14	07/22/14
	Primary Reviewer 2 critique submitted	07/07/14	07/22/14
	COI indicated by non-primary reviewer	NONE	07/22/14
	COI recused from participation	N/A	07/22/14
	Discussed at Teleconference Meeting	YES	07/22/14
	Peer Review: Teleconference Meeting	07/11/14	07/22/14
	Post review statements signed	07/22/14	07/23/14
	Third Party Observer Report	07/12/14	07/23/14
4. Final SRC Recommendation	Score report delivered to CSO	07/12/14	07/22/14
	COI indicated by SRC member	NONE	07/22/14
	COI recused from participation	N/A	07/22/14
	SRC Meeting	07/11/14	07/22/14
	Thlrld Party Observer Report	07/12/14	07/23/14
	Recommended for grant award	YES	07/23/14
5. PIC Review	SRC Chair Notification to PIC and OC	07/11/14	07/23/14
	COI indicated by PIC member	NONE	07/23/14
	COI recused from participation	N/A	07/23/14
	PIC review meeting	07/15/14	07/23/14
6. Oversight Committee Approval	Recommended for grant award	YES	07/23/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT

Application RR140082

Recruitment of Rising Stars Nomination of Daniela Nicastro

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Recruitment of Rising Stars* Request for Applications (RFA). CPRIT received six applications for this RFA. The application was assigned to the Scientific Review Council for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

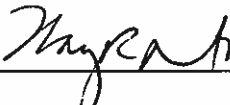
- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

This statement is true."



Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 4th day of August, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 2
PROGRAM Research
AWARD MECHANISM Recruitment of Rising Stars (RRS)
APPLICATION ID RR140082
APPLICATION TITLE High-Resolution Visualization of Native, Dynamic DNA-Interacting Complexes Inside Normal and Cancerous Cells
APPLICANT NAME Fitz, John
ORGANIZATION The University of Texas Southwestern Medical Center
PANEL NAME Recruitment Review Panel - 3 (RRP-3)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	05/16/14	07/22/14
	CPRIT Application Receipt System (CARS) opened	04/01/14	07/22/14
	CPRIT Application Receipt System (CARS) closed	06/11/14	07/22/14
	Date application submitted	06/10/14	07/22/14
	Method of submission	CARS	07/22/14
	Within receipt period	YES	07/22/14
	Appeal to submit application after CARS closed	N/A	07/22/14
	Appeal for late application submission accepted	N/A	07/22/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/22/14
	Donation(s) made to CPRIT/foundation	NO	07/22/14
	Assigned to primary reviewers	06/20/14	07/22/14
	Applicant notified of review panel assignment	N/A	07/22/14
	Primary Reviewer 1 COI signed	06/18/14	07/22/14
	Primary Reviewer 2 COI signed	06/19/14	07/22/14
3. Peer Review: Teleconference Meeting	Primary Reviewer 1 critique submitted	07/10/14	07/22/14
	Primary Reviewer 2 critique submitted	07/10/14	07/22/14
	COI indicated by non-primary reviewer	NONE	07/22/14
	COI recused from participation	N/A	07/22/14
	Discussed at Teleconference Meeting	YES	07/22/14
	Peer Review: Teleconference Meeting	07/11/14	07/22/14
	Post review statements signed	07/22/14	07/23/14
	Third Party Observer Report	07/12/14	07/23/14
4. Final SRC Recommendation	Score report delivered to CSO	07/12/14	07/22/14
	COI indicated by SRC member	NONE	07/22/14
	COI recused from participation	N/A	07/22/14
	SRC Meeting	07/11/14	07/22/14
	Third Party Observer Report	07/12/14	07/23/14
	Recommended for grant award	YES	07/23/14
5. PIC Review	SRC Chair Notification to PIC and OC	07/11/14	07/23/14
	COI indicated by PIC member	NONE	07/23/14
	COI recused from participation	N/A	07/23/14
	PIC review meeting	07/15/14	07/23/14
6. Oversight Committee Approval	Recommended for grant award	YES	07/23/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT

Application RR140084

Recruitment of First-Time, Tenure Track Nomination of David McFadden

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Recruitment of First-Time, Tenure Track Faculty Member* Request for Applications (RFA). CPRIT received seven applications for this RFA. The application was assigned to the Scientific Review Council for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

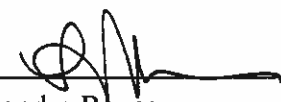
This statement is true."



Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 4th day of August, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 2
PROGRAM Research
AWARD MECHANISM Recruitment of First-Time Faculty Members (RFTFM)
APPLICATION ID RR140084
APPLICATION TITLE Deciphering Genetic and Epigenetic Mechanisms of Endocrine Cancer Progression and Therapy Resistance by Cross-Species Genomics
APPLICANT NAME Fitz, John
ORGANIZATION The University of Texas Southwestern Medical Center
PANEL NAME Recruitment Review Panel - 3 (RRP-3)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	05/16/14	07/22/14
	CPRIT Application Receipt System (CARS) opened	04/01/14	07/22/14
	CPRIT Application Receipt System (CARS) closed	06/11/14	07/22/14
	Date application submitted	06/10/14	07/22/14
	Method of submission	CARS	07/22/14
	Within receipt period	YES	07/22/14
	Appeal to submit application after CARS closed	N/A	07/22/14
	Appeal for late application submission accepted	N/A	07/22/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/22/14
	Donation(s) made to CPRIT/foundation	NO	07/22/14
	Assigned to primary reviewers	06/20/14	07/22/14
	Applicant notified of review panel assignment	N/A	07/22/14
	Primary Reviewer 1 COI signed	06/18/14	07/22/14
	Primary Reviewer 2 COI signed	06/17/14	07/22/14
3. Peer Review: Teleconference Meeting	Primary Reviewer 1 critique submitted	07/08/14	07/22/14
	Primary Reviewer 2 critique submitted	07/07/14	07/22/14
	COI indicated by non-primary reviewer	NONE	07/22/14
	COI recused from participation	N/A	07/22/14
	Discussed at Teleconference Meeting	YES	07/22/14
	Peer Review: Teleconference Meeting	07/11/14	07/22/14
	Post review statements signed	07/22/14	07/23/14
	Third Party Observer Report	07/12/14	07/23/14
	Score report delivered to CSO	07/12/14	07/22/14
4. Final SRC Recommendation	COI indicated by SRC member	NONE	07/22/14
	COI recused from participation	N/A	07/22/14
	SRC Meeting	07/11/14	07/22/14
	Third Party Observer Report	07/12/14	07/23/14
	Recommended for grant award	YES	07/23/14
	SRC Chair Notification to PIC and OC	07/11/14	07/23/14
5. PIC Review	COI indicated by PIC member	NONE	07/23/14
	COI recused from participation	N/A	07/23/14
	PIC review meeting	07/15/14	07/23/14
	Recommended for grant award	YES	07/23/14
6. Oversight Committee Approval	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140132
Individual Investigator Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Imaging Technology and Informatics panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

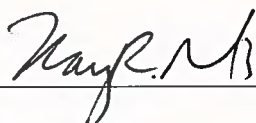
The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

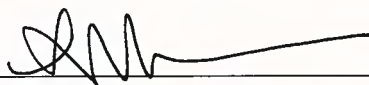
This statement is true."



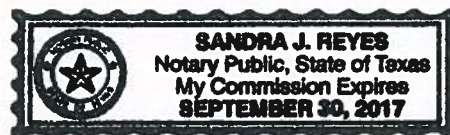
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research
AWARD MECHANISM Individual Investigator Research Awards (IIRA)
APPLICATION ID RP140132

APPLICATION TITLE Towards Point-of-Care Nucleic Acid Cancer Diagnostics

APPLICANT NAME Zhang, David
ORGANIZATION Rice University
PANEL NAME Imaging Technology and Informatics (ITI)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	01/29/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
2. Receipt, Referral, and Assignment	Appeal for late application submission accepted	N/A	07/02/14
	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	03/17/14	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	04/11/14	07/02/14
	Primary Reviewer 2 COI signed	04/16/14	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	04/09/14	07/02/14
	Primary Reviewer 1 critique submitted	04/07/14	07/02/14
	Primary Reviewer 2 critique submitted	04/06/14	07/02/14
	Primary Reviewer 3 critique submitted	04/07/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	Preliminary Evaluation score summary sent to Chair	04/11/14	07/02/14
	Recommended for full review	YES	07/02/14
4. Peer Review: On-Site Meeting	Applicant notified of outcome	05/21/14	07/02/14
	Assigned to primary reviewers	04/25/14	07/02/14
	Primary Reviewer 1 COI signed	04/11/14	07/02/14
	Primary Reviewer 2 COI signed	04/16/14	07/02/14
	Primary Reviewer 3 COI signed	04/09/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/24/14	07/02/14
	Primary Reviewer 1 critique submitted	05/20/14	07/02/14
	Primary Reviewer 2 critique submitted	05/21/14	07/02/14
	Primary Reviewer 3 critique submitted	05/14/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	05/28/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	05/29/14-05/30/14	07/02/14
	Post review statements signed	05/30/14	07/02/14
5. Final SRC Recommendation	Third Party Observer Report	05/30/14	07/02/14
	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRCPDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
6. PIC Review	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/02/14
	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
7. Oversight Committee Approval	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP140140
Individual Investigator Research Award

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Imaging Technology and Informatics panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

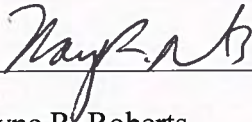
The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

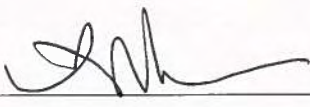
I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

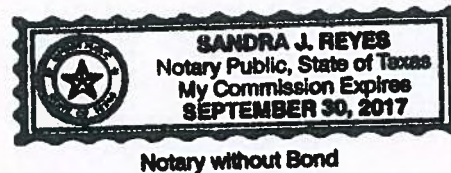
This statement is true."


Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research
AWARD MECHANISM Individual Investigator Research Awards (IIRA)
APPLICATION ID RP140140
APPLICATION TITLE Turn ON the Tumor Contrast for Surgical Resection of Head and Neck Cancers
APPLICANT NAME Gao, Jinming
ORGANIZATION The University of Texas Southwestern Medical Center
PANEL NAME Imaging Technology and Informatics (ITI)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	02/02/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	N/A	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	N/A	07/02/14
	Primary Reviewer 2 COI signed	N/A	07/02/14
	Primary Reviewer 3 COI signed	N/A	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 1 critique submitted	N/A	07/02/14
	Primary Reviewer 2 critique submitted	N/A	07/02/14
	Primary Reviewer 3 critique submitted	N/A	07/02/14
	COI indicated by non-primary reviewer	N/A	07/02/14
	Preliminary Evaluation score summary sent to Chair	N/A	07/02/14
	Recommended for full review	N/A	07/02/14
	Applicant notified of outcome	N/A	07/02/14
4. Peer Review: On-Site Meeting	Assigned to primary reviewers	04/25/14	07/02/14
	Primary Reviewer 1 COI signed	04/16/14	07/02/14
	Primary Reviewer 2 COI signed	04/17/14	07/02/14
	Primary Reviewer 3 COI signed	04/23/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/23/14	07/02/14
	Primary Reviewer 1 critique submitted	05/18/14	07/02/14
	Primary Reviewer 2 critique submitted	05/18/14	07/02/14
	Primary Reviewer 3 critique submitted	05/20/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	05/28/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	05/29/14-05/30/14	07/02/14
	Post review statements signed	05/30/14	07/02/14
	Third Party Observer Report	05/30/14	07/02/14
5. Final SRC Recommendation	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRCPDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/02/14
6. PIC Review	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
7. Oversight Committee Approval	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP140141
Individual Investigator Research Award

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Translational Cancer Research panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

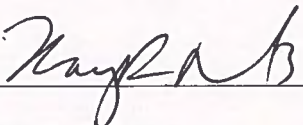
The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

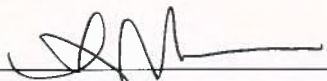
This statement is true."



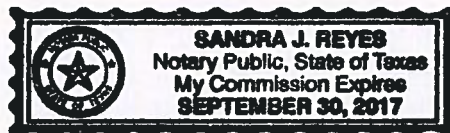
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research
AWARD MECHANISM Individual Investigator Research Awards (IIRA)
APPLICATION ID RP140141
APPLICATION TITLE Targeting HER2 for Cancer Therapy
APPLICANT NAME Ward, Elizabeth
ORGANIZATION The University of Texas Southwestern Medical Center
PANEL NAME Translational Cancer Research (TCR)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	01/29/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	N/A	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	N/A	07/02/14
	Primary Reviewer 2 COI signed	N/A	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	N/A	07/02/14
	Primary Reviewer 1 critique submitted	N/A	07/02/14
	Primary Reviewer 2 critique submitted	N/A	07/02/14
	Primary Reviewer 3 critique submitted	N/A	07/02/14
	COI indicated by non-primary reviewer	N/A	07/02/14
	Preliminary Evaluation score summary sent to Chair	N/A	07/02/14
	Recommended for full review	N/A	07/02/14
4. Peer Review: On-Site Meeting	Applicant notified of outcome	N/A	07/02/14
	Assigned to primary reviewers	05/08/14	07/02/14
	Primary Reviewer 1 COI signed	04/21/14	07/02/14
	Primary Reviewer 2 COI signed	04/21/14	07/02/14
	Primary Reviewer 3 COI signed	04/24/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/27/14	07/02/14
	Primary Reviewer 1 critique submitted	06/01/14	07/02/14
	Primary Reviewer 2 critique submitted	05/28/14	07/02/14
	Primary Reviewer 3 critique submitted	06/01/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	06/05/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	06/06/14	07/02/14
	Post review statements signed	06/06/14	07/02/14
	Third Party Observer Report	06/12/14	07/02/14
5. Final SRC Recommendation	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRCPDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/02/14
6. PIC Review	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
7. Oversight Committee Approval	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP140143
Individual Investigator Research Award

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Basic Cancer Research Panel 1 for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

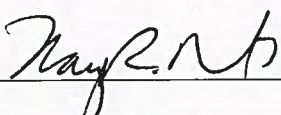
The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

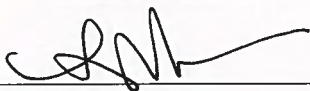
This statement is true."



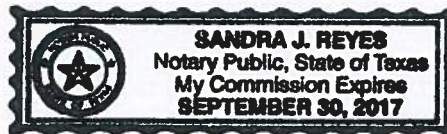
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

FY 2014
 CYCLE 1
 PROGRAM Research
 AWARD MECHANISM Individual Investigator Research Awards (IIRA)
 APPLICATION ID RP140143
 APPLICATION TITLE Dependence of small cell lung cancer on the basic helix-loop-helix transcription factors Ascl1 and NeuroD1
 APPLICANT NAME Cobb, Melanie
 ORGANIZATION The University of Texas Southwestern Medical Center
 PANEL NAME Basic Cancer Research-1 (BCR-1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	02/03/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	N/A	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	N/A	07/02/14
	Primary Reviewer 2 COI signed	N/A	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	N/A	07/02/14
	Primary Reviewer 1 critique submitted	N/A	07/02/14
	Primary Reviewer 2 critique submitted	N/A	07/02/14
	Primary Reviewer 3 critique submitted	N/A	07/02/14
	COI indicated by non-primary reviewer	N/A	07/02/14
	Preliminary Evaluation score summary sent to Chair	N/A	07/02/14
	Recommended for full review	N/A	07/02/14
	Applicant notified of outcome	N/A	07/02/14
4. Peer Review: On-Site Meeting	Assigned to primary reviewers	04/18/14	07/02/14
	Primary Reviewer 1 COI signed	04/09/14	07/02/14
	Primary Reviewer 2 COI signed	04/14/14	07/02/14
	Primary Reviewer 3 COI signed	04/09/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/23/14	07/02/14
	Primary Reviewer 1 critique submitted	05/18/14	07/02/14
	Primary Reviewer 2 critique submitted	05/20/14	07/02/14
	Primary Reviewer 3 critique submitted	05/14/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	05/24/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	05/31/14-06/01/14	07/02/14
	Post review statements signed	06/11/14	07/02/14
	Third Party Observer Report	06/12/14	07/02/14
5. Final SRC Recommendation	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRCPDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/02/14
6. PIC Review	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
7. Oversight Committee Approval	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140152
Individual Investigator Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to Translational Cancer Research panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

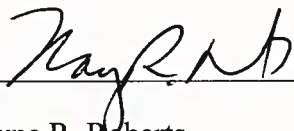
The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

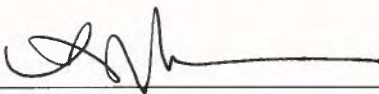
This statement is true."



Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research
AWARD MECHANISM Individual Investigator Research Awards (IIRA)
APPLICATION ID RP140152
APPLICATION TITLE Natural Product for Treatment of Non Small Cell Lung Cancer
APPLICANT NAME MacMillan, John
ORGANIZATION The University of Texas Southwestern Medical Center
PANEL NAME Translational Cancer Research (TCR)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	02/02/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	03/24/14	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	04/21/14	07/02/14
	Primary Reviewer 2 COI signed	04/21/14	07/02/14
	Primary Reviewer 3 COI signed	04/21/14	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 1 critique submitted	04/04/14	07/02/14
	Primary Reviewer 2 critique submitted	04/07/14	07/02/14
	Primary Reviewer 3 critique submitted	04/20/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	Preliminary Evaluation score summary sent to Chair	05/01/14	07/02/14
	Recommended for full review	YES	07/02/14
	Applicant notified of outcome	05/21/14	07/02/14
4. Peer Review: On-Site Meeting	Assigned to primary reviewers	05/08/14	07/02/14
	Primary Reviewer 1 COI signed	04/21/14	07/02/14
	Primary Reviewer 2 COI signed	04/23/14	07/02/14
	Primary Reviewer 3 COI signed	04/21/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/27/14	07/02/14
	Primary Reviewer 1 critique submitted	05/28/14	07/02/14
	Primary Reviewer 2 critique submitted	05/29/14	07/02/14
	Primary Reviewer 3 critique submitted	05/27/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	06/05/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	06/06/14	07/02/14
	Post review statements signed	06/06/14	07/02/14
	Third Party Observer Report	06/12/14	07/02/14
5. Final SRC Recommendation	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRC/PDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/02/14
	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
6. PIC Review	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
7. Oversight Committee Approval	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140179
Individual Investigator Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Basic Cancer Research Panel 1 for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

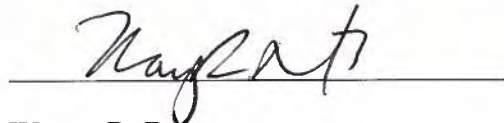
The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.


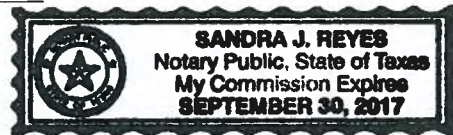
This statement is true."



Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas

Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research
AWARD MECHANISM Individual Investigator Research Awards - (IIRA)
APPLICATION ID RP140179
APPLICATION TITLE Targeting Self-renewal in Leukemic Stem Cells Through the Inactivation of KLF4
APPLICANT NAME Lacorazza, Daniel
ORGANIZATION Baylor College of Medicine
PANEL NAME Basic Cancer Research-1(BCR-1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	01/28/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
2. Receipt, Referral, and Assignment	Appeal for late application submission accepted	N/A	07/02/14
	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	03/17/14	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	04/14/14	07/02/14
	Primary Reviewer 2 COI signed	04/09/14	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	04/21/14	07/02/14
	Primary Reviewer 1 critique submitted	04/14/14	07/02/14
	Primary Reviewer 2 critique submitted	04/02/14	07/02/14
	Primary Reviewer 3 critique submitted	04/05/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	Preliminary Evaluation score summary sent to Chair	04/15/14	07/02/14
	Recommended for full review	YES	07/02/14
4. Peer Review: On-Site Meeting	Applicant notified of outcome	05/21/14	07/02/14
	Assigned to primary reviewers	04/18/14	07/02/14
	Primary Reviewer 1 COI signed	04/14/14	07/02/14
	Primary Reviewer 2 COI signed	04/09/14	07/02/14
	Primary Reviewer 3 COI signed	04/21/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/23/14	07/02/14
	Primary Reviewer 1 critique submitted	05/20/14	07/02/14
	Primary Reviewer 2 critique submitted	05/16/14	07/02/14
	Primary Reviewer 3 critique submitted	05/14/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	05/26/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	05/31/14-06/01/14	07/02/14
	Post review statements signed	06/11/14	07/02/14
5. Final SRC Recommendation	Third Party Observer Report	06/12/14	07/02/14
	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRC/DRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
6. PIC Review	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/02/14
	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
7. Oversight Committee Approval	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140181
Individual Investigator Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Cancer Biology panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

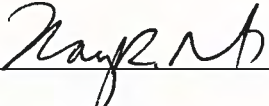
The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

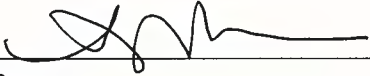
This statement is true."



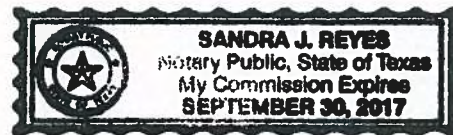
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research
AWARD MECHANISM Individual Investigator Research Awards (IIRA)
APPLICATION ID RP140181
APPLICATION TITLE Mechanisms of CTC Biomarkers in Breast Cancer Brain Metastasis
APPLICANT NAME MARCHETTI, DARIO
ORGANIZATION Baylor College of Medicine
PANEL NAME Cancer Biology (CB)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	01/21/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	03/17/14	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	04/09/14	07/02/14
	Primary Reviewer 2 COI signed	04/09/14	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	03/11/14	07/02/14
	Primary Reviewer 1 critique submitted	04/08/14	07/02/14
	Primary Reviewer 2 critique submitted	04/06/14	07/02/14
	Primary Reviewer 3 critique submitted	04/07/14	07/02/14
	COI indicated by non-primary reviewer	Costello, Joseph	07/02/14
	Preliminary Evaluation score summary sent to Chair	04/11/14	07/02/14
	Recommended for full review	YES	07/02/14
4. Peer Review: On-Site Meeting	Applicant notified of outcome	05/21/14	07/02/14
	Assigned to primary reviewers	04/22/14	07/02/14
	Primary Reviewer 1 COI signed	04/09/14	07/02/14
	Primary Reviewer 2 COI signed	04/09/14	07/02/14
	Primary Reviewer 3 COI signed	04/21/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/21/14	07/02/14
	Primary Reviewer 1 critique submitted	05/20/14	07/02/14
	Primary Reviewer 2 critique submitted	05/20/14	07/02/14
	Primary Reviewer 3 critique submitted	05/18/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	05/25/14	07/02/14
	COI indicated by non-primary reviewer	Costello, Joseph	07/02/14
	COI recused from participation	YES	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	05/28/14-05/29/14	07/02/14
	Post review statements signed	05/29/14	07/02/14
	Third Party Observer Report	06/12/14	07/02/14
5. Final SRC Recommendation	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRCPDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/02/14
6. PIC Review	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
7. Oversight Committee Approval	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140216
High-Impact/High-Risk Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *High-Impact/High-Risk Research Award* Request for Applications (RFA). CPRIT received 100 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Basic Cancer Research Panel 1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that one application was not recommended for a grant award that has the same score as an application that was recommended for a grant award. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score. The two applications were reviewed by different review panels.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

No individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a 3.5 score, another panel may decide based on the totality of factors that an application with a 3.5 score should not be recommended. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

This statement is true."

Wayne R. Roberts

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.

Sandra Reyes

Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research
AWARD MECHANISM High-Impact/High-Risk Research Awards (HIHRA)
APPLICATION ID RP140216
APPLICATION TITLE Context-Specific In Vivo Screening for KRAS-Associated Gene Aberration Drivers Using Genetically Engineered Mouse Models of Lung Cancer
APPLICANT NAME Scott, Kenneth
ORGANIZATION Baylor College of Medicine
PANEL NAME Basic Cancer Research-1 (BCR-1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	01/24/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	N/A	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	N/A	07/02/14
	Primary Reviewer 2 COI signed	N/A	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	N/A	07/02/14
	Primary Reviewer 1 critique submitted	N/A	07/02/14
	Primary Reviewer 2 critique submitted	N/A	07/02/14
	Primary Reviewer 3 critique submitted	N/A	07/02/14
	COI indicated by non-primary reviewer	N/A	07/02/14
	Preliminary Evaluation score summary sent to Chair	N/A	07/02/14
	Recommended for full review	N/A	07/02/14
	Applicant notified of outcome	N/A	07/02/14
4. Peer Review: On-Site Meeting	Assigned to primary reviewers	04/18/14	07/02/14
	Primary Reviewer 1 COI signed	04/09/14	07/02/14
	Primary Reviewer 2 COI signed	04/09/14	07/02/14
	Primary Reviewer 3 COI signed	04/16/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/21/14	07/02/14
	Primary Reviewer 1 critique submitted	05/07/14	07/02/14
	Primary Reviewer 2 critique submitted	05/01/14	07/02/14
	Primary Reviewer 3 critique submitted	05/17/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	05/24/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	05/31/14-06/01/14	07/02/14
	Post review statements signed	06/11/14	07/02/14
	Third Party Observer Report	06/12/14	07/02/14
	Score report delivered to CSO	06/19/14	07/02/14
5. Final SRC Recommendation	COI indicated by SRCPDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/02/14
	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
6. PIC Review	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
7. Oversight Committee Approval	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140218
Individual Investigator Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to Translational Cancer Research panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

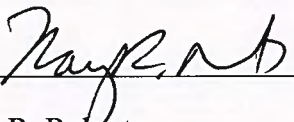
The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

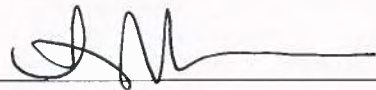
This statement is true."



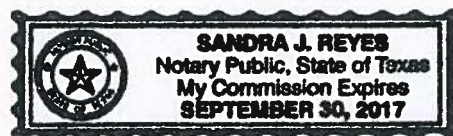
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research
AWARD MECHANISM Individual Investigator Research Awards (IIRA)
APPLICATION ID RP140218
APPLICATION TITLE Inhibiting Oxidative Phosphorylation: A Novel Strategy in Leukemia
APPLICANT NAME Konopleva, Marina
ORGANIZATION The University of Texas M. D. Anderson Cancer Center
PANEL NAME Translational Cancer Research (TCR)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	01/31/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	03/24/14	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	04/23/14	07/02/14
	Primary Reviewer 2 COI signed	03/13/14	07/02/14
	Primary Reviewer 3 COI signed	04/25/14	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 1 critique submitted	N/A	07/02/14
	Primary Reviewer 2 critique submitted	04/12/14	07/02/14
	Primary Reviewer 3 critique submitted	04/17/14	07/02/14
	COI indicated by non-primary reviewer	Mullighan, Charles	07/02/14
	Preliminary Evaluation score summary sent to Chair	05/01/14	07/02/14
	Recommended for full review	YES	07/02/14
	Applicant notified of outcome	05/21/14	07/02/14
4. Peer Review: On-Site Meeting	Assigned to primary reviewers	05/08/14	07/02/14
	Primary Reviewer 1 COI signed	04/23/14	07/02/14
	Primary Reviewer 2 COI signed	04/25/14	07/02/14
	Primary Reviewer 3 COI signed	04/24/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/27/14	07/02/14
	Primary Reviewer 1 critique submitted	05/29/14	07/02/14
	Primary Reviewer 2 critique submitted	06/03/14	07/02/14
	Primary Reviewer 3 critique submitted	06/01/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	06/05/14	07/02/14
	COI indicated by non-primary reviewer	DiPersio, John	07/02/14
	COI recused from participation	YES	07/02/14
	COI indicated by non-primary reviewer	Mullighan, Charles	07/02/14
	COI recused from participation	YES	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	06/06/14	07/02/14
	Post review statements signed	06/06/14	07/02/14
	Third Party Observer Report	06/12/14	07/02/14
	Score report delivered to CSO	06/19/14	07/02/14
5. Final SRC Recommendation	COI indicated by SRCPDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/02/14
6. PIC Review	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
7. Oversight Committee Approval	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP140222
Individual Investigator Research Award

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Cancer Biology panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

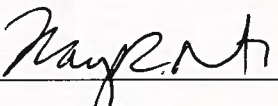
The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

This statement is true."



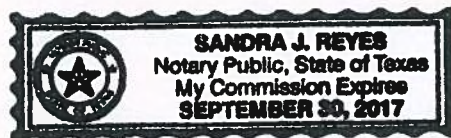
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research
AWARD MECHANISM Individual Investigator Research Awards (IIRA)
APPLICATION ID RP140222
APPLICATION TITLE Direct Roles for RB and E2F1 in DNA Repair
APPLICANT NAME Johnson, David
ORGANIZATION The University of Texas M. D. Anderson Cancer Center
PANEL NAME Cancer Biology (CB)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	01/30/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	03/17/14	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	04/09/14	07/02/14
	Primary Reviewer 2 COI signed	04/14/14	07/02/14
	Primary Reviewer 3 COI signed	04/09/14	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 1 critique submitted	03/19/14	07/02/14
	Primary Reviewer 2 critique submitted	04/08/14	07/02/14
	Primary Reviewer 3 critique submitted	04/07/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	Preliminary Evaluation score summary sent to Chair	04/11/14	07/02/14
	Recommended for full review	YES	07/02/14
	Applicant notified of outcome	05/21/14	07/02/14
4. Peer Review: On-Site Meeting	Assigned to primary reviewers	04/22/14	07/02/14
	Primary Reviewer 1 COI signed	N/A	07/02/14
	Primary Reviewer 2 COI signed	04/14/14	07/02/14
	Primary Reviewer 3 COI signed	04/09/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/21/14	07/02/14
	Primary Reviewer 1 critique submitted	N/A	07/02/14
	Primary Reviewer 2 critique submitted	05/16/14	07/02/14
	Primary Reviewer 3 critique submitted	05/14/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	05/25/14	07/02/14
	COI indicated by non-primary reviewer	Wahl, Geoffrey	07/02/14
	COI recused from participation	YES	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	05/28/14-05/29/14	07/02/14
	Post review statements signed	05/29/14	07/02/14
5. Final SRC Recommendation	Third Party Observer Report	06/12/14	07/02/14
	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRCPDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
	Third Party Observer Report	07/07/14	07/08/14
6. PIC Review	Recommended for grant award	YES	07/02/14
	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
7. Oversight Committee Approval	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP140223
High-Impact/High-Risk Research Award

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *High-Impact/High-Risk Research Award* Request for Applications (RFA). CPRIT received 100 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Basic Cancer Research Panel 2 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT’s grant review processes were followed by the review panel evaluating the applications in this grant cycle

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that one application was not recommended for a grant award that has the same score as an application that was recommended for a grant award. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score. The two applications were reviewed by different review panels.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

No individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a 3.5 score, another panel may decide based on the totality of factors that an application with a 3.5 score should not be recommended. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

This statement is true."

Wayne R. Roberts

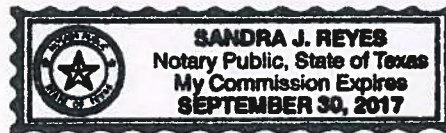
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.

[Signature]

Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research
AWARD MECHANISM High-Impact/High-Risk Research Awards (HIHRA)
APPLICATION ID RP140223
APPLICATION TITLE Viral MicroRNAs in Ovarian Cancer Growth and Metastasis
APPLICANT NAME Anderson, Matthew
ORGANIZATION Baylor College of Medicine
PANEL NAME Basic Cancer Research-2 (BCR-2)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/01/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/01/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/01/14
	Date application submitted	01/31/14	07/01/14
	Method of submission	CARS	07/01/14
	Within receipt period	YES	07/01/14
	Appeal to submit application after CARS closed	N/A	07/01/14
	Appeal for late application submission accepted	N/A	07/01/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/01/14
	Donation(s) made to CPRIT/foundation	NO	07/01/14
	Assigned to primary reviewers	N/A	07/01/14
	Applicant notified of review panel assignment	05/14/14	07/01/14
	Primary Reviewer 1 COI signed	N/A	07/01/14
	Primary Reviewer 2 COI signed	N/A	07/01/14
	Primary Reviewer 3 COI signed	N/A	07/01/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 1 critique submitted	N/A	07/01/14
	Primary Reviewer 2 critique submitted	N/A	07/01/14
	Primary Reviewer 3 critique submitted	N/A	07/01/14
	COI indicated by non-primary reviewer	N/A	07/01/14
	Preliminary Evaluation score summary sent to Chair	N/A	07/01/14
	Recommended for full review	N/A	07/01/14
4. Peer Review: On-Site Meeting	Applicant notified of outcome	N/A	07/01/14
	Assigned to primary reviewers	05/07/14	07/01/14
	Primary Reviewer 1 COI signed	04/21/14	07/01/14
	Primary Reviewer 2 COI signed	03/06/14	07/01/14
	Primary Reviewer 3 COI signed	05/08/14	07/01/14
	Primary (Advocate) Reviewer 4 COI signed	04/29/14	07/01/14
	Primary Reviewer 1 critique submitted	05/12/14	07/01/14
	Primary Reviewer 2 critique submitted	05/27/14	07/01/14
	Primary Reviewer 3 critique submitted	05/28/14	07/01/14
	Primary (Advocate) Reviewer 4 critique submitted	06/02/14	07/01/14
	COI indicated by non-primary reviewer	NONE	07/01/14
	COI recused from participation	N/A	07/01/14
	Discussed at On-Site Meeting	YES	07/01/14
	Peer Review: On-Site Meeting	06/04/14 - 06/05/14	07/01/14
	Post review statements signed	06/05/14	07/01/14
	Third Party Observer Report	06/12/14	07/01/14
	Score report delivered to CSO	06/19/14	07/01/14
5. Final SRC Recommendation	COI indicated by SRCPDRC member	NONE	07/01/14
	COI recused from participation	N/A	07/01/14
	SRC Meeting	06/24/14	07/01/14
	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/01/14
6. PIC Review	SRC Chair Notification to PIC and OC	06/24/14	07/01/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
7. Oversight Committee Approval	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140224
Individual Investigator Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Cancer Biology panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

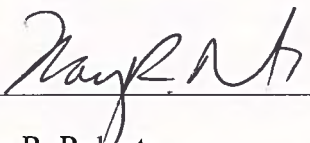
The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.


This statement is true."



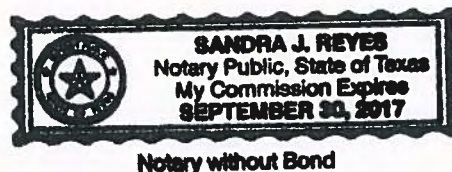
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research
AWARD MECHANISM Individual Investigator Research Awards (IIRA)
APPLICATION ID RP140224
APPLICATION TITLE PPAR-delta Regulation of Wnt/B-catenin to Drive Colon Cancer
APPLICANT NAME Shureiqi, Imad
ORGANIZATION The University of Texas M. D. Anderson Cancer Center
PANEL NAME Cancer Biology (CB)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	01/29/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	03/17/14	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	04/16/14	07/02/14
	Primary Reviewer 2 COI signed	04/09/14	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	04/09/14	07/02/14
	Primary Reviewer 1 critique submitted	03/18/14	07/02/14
	Primary Reviewer 2 critique submitted	04/04/14	07/02/14
	Primary Reviewer 3 critique submitted	03/29/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	Preliminary Evaluation score summary sent to Chair	04/11/14	07/02/14
	Recommended for full review	YES	07/02/14
4. Peer Review: On-Site Meeting	Applicant notified of outcome	05/21/14	07/02/14
	Assigned to primary reviewers	04/22/14	07/02/14
	Primary Reviewer 1 COI signed	04/16/14	07/02/14
	Primary Reviewer 2 COI signed	04/09/14	07/02/14
	Primary Reviewer 3 COI signed	04/09/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/21/14	07/02/14
	Primary Reviewer 1 critique submitted	05/15/14	07/02/14
	Primary Reviewer 2 critique submitted	05/15/14	07/02/14
	Primary Reviewer 3 critique submitted	05/15/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	05/25/14	07/02/14
	COI indicated by non-primary reviewer	Wahl, Geoffrey	07/02/14
	COI recused from participation	YES	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	05/28/14-05/29/14	07/02/14
	Post review statements signed	05/29/14	07/02/14
5. Final SRC Recommendation	Third Party Observer Report	06/12/14	07/02/14
	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRCPDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
	Third Party Observer Report	07/07/14	07/08/14
6. PIC Review	Recommended for grant award	YES	07/02/14
	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
7. Oversight Committee Approval	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140233
Individual Investigator Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to Translational Cancer Research panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

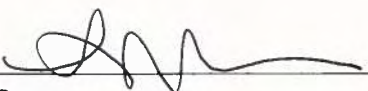
This statement is true."



Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS



Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research
AWARD MECHANISM Individual Investigator Research Awards (IIRA)
APPLICATION ID RP140233
APPLICATION TITLE Structure-guided Kinase Inhibitor Design for Cancer Therapy
APPLICANT NAME Westover, Kenneth
ORGANIZATION The University of Texas Southwestern Medical Center
PANEL NAME Translational Cancer Research (TCR)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	02/02/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	03/24/14	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	04/21/14	07/02/14
	Primary Reviewer 2 COI signed	04/21/14	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	05/03/14	07/02/14
	Primary Reviewer 1 critique submitted	04/21/14	07/02/14
	Primary Reviewer 2 critique submitted	04/04/14	07/02/14
	Primary Reviewer 3 critique submitted	04/15/14	07/02/14
	COI indicated by non-primary reviewer	Balk, Steven	07/02/14
	Preliminary Evaluation score summary sent to Chair	05/01/14	07/02/14
	Recommended for full review	YES	07/02/14
4. Peer Review: On-Site Meeting	Applicant notified of outcome	05/21/14	07/02/14
	Assigned to primary reviewers	05/08/14	07/02/14
	Primary Reviewer 1 COI signed	04/21/14	07/02/14
	Primary Reviewer 2 COI signed	04/21/14	07/02/14
	Primary Reviewer 3 COI signed	04/23/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/27/14	07/02/14
	Primary Reviewer 1 critique submitted	06/02/14	07/02/14
	Primary Reviewer 2 critique submitted	05/28/14	07/02/14
	Primary Reviewer 3 critique submitted	05/29/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	06/05/14	07/02/14
	COI indicated by non-primary reviewer	Balk, Steven	07/02/14
	COI recused from participation	YES	07/02/14
	COI indicated by non-primary reviewer	Ritz, Jerome	07/02/14
	COI recused from participation	YES	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	06/06/14	07/02/14
	Post review statements signed	06/06/14	07/02/14
	Third Party Observer Report	06/12/14	07/02/14
5. Final SRC Recommendation	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRCPDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/02/14
6. PIC Review	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
7. Oversight Committee Approval	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140244
Individual Investigator Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Translational Cancer Research panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

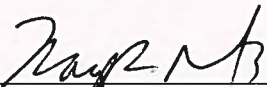
The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

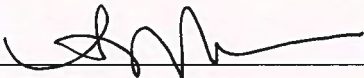
This statement is true."



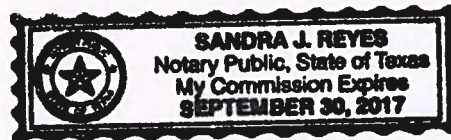
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research
AWARD MECHANISM Individual Investigator Research Awards (IIRA)
APPLICATION ID RP140244
APPLICATION TITLE Regulation of MDM2-Mediated Oncogenesis and Anti-Tumor Immunity by USP15
APPLICANT NAME Sun, Shao-Cong
ORGANIZATION The University of Texas M. D. Anderson Cancer Center
PANEL NAME Translational Cancer Research (TCR)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	01/30/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	03/24/14	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	04/27/14	07/02/14
	Primary Reviewer 2 COI signed	04/22/14	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	04/21/14	07/02/14
	Primary Reviewer 1 critique submitted	04/10/14	07/02/14
	Primary Reviewer 2 critique submitted	04/15/14	07/02/14
	Primary Reviewer 3 critique submitted	04/07/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	Preliminary Evaluation score summary sent to Chair	05/01/14	07/02/14
4. Peer Review: On-Site Meeting	Recommended for full review	YES	07/02/14
	Applicant notified of outcome	05/21/14	07/02/14
	Assigned to primary reviewers	05/08/14	07/02/14
	Primary Reviewer 1 COI signed	04/27/14	07/02/14
	Primary Reviewer 2 COI signed	04/22/14	07/02/14
	Primary Reviewer 3 COI signed	05/06/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/27/14	07/02/14
	Primary Reviewer 1 critique submitted	05/19/14	07/02/14
	Primary Reviewer 2 critique submitted	05/24/14	07/02/14
	Primary Reviewer 3 critique submitted	05/31/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	06/05/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	06/06/14	07/02/14
5. Final SRC Recommendation	Post review statements signed	06/06/14	07/02/14
	Third Party Observer Report	06/12/14	07/02/14
	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRCPDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
6. PIC Review	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/02/14
	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
7. Oversight Committee Approval	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140252
Individual Investigator Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Cancer Biology panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

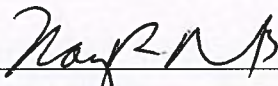
The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

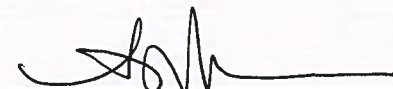
This statement is true."



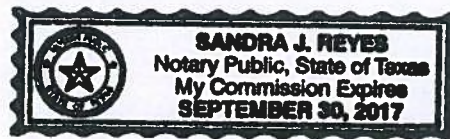
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research
AWARD MECHANISM Individual Investigator Research Awards (IIRA)
APPLICATION ID RP140252
APPLICATION TITLE Investigating and Preclinical Targeting Molecular Drivers of Muscle-invasive Bladder Cancer
APPLICANT NAME Chan, Keith
ORGANIZATION Baylor College of Medicine
PANEL NAME Cancer Biology (CB)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	01/31/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	03/17/14	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	04/09/14	07/02/14
	Primary Reviewer 2 COI signed	04/09/14	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	04/09/14	07/02/14
	Primary Reviewer 1 critique submitted	04/08/14	07/02/14
	Primary Reviewer 2 critique submitted	04/04/14	07/02/14
	Primary Reviewer 3 critique submitted	04/07/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	Preliminary Evaluation score summary sent to Chair	04/11/14	07/02/14
	Recommended for full review	YES	07/02/14
4. Peer Review: On-Site Meeting	Applicant notified of outcome	05/21/14	07/02/14
	Assigned to primary reviewers	04/22/14	07/02/14
	Primary Reviewer 1 COI signed	04/14/14	07/02/14
	Primary Reviewer 2 COI signed	04/09/14	07/02/14
	Primary Reviewer 3 COI signed	04/09/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/21/14	07/02/14
	Primary Reviewer 1 critique submitted	05/16/14	07/02/14
	Primary Reviewer 2 critique submitted	05/03/14	07/02/14
	Primary Reviewer 3 critique submitted	05/14/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	05/25/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	05/28/14-05/29/14	07/02/14
	Post review statements signed	05/29/14	07/02/14
5. Final SRC Recommendation	Third Party Observer Report	06/12/14	07/02/14
	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRC/DRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
	Third Party Observer Report	07/07/14	07/08/14
6. PIC Review	Recommended for grant award	YES	07/02/14
	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
7. Oversight Committee Approval	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP140258
Individual Investigator Research Award

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Cancer Prevention Research panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

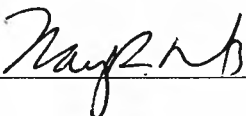
The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

This statement is true."



Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research
AWARD MECHANISM Individual Investigator Research Awards (IIRA)
APPLICATION ID RP140258
APPLICATION TITLE The Intersection between Childhood Cancer and Congenital Anomalies: Identifying Novel Cancer Predisposition Syndromes
APPLICANT NAME Lupo, Philip
ORGANIZATION Baylor College of Medicine
PANEL NAME Cancer Prevention Research (CPR)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	01/27/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	03/16/14	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	04/09/14	07/02/14
	Primary Reviewer 2 COI signed	04/14/14	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	04/15/14	07/02/14
	Primary Reviewer 1 critique submitted	03/28/14	07/02/14
	Primary Reviewer 2 critique submitted	04/05/14	07/02/14
	Primary Reviewer 3 critique submitted	04/08/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	Preliminary Evaluation score summary sent to Chair	04/11/14	07/02/14
4. Peer Review: On-Site Meeting	Recommended for full review	YES	07/02/14
	Applicant notified of outcome	05/21/14	07/02/14
	Assigned to primary reviewers	04/23/14	07/02/14
	Primary Reviewer 1 COI signed	04/09/14	07/02/14
	Primary Reviewer 2 COI signed	04/14/14	07/02/14
	Primary Reviewer 3 COI signed	04/15/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/21/14	07/02/14
	Primary Reviewer 1 critique submitted	05/19/14	07/02/14
	Primary Reviewer 2 critique submitted	05/19/14	07/02/14
	Primary Reviewer 3 critique submitted	05/24/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	06/02/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	06/03/04-06/04/14	07/02/14
5. Final SRC Recommendation	Post review statements signed	06/04/14	07/02/14
	Third Party Observer Report	06/12/14	07/02/14
	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRCPDRC member	DONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
6. PIC Review	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/02/14
	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
7. Oversight Committee Approval	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
7. Oversight Committee Approval	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140262
Individual Investigator Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Cancer Prevention Research panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

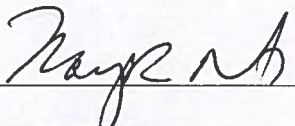
The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

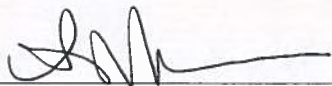
This statement is true."



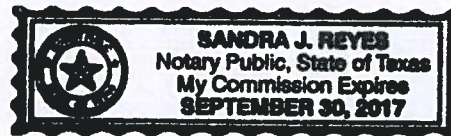
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research
AWARD MECHANISM Individual Investigator Research Awards (IIRA)
APPLICATION ID RP140262

APPLICATION TITLE Intrinsic Reward Sensitivity & Smoking Cessation with Varenicline or Patch NRT

APPLICANT NAME Cinciripini, Paul
ORGANIZATION The University of Texas M. D. Anderson Cancer Center
PANEL NAME Cancer Prevention Research (CPR)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	01/29/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	03/16/14	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	04/23/14	07/02/14
	Primary Reviewer 2 COI signed	04/14/14	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	04/10/14	07/02/14
	Primary Reviewer 1 critique submitted	04/06/14	07/02/14
	Primary Reviewer 2 critique submitted	04/08/14	07/02/14
	Primary Reviewer 3 critique submitted	04/10/14	07/02/14
	COI indicated by non-primary reviewer	Brandon, Thomas	07/02/14
	Preliminary Evaluation score summary sent to Chair	04/11/14	07/02/14
4. Peer Review: On-Site Meeting	Recommended for full review	YES	07/02/14
	Applicant notified of outcome	05/21/14	07/02/14
	Assigned to primary reviewers	04/23/14	07/02/14
	Primary Reviewer 1 COI signed	04/23/14	07/02/14
	Primary Reviewer 2 COI signed	04/14/14	07/02/14
	Primary Reviewer 3 COI signed	04/10/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/22/14	07/02/14
	Primary Reviewer 1 critique submitted	05/20/14	07/02/14
	Primary Reviewer 2 critique submitted	05/15/14	07/02/14
	Primary Reviewer 3 critique submitted	05/17/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	05/31/14	07/02/14
	COI indicated by non-primary reviewer	Brandon, Thomas	07/02/14
	COI recused from participation	YES	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
5. Final SRC Recommendation	Peer Review: On-Site Meeting	06/03/14-06/04/14	07/02/14
	Post review statements signed	06/04/14	07/02/14
	Third Party Observer Report	06/12/14	07/02/14
	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRC/DRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
6. PIC Review	SRC Meeting	06/24/14	07/02/14
	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/02/14
	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
7. Oversight Committee Approval	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
7. Oversight Committee Approval	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
7. Oversight Committee Approval	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140271
Individual Investigator Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Basic Cancer Research Panel 2 for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

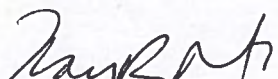
The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

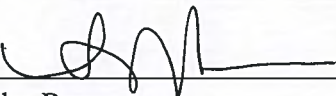
This statement is true."



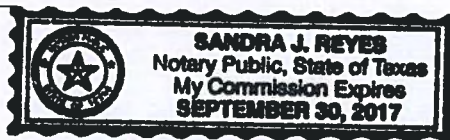
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

FY 2014
 CYCLE 1
 PROGRAM Research
 AWARD MECHANISM Individual Investigator Research Awards (IIRA)
 APPLICATION ID RP140271

APPLICATION TITLE Targeting p53 in Cancer Through Manipulation of p63 and p73

APPLICANT NAME Flores, Elsa

ORGANIZATION The University of Texas M. D. Anderson Cancer Center

PANEL NAME Basic Cancer Research-2 (BCR-2)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/01/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/01/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/01/14
	Date application submitted	01/27/14	07/01/14
	Method of submission	CARS	07/01/14
	Within receipt period	YES	07/01/14
	Appeal to submit application after CARS closed	N/A	07/01/14
	Appeal for late application submission accepted	N/A	07/01/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/01/14
	Donation(s) made to CPRIT/foundation	NO	07/01/14
	Assigned to primary reviewers	03/31/14	07/01/14
	Applicant notified of review panel assignment	05/14/14	07/01/14
	Primary Reviewer 1 COI signed	04/23/14	07/01/14
	Primary Reviewer 2 COI signed	04/21/14	07/01/14
	Primary Reviewer 3 COI signed	04/21/14	07/01/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 1 critique submitted	04/15/14	07/01/14
	Primary Reviewer 2 critique submitted	04/03/14	07/01/14
	Primary Reviewer 3 critique submitted	04/13/14	07/01/14
	COI indicated by non-primary reviewer	NONE	07/01/14
	Preliminary Evaluation score summary sent to Chair	04/28/14	07/01/14
	Recommended for full review	YES	07/01/14
	Applicant notified of outcome	05/21/14	07/01/14
4. Peer Review: On-Site Meeting	Assigned to primary reviewers	05/07/14	07/01/14
	Primary Reviewer 1 COI signed	04/23/14	07/01/14
	Primary Reviewer 2 COI signed	04/21/14	07/01/14
	Primary Reviewer 3 COI signed	04/21/14	07/01/14
	Primary (Advocate) Reviewer 4 COI signed	04/29/14	07/01/14
	Primary Reviewer 1 critique submitted	05/27/14	07/01/14
	Primary Reviewer 2 critique submitted	05/26/14	07/01/14
	Primary Reviewer 3 critique submitted	05/30/14	07/01/14
	Primary (Advocate) Reviewer 4 critique submitted	06/01/14	07/01/14
	COI indicated by non-primary reviewer	Pure, Ellen	07/01/14
	COI recused from participation	YES	07/01/14
	Discussed at On-Site Meeting	YES	07/01/14
	Peer Review: On-Site Meeting	06/04/14 - 06/05/14	07/01/14
	Post review statements signed	06/05/14	07/01/14
5. Final SRC Recommendation	Third Party Observer Report	06/12/14	07/01/14
	Score report delivered to CSO	06/19/14	07/01/14
	COI indicated by SRCPDRC member	NONE	07/01/14
	COI recused from participation	N/A	07/01/14
	SRC Meeting	06/24/14	07/01/14
6. PIC Review	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/01/14
	SRC Chair Notification to PIC and OC	06/24/14	07/01/14
	COI indicated by PIC member	NONE	07/15/14
7. Oversight Committee Approval	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140285
Individual Investigator Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Imaging Technology and Informatics panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

This statement is true."



Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

FY 2014
 CYCLE 1
 PROGRAM Research
 AWARD MECHANISM Individual Investigator Research Awards (IIRA)
 APPLICATION ID RP140285
 APPLICATION TITLE Noninvasive Identification of Prostate Tumor Hypoxia as a Prognostic Biomarker of Radiation Response
 APPLICANT NAME Mason, Ralph
 ORGANIZATION The University of Texas Southwestern Medical Center
 PANEL NAME Imaging Technology and Informatics (ITI)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	02/02/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
2. Receipt, Referral, and Assignment	Appeal for late application submission accepted	N/A	07/02/14
	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	03/17/14	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	04/09/14	07/02/14
	Primary Reviewer 2 COI signed	04/09/14	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	04/14/14	07/02/14
	Primary Reviewer 1 critique submitted	03/26/14	07/02/14
	Primary Reviewer 2 critique submitted	03/19/14	07/02/14
	Primary Reviewer 3 critique submitted	04/09/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	Preliminary Evaluation score summary sent to Chair	04/11/14	07/02/14
	Recommended for full review	YES	07/02/14
4. Peer Review: On-Site Meeting	Applicant notified of outcome	05/21/14	07/02/14
	Assigned to primary reviewers	04/25/14	07/02/14
	Primary Reviewer 1 COI signed	04/14/14	07/02/14
	Primary Reviewer 2 COI signed	04/10/14	07/02/14
	Primary Reviewer 3 COI signed	04/09/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/23/14	07/02/14
	Primary Reviewer 1 critique submitted	05/20/14	07/02/14
	Primary Reviewer 2 critique submitted	05/20/14	07/02/14
	Primary Reviewer 3 critique submitted	05/20/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	05/27/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	05/29/14-05/30/14	07/02/14
	Post review statements signed	05/30/14	07/02/14
5. Final SRC Recommendation	Third Party Observer Report	05/30/14	07/02/14
	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRC/DRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
6. PIC Review	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/02/14
	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
7. Oversight Committee Approval	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140298
Individual Investigator Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Imaging Technology and Informatics panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

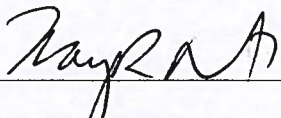
The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

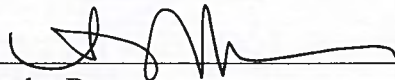
This statement is true."



Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research
AWARD MECHANISM Individual Investigator Research Awards (IIRA)
APPLICATION ID RP140298
APPLICATION TITLE Engineering Microfluidic Devices for Multimodal Mechanical Phenotyping of Tumor Cells in Flow
APPLICANT NAME Vanapalli, Siva
ORGANIZATION Texas Tech University
PANEL NAME Imaging Technology and Informatics (ITI)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	02/03/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	03/17/14	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	04/10/14	07/02/14
	Primary Reviewer 2 COI signed	03/14/14	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	04/14/14	07/02/14
	Primary Reviewer 1 critique submitted	04/02/14	07/02/14
	Primary Reviewer 2 critique submitted	04/10/14	07/02/14
	Primary Reviewer 3 critique submitted	04/09/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	Preliminary Evaluation score summary sent to Chair	04/11/14	07/02/14
	Recommended for full review	YES	07/02/14
4. Peer Review: On-Site Meeting	Applicant notified of outcome	05/21/14	07/02/14
	Assigned to primary reviewers	04/25/14	07/02/14
	Primary Reviewer 1 COI signed	04/10/14	07/02/14
	Primary Reviewer 2 COI signed	04/16/14	07/02/14
	Primary Reviewer 3 COI signed	04/14/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/23/14	07/02/14
	Primary Reviewer 1 critique submitted	05/18/14	07/02/14
	Primary Reviewer 2 critique submitted	05/21/14	07/02/14
	Primary Reviewer 3 critique submitted	05/20/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	05/27/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	05/29/14-05/30/14	07/02/14
	Post review statements signed	05/30/14	07/02/14
5. Final SRC Recommendation	Third Party Observer Report	05/30/14	07/02/14
	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRCPDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
	Third Party Observer Report	07/07/14	07/08/14
6. PIC Review	Recommended for grant award	YES	07/02/14
	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
7. Oversight Committee Approval	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140315
Individual Investigator Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Imaging Technology and Informatics panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

This statement is true."



Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

FY 2014
 CYCLE 1
 PROGRAM Research
 AWARD MECHANISM Individual Investigator Research Awards (IIRA)
 APPLICATION ID RP140315
 APPLICATION TITLE Accurate and High Throughput Detection of Breast and Ovarian Cancer Cells in Whole Blood
 APPLICANT NAME Zu, Youli
 ORGANIZATION The Methodist Hospital Research Institute
 PANEL NAME Imaging Technology and Informatics (ITI)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	01/31/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	03/17/14	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	04/10/14	07/02/14
	Primary Reviewer 2 COI signed	04/16/14	07/02/14
	Primary Reviewer 3 COI signed	04/10/14	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 1 critique submitted	04/02/14	07/02/14
	Primary Reviewer 2 critique submitted	04/04/14	07/02/14
	Primary Reviewer 3 critique submitted	04/04/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	Preliminary Evaluation score summary sent to Chair	04/11/14	07/02/14
	Recommended for full review	YES	07/02/14
	Applicant notified of outcome	05/21/14	07/02/14
4. Peer Review: On-Site Meeting	Assigned to primary reviewers	04/25/14	07/02/14
	Primary Reviewer 1 COI signed	04/10/14	07/02/14
	Primary Reviewer 2 COI signed	04/16/14	07/02/14
	Primary Reviewer 3 COI signed	04/10/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/23/14	07/02/14
	Primary Reviewer 1 critique submitted	05/13/14	07/02/14
	Primary Reviewer 2 critique submitted	05/05/14	07/02/14
	Primary Reviewer 3 critique submitted	05/20/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	05/27/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	05/29/14-05/30/14	07/02/14
	Post review statements signed	05/30/14	07/02/14
5. Final SRC Recommendation	Third Party Observer Report	05/30/14	07/02/14
	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRCPDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
6. PIC Review	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/02/14
	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
7. Oversight Committee Approval	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140320
High-Impact/High-Risk Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *High-Impact/High-Risk Research Award Request for Applications (RFA)*. CPRIT received 100 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Basic Cancer Research Panel 2 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT’s grant review processes were followed by the review panel evaluating the applications in this grant cycle

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that one application was not recommended for a grant award that has the same score as an application that was recommended for a grant award. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score. The two applications were reviewed by different review panels.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

No individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a 3.5 score, another panel may decide based on the totality of factors that an application with a 3.5 score should not be recommended. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

This statement is true."

Wayne R. Roberts

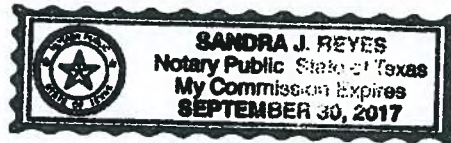
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.

Sandra Reyes

Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

FY 2014
 CYCLE 1
 PROGRAM Research
 AWARD MECHANISM High-Impact/High-Risk Research Awards (HIHRA)
 APPLICATION ID RP140320
 APPLICATION TITLE DISSECTING A Necrotic Signaling Pathway in Human Cancer Cells
 APPLICANT NAME Zhong, Qing
 ORGANIZATION The University of Texas Southwestern Medical Center
 PANEL NAME Basic Cancer Research-2 (BCR-2)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/01/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/01/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/01/14
	Date application submitted	01/30/14	07/01/14
	Method of submission	CARS	07/01/14
	Within receipt period	YES	07/01/14
	Appeal to submit application after CARS closed	N/A	07/01/14
	Appeal for late application submission accepted	N/A	07/01/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/01/14
	Donation(s) made to CPRIT/foundation	NO	07/01/14
	Assigned to primary reviewers	N/A	07/01/14
	Applicant notified of review panel assignment	05/14/14	07/01/14
	Primary Reviewer 1 COI signed	N/A	07/01/14
	Primary Reviewer 2 COI signed	N/A	07/01/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	N/A	07/01/14
	Primary Reviewer 1 critique submitted	N/A	07/01/14
	Primary Reviewer 2 critique submitted	N/A	07/01/14
	Primary Reviewer 3 critique submitted	N/A	07/01/14
	COI indicated by non-primary reviewer	N/A	07/01/14
	Preliminary Evaluation score summary sent to Chair	N/A	07/01/14
	Recommended for full review	N/A	07/01/14
4. Peer Review: On-Site Meeting	Applicant notified of outcome	N/A	07/01/14
	Assigned to primary reviewers	05/07/14	07/01/14
	Primary Reviewer 1 COI signed	04/24/14	07/01/14
	Primary Reviewer 2 COI signed	04/21/14	07/01/14
	Primary Reviewer 3 COI signed	04/21/14	07/01/14
	Primary (Advocate) Reviewer 4 COI signed	04/29/14	07/01/14
	Primary Reviewer 1 critique submitted	05/25/14	07/01/14
	Primary Reviewer 2 critique submitted	05/26/14	07/01/14
	Primary Reviewer 3 critique submitted	05/18/14	07/01/14
	Primary (Advocate) Reviewer 4 critique submitted	06/02/14	07/01/14
	COI indicated by non-primary reviewer	NONE	07/01/14
	COI recused from participation	N/A	07/01/14
	Discussed at On-Site Meeting	YES	07/01/14
	Peer Review: On-Site Meeting	06/04/14 - 06/05/14	07/01/14
	Post review statements signed	06/05/14	07/01/14
5. Final SRC Recommendation	Third Party Observer Report	06/12/14	07/01/14
	Score report delivered to CSO	06/19/14	07/01/14
	COI indicated by SRCPDRC member	NONE	07/01/14
	COI recused from participation	N/A	07/01/14
	SRC Meeting	06/24/14	07/01/14
	Third Party Observer Report	07/07/14	07/08/14
6. PIC Review	Recommended for grant award	YES	07/01/14
	SRC Chair Notification to PIC and OC	06/24/14	07/01/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
7. Oversight Committee Approval	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140323
Individual Investigator Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Cancer Biology panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

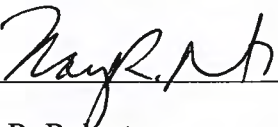
The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

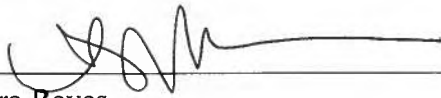
This statement is true."



Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

FY 2014
 CYCLE 1
 PROGRAM Research
 AWARD MECHANISM Individual Investigator Research Awards (IIRA)
 APPLICATION ID RP140323
 APPLICATION TITLE Role of a Novel Histone Variant-specific Epigenetic Reader ZMYND11 in Breast Cancer
 APPLICANT NAME Shi, Xiaobing
 ORGANIZATION The University of Texas M. D. Anderson Cancer Center
 PANEL NAME Cancer Biology (CB)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	01/29/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	03/17/14	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	04/09/14	07/02/14
	Primary Reviewer 2 COI signed	04/16/14	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	04/09/14	07/02/14
	Primary Reviewer 1 critique submitted	04/07/14	07/02/14
	Primary Reviewer 2 critique submitted	03/18/14	07/02/14
	Primary Reviewer 3 critique submitted	04/07/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	Preliminary Evaluation score summary sent to Chair	04/11/14	07/02/14
	Recommended for full review	YES	07/02/14
4. Peer Review: On-Site Meeting	Applicant notified of outcome	05/21/14	07/02/14
	Assigned to primary reviewers	04/22/14	07/02/14
	Primary Reviewer 1 COI signed	04/09/14	07/02/14
	Primary Reviewer 2 COI signed	04/16/14	07/02/14
	Primary Reviewer 3 COI signed	04/09/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/21/14	07/02/14
	Primary Reviewer 1 critique submitted	05/14/14	07/02/14
	Primary Reviewer 2 critique submitted	05/15/14	07/02/14
	Primary Reviewer 3 critique submitted	05/19/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	05/22/14	07/02/14
	COI indicated by non-primary reviewer	Wahl, Geoffrey	07/02/14
	COI recused from participation	YES	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	05/28/14-05/29/14	07/02/14
	Post review statements signed	05/29/14	07/02/14
5. Final SRC Recommendation	Third Party Observer Report	06/12/14	07/02/14
	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRCPDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
6. PIC Review	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/02/14
	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
7. Oversight Committee Approval	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140328
High-Impact/High-Risk Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *High-Impact/High-Risk Research Award* Request for Applications (RFA). CPRIT received 100 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Basic Cancer Research Panel 1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that one application was not recommended for a grant award that has the same score as an application that was recommended for a grant award. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score. The two applications were reviewed by different review panels.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

No individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a 3.5 score, another panel may decide based on the totality of factors that an application with a 3.5 score should not be recommended. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

This statement is true."

Wayne R. Roberts

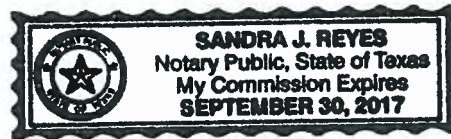
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.

Sandra Reyes

Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

FY 2014
 CYCLE 1
 PROGRAM Research
 AWARD MECHANISM High-Impact/High-Risk Research Awards (HIHRA)
 APPLICATION ID RP140328
 APPLICATION TITLE Synthetic Protein Degradation Agents to Clear Oncogenic Proteins from Cells
 APPLICANT NAME Matouschek, Andreas
 ORGANIZATION The University of Texas at Austin
 PANEL NAME Basic Cancer Research-1 (BCR-1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	02/03/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	N/A	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	N/A	07/02/14
	Primary Reviewer 2 COI signed	N/A	07/02/14
	Primary Reviewer 3 COI signed	N/A	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 1 critique submitted	N/A	07/02/14
	Primary Reviewer 2 critique submitted	N/A	07/02/14
	Primary Reviewer 3 critique submitted	N/A	07/02/14
	COI indicated by non-primary reviewer	N/A	07/02/14
	Preliminary Evaluation score summary sent to Chair	N/A	07/02/14
	Recommended for full review	N/A	07/02/14
	Applicant notified of outcome	N/A	07/02/14
4. Peer Review: On-Site Meeting	Assigned to primary reviewers	04/18/14	07/02/14
	Primary Reviewer 1 COI signed	04/09/14	07/02/14
	Primary Reviewer 2 COI signed	04/09/14	07/02/14
	Primary Reviewer 3 COI signed	04/09/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/21/14	07/02/14
	Primary Reviewer 1 critique submitted	04/28/14	07/02/14
	Primary Reviewer 2 critique submitted	05/14/14	07/02/14
	Primary Reviewer 3 critique submitted	05/15/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	05/24/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	05/31/14-06/01/14	07/02/14
	Post review statements signed	06/11/14	07/02/14
	Third Party Observer Report	06/12/14	07/02/14
	Score report delivered to CSO	06/19/14	07/02/14
5. Final SRC Recommendation	COI indicated by SRCPDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/02/14
6. PIC Review	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
7. Oversight Committee Approval	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140329
High-Impact/High-Risk Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *High-Impact/High-Risk Research Award* Request for Applications (RFA). CPRIT received 100 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Basic Cancer Research Panel 1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that one application was not recommended for a grant award that has the same score as an application that was recommended for a grant award. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score. The two applications were reviewed by different review panels.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

No individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a 3.5 score, another panel may decide based on the totality of factors that an application with a 3.5 score should not be recommended. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

This statement is true."

Wayne R. Roberts

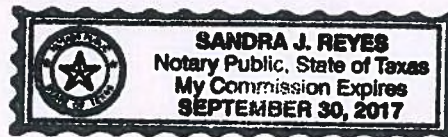
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.

Sandra Reyes

Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research
AWARD MECHANISM High-Impact/High-Risk Research Awards (HIHRA)
APPLICATION ID RP140329
APPLICATION TITLE Opening the Central Nervous System to Immunotherapy by Blocking TREK1
APPLICANT NAME Curran, Michael
ORGANIZATION The University of Texas M. D. Anderson Cancer Center
PANEL NAME Basic Cancer Research-1 (BCR-1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	01/29/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	N/A	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	N/A	07/02/14
	Primary Reviewer 2 COI signed	N/A	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	N/A	07/02/14
	Primary Reviewer 1 critique submitted	N/A	07/02/14
	Primary Reviewer 2 critique submitted	N/A	07/02/14
	Primary Reviewer 3 critique submitted	N/A	07/02/14
	COI indicated by non-primary reviewer	N/A	07/02/14
	Preliminary Evaluation score summary sent to Chair	N/A	07/02/14
4. Peer Review: On-Site Meeting	Recommended for full review	N/A	07/02/14
	Applicant notified of outcome	N/A	07/02/14
	Assigned to primary reviewers	04/18/14	07/02/14
	Primary Reviewer 1 COI signed	04/10/14	07/02/14
	Primary Reviewer 2 COI signed	04/09/14	07/02/14
	Primary Reviewer 3 COI signed	04/10/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/23/14	07/02/14
	Primary Reviewer 1 critique submitted	05/19/14	07/02/14
	Primary Reviewer 2 critique submitted	05/15/14	07/02/14
	Primary Reviewer 3 critique submitted	05/16/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	05/23/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	05/31/14-06/01/14	07/02/14
	Post review statements signed	06/11/14	07/02/14
5. Final SRC Recommendation	Third Party Observer Report	06/12/14	07/02/14
	Score report delivered to CSO	06/19/14	07/02/14
	COI Indicated by SRCPDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
	Third Party Observer Report	07/07/14	07/08/14
6. PIC Review	Recommended for grant award	YES	07/02/14
	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI Indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
7. Oversight Committee Approval	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140350
High-Impact/High-Risk Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *High-Impact/High-Risk Research Award Request for Applications (RFA)*. CPRIT received 100 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Cancer Prevention Research panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT’s grant review processes were followed by the review panel evaluating the applications in this grant cycle

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that one application was not recommended for a grant award that has the same score as an application that was recommended for a grant award. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score. The two applications were reviewed by different review panels.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

No individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a 3.5 score, another panel may decide based on the totality of factors that an application with a 3.5 score should not be recommended. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

This statement is true."

Wayne R. Roberts

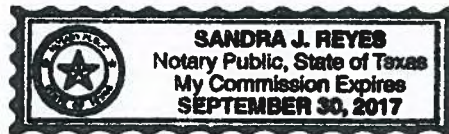
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.

Sandra Reyes

Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research
AWARD MECHANISM High-Impact/High-Risk Research Awards (HIHRA)
APPLICATION ID RP140350
APPLICATION TITLE Integrated Human Herpesvirus 6 as a Novel Heritable Risk Factor for Glioma
APPLICANT NAME Amirian, E Susan
ORGANIZATION Baylor College of Medicine
PANEL NAME Cancer Prevention Research (CPR)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	01/29/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	N/A	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	N/A	07/02/14
	Primary Reviewer 2 COI signed	N/A	07/02/14
	Primary Reviewer 3 COI signed	N/A	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 1 critique submitted	N/A	07/02/14
	Primary Reviewer 2 critique submitted	N/A	07/02/14
	Primary Reviewer 3 critique submitted	N/A	07/02/14
	COI indicated by non-primary reviewer	N/A	07/02/14
	Preliminary Evaluation score summary sent to Chair	N/A	07/02/14
	Recommended for full review	N/A	07/02/14
	Applicant notified of outcome	N/A	07/02/14
4. Peer Review: On-Site Meeting	Assigned to primary reviewers	04/23/14	07/02/14
	Primary Reviewer 1 COI signed	04/13/14	07/02/14
	Primary Reviewer 2 COI signed	04/10/14	07/02/14
	Primary Reviewer 3 COI signed	04/09/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/21/14	07/02/14
	Primary Reviewer 1 critique submitted	05/19/14	07/02/14
	Primary Reviewer 2 critique submitted	05/20/14	07/02/14
	Primary Reviewer 3 critique submitted	05/19/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	06/01/14	07/02/14
	COI indicated by non-primary reviewer	Kushi, Lawrence	07/02/14
	COI recused from participation	YES	07/02/14
	COI indicated by non-primary reviewer	Martinez, Maria	07/02/14
	COI recused from participation	YES	07/02/14
	COI indicated by non-primary reviewer	Petersen, Gloria	07/02/14
	COI recused from participation	YES	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	06/03/14-06/04/14	07/02/14
	Post review statements signed	06/04/14	07/02/14
	Third Party Observer Report	06/12/14	07/02/14
5. Final SRC Recommendation	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRCPDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/02/14
6. PIC Review	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
7. Oversight Committee Approval	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140367
Individual Investigator Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Basic Cancer Research Panel 2 for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.


The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

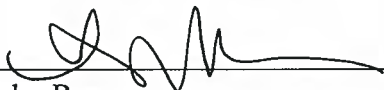
This statement is true."



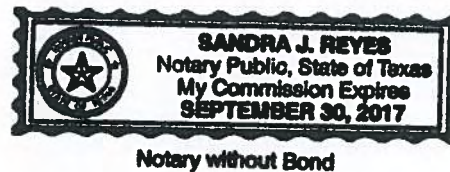
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

FY 2014
 CYCLE 1
 PROGRAM Research
 AWARD MECHANISM Individual Investigator Research Awards (IIRA)
 APPLICATION ID RP140367
 APPLICATION TITLE Targeting BRD4 in Breast Cancer
 APPLICANT NAME Chiang, Cheng-Ming
 ORGANIZATION The University of Texas Southwestern Medical Center
 PANEL NAME Basic Cancer Research-2 (BCR-2)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/01/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/01/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/01/14
	Date application submitted	02/02/14	07/01/14
	Method of submission	CARS	07/01/14
	Within receipt period	YES	07/01/14
	Appeal to submit application after CARS closed	N/A	07/01/14
	Appeal for late application submission accepted	N/A	07/01/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/01/14
	Donation(s) made to CPRIT/foundation	NO	07/01/14
	Assigned to primary reviewers	03/31/14	07/01/14
	Applicant notified of review panel assignment	05/14/14	07/01/14
	Primary Reviewer 1 COI signed	04/21/14	07/01/14
	Primary Reviewer 2 COI signed	04/25/14	07/01/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	03/06/14	07/01/14
	Primary Reviewer 1 critique submitted	04/04/14	07/01/14
	Primary Reviewer 2 critique submitted	04/23/14	07/01/14
	Primary Reviewer 3 critique submitted	04/28/14	07/01/14
	COI indicated by non-primary reviewer	NONE	07/01/14
	Preliminary Evaluation score summary sent to Chair	04/28/14	07/01/14
	Recommended for full review	YES	07/01/14
	Applicant notified of outcome	05/21/14	07/01/14
4. Peer Review: On-Site Meeting	Assigned to primary reviewers	05/07/14	07/01/14
	Primary Reviewer 1 COI signed	04/21/14	07/01/14
	Primary Reviewer 2 COI signed	04/25/14	07/01/14
	Primary Reviewer 3 COI signed	03/06/14	07/01/14
	Primary (Advocate) Reviewer 4 COI signed	04/29/14	07/01/14
	Primary Reviewer 1 critique submitted	05/27/14	07/01/14
	Primary Reviewer 2 critique submitted	06/01/14	07/01/14
	Primary Reviewer 3 critique submitted	05/27/14	07/01/14
	Primary (Advocate) Reviewer 4 critique submitted	06/02/14	07/01/14
	COI indicated by non-primary reviewer	NONE	07/01/14
	COI recused from participation	N/A	07/01/14
	Discussed at On-Site Meeting	YES	07/01/14
	Peer Review: On-Site Meeting	06/04/14 - 06/05/14	07/01/14
	Post review statements signed	06/05/14	07/01/14
5. Final SRC Recommendation	Third Party Observer Report	06/12/14	07/01/14
	Score report delivered to CSO	06/19/14	07/01/14
	COI indicated by SRC/DRC member	NONE	07/01/14
	COI recused from participation	N/A	07/01/14
	SRC Meeting	06/24/14	07/01/14
	Third Party Observer Report	07/07/14	07/08/14
6. PIC Review	Recommended for grant award	YES	07/01/14
	SRC Chair Notification to PIC and OC	06/24/14	07/01/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
7. Oversight Committee Approval	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP140399
Individual Investigator Research Award

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Imaging Technology and Informatics panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

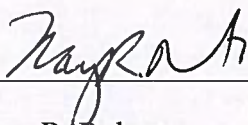
The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

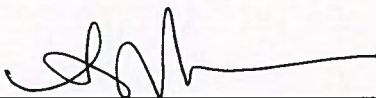
This statement is true."



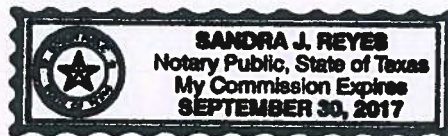
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

FY 2014
 CYCLE 1
 PROGRAM Research
 AWARD MECHANISM Individual Investigator Research Awards (IIRA)
 APPLICATION ID RP140399
 APPLICATION TITLE Targeting Hypoxia in Breast Cancer with Highly Potent Small-Molecule Anticancer Prodrugs
 APPLICANT NAME Pinney, Kevin
 ORGANIZATION Baylor University
 PANEL NAME Imaging Technology and Informatics (ITI)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	02/03/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	03/17/14	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	04/17/14	07/02/14
	Primary Reviewer 2 COI signed	04/09/14	07/02/14
	Primary Reviewer 3 COI signed	04/17/14	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 1 critique submitted	04/07/14	07/02/14
	Primary Reviewer 2 critique submitted	03/20/14	07/02/14
	Primary Reviewer 3 critique submitted	04/06/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	Preliminary Evaluation score summary sent to Chair	04/11/14	07/02/14
	Recommended for full review	YES	07/02/14
	Applicant notified of outcome	05/21/14	07/02/14
4. Peer Review: On-Site Meeting	Assigned to primary reviewers	04/25/14	07/02/14
	Primary Reviewer 1 COI signed	04/17/14	07/02/14
	Primary Reviewer 2 COI signed	04/09/14	07/02/14
	Primary Reviewer 3 COI signed	04/17/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/24/14	07/02/14
	Primary Reviewer 1 critique submitted	05/21/14	07/02/14
	Primary Reviewer 2 critique submitted	05/16/14	07/02/14
	Primary Reviewer 3 critique submitted	05/20/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	05/28/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	05/29/14-05/30/14	07/02/14
	Post review statements signed	05/30/14	07/02/14
5. Final SRC Recommendation	Third Party Observer Report	05/30/14	07/02/14
	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRCPDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
	Third Party Observer Report	07/07/14	07/08/14
6. PIC Review	Recommended for grant award	YES	07/02/14
	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
7. Oversight Committee Approval	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140402
Individual Investigator Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Basic Cancer Research Panel 2 for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

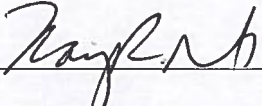
The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

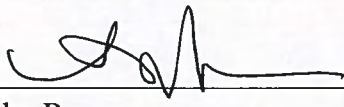
This statement is true."



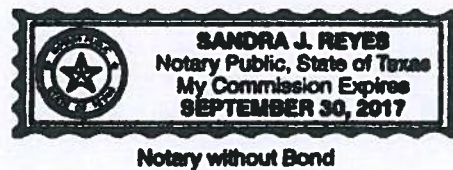
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

FY 2014
 CYCLE 1
 PROGRAM Research
 AWARD MECHANISM Individual Investigator Research Awards (IIRA)
 APPLICATION ID RP140402
 APPLICATION TITLE Novel Targets for Acute Myeloid Leukemia Treatment
 APPLICANT NAME Zhang, Chengcheng
 ORGANIZATION The University of Texas Southwestern Medical Center
 PANEL NAME Basic Cancer Research-2 (BCR-2)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/01/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/01/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/01/14
	Date application submitted	02/02/14	07/01/14
	Method of submission	CARS	07/01/14
	Within receipt period	YES	07/01/14
	Appeal to submit application after CARS closed	N/A	07/01/14
	Appeal for late application submission accepted	N/A	07/01/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/01/14
	Donation(s) made to CPRIT/foundation	NO	07/01/14
	Assigned to primary reviewers	03/31/14	07/01/14
	Applicant notified of review panel assignment	05/14/14	07/01/14
	Primary Reviewer 1 COI signed	04/21/14	07/01/14
	Primary Reviewer 2 COI signed	04/22/14	07/01/14
	Primary Reviewer 3 COI signed	03/12/14	07/01/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 1 critique submitted	04/06/14	07/01/14
	Primary Reviewer 2 critique submitted	04/16/14	07/01/14
	Primary Reviewer 3 critique submitted	04/18/14	07/01/14
	COI indicated by non-primary reviewer	NONE	07/01/14
	Preliminary Evaluation score summary sent to Chair	04/28/14	07/01/14
	Recommended for full review	YES	07/01/14
4. Peer Review: On-Site Meeting	Applicant notified of outcome	05/21/14	07/01/14
	Assigned to primary reviewers	05/07/14	07/01/14
	Primary Reviewer 1 COI signed	04/21/14	07/01/14
	Primary Reviewer 2 COI signed	04/21/14	07/01/14
	Primary Reviewer 3 COI signed	04/24/14	07/01/14
	Primary (Advocate) Reviewer 4 COI signed	04/29/14	07/01/14
	Primary Reviewer 1 critique submitted	05/27/14	07/01/14
	Primary Reviewer 2 critique submitted	05/29/14	07/01/14
	Primary Reviewer 3 critique submitted	05/25/14	07/01/14
	Primary (Advocate) Reviewer 4 critique submitted	06/02/14	07/01/14
	COI indicated by non-primary reviewer	NONE	07/01/14
	COI recused from participation	N/A	07/01/14
	Discussed at On-Site Meeting	YES	07/01/14
	Peer Review: On-Site Meeting	06/04/14 - 06/05/14	07/01/14
	Post review statements signed	06/05/14	07/01/14
5. Final SRC Recommendation	Third Party Observer Report	06/12/14	07/01/14
	Score report delivered to CSO	06/19/14	07/01/14
	COI Indicated by SRC/DRC member	NONE	07/01/14
	COI recused from participation	N/A	07/01/14
	SRC Meeting	06/24/14	07/01/14
	Third Party Observer Report	07/07/14	07/08/14
6. PIC Review	Recommended for grant award	YES	07/01/14
	SRC Chair Notification to PIC and OC	06/24/14	07/01/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
7. Oversight Committee Approval	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140408
Individual Investigator Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Cancer Biology panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

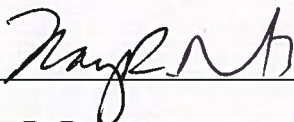
The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

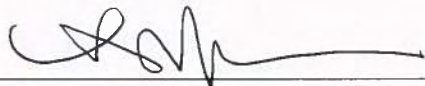
This statement is true."



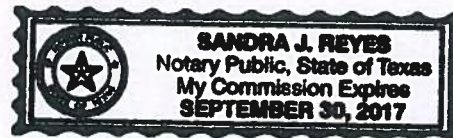
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

FY 2014
 CYCLE 1
 PROGRAM Research
 AWARD MECHANISM Individual Investigator Research Awards (IIRA)
 APPLICATION ID RP140408
 APPLICATION TITLE Identificaiton of a Novel Mechanism of mTORC1 and Autophagy Regulation for Cancer Therapy.
 APPLICANT NAME Lin, Hui-Kuan
 ORGANIZATION The University of Texas M. D. Anderson Cancer Center
 PANEL NAME Cancer Biology (CB)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	01/29/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	03/17/14	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	04/09/14	07/02/14
	Primary Reviewer 2 COI signed	04/16/14	07/02/14
	Primary Reviewer 3 COI signed	04/09/14	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 1 critique submitted	03/19/14	07/02/14
	Primary Reviewer 2 critique submitted	04/09/14	07/02/14
	Primary Reviewer 3 critique submitted	04/06/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	Preliminary Evaluation score summary sent to Chair	04/11/14	07/02/14
	Recommended for full review	YES	07/02/14
	Applicant notified of outcome	05/21/14	07/02/14
4. Peer Review: On-Site Meeting	Assigned to primary reviewers	04/22/14	07/02/14
	Primary Reviewer 1 COI signed	N/A	07/02/14
	Primary Reviewer 2 COI signed	04/16/14	07/02/14
	Primary Reviewer 3 COI signed	04/09/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/21/14	07/02/14
	Primary Reviewer 1 critique submitted	N/A	07/02/14
	Primary Reviewer 2 critique submitted	05/16/14	07/02/14
	Primary Reviewer 3 critique submitted	05/21/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	05/25/14	07/02/14
	COI indicated by non-primary reviewer	Walhl, Geoffrey	07/02/14
	COI recused from participation	YES	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	05/28/14-05/29/14	07/02/14
	Post review statements signed	05/29/14	07/02/14
	Third Party Observer Report	06/12/14	07/02/14
5. Final SRC Recommendation	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRCPDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/02/14
6. PIC Review	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
7. Oversight Committee Approval	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140411
Individual Investigator Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Cancer Biology panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

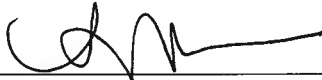
This statement is true."



Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

FY 2014
 CYCLE 1
 PROGRAM Research
 AWARD MECHANISM Individual Investigator Research Awards (IIRA)
 APPLICATION ID RP140411
 APPLICATION TITLE Targeting Tumor Cell Invasion in Glioblastoma
 APPLICANT NAME McCarty, Joseph
 ORGANIZATION The University of Texas M. D. Anderson Cancer Center
 PANEL NAME Cancer Biology (CB)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	01/31/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	03/17/14	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	04/16/14	07/02/14
	Primary Reviewer 2 COI signed	04/09/14	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	04/09/14	07/02/14
	Primary Reviewer 1 critique submitted	04/09/14	07/02/14
	Primary Reviewer 2 critique submitted	04/07/14	07/02/14
	Primary Reviewer 3 critique submitted	04/06/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	Preliminary Evaluation score summary sent to Chair	04/11/14	07/02/14
4. Peer Review: On-Site Meeting	Recommended for full review	YES	07/02/14
	Applicant notified of outcome	05/21/14	07/02/14
	Assigned to primary reviewers	04/22/14	07/02/14
	Primary Reviewer 1 COI signed	04/16/14	07/02/14
	Primary Reviewer 2 COI signed	04/09/14	07/02/14
	Primary Reviewer 3 COI signed	04/09/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/21/14	07/02/14
	Primary Reviewer 1 critique submitted	05/15/14	07/02/14
	Primary Reviewer 2 critique submitted	05/14/14	07/02/14
	Primary Reviewer 3 critique submitted	05/21/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	05/23/14	07/02/14
	COI indicated by non-primary reviewer	Walhl, Geoffrey	07/02/14
	COI recused from participation	YES	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	05/28/14-05/29/14	07/02/14
5. Final SRC Recommendation	Post review statements signed	05/29/14	07/02/14
	Third Party Observer Report	06/12/14	07/02/14
	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRCPDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
6. PIC Review	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/02/14
	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
7. Oversight Committee Approval	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140412
Individual Investigator Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Cancer Biology panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

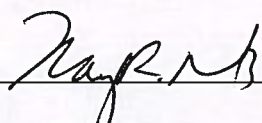
The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

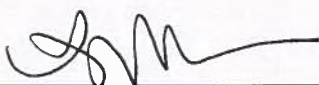
This statement is true."



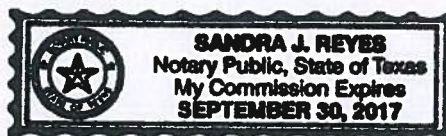
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

FY 2014
 CYCLE 1
 PROGRAM Research
 AWARD MECHANISM Individual Investigator Research Awards (IIRA)
 APPLICATION ID RP140412
 APPLICATION TITLE Endotrophin and the Obesity/Cancer Nexus: Role in Growth and Chemoresistance
 APPLICANT NAME Scherer, Philipp
 ORGANIZATION The University of Texas Southwestern Medical Center
 PANEL NAME Cancer Biology (CB)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	02/02/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	03/17/14	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	03/11/14	07/02/14
	Primary Reviewer 2 COI signed	04/09/14	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	04/11/14	07/02/14
	Primary Reviewer 1 critique submitted	04/07/14	07/02/14
	Primary Reviewer 2 critique submitted	04/08/14	07/02/14
	Primary Reviewer 3 critique submitted	04/01/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	Preliminary Evaluation score summary sent to Chair	04/11/14	07/02/14
4. Peer Review: On-Site Meeting	Recommended for full review	YES	07/02/14
	Applicant notified of outcome	05/21/14	07/02/14
	Assigned to primary reviewers	04/22/14	07/02/14
	Primary Reviewer 1 COI signed	04/11/14	07/02/14
	Primary Reviewer 2 COI signed	04/09/14	07/02/14
	Primary Reviewer 3 COI signed	04/09/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/21/14	07/02/14
	Primary Reviewer 1 critique submitted	05/14/14	07/02/14
	Primary Reviewer 2 critique submitted	05/20/14	07/02/14
	Primary Reviewer 3 critique submitted	05/16/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	05/23/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	05/28/14-05/29/14	07/02/14
	Post review statements signed	05/29/14	07/02/14
5. Final SRC Recommendation	Third Party Observer Report	06/12/14	07/02/14
	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRC/DRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
	Third Party Observer Report	07/07/14	07/08/14
6. PIC Review	Recommended for grant award	YES	07/02/14
	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
7. Oversight Committee Approval	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP140429
Individual Investigator Research Award

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Cancer Biology panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

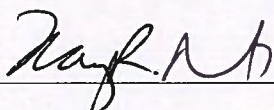
The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

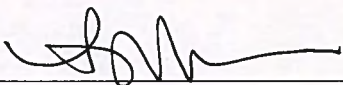
This statement is true."



Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

FY 2014
 CYCLE 1
 PROGRAM Research
 AWARD MECHANISM Individual Investigator Research Awards (IIRA)
 APPLICATION ID RP140429
 APPLICATION TITLE The Role of DIRAS3 (ARHI) in Initiating Autophagy and Tumor Dormancy
 APPLICANT NAME Bast, Robert
 ORGANIZATION The University of Texas M. D. Anderson Cancer Center
 PANEL NAME Cancer Biology (CB)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	02/03/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	03/17/14	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	04/09/14	07/02/14
	Primary Reviewer 2 COI signed	04/21/14	07/02/14
	Primary Reviewer 3 COI signed	05/07/14	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 1 critique submitted	03/24/14	07/02/14
	Primary Reviewer 2 critique submitted	04/03/14	07/02/14
	Primary Reviewer 3 critique submitted	04/02/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	Preliminary Evaluation score summary sent to Chair	04/11/14	07/02/14
	Recommended for full review	YES	07/02/14
	Applicant notified of outcome	05/21/14	07/02/14
4. Peer Review: On-Site Meeting	Assigned to primary reviewers	04/22/14	07/02/14
	Primary Reviewer 1 COI signed	04/09/14	07/02/14
	Primary Reviewer 2 COI signed	04/21/14	07/02/14
	Primary Reviewer 3 COI signed	05/07/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/21/14	07/02/14
	Primary Reviewer 1 critique submitted	05/19/14	07/02/14
	Primary Reviewer 2 critique submitted	05/19/14	07/02/14
	Primary Reviewer 3 critique submitted	05/17/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	05/26/14	07/02/14
	COI indicated by non-primary reviewer	Walhl, Geoffrey	07/02/14
	COI recused from participation	YES	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	05/28/14-05/29/14	07/02/14
	Post review statements signed	05/29/14	07/02/14
	Third Party Observer Report	06/12/14	07/02/14
	Score report delivered to CSO	06/19/14	07/02/14
5. Final SRC Recommendation	COI indicated by SRC/PDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/02/14
	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
6. PIC Review	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
7. Oversight Committee Approval	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP140430
Individual Investigator Research Award

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award Request for Applications* (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Basic Cancer Research Panel 1 for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

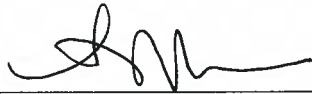
This statement is true."



Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research
AWARD MECHANISM Individual Investigator Research Awards - (IIRA)
APPLICATION ID RP140430
APPLICATION TITLE Synaptic Mechanisms of Cognitive Decline after Cranial Radiation
APPLICANT NAME Grosshans, David
ORGANIZATION The University of Texas M. D. Anderson Cancer Center
PANEL NAME Basic Cancer Research-1 (BCR-1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	01/31/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	03/17/14	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	04/09/14	07/02/14
	Primary Reviewer 2 COI signed	04/10/14	07/02/14
	Primary Reviewer 3 COI signed	04/16/14	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 1 critique submitted	04/04/14	07/02/14
	Primary Reviewer 2 critique submitted	04/10/14	07/02/14
	Primary Reviewer 3 critique submitted	04/06/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	Preliminary Evaluation score summary sent to Chair	04/15/14	07/02/14
	Recommended for full review	YES	07/02/14
	Applicant notified of outcome	05/21/14	07/02/14
4. Peer Review: On-Site Meeting	Assigned to primary reviewers	04/18/14	07/02/14
	Primary Reviewer 1 COI signed	04/09/14	07/02/14
	Primary Reviewer 2 COI signed	04/10/14	07/02/14
	Primary Reviewer 3 COI signed	04/16/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/21/14	07/02/14
	Primary Reviewer 1 critique submitted	05/15/14	07/02/14
	Primary Reviewer 2 critique submitted	05/16/14	07/02/14
	Primary Reviewer 3 critique submitted	05/16/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	05/25/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	05/31/14-06/01/14	07/02/14
	Post review statements signed	06/11/14	07/02/14
5. Final SRC Recommendation	Third Party Observer Report	06/12/14	07/02/14
	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRC/DRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
6. PIC Review	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/02/14
	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
7. Oversight Committee Approval	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP140435
High-Impact/High-Risk Research Award

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *High-Impact/High-Risk Research Award* Request for Applications (RFA). CPRIT received 100 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Basic Cancer Research Panel 2 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that one application was not recommended for a grant award that has the same score as an application that was recommended for a grant award. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score. The two applications were reviewed by different review panels.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

No individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a 3.5 score, another panel may decide based on the totality of factors that an application with a 3.5 score should not be recommended. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

This statement is true."

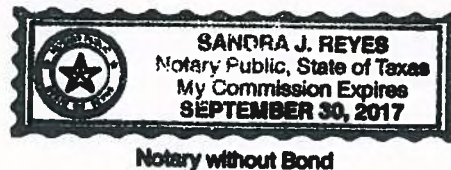
Wayne R. Roberts

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.

Sandra Reyes
Sandra Reyes
Notary Public, State of Texas



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

FY 2014
 CYCLE 1
 PROGRAM Research
 AWARD MECHANISM High-Impact/High-Risk Research Awards (HIHRA)
 APPLICATION ID RP140435
 APPLICATION TITLE SHH/GLI3 Signaling Axis as a Therapeutic Target in
 Castration Resistant Prostate Cancer
 APPLICANT NAME Boyer, Thomas
 ORGANIZATION The University of Texas Health Science Center at San Antonio
 PANEL NAME Basic Cancer Research-2 (BCR-2)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/01/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/01/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/01/14
	Date application submitted	02/03/14	07/01/14
	Method of submission	CARS	07/01/14
	Within receipt period	YES	07/01/14
	Appeal to submit application after CARS closed	N/A	07/01/14
	Appeal for late application submission accepted	N/A	07/01/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/01/14
	Donation(s) made to CPRIT/foundation	NO	07/01/14
	Assigned to primary reviewers	N/A	07/01/14
	Applicant notified of review panel assignment	05/14/14	07/01/14
	Primary Reviewer 1 COI signed	N/A	07/01/14
	Primary Reviewer 2 COI signed	N/A	07/01/14
	Primary Reviewer 3 COI signed	N/A	07/01/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 1 critique submitted	N/A	07/01/14
	Primary Reviewer 2 critique submitted	N/A	07/01/14
	Primary Reviewer 3 critique submitted	N/A	07/01/14
	COI indicated by non-primary reviewer	N/A	07/01/14
	Preliminary Evaluation score summary sent to Chair	N/A	07/01/14
	Recommended for full review	N/A	07/01/14
	Applicant notified of outcome	N/A	07/01/14
4. Peer Review: On-Site Meeting	Assigned to primary reviewers	05/07/14	07/01/14
	Primary Reviewer 1 COI signed	04/21/14	07/01/14
	Primary Reviewer 2 COI signed	04/25/14	07/01/14
	Primary Reviewer 3 COI signed	04/21/14	07/01/14
	Primary (Advocate) Reviewer 4 COI signed	04/29/14	07/01/14
	Primary Reviewer 1 critique submitted	05/29/14	07/01/14
	Primary Reviewer 2 critique submitted	06/01/14	07/01/14
	Primary Reviewer 3 critique submitted	05/28/14	07/01/14
	Primary (Advocate) Reviewer 4 critique submitted	06/02/14	07/01/14
	COI indicated by non-primary reviewer	NONE	07/01/14
	COI recused from participation	N/A	07/01/14
	Discussed at On-Site Meeting	YES	07/01/14
	Peer Review: On-Site Meeting	06/04/14 - 06/05/14	07/01/14
	Post review statements signed	06/05/14	07/01/14
	Third Party Observer Report	06/12/14	07/01/14
5. Final SRC Recommendation	Score report delivered to CSO	06/19/14	07/01/14
	COI indicated by SRCPDRC member	NONE	07/01/14
	COI recused from participation	N/A	07/01/14
	SRC Meeting	06/24/14	07/01/14
	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/01/14
	SRC Chair Notification to PIC and OC	06/24/14	07/01/14
6. PIC Review	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
7. Oversight Committee Approval	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP140449
High-Impact/High-Risk Research Award

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *High-Impact/High-Risk Research Award* Request for Applications (RFA). CPRIT received 100 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Basic Cancer Research Panel 2 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT’s grant review processes were followed by the review panel evaluating the applications in this grant cycle

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that one application was not recommended for a grant award that has the same score as an application that was recommended for a grant award. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score. The two applications were reviewed by different review panels.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

No individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a 3.5 score, another panel may decide based on the totality of factors that an application with a 3.5 score should not be recommended. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

This statement is true."

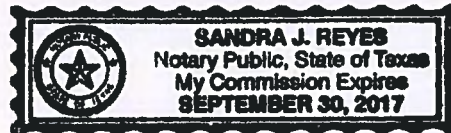
Wayne R. Roberts

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.

Sandra Reyes
Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

FY 2014
 CYCLE 1
 PROGRAM Research
 AWARD MECHANISM High-Impact/High-Risk Research Awards (HIHRRRA)
 APPLICATION ID RP140449
 APPLICATION TITLE A New Cancer Target: AMPylation Machinery
 APPLICANT NAME Orth, Kim
 ORGANIZATION The University of Texas Southwestern Medical Center
 PANEL NAME Basic Cancer Research-2 (BCR-2)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/01/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/01/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/01/14
	Date application submitted	02/03/14	07/01/14
	Method of submission	CARS	07/01/14
	Within receipt period	YES	07/01/14
	Appeal to submit application after CARS closed	N/A	07/01/14
	Appeal for late application submission accepted	N/A	07/01/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/01/14
	Donation(s) made to CPRIT/foundation	NO	07/01/14
	Assigned to primary reviewers	N/A	07/01/14
	Applicant notified of review panel assignment	05/14/14	07/01/14
	Primary Reviewer 1 COI signed	N/A	07/01/14
	Primary Reviewer 2 COI signed	N/A	07/01/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	N/A	07/01/14
	Primary Reviewer 1 critique submitted	N/A	07/01/14
	Primary Reviewer 2 critique submitted	N/A	07/01/14
	Primary Reviewer 3 critique submitted	N/A	07/01/14
	COI indicated by non-primary reviewer	N/A	07/01/14
	Preliminary Evaluation score summary sent to Chair	N/A	07/01/14
	Recommended for full review	N/A	07/01/14
	Applicant notified of outcome	N/A	07/01/14
4. Peer Review: On-Site Meeting	Assigned to primary reviewers	05/07/14	07/01/14
	Primary Reviewer 1 COI signed	04/21/14	07/01/14
	Primary Reviewer 2 COI signed	04/25/14	07/01/14
	Primary Reviewer 3 COI signed	05/08/14	07/01/14
	Primary (Advocate) Reviewer 4 COI signed	04/29/14	07/01/14
	Primary Reviewer 1 critique submitted	05/28/14	07/01/14
	Primary Reviewer 2 critique submitted	06/01/14	07/01/14
	Primary Reviewer 3 critique submitted	05/27/14	07/01/14
	Primary (Advocate) Reviewer 4 critique submitted	06/02/14	07/01/14
	COI indicated by non-primary reviewer	NONE	07/01/14
	COI recused from participation	N/A	07/01/14
	Discussed at On-Site Meeting	YES	07/01/14
	Peer Review: On-Site Meeting	06/04/14 - 06/05/14	07/01/14
	Post review statements signed	06/05/14	07/01/14
5. Final SRC Recommendation	Third Party Observer Report	06/12/14	07/01/14
	Score report delivered to CSO	06/19/14	07/01/14
	COI indicated by SRCPDRC member	NONE	07/01/14
	COI recused from participation	N/A	07/01/14
	SRC Meeting	06/24/14	07/01/14
	Third Party Observer Report	07/07/14	07/08/14
6. PIC Review	Recommended for grant award	YES	07/01/14
	SRC Chair Notification to PIC and OC	06/24/14	07/01/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
7. Oversight Committee Approval	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140452
Individual Investigator Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Cancer Biology panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

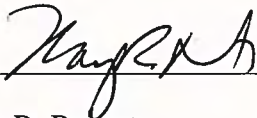
The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

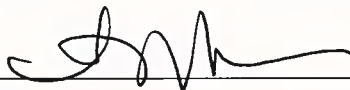
This statement is true."



Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research
AWARD MECHANISM Individual Investigator Research Awards (IIRA)
APPLICATION ID RP140452

APPLICATION TITLE Inactivating Mutation of D2HGDH Establishes a Novel Link Between Metabolism, Alpha-KG Dependent Dioxygenases and Epigenetic Reprograming in B Cell Lymphoma

APPLICANT NAME Aguiar, Ricardo
ORGANIZATION The University of Texas Health Science Center at San Antonio
PANEL NAME Cancer Biology (CB)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	01/30/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	03/17/14	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	04/09/14	07/02/14
	Primary Reviewer 2 COI signed	04/09/14	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	05/07/14	07/02/14
	Primary Reviewer 1 critique submitted	04/07/14	07/02/14
	Primary Reviewer 2 critique submitted	04/07/14	07/02/14
	Primary Reviewer 3 critique submitted	04/02/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	Preliminary Evaluation score summary sent to Chair	04/11/14	07/02/14
	Recommended for full review	YES	07/02/14
4. Peer Review: On-Site Meeting	Applicant notified of outcome	05/21/14	07/02/14
	Assigned to primary reviewers	04/22/14	07/02/14
	Primary Reviewer 1 COI signed	04/09/14	07/02/14
	Primary Reviewer 2 COI signed	04/09/14	07/02/14
	Primary Reviewer 3 COI signed	05/07/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/21/14	07/02/14
	Primary Reviewer 1 critique submitted	05/19/14	07/02/14
	Primary Reviewer 2 critique submitted	05/14/14	07/02/14
	Primary Reviewer 3 critique submitted	05/17/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	05/23/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	05/28/14-05/29/14	07/02/14
	Post review statements signed	05/29/14	07/02/14
5. Final SRC Recommendation	Third Party Observer Report	06/12/14	07/02/14
	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRCPDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
	Third Party Observer Report	07/07/14	07/08/14
6. PIC Review	Recommended for grant award	YES	07/02/14
	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
7. Oversight Committee Approval	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140456
Individual Investigator Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Basic Cancer Research Panel 2 for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

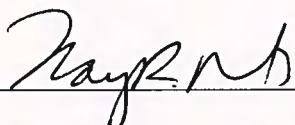
The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

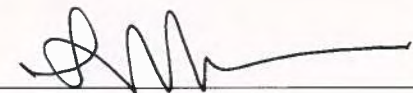
This statement is true."



Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research
AWARD MECHANISM Individual Investigator Research Awards (IIRA)
APPLICATION ID RP140456

APPLICATION TITLE Role of DNA2 Nuclease in Cellular Tolerance of Replication Stress and Telomere Maintenance - Implications for Cancer Biology and Anticancer Therapy

APPLICANT NAME Ira, Grzegorz
ORGANIZATION Baylor College of Medicine
PANEL NAME Basic Cancer Research-2 (BCR-2)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/01/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/01/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/01/14
	Date application submitted	01/29/14	07/01/14
	Method of submission	CARS	07/01/14
	Within receipt period	YES	07/01/14
	Appeal to submit application after CARS closed	N/A	07/01/14
	Appeal for late application submission accepted	N/A	07/01/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/01/14
	Donation(s) made to CPRIT/foundation	NO	07/01/14
	Assigned to primary reviewers	03/31/14	07/01/14
	Applicant notified of review panel assignment	05/14/14	07/01/14
	Primary Reviewer 1 COI signed	04/23/14	07/01/14
	Primary Reviewer 2 COI signed	04/22/14	07/01/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	04/22/14	07/01/14
	Primary Reviewer 1 critique submitted	04/15/14	07/01/14
	Primary Reviewer 2 critique submitted	04/16/14	07/01/14
	Primary Reviewer 3 critique submitted	04/21/14	07/01/14
	COI indicated by non-primary reviewer	NONE	07/01/14
	Preliminary Evaluation score summary sent to Chair	04/28/14	07/01/14
	Recommended for full review	YES	07/01/14
4. Peer Review: On-Site Meeting	Applicant notified of outcome	05/21/14	07/01/14
	Assigned to primary reviewers	05/07/14	07/01/14
	Primary Reviewer 1 COI signed	04/22/14	07/01/14
	Primary Reviewer 2 COI signed	04/23/14	07/01/14
	Primary Reviewer 3 COI signed	04/22/14	07/01/14
	Primary (Advocate) Reviewer 4 COI signed	04/29/14	07/01/14
	Primary Reviewer 1 critique submitted	05/28/14	07/01/14
	Primary Reviewer 2 critique submitted	05/27/14	07/01/14
	Primary Reviewer 3 critique submitted	05/13/14	07/01/14
	Primary (Advocate) Reviewer 4 critique submitted	06/01/14	07/01/14
	COI indicated by non-primary reviewer	NONE	07/01/14
	COI recused from participation	N/A	07/01/14
	Discussed at On-Site Meeting	YES	07/01/14
	Peer Review: On-Site Meeting	06/04/14 - 06/05/14	07/01/14
	Post review statements signed	06/05/14	07/01/14
5. Final SRC Recommendation	Third Party Observer Report	06/12/14	07/01/14
	Score report delivered to CSO	06/19/14	07/01/14
	COI indicated by SRC/CDRC member	NONE	07/01/14
	COI recused from participation	N/A	07/01/14
	SRC Meeting	06/24/14	07/01/14
	Third Party Observer Report	07/07/14	07/08/14
6. PIC Review	Recommended for grant award	YES	07/01/14
	SRC Chair Notification to PIC and OC	06/24/14	07/01/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
7. Oversight Committee Approval	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140462
Individual Investigator Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Cancer Prevention Research panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

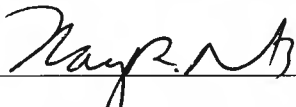
The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

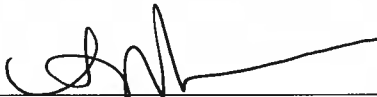
This statement is true."



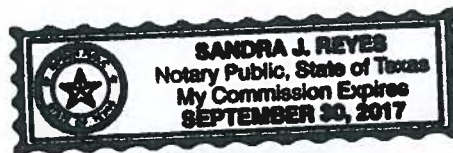
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research
AWARD MECHANISM Individual Investigator Research Awards (IIRA)
APPLICATION ID RP140462
APPLICATION TITLE Systematic Investigation of Clinically Relevant Expressed Pseudogenes in Cancer
APPLICANT NAME Liang, Han
ORGANIZATION The University of Texas M. D. Anderson Cancer Center
PANEL NAME Cancer Prevention Research (CPR)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	01/31/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	03/16/14	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	04/09/14	07/02/14
	Primary Reviewer 2 COI signed	04/13/14	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	04/15/14	07/02/14
	Primary Reviewer 1 critique submitted	03/28/14	07/02/14
	Primary Reviewer 2 critique submitted	04/06/14	07/02/14
	Primary Reviewer 3 critique submitted	04/08/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	Preliminary Evaluation score summary sent to Chair	04/11/14	07/02/14
	Recommended for full review	YES	07/02/14
	Applicant notified of outcome	05/21/14	07/02/14
4. Peer Review: On-Site Meeting	Assigned to primary reviewers	04/23/14	07/02/14
	Primary Reviewer 1 COI signed	04/09/14	07/02/14
	Primary Reviewer 2 COI signed	04/13/14	07/02/14
	Primary Reviewer 3 COI signed	04/15/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/21/14	07/02/14
	Primary Reviewer 1 critique submitted	05/19/14	07/02/14
	Primary Reviewer 2 critique submitted	05/19/14	07/02/14
	Primary Reviewer 3 critique submitted	05/24/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	06/01/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	06/03/14-06/04/14	07/02/14
	Post review statements signed	06/04/14	07/02/14
5. Final SRC Recommendation	Third Party Observer Report	06/12/14	07/02/14
	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRCPDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
	Third Party Observer Report	07/07/14	07/08/14
6. PIC Review	Recommended for grant award	YES	07/02/14
	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
7. Oversight Committee Approval	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140464
Individual Investigator Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Cancer Prevention Research panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

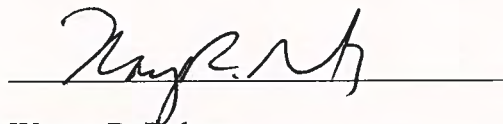
The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

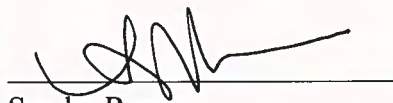
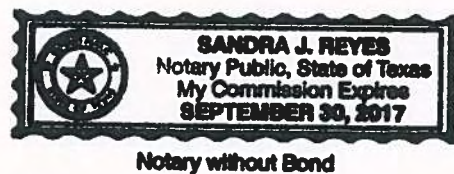
This statement is true."



Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research
AWARD MECHANISM Individual Investigator Research Awards (IIRA)
APPLICATION ID RP140464

APPLICATION TITLE Next Generation Sequencing and Transcriptome Profiling of Oral Potentially Malignant Lesions to Identify Markers of Cancer Risk and Targets for Chemoprevention

APPLICANT NAME William, William
ORGANIZATION The University of Texas M. D. Anderson Cancer Center
PANEL NAME Cancer Prevention Research (CPR)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	01/30/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	03/16/14	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	04/16/14	07/02/14
	Primary Reviewer 2 COI signed	04/09/14	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	04/13/14	07/02/14
	Primary Reviewer 1 critique submitted	04/05/14	07/02/14
	Primary Reviewer 2 critique submitted	03/25/14	07/02/14
	Primary Reviewer 3 critique submitted	04/06/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	Preliminary Evaluation score summary sent to Chair	04/11/14	07/02/14
4. Peer Review: On-Site Meeting	Recommended for full review	YES	07/02/14
	Applicant notified of outcome	05/21/14	07/02/14
	Assigned to primary reviewers	04/23/14	07/02/14
	Primary Reviewer 1 COI signed	04/16/14	07/02/14
	Primary Reviewer 2 COI signed	04/09/14	07/02/14
	Primary Reviewer 3 COI signed	04/13/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/21/14	07/02/14
	Primary Reviewer 1 critique submitted	05/16/14	07/02/14
	Primary Reviewer 2 critique submitted	05/13/14	07/02/14
	Primary Reviewer 3 critique submitted	05/19/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	06/02/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	06/03/14-06/04/14	07/02/14
	Post review statements signed	06/04/14	07/02/14
5. Final SRC Recommendation	Third Party Observer Report	06/12/14	07/02/14
	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRCPDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
	Third Party Observer Report	07/07/14	07/08/14
6. PIC Review	Recommended for grant award	YES	07/02/14
	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
7. Oversight Committee Approval	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140468
Individual Investigator Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Translational Cancer Research panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

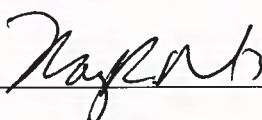
The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

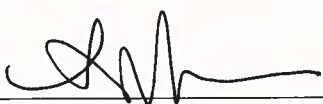
This statement is true."



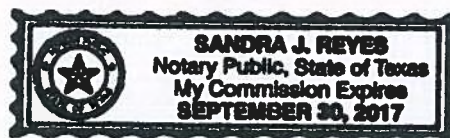
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research
AWARD MECHANISM Individual Investigator Research Awards (IIRA)
APPLICATION ID RP140468
APPLICATION TITLE Targeting Of Chronic Lymphocytic Leukemia By Designer T Cells
APPLICANT NAME Cooper, Laurence
ORGANIZATION The University of Texas M. D. Anderson Cancer Center
PANEL NAME Translational Cancer Research (TCR)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	01/31/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	03/24/14	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	04/24/14	07/02/14
	Primary Reviewer 2 COI signed	04/21/14	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	03/10/14	07/02/14
	Primary Reviewer 1 critique submitted	04/21/14	07/02/14
	Primary Reviewer 2 critique submitted	04/07/14	07/02/14
	Primary Reviewer 3 critique submitted	04/11/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	Preliminary Evaluation score summary sent to Chair	05/01/14	07/02/14
	Recommended for full review	YES	07/02/14
	Applicant notified of outcome	05/21/14	07/02/14
4. Peer Review: On-Site Meeting	Assigned to primary reviewers	05/08/14	07/02/14
	Primary Reviewer 1 COI signed	04/24/14	07/02/14
	Primary Reviewer 2 COI signed	04/21/14	07/02/14
	Primary Reviewer 3 COI signed	04/21/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/27/14	07/02/14
	Primary Reviewer 1 critique submitted	06/01/14	07/02/14
	Primary Reviewer 2 critique submitted	05/19/14	07/02/14
	Primary Reviewer 3 critique submitted	05/28/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	06/04/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	06/06/14	07/02/14
	Post review statements signed	06/06/14	07/02/14
5. Final SRC Recommendation	Third Party Observer Report	06/12/14	07/02/14
	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRC/DRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
	Third Party Observer Report	07/07/14	07/08/14
6. PIC Review	Recommended for grant award	YES	07/02/14
	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
7. Oversight Committee Approval	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP140469
Individual Investigator Research Award

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Basic Cancer Research Panel 1 for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

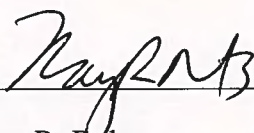
The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

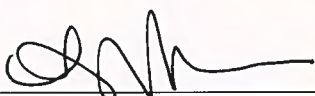
This statement is true."



Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research
AWARD MECHANISM Individual Investigator Research Awards - (IIRA)
APPLICATION ID RP140469
APPLICATION TITLE Novel Small Molecule Probes Targeting IDH Mutated Glioma
APPLICANT NAME Song, Yongcheng
ORGANIZATION Baylor College of Medicine
PANEL NAME Basic Cancer Research-1 (BCR-1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	01/28/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	03/17/14	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	04/10/14	07/02/14
	Primary Reviewer 2 COI signed	04/09/14	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	04/14/14	07/02/14
	Primary Reviewer 1 critique submitted	04/10/14	07/02/14
	Primary Reviewer 2 critique submitted	03/18/14	07/02/14
	Primary Reviewer 3 critique submitted	04/14/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	Preliminary Evaluation score summary sent to Chair	04/15/14	07/02/14
	Recommended for full review	YES	07/02/14
4. Peer Review: On-Site Meeting	Applicant notified of outcome	05/21/14	07/02/14
	Assigned to primary reviewers	04/18/14	07/02/14
	Primary Reviewer 1 COI signed	04/10/14	07/02/14
	Primary Reviewer 2 COI signed	04/09/14	07/02/14
	Primary Reviewer 3 COI signed	04/14/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/23/14	07/02/14
	Primary Reviewer 1 critique submitted	05/16/14	07/02/14
	Primary Reviewer 2 critique submitted	05/12/14	07/02/14
	Primary Reviewer 3 critique submitted	05/21/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	05/28/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	05/31/14-06/01/14	07/02/14
	Post review statements signed	06/11/14	07/02/14
5. Final SRC Recommendation	Third Party Observer Report	06/12/14	07/02/14
	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRCPDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
	Third Party Observer Report	07/07/14	07/08/14
6. PIC Review	Recommended for grant award	YES	07/02/14
	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
7. Oversight Committee Approval	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140473
Individual Investigator Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Cancer Biology panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

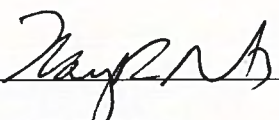
The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

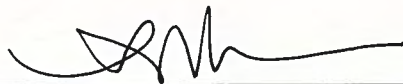
This statement is true."



Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research
AWARD MECHANISM Individual Investigator Research Awards (IIRA)
APPLICATION ID RP140473
APPLICATION TITLE Investigation of the Tumor Suppressor TMEM127 on Lysosome Function and Lipid Metabolism
APPLICANT NAME Dahia, Patricia
ORGANIZATION The University of Texas Health Science Center at San Antonio
PANEL NAME Cancer Biology (CB)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	02/03/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	N/A	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	N/A	07/02/14
	Primary Reviewer 2 COI signed	N/A	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	N/A	07/02/14
	Primary Reviewer 1 critique submitted	N/A	07/02/14
	Primary Reviewer 2 critique submitted	N/A	07/02/14
	Primary Reviewer 3 critique submitted	N/A	07/02/14
	COI indicated by non-primary reviewer	N/A	07/02/14
	Preliminary Evaluation score summary sent to Chair	N/A	07/02/14
	Recommended for full review	N/A	07/02/14
4. Peer Review: On-Site Meeting	Applicant notified of outcome	N/A	07/02/14
	Assigned to primary reviewers	04/22/14	07/02/14
	Primary Reviewer 1 COI signed	05/07/14	07/02/14
	Primary Reviewer 2 COI signed	04/09/14	07/02/14
	Primary Reviewer 3 COI signed	04/09/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/21/14	07/02/14
	Primary Reviewer 1 critique submitted	05/17/14	07/02/14
	Primary Reviewer 2 critique submitted	05/16/14	07/02/14
	Primary Reviewer 3 critique submitted	05/15/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	05/23/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	05/28/14-05/29/14	07/02/14
	Post review statements signed	05/29/14	07/02/14
5. Final SRC Recommendation	Third Party Observer Report	06/12/14	07/02/14
	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRCPDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
	Third Party Observer Report	07/07/14	07/08/14
6. PIC Review	Recommended for grant award	YES	07/02/14
	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
7. Oversight Committee Approval	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP140478
High-Impact/High-Risk Research Award

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *High-Impact/High-Risk Research Award* Request for Applications (RFA). CPRIT received 100 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Imaging Technology and Informatics panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that one application was not recommended for a grant award that has the same score as an application that was recommended for a grant award. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score. The two applications were reviewed by different review panels.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

No individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a 3.5 score, another panel may decide based on the totality of factors that an application with a 3.5 score should not be recommended. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

This statement is true."

Wayne R. Roberts

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.

Sandra Reyes
Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

FY 2014
 CYCLE 1
 PROGRAM Research
 AWARD MECHANISM High-Impact/High-Risk Research Awards (HIHRA)
 APPLICATION ID RP140478
 APPLICATION TITLE Computational Chemistry Determination of DNA Damage Mechanisms in Proton Cancer Therapy to Optimize Its Clinical Use
 APPLICANT NAME Morales, Jorge
 ORGANIZATION Texas Tech University
 PANEL NAME Imaging Technology and Informatics (ITI)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	02/03/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	N/A	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	N/A	07/02/14
	Primary Reviewer 2 COI signed	N/A	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	N/A	07/02/14
	Primary Reviewer 1 critique submitted	N/A	07/02/14
	Primary Reviewer 2 critique submitted	N/A	07/02/14
	Primary Reviewer 3 critique submitted	N/A	07/02/14
	COI indicated by non-primary reviewer	N/A	07/02/14
	Preliminary Evaluation score summary sent to Chair	N/A	07/02/14
	Recommended for full review	N/A	07/02/14
	Applicant notified of outcome	N/A	07/02/14
4. Peer Review: On-Site Meeting	Assigned to primary reviewers	04/25/14	07/02/14
	Primary Reviewer 1 COI signed	04/09/14	07/02/14
	Primary Reviewer 2 COI signed	04/22/14	07/02/14
	Primary Reviewer 3 COI signed	04/18/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/24/14	07/02/14
	Primary Reviewer 1 critique submitted	05/20/14	07/02/14
	Primary Reviewer 2 critique submitted	05/20/14	07/02/14
	Primary Reviewer 3 critique submitted	05/17/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	05/28/14	07/02/14
	COI indicated by non-primary reviewer	Mitchell, Duane	07/02/14
	COI recused from participation	YES	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	05/29/14-05/30/14	07/02/14
	Post review statements signed	05/30/14	07/02/14
	Third Party Observer Report	05/30/14	07/02/14
5. Final SRC Recommendation	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRC/PDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/02/14
6. PIC Review	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
7. Oversight Committee Approval	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP140479
High-Impact/High-Risk Research Award

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *High-Impact/High-Risk Research Award Request for Applications (RFA)*. CPRIT received 100 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Basic Cancer Research Panel 1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that one application was not recommended for a grant award that has the same score as an application that was recommended for a grant award. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score. The two applications were reviewed by different review panels.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

No individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a 3.5 score, another panel may decide based on the totality of factors that an application with a 3.5 score should not be recommended. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

This statement is true."

Wayne R. Roberts

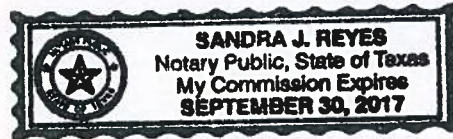
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.

Sandra Reyes

Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research
AWARD MECHANISM High-Impact/High-Risk Research Awards (HIHRA)
APPLICATION ID RP140479
APPLICATION TITLE Screening for Melanoma Genes using Natural Hybrid Incompatibilities
APPLICANT NAME Rosenthal, Gil
ORGANIZATION Texas A&M University
PANEL NAME Basic Cancer Research-1 (BCR-1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	02/03/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	N/A	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	N/A	07/02/14
	Primary Reviewer 2 COI signed	N/A	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	N/A	07/02/14
	Primary Reviewer 1 critique submitted	N/A	07/02/14
	Primary Reviewer 2 critique submitted	N/A	07/02/14
	Primary Reviewer 3 critique submitted	N/A	07/02/14
	COI indicated by non-primary reviewer	N/A	07/02/14
	Preliminary Evaluation score summary sent to Chair	N/A	07/02/14
4. Peer Review: On-Site Meeting	Recommended for full review	N/A	07/02/14
	Applicant notified of outcome	N/A	07/02/14
	Assigned to primary reviewers	04/18/14	07/02/14
	Primary Reviewer 1 COI signed	04/09/14	07/02/14
	Primary Reviewer 2 COI signed	04/09/14	07/02/14
	Primary Reviewer 3 COI signed	04/09/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/21/14	07/02/14
	Primary Reviewer 1 critique submitted	05/13/14	07/02/14
	Primary Reviewer 2 critique submitted	05/12/14	07/02/14
	Primary Reviewer 3 critique submitted	05/15/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	05/25/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	05/31/14-06/01/14	07/02/14
5. Final SRC Recommendation	Post review statements signed	06/11/14	07/02/14
	Third Party Observer Report	06/12/14	07/02/14
	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRCPDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
6. PIC Review	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/02/14
	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
7. Oversight Committee Approval	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP140482
Individual Investigator Research Award

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Imaging Technology and Informatics panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

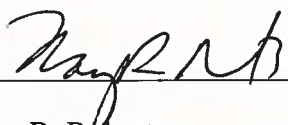
The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

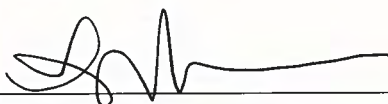
This statement is true."



Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research
AWARD MECHANISM Individual Investigator Research Awards (IIRA)
APPLICATION ID RP140482
APPLICATION TITLE Preclinical Intravital Microscopy of Prostate Cancer Lesions in Bone: Identification and Eradication of Survival Niches by Combination Therapy
APPLICANT NAME Dondossola, Eleonora
ORGANIZATION The University of Texas M. D. Anderson Cancer Center
PANEL NAME Imaging Technology and Informatics (ITI)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	01/29/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	03/17/14	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	04/10/14	07/02/14
	Primary Reviewer 2 COI signed	04/16/14	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	04/09/14	07/02/14
	Primary Reviewer 1 critique submitted	04/04/14	07/02/14
	Primary Reviewer 2 critique submitted	04/04/14	07/02/14
	Primary Reviewer 3 critique submitted	04/07/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	Preliminary Evaluation score summary sent to Chair	04/11/14	07/02/14
	Recommended for full review	YES	07/02/14
4. Peer Review: On-Site Meeting	Applicant notified of outcome	05/21/14	07/02/14
	Assigned to primary reviewers	04/25/14	07/02/14
	Primary Reviewer 1 COI signed	04/09/14	07/02/14
	Primary Reviewer 2 COI signed	04/16/14	07/02/14
	Primary Reviewer 3 COI signed	04/10/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/23/14	07/02/14
	Primary Reviewer 1 critique submitted	05/20/14	07/02/14
	Primary Reviewer 2 critique submitted	05/08/14	07/02/14
	Primary Reviewer 3 critique submitted	05/18/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	05/28/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	05/09/14-05/30/14	07/02/14
	Post review statements signed	05/30/14	07/02/14
5. Final SRC Recommendation	Third Party Observer Report	05/30/14	07/02/14
	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRCPDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
	Third Party Observer Report	07/07/14	07/08/14
6. PIC Review	Recommended for grant award	YES	07/02/14
	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
7. Oversight Committee Approval	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140500
Individual Investigator Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Translational Cancer Research panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

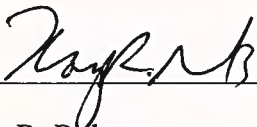
The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

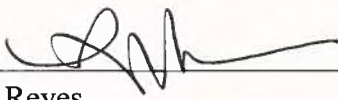
This statement is true."



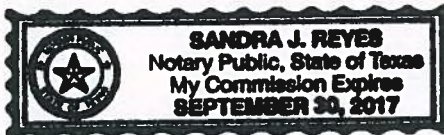
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research
AWARD MECHANISM Individual Investigator Research Awards (IIRA)
APPLICATION ID RP140500
APPLICATION TITLE Towards the Cure of Myelodysplastic Syndrome: Interfering with Innate Immunity Alterations in Human and Mouse Systems
APPLICANT NAME Garcia-Manero, Guillermo
ORGANIZATION The University of Texas M. D. Anderson Cancer Center
PANEL NAME Translational Cancer Research (TCR)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	02/03/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	03/24/14	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	04/21/14	07/02/14
	Primary Reviewer 2 COI signed	04/23/14	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	04/21/14	07/02/14
	Primary Reviewer 1 critique submitted	04/20/14	07/02/14
	Primary Reviewer 2 critique submitted	N/A	07/02/14
	Primary Reviewer 3 critique submitted	04/07/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	Preliminary Evaluation score summary sent to Chair	05/01/14	07/02/14
	Recommended for full review	YES	07/02/14
	Applicant notified of outcome	05/21/14	07/02/14
4. Peer Review: On-Site Meeting	Assigned to primary reviewers	05/08/14	07/02/14
	Primary Reviewer 1 COI signed	04/21/14	07/02/14
	Primary Reviewer 2 COI signed	05/05/14	07/02/14
	Primary Reviewer 3 COI signed	04/23/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/27/14	07/02/14
	Primary Reviewer 1 critique submitted	05/28/14	07/02/14
	Primary Reviewer 2 critique submitted	05/28/14	07/02/14
	Primary Reviewer 3 critique submitted	05/29/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	06/04/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	06/06/14	07/02/14
	Post review statements signed	06/06/14	07/02/14
5. Final SRC Recommendation	Third Party Observer Report	06/12/14	07/02/14
	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRCPDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
	Third Party Observer Report	07/07/14	07/08/14
6. PIC Review	Recommended for grant award	YES	07/02/14
	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
7. Oversight Committee Approval	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140515
Individual Investigator Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Cancer Prevention Research panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

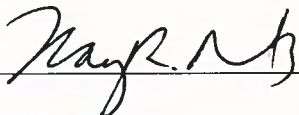
The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.


This statement is true."

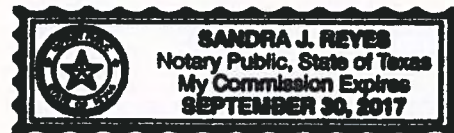


Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

FY 2014
 CYCLE 1
 PROGRAM Research
 AWARD MECHANISM Individual Investigator Research Awards (IIRA)
 APPLICATION ID RP140515
 APPLICATION TITLE CDK Inhibitors as Adjunctive to 5-FU and/or Radiation in Esophageal Adenocarcinoma- Assessment of Efficacy and Predictive Biomarkers
 APPLICANT NAME Maru, Dipen
 ORGANIZATION The University of Texas M. D. Anderson Cancer Center
 PANEL NAME Cancer Prevention Research (CPR)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	01/29/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	03/16/14	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	04/16/14	07/02/14
	Primary Reviewer 2 COI signed	04/09/14	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	04/16/14	07/02/14
	Primary Reviewer 1 critique submitted	04/08/14	07/02/14
	Primary Reviewer 2 critique submitted	03/25/14	07/02/14
	Primary Reviewer 3 critique submitted	04/05/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	Preliminary Evaluation score summary sent to Chair	04/11/14	07/02/14
4. Peer Review: On-Site Meeting	Recommended for full review	YES	07/02/14
	Applicant notified of outcome	05/21/14	07/02/14
	Assigned to primary reviewers	04/23/14	07/02/14
	Primary Reviewer 1 COI signed	04/16/14	07/02/14
	Primary Reviewer 2 COI signed	04/09/14	07/02/14
	Primary Reviewer 3 COI signed	04/16/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/22/14	07/02/14
	Primary Reviewer 1 critique submitted	05/19/14	07/02/14
	Primary Reviewer 2 critique submitted	05/14/14	07/02/14
	Primary Reviewer 3 critique submitted	05/14/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	06/01/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	06/03/14-06/04/14	07/02/14
5. Final SRC Recommendation	Post review statements signed	06/04/14	07/02/14
	Third Party Observer Report	06/12/14	07/02/14
	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRCPDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
6. PIC Review	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/02/14
	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
7. Oversight Committee Approval	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140517
Individual Investigator Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Imaging Technology and Informatics panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

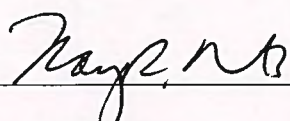
The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

This statement is true."



Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research
AWARD MECHANISM Individual Investigator Research Awards (IIRA)
APPLICATION ID RP140517
APPLICATION TITLE Optimal Biomarkers for Personalized Cancer Therapy: A Network-Based Approach
APPLICANT NAME Vidyasagar, Mathukumalli
ORGANIZATION The University of Texas at Dallas
PANEL NAME Imaging Technology and Informatics (ITI)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	01/31/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	03/17/14	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	04/10/14	07/02/14
	Primary Reviewer 2 COI signed	04/09/14	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	04/10/14	07/02/14
	Primary Reviewer 1 critique submitted	04/02/14	07/02/14
	Primary Reviewer 2 critique submitted	03/19/14	07/02/14
	Primary Reviewer 3 critique submitted	04/04/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	Preliminary Evaluation score summary sent to Chair	04/11/14	07/02/14
	Recommended for full review	YES	07/02/14
4. Peer Review: On-Site Meeting	Applicant notified of outcome	05/21/14	07/02/14
	Assigned to primary reviewers	04/25/14	07/02/14
	Primary Reviewer 1 COI signed	04/16/14	07/02/14
	Primary Reviewer 2 COI signed	04/10/14	07/02/14
	Primary Reviewer 3 COI signed	04/16/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/23/14	07/02/14
	Primary Reviewer 1 critique submitted	05/20/14	07/02/14
	Primary Reviewer 2 critique submitted	05/18/14	07/02/14
	Primary Reviewer 3 critique submitted	05/19/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	05/28/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	05/29/14-05/30/14	07/02/14
	Post review statements signed	05/30/14	07/02/14
5. Final SRC Recommendation	Third Party Observer Report	05/30/14	07/02/14
	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRCPDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
	Third Party Observer Report	07/07/14	07/08/14
6. PIC Review	Recommended for grant award	YES	07/02/14
	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
7. Oversight Committee Approval	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140522
Individual Investigator Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to Translational Cancer Research panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

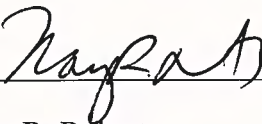
The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

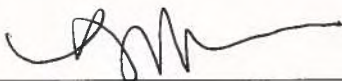
This statement is true."

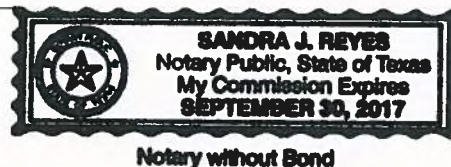


Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research
AWARD MECHANISM Individual Investigator Research Awards (IIRA)
APPLICATION ID RP140522
APPLICATION TITLE Reversing Vaccination-Induced Impairment of Anti-CTLA-4-Based Cancer Therapy.
APPLICANT NAME Overwijk, Willem
ORGANIZATION The University of Texas M. D. Anderson Cancer Center
PANEL NAME Translational Cancer Research (TCR)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	01/27/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	03/24/14	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	04/22/14	07/02/14
	Primary Reviewer 2 COI signed	03/10/14	07/02/14
	Primary Reviewer 3 COI signed	04/24/14	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 1 critique submitted	04/15/14	07/02/14
	Primary Reviewer 2 critique submitted	04/11/14	07/02/14
	Primary Reviewer 3 critique submitted	05/08/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	Preliminary Evaluation score summary sent to Chair	05/01/14	07/02/14
	Recommended for full review	YES	07/02/14
	Applicant notified of outcome	05/21/14	07/02/14
4. Peer Review: On-Site Meeting	Assigned to primary reviewers	05/08/14	07/02/14
	Primary Reviewer 1 COI signed	04/24/14	07/02/14
	Primary Reviewer 2 COI signed	04/22/14	07/02/14
	Primary Reviewer 3 COI signed	04/24/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/27/14	07/02/14
	Primary Reviewer 1 critique submitted	05/28/14	07/02/14
	Primary Reviewer 2 critique submitted	05/26/14	07/02/14
	Primary Reviewer 3 critique submitted	06/02/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	06/04/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	06/06/14	07/02/14
	Post review statements signed	06/06/14	07/02/14
	Third Party Observer Report	06/12/14	07/02/14
5. Final SRC Recommendation	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRCPDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/02/14
6. PIC Review	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
7. Oversight Committee Approval	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140542
Individual Investigator Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Clinical and Translational Cancer Research panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

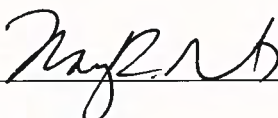
The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

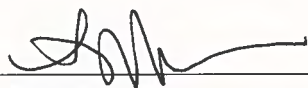
This statement is true."



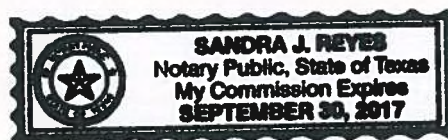
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

FY 2014
 CYCLE 1
 PROGRAM Research
 AWARD MECHANISM Individual Investigator Research Awards (IIRA)
 APPLICATION ID RP140542
 APPLICATION TITLE Biology and Therapy of Basal Bladder Cancers
 APPLICANT NAME McConkey, David
 ORGANIZATION The University of Texas M. D. Anderson Cancer Center
 PANEL NAME Clinical and Translational Cancer Research (CTCR)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	01/30/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	04/08/14	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	05/02/14	07/02/14
	Primary Reviewer 2 COI signed	05/01/14	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	04/30/14	07/02/14
	Primary Reviewer 1 critique submitted	04/19/14	07/02/14
	Primary Reviewer 2 critique submitted	05/01/14	07/02/14
	Primary Reviewer 3 critique submitted	04/20/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	Preliminary Evaluation score summary sent to Chair	05/01/14	07/02/14
	Recommended for full review	YES	07/02/14
4. Peer Review: On-Site Meeting	Applicant notified of outcome	05/21/14	07/02/14
	Assigned to primary reviewers	05/13/14	07/02/14
	Primary Reviewer 1 COI signed	05/02/14	07/02/14
	Primary Reviewer 2 COI signed	05/01/14	07/02/14
	Primary Reviewer 3 COI signed	04/30/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/29/14	07/02/14
	Primary Reviewer 1 critique submitted	05/24/14	07/02/14
	Primary Reviewer 2 critique submitted	06/04/14	07/02/14
	Primary Reviewer 3 critique submitted	05/30/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	06/09/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	06/10/14	07/02/14
	Post review statements signed	07/03/14	07/07/14
	Third Party Observer Report	06/12/14	07/02/14
5. Final SRC Recommendation	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRCPDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
	Third Party Observer Report	07/07/14	07/08/14
6. PIC Review	Recommended for grant award	YES	07/02/14
	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
7. Oversight Committee Approval	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140544
Individual Investigator Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Imaging Technology and Informatics panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

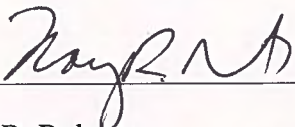
The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

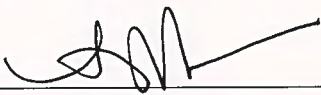
This statement is true."



Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

FY 2014
 CYCLE 1
 PROGRAM Research
 AWARD MECHANISM Individual Investigator Research Awards (IIRA)
 APPLICATION ID RP140544
 APPLICATION TITLE Mapping Acidic Tumor Microenvironment with Renal Clearable pH Nanoindicators
 APPLICANT NAME Zheng, Jie
 ORGANIZATION The University of Texas at Dallas
 PANEL NAME Imaging Technology and Informatics (ITI)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	02/03/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	N/A	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	N/A	07/02/14
	Primary Reviewer 2 COI signed	N/A	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	N/A	07/02/14
	Primary Reviewer 1 critique submitted	N/A	07/02/14
	Primary Reviewer 2 critique submitted	N/A	07/02/14
	Primary Reviewer 3 critique submitted	N/A	07/02/14
	COI indicated by non-primary reviewer	N/A	07/02/14
	Preliminary Evaluation score summary sent to Chair	N/A	07/02/14
4. Peer Review: On-Site Meeting	Recommended for full review	N/A	07/02/14
	Applicant notified of outcome	N/A	07/02/14
	Assigned to primary reviewers	04/25/14	07/02/14
	Primary Reviewer 1 COI signed	04/16/14	07/02/14
	Primary Reviewer 2 COI signed	04/14/14	07/02/14
	Primary Reviewer 3 COI signed	04/22/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/23/14	07/02/14
	Primary Reviewer 1 critique submitted	05/21/14	07/02/14
	Primary Reviewer 2 critique submitted	05/20/14	07/02/14
	Primary Reviewer 3 critique submitted	05/20/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	05/28/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	05/29/14-05/30/14	07/02/14
	Post review statements signed	05/30/14	07/02/14
5. Final SRC Recommendation	Third Party Observer Report	05/30/14	07/02/14
	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRCPDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
	Third Party Observer Report	07/07/14	07/08/14
6. PIC Review	Recommended for grant award	YES	07/02/14
	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
7. Oversight Committee Approval	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140553
Individual Investigator Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Basic Cancer Research Panel 2 for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

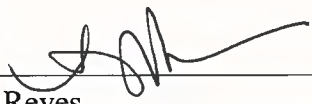
This statement is true."

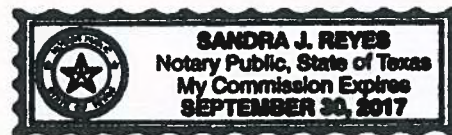


Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

FY 2014
 CYCLE 1
 PROGRAM Research
 AWARD MECHANISM Individual Investigator Research Awards (IIRA)
 APPLICATION ID RP140553
 APPLICATION TITLE Translational Discovery of Resistance Genes and Cancer Gene Functions
 APPLICANT NAME Rosenberg, Susan
 ORGANIZATION Baylor College of Medicine
 PANEL NAME Basic Cancer Research-2 (BCR-2)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/01/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/01/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/01/14
	Date application submitted	02/03/14	07/01/14
	Method of submission	CARS	07/01/14
	Within receipt period	YES	07/01/14
	Appeal to submit application after CARS closed	N/A	07/01/14
	Appeal for late application submission accepted	N/A	07/01/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/01/14
	Donation(s) made to CPRIT/foundation	NO	07/01/14
	Assigned to primary reviewers	03/31/14	07/01/14
	Applicant notified of review panel assignment	05/14/14	07/01/14
	Primary Reviewer 1 COI signed	04/24/14	07/01/14
	Primary Reviewer 2 COI signed	04/21/14	07/01/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	04/22/14	07/01/14
	Primary Reviewer 1 critique submitted	04/20/14	07/01/14
	Primary Reviewer 2 critique submitted	04/06/14	07/01/14
	Primary Reviewer 3 critique submitted	04/16/14	07/01/14
	COI indicated by non-primary reviewer	NONE	07/01/14
	Preliminary Evaluation score summary sent to Chair	04/28/14	07/01/14
	Recommended for full review	YES	07/01/14
	Applicant notified of outcome	05/21/14	07/01/14
4. Peer Review: On-Site Meeting	Assigned to primary reviewers	05/07/14	07/01/14
	Primary Reviewer 1 COI signed	04/22/14	07/01/14
	Primary Reviewer 2 COI signed	04/21/14	07/01/14
	Primary Reviewer 3 COI signed	04/22/14	07/01/14
	Primary (Advocate) Reviewer 4 COI signed	04/29/14	07/01/14
	Primary Reviewer 1 critique submitted	05/15/14	07/01/14
	Primary Reviewer 2 critique submitted	05/27/14	07/01/14
	Primary Reviewer 3 critique submitted	05/28/14	07/01/14
	Primary (Advocate) Reviewer 4 critique submitted	06/02/14	07/01/14
	COI indicated by non-primary reviewer	NONE	07/01/14
	COI recused from participation	N/A	07/01/14
	Discussed at On-Site Meeting	YES	07/01/14
	Peer Review: On-Site Meeting	06/04/14 - 06/05/14	07/01/14
	Post review statements signed	06/05/14	07/01/14
	Third Party Observer Report	06/12/14	07/01/14
5. Final SRC Recommendation	Score report delivered to CSO	06/19/14	07/01/14
	COI indicated by SRCPDRC member	NONE	07/01/14
	COI recused from participation	N/A	07/01/14
	SRC Meeting	06/24/14	07/01/14
	Third Party Observer Report	07/07/14	07/08/14
6. PIC Review	Recommended for grant award	YES	07/01/14
	SRC Chair Notification to PIC and OC	06/24/14	07/01/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
7. Oversight Committee Approval	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140556
Individual Investigator Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Clinical and Translational Cancer Research panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

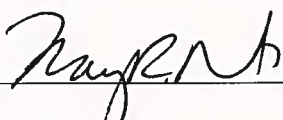
The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

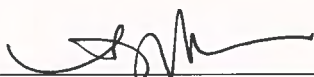
This statement is true."



Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

FY 2014
 CYCLE 1
 PROGRAM Research
 AWARD MECHANISM Individual Investigator Research Awards (IIRA)
 APPLICATION ID RP140556
 APPLICATION TITLE DNA Methylation and Telomere Length in Peripheral Blood as Predictors of Aggressive Prostate Cancer
 APPLICANT NAME Gu, Jian
 ORGANIZATION The University of Texas M. D. Anderson Cancer Center
 PANEL NAME Clinical and Translational Cancer Research (CTCR)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	01/29/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	04/08/14	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	04/29/14	07/02/14
	Primary Reviewer 2 COI signed	05/01/14	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	05/05/14	07/02/14
	Primary Reviewer 1 critique submitted	04/09/14	07/02/14
	Primary Reviewer 2 critique submitted	05/01/14	07/02/14
	Primary Reviewer 3 critique submitted	04/22/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	Preliminary Evaluation score summary sent to Chair	05/01/14	07/02/14
4. Peer Review: On-Site Meeting	Recommended for full review	YES	07/02/14
	Applicant notified of outcome	05/21/14	07/02/14
	Assigned to primary reviewers	05/13/14	07/02/14
	Primary Reviewer 1 COI signed	04/29/14	07/02/14
	Primary Reviewer 2 COI signed	05/01/14	07/02/14
	Primary Reviewer 3 COI signed	05/05/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/29/14	07/02/14
	Primary Reviewer 1 critique submitted	05/14/14	07/02/14
	Primary Reviewer 2 critique submitted	05/30/14	07/02/14
	Primary Reviewer 3 critique submitted	05/30/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	06/07/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	06/10/14	07/02/14
5. Final SRC Recommendation	Post review statements signed	07/03/14	07/07/14
	Third Party Observer Report	06/12/14	07/02/14
	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRCPDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
6. PIC Review	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/02/14
	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
7. Oversight Committee Approval	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
7. Oversight Committee Approval	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
7. Oversight Committee Approval	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140563
Individual Investigator Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Basic Cancer Research Panel 1 for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

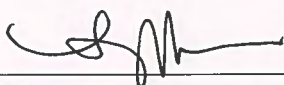
This statement is true."



Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

FY 2014
 CYCLE 1
 PROGRAM Research
 AWARD MECHANISM Individual Investigator Research Awards - (IIRA)
 APPLICATION ID RP140563
 APPLICATION TITLE PAF, a Novel Wnt Signaling Regulator, in Colorectal Cancer
 APPLICANT NAME PARK, JAE-IL
 ORGANIZATION The University of Texas M. D. Anderson Cancer Center
 PANEL NAME Basic Cancer Research-1 (BCR-1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	01/30/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	03/17/14	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	04/09/14	07/02/14
	Primary Reviewer 2 COI signed	04/21/14	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	04/14/14	07/02/14
	Primary Reviewer 1 critique submitted	03/22/14	07/02/14
	Primary Reviewer 2 critique submitted	04/05/14	07/02/14
	Primary Reviewer 3 critique submitted	04/14/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	Preliminary Evaluation score summary sent to Chair	04/15/14	07/02/14
4. Peer Review: On-Site Meeting	Recommended for full review	YES	07/02/14
	Applicant notified of outcome	05/21/14	07/02/14
	Assigned to primary reviewers	04/18/14	07/02/14
	Primary Reviewer 1 COI signed	04/09/14	07/02/14
	Primary Reviewer 2 COI signed	04/21/14	07/02/14
	Primary Reviewer 3 COI signed	04/14/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/23/14	07/02/14
	Primary Reviewer 1 critique submitted	04/26/14	07/02/14
	Primary Reviewer 2 critique submitted	05/14/14	07/02/14
	Primary Reviewer 3 critique submitted	05/21/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	05/29/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	05/31/14-06/01/14	07/02/14
	Post review statements signed	06/11/14	07/02/14
5. Final SRC Recommendation	Third Party Observer Report	06/12/14	07/02/14
	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRCPDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
	Third Party Observer Report	07/07/14	07/08/14
6. PIC Review	Recommended for grant award	YES	07/02/14
	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
7. Oversight Committee Approval	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140594
Individual Investigator Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Clinical and Translational Cancer Research panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

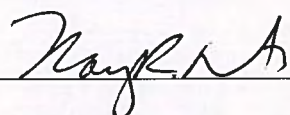
The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

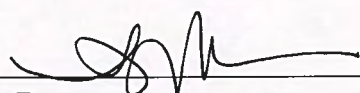
This statement is true."

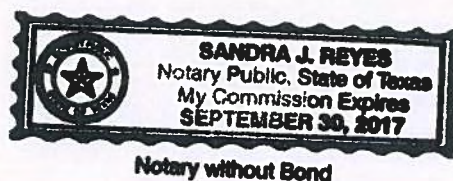


Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

FY 2014
 CYCLE 1
 PROGRAM Research
 AWARD MECHANISM Individual Investigator Research Awards (IIRA)
 APPLICATION ID RP140594
 APPLICATION TITLE microRNAs: safe and effective therapeutic adjuvants for treating drug resistant breast cancers
 APPLICANT NAME Rao, Manjeet
 ORGANIZATION The University of Texas Health Science Center at San Antonio
 PANEL NAME Clinical and Translational Cancer Research (CTCR)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	02/03/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	04/08/14	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	04/29/14	07/02/14
	Primary Reviewer 2 COI signed	04/30/14	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	05/02/14	07/02/14
	Primary Reviewer 1 critique submitted	04/22/14	07/02/14
	Primary Reviewer 2 critique submitted	04/20/14	07/02/14
	Primary Reviewer 3 critique submitted	04/27/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	Preliminary Evaluation score summary sent to Chair	05/01/14	07/02/14
4. Peer Review: On-Site Meeting	Recommended for full review	YES	07/02/14
	Applicant notified of outcome	05/21/14	07/02/14
	Assigned to primary reviewers	05/13/14	07/02/14
	Primary Reviewer 1 COI signed	04/29/14	07/02/14
	Primary Reviewer 2 COI signed	04/30/14	07/02/14
	Primary Reviewer 3 COI signed	05/07/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	05/14/14	07/02/14
	Primary Reviewer 1 critique submitted	05/29/14	07/02/14
	Primary Reviewer 2 critique submitted	05/29/14	07/02/14
	Primary Reviewer 3 critique submitted	06/10/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	06/08/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	06/10/14	07/02/14
	Post review statements signed	07/03/14	07/07/14
5. Final SRC Recommendation	Third Party Observer Report	06/12/14	07/02/14
	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRCPDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
	Third Party Observer Report	07/07/14	07/08/14
6. PIC Review	Recommended for grant award	YES	07/02/14
	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
7. Oversight Committee Approval	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP140597
Individual Investigator Research Award

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Cancer Biology panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

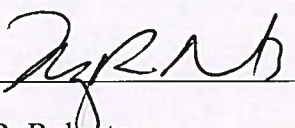
The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

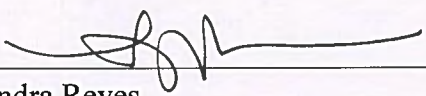
This statement is true."



Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research
AWARD MECHANISM Individual Investigator Research Awards (IIRA)
APPLICATION ID RP140597
APPLICATION TITLE Role of TJP1 in Sensitivity and Resistance to Proteasome Inhibitors in Myeloma
APPLICANT NAME Orłowski, Robert
ORGANIZATION The University of Texas M. D. Anderson Cancer Center
PANEL NAME Cancer Biology (CB)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	01/31/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
2. Receipt, Referral, and Assignment	Appeal for late application submission accepted	N/A	07/02/14
	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	03/17/14	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	04/16/14	07/02/14
	Primary Reviewer 2 COI signed	04/09/14	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	04/14/14	07/02/14
	Primary Reviewer 1 critique submitted	04/09/14	07/02/14
	Primary Reviewer 2 critique submitted	03/24/14	07/02/14
	Primary Reviewer 3 critique submitted	04/08/14	07/02/14
	COI indicated by non-primary reviewer	Lawlor, Elizabeth	07/02/14
	Preliminary Evaluation score summary sent to Chair	4/11/2014	07/02/14
	Recommended for full review	YES	07/02/14
4. Peer Review: On-Site Meeting	Applicant notified of outcome	05/21/14	07/02/14
	Assigned to primary reviewers	04/22/14	07/02/14
	Primary Reviewer 1 COI signed	04/16/14	07/02/14
	Primary Reviewer 2 COI signed	04/21/14	07/02/14
	Primary Reviewer 3 COI signed	04/14/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/21/14	07/02/14
	Primary Reviewer 1 critique submitted	05/16/14	07/02/14
	Primary Reviewer 2 critique submitted	05/17/14	07/02/14
	Primary Reviewer 3 critique submitted	05/16/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	05/23/14	07/02/14
	COI indicated by non-primary reviewer	Lawlor, Elizabeth	07/02/14
	COI recused from participation	YES	07/02/14
	COI indicated by non-primary reviewer	Wahl, Geoffrey	07/02/14
	COI recused from participation	YES	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
5. Final SRC Recommendation	Peer Review: On-Site Meeting	05/28/14-05/29/14	07/02/14
	Post review statements signed	05/29/14	07/02/14
	Third Party Observer Report	06/12/14	07/02/14
	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRCPDRC member	NONE	07/02/14
6. PIC Review	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/02/14
	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
7. Oversight Committee Approval	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
8. Final Award	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
9. Final Disbursement	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140606
Individual Investigator Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Imaging Technology and Informatics panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

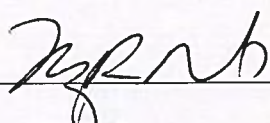
The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

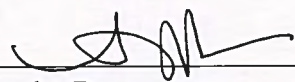
This statement is true."



Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research
AWARD MECHANISM Individual Investigator Research Awards (IIRA)
APPLICATION ID RP140606
APPLICATION TITLE Optimizing Therapy for Glioblastoma Through Genomic Profiling of Treatment Failure
APPLICANT NAME Verhaak, Roeland
ORGANIZATION The University of Texas M. D. Anderson Cancer Center
PANEL NAME Imaging Technology and Informatics (ITI)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	01/31/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	03/17/14	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	04/16/14	07/02/14
	Primary Reviewer 2 COI signed	04/17/14	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	04/09/14	07/02/14
	Primary Reviewer 1 critique submitted	04/06/14	07/02/14
	Primary Reviewer 2 critique submitted	04/07/14	07/02/14
	Primary Reviewer 3 critique submitted	04/07/14	07/02/14
	COI indicated by non-primary reviewer	Basilion, James	07/02/14
	Preliminary Evaluation score summary sent to Chair	04/11/14	07/02/14
	Recommended for full review	YES	07/02/14
4. Peer Review: On-Site Meeting	Applicant notified of outcome	05/21/14	07/02/14
	Assigned to primary reviewers	04/25/14	07/02/14
	Primary Reviewer 1 COI signed	04/23/14	07/02/14
	Primary Reviewer 2 COI signed	04/17/14	07/02/14
	Primary Reviewer 3 COI signed	04/16/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/24/14	07/02/14
	Primary Reviewer 1 critique submitted	05/20/14	07/02/14
	Primary Reviewer 2 critique submitted	05/21/14	07/02/14
	Primary Reviewer 3 critique submitted	05/21/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	05/28/14	07/02/14
	COI indicated by non-primary reviewer	Basilion, James	07/02/14
	COI recused from participation	YES	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	05/29/14-05/30/14	07/02/14
5. Final SRC Recommendation	Post review statements signed	05/30/14	07/02/14
	Third Party Observer Report	05/30/14	07/02/14
	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRCPDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
6. PIC Review	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/02/14
	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
7. Oversight Committee Approval	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140609
Individual Investigator Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Cancer Prevention Research panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

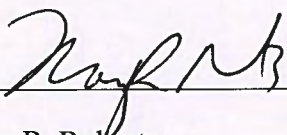
The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

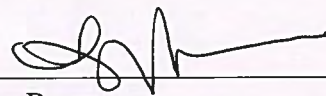
This statement is true."



Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research
AWARD MECHANISM Individual Investigator Research Awards (IIRA)
APPLICATION ID RP140609
APPLICATION TITLE A Missing Link Between Obesity and Cancer: Adipose
Derived Stem Cells
APPLICANT NAME Klopp, Ann
ORGANIZATION The University of Texas M. D. Anderson Cancer Center
PANEL NAME Cancer Prevention Research (CPR)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	01/31/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	03/16/14	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	04/23/14	07/02/14
	Primary Reviewer 2 COI signed	04/16/14	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	04/14/14	07/02/14
	Primary Reviewer 1 critique submitted	04/06/14	07/02/14
	Primary Reviewer 2 critique submitted	04/05/14	07/02/14
	Primary Reviewer 3 critique submitted	03/18/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	Preliminary Evaluation score summary sent to Chair	04/11/14	07/02/14
4. Peer Review: On-Site Meeting	Recommended for full review	YES	07/02/14
	Applicant notified of outcome	05/21/14	07/02/14
	Assigned to primary reviewers	04/23/14	07/02/14
	Primary Reviewer 1 COI signed	04/23/14	07/02/14
	Primary Reviewer 2 COI signed	04/16/14	07/02/14
	Primary Reviewer 3 COI signed	04/14/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/22/14	07/02/14
	Primary Reviewer 1 critique submitted	05/18/14	07/02/14
	Primary Reviewer 2 critique submitted	05/12/14	07/02/14
	Primary Reviewer 3 critique submitted	05/15/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	05/31/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	06/03/14-06/04/14	07/02/14
	Post review statements signed	06/04/14	07/02/14
5. Final SRC Recommendation	Third Party Observer Report	06/12/14	07/02/14
	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRCPDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
	Third Party Observer Report	07/07/14	07/08/14
6. PIC Review	Recommended for grant award	YES	07/02/14
	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
7. Oversight Committee Approval	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140612
Individual Investigator Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Basic Cancer Research Panel 1 for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

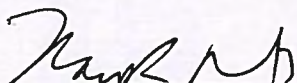
The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

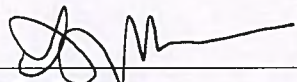
This statement is true."



Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research
AWARD MECHANISM Individual Investigator Research Awards - (IIRA)
APPLICATION ID RP140612
APPLICATION TITLE Collateral Genomic Deletions As Targetable Vulnerabilities in Cancer
APPLICANT NAME DePinho, Ronald
ORGANIZATION The University of Texas M. D. Anderson Cancer Center
PANEL NAME Basic Cancer Research-1 (BCR-1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	02/03/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	03/17/14	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	04/16/14	07/02/14
	Primary Reviewer 2 COI signed	03/06/14	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	04/09/14	07/02/14
	Primary Reviewer 1 critique submitted	04/06/14	07/02/14
	Primary Reviewer 2 critique submitted	04/05/14	07/02/14
	Primary Reviewer 3 critique submitted	03/18/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	Preliminary Evaluation score summary sent to Chair	04/15/14	07/02/14
	Recommended for full review	YES	07/02/14
4. Peer Review: On-Site Meeting	Applicant notified of outcome	05/21/14	07/02/14
	Assigned to primary reviewers	04/18/14	07/02/14
	Primary Reviewer 1 COI signed	04/16/14	07/02/14
	Primary Reviewer 2 COI signed	04/10/14	07/02/14
	Primary Reviewer 3 COI signed	04/09/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/21/14	07/02/14
	Primary Reviewer 1 critique submitted	05/16/14	07/02/14
	Primary Reviewer 2 critique submitted	05/22/14	07/02/14
	Primary Reviewer 3 critique submitted	05/12/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	05/26/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	05/31/14-06/01/14	07/02/14
	Post review statements signed	06/11/14	07/02/14
5. Final SRC Recommendation	Third Party Observer Report	06/12/14	07/02/14
	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRCPDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
	Third Party Observer Report	07/07/14	07/08/14
6. PIC Review	Recommended for grant award	YES	07/02/14
	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
7. Oversight Committee Approval	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140616
Individual Investigator Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Cancer Biology panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

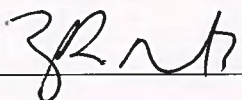
The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

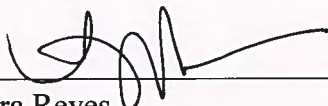
This statement is true."



Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas

Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research
AWARD MECHANISM Individual Investigator Research Awards (IIRA)
APPLICATION ID RP140616

APPLICATION TITLE Tenascin-C and Metastatic Prostate Cancer Progression

APPLICANT NAME Rowley, David
ORGANIZATION Baylor College of Medicine
PANEL NAME Cancer Biology (CB)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	01/27/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
	Administrative review notification	N/A	07/02/14
2. Receipt, Referral, and Assignment	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	03/17/14	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	04/09/14	07/02/14
	Primary Reviewer 2 COI signed	04/14/14	07/02/14
	Primary Reviewer 3 COI signed	04/09/14	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 1 critique submitted	04/08/14	07/02/14
	Primary Reviewer 2 critique submitted	04/08/14	07/02/14
	Primary Reviewer 3 critique submitted	04/07/14	07/02/14
	COI indicated by non-primary reviewer	DeClerck, Yves	07/02/14
	Preliminary Evaluation score summary sent to Chair	04/11/14	07/02/14
	Recommended for full review	YES	07/02/14
4. Peer Review: On-Site Meeting	Applicant notified of outcome	05/21/14	07/02/14
	Assigned to primary reviewers	04/22/14	07/02/14
	Primary Reviewer 1 COI signed	04/09/14	07/02/14
	Primary Reviewer 2 COI signed	04/14/14	07/02/14
	Primary Reviewer 3 COI signed	04/09/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/21/14	07/02/14
	Primary Reviewer 1 critique submitted	05/21/14	07/02/14
	Primary Reviewer 2 critique submitted	05/16/14	07/02/14
	Primary Reviewer 3 critique submitted	05/17/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	05/26/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	05/28/14-05/29/14	07/02/14
	Post review statements signed	05/29/14	07/02/14
	Third Party Observer Report	06/12/14	07/02/14
5. Final SRC Recommendation	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRCPDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/02/14
6. PIC Review	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
7. Oversight Committee Approval	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140648
Individual Investigator Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to Basic Cancer Research Panel 2 for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

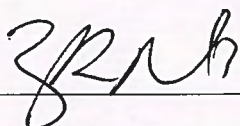
The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

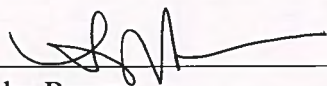
This statement is true."



Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas

Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research
AWARD MECHANISM Individual Investigator Research Awards (IIRA)
APPLICATION ID RP140648
APPLICATION TITLE New Therapeutic Strategies for Metastatic Melanoma
APPLICANT NAME Dalby, Kevin
ORGANIZATION The University of Texas at Austin
PANEL NAME Basic Cancer Research-2 (BCR-2)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/01/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/01/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/01/14
	Date application submitted	02/03/14	07/01/14
	Method of submission	CARS	07/01/14
	Within receipt period	YES	07/01/14
	Appeal to submit application after CARS closed	N/A	07/01/14
	Appeal for late application submission accepted	N/A	07/01/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/01/14
	Donation(s) made to CPRIT/foundation	NO	07/01/14
	Assigned to primary reviewers	03/31/14	07/01/14
	Applicant notified of review panel assignment	05/14/14	07/01/14
	Primary Reviewer 1 COI signed	04/21/14	07/01/14
	Primary Reviewer 2 COI signed	03/12/14	07/01/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	04/21/14	07/01/14
	Primary Reviewer 1 critique submitted	04/21/14	07/01/14
	Primary Reviewer 2 critique submitted	04/18/14	07/01/14
	Primary Reviewer 3 critique submitted	04/09/14	07/01/14
	COI indicated by non-primary reviewer	NONE	07/01/14
	Preliminary Evaluation score summary sent to Chair	04/28/14	07/01/14
4. Peer Review: On-Site Meeting	Recommended for full review	YES	07/01/14
	Applicant notified of outcome	05/21/14	07/01/14
	Assigned to primary reviewers	05/07/14	07/01/14
	Primary Reviewer 1 COI signed	04/21/14	07/01/14
	Primary Reviewer 2 COI signed	04/21/14	07/01/14
	Primary Reviewer 3 COI signed	04/21/14	07/01/14
	Primary (Advocate) Reviewer 4 COI signed	04/29/14	07/01/14
	Primary Reviewer 1 critique submitted	05/28/14	07/01/14
	Primary Reviewer 2 critique submitted	05/30/14	07/01/14
	Primary Reviewer 3 critique submitted	05/27/14	07/01/14
	Primary (Advocate) Reviewer 4 critique submitted	06/02/14	07/01/14
	COI indicated by non-primary reviewer	NONE	07/01/14
	COI recused from participation	N/A	07/01/14
	Discussed at On-Site Meeting	YES	07/01/14
	Peer Review: On-Site Meeting	06/04/14 - 06/05/14	07/01/14
	Post review statements signed	06/05/14	07/01/14
5. Final SRC Recommendation	Third Party Observer Report	06/12/14	07/01/14
	Score report delivered to CSO	06/19/14	07/01/14
	COI indicated by SRCPDRC member	NONE	07/01/14
	COI recused from participation	N/A	07/01/14
	SRC Meeting	06/24/14	07/01/14
	Third Party Observer Report	07/07/14	07/08/14
6. PIC Review	Recommended for grant award	YES	07/01/14
	SRC Chair Notification to PIC and OC	06/24/14	07/01/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
7. Oversight Committee Approval	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP140649
High-Impact/High-Risk Research Award

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *High-Impact/High-Risk Research Award* Request for Applications (RFA). CPRIT received 100 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Translational Cancer Research panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT’s grant review processes were followed by the review panel evaluating the applications in this grant cycle

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that one application was not recommended for a grant award that has the same score as an application that was recommended for a grant award. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score. The two applications were reviewed by different review panels.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

No individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a 3.5 score, another panel may decide based on the totality of factors that an application with a 3.5 score should not be recommended. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

This statement is true."

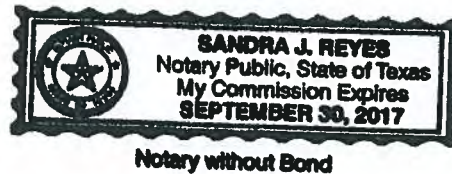
Wayne R. Roberts

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.

Sandra Reyes
Sandra Reyes
Notary Public, State of Texas



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research
AWARD MECHANISM High-Impact/High-Risk Research Awards (HIHRA)
APPLICATION ID RP140649
APPLICATION TITLE Realizing Personalized and Precision Medicine for Melanoma: A Rapid Assay for Measuring ERK Activity
APPLICANT NAME Dalby, Kevin
ORGANIZATION The University of Texas at Austin
PANEL NAME Translational Cancer Research (TCR)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	02/03/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
2. Receipt, Referral, and Assignment	Appeal for late application submission accepted	N/A	07/02/14
	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	N/A	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	N/A	07/02/14
	Primary Reviewer 2 COI signed	N/A	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	N/A	07/02/14
	Primary Reviewer 1 critique submitted	N/A	07/02/14
	Primary Reviewer 2 critique submitted	N/A	07/02/14
	Primary Reviewer 3 critique submitted	N/A	07/02/14
	COI indicated by non-primary reviewer	N/A	07/02/14
	Preliminary Evaluation score summary sent to Chair	N/A	07/02/14
	Recommended for full review	N/A	07/02/14
4. Peer Review: On-Site Meeting	Applicant notified of outcome	N/A	07/02/14
	Assigned to primary reviewers	05/08/14	07/02/14
	Primary Reviewer 1 COI signed	04/21/14	07/02/14
	Primary Reviewer 2 COI signed	05/03/14	07/02/14
	Primary Reviewer 3 COI signed	04/28/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/27/14	07/02/14
	Primary Reviewer 1 critique submitted	06/03/14	07/02/14
	Primary Reviewer 2 critique submitted	06/03/14	07/02/14
	Primary Reviewer 3 critique submitted	05/29/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	06/05/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	06/06/14	07/02/14
	Post review statements signed	06/06/14	07/02/14
5. Final SRC Recommendation	Third Party Observer Report	06/12/14	07/02/14
	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRCPDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
	Third Party Observer Report	07/07/14	07/08/14
6. PIC Review	Recommended for grant award	YES	07/02/14
	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
7. Oversight Committee Approval	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP140655
Individual Investigator Research Award

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Basic Cancer Research Panel 2 for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

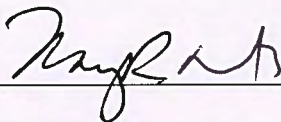
The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

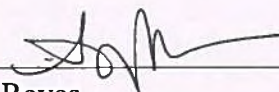
This statement is true."

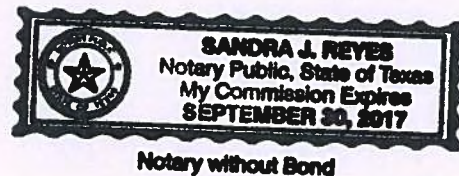


Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas

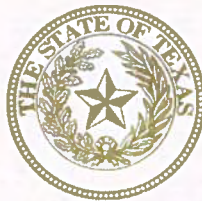


CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research
AWARD MECHANISM Individual Investigator Research Awards (IIRA)
APPLICATION ID RP140655
APPLICATION TITLE Evaluation of the Role of Tumor Suppressor Candidate
NPRL2 in Cell Growth Control
APPLICANT NAME Tu, Benjamin
ORGANIZATION The University of Texas Southwestern Medical Center
PANEL NAME Basic Cancer Research-2 (BCR-2)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/01/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/01/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/01/14
	Date application submitted	02/02/14	07/01/14
	Method of submission	CARS	07/01/14
	Within receipt period	YES	07/01/14
	Appeal to submit application after CARS closed	N/A	07/01/14
	Appeal for late application submission accepted	N/A	07/01/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/01/14
	Donation(s) made to CPRIT/foundation	NO	07/01/14
	Assigned to primary reviewers	03/31/14	07/01/14
	Applicant notified of review panel assignment	05/14/14	07/01/14
	Primary Reviewer 1 COI signed	04/25/14	07/01/14
	Primary Reviewer 2 COI signed	04/23/14	07/01/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	03/11/14	07/01/14
	Primary Reviewer 1 critique submitted	04/23/14	07/01/14
	Primary Reviewer 2 critique submitted	04/15/14	07/01/14
	Primary Reviewer 3 critique submitted	04/21/14	07/01/14
	COI indicated by non-primary reviewer	NONE	07/01/14
	Preliminary Evaluation score summary sent to Chair	04/28/14	07/01/14
	Recommended for full review	YES	07/01/14
4. Peer Review: On-Site Meeting	Applicant notified of outcome	05/21/14	07/01/14
	Assigned to primary reviewers	05/07/14	07/01/14
	Primary Reviewer 1 COI signed	04/25/14	07/01/14
	Primary Reviewer 2 COI signed	04/23/14	07/01/14
	Primary Reviewer 3 COI signed	03/06/14	07/01/14
	Primary (Advocate) Reviewer 4 COI signed	04/29/14	07/01/14
	Primary Reviewer 1 critique submitted	06/01/14	07/01/14
	Primary Reviewer 2 critique submitted	05/27/14	07/01/14
	Primary Reviewer 3 critique submitted	05/28/14	07/01/14
	Primary (Advocate) Reviewer 4 critique submitted	06/02/14	07/01/14
	COI indicated by non-primary reviewer	NONE	07/01/14
	COI recused from participation	N/A	07/01/14
	Discussed at On-Site Meeting	YES	07/01/14
	Peer Review: On-Site Meeting	06/04/14 - 06/05/14	07/01/14
5. Final SRC Recommendation	Post review statements signed	06/05/14	07/01/14
	Third Party Observer Report	06/12/14	07/01/14
	Score report delivered to CSO	06/19/14	07/01/14
	COI indicated by SRCPDRC member	NONE	07/01/14
	COI recused from participation	N/A	07/01/14
	SRC Meeting	06/24/14	07/01/14
6. PIC Review	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/01/14
	SRC Chair Notification to PIC and OC	06/24/14	07/01/14
	COI indicated by PIC member	NONE	07/15/14
7. Oversight Committee Approval	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140661
Individual Investigator Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Basic Cancer Research Panel 2 for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

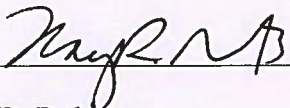
The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

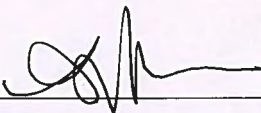
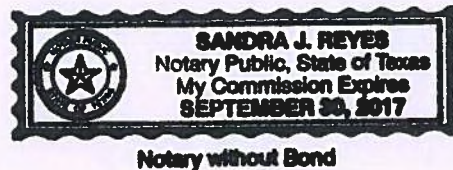
This statement is true."



Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research
AWARD MECHANISM Individual Investigator Research Awards (IIRA)
APPLICATION ID RP140661
APPLICATION TITLE Analyses of the Regulatory Mechanisms of Tankyrase and its Role in Tumorigenesis
APPLICANT NAME Zhang, Xuewu
ORGANIZATION The University of Texas Southwestern Medical Center
PANEL NAME Basic Cancer Research-2 (BCR-2)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/01/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/01/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/01/14
	Date application submitted	02/02/14	07/01/14
	Method of submission	CARS	07/01/14
	Within receipt period	YES	07/01/14
	Appeal to submit application after CARS closed	N/A	07/01/14
	Appeal for late application submission accepted	N/A	07/01/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/01/14
	Donation(s) made to CPRIT/foundation	NO	07/01/14
	Assigned to primary reviewers	03/31/14	07/01/14
	Applicant notified of review panel assignment	05/14/14	07/01/14
	Primary Reviewer 1 COI signed	04/21/14	07/01/14
	Primary Reviewer 2 COI signed	04/24/14	07/01/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	04/23/14	07/01/14
	Primary Reviewer 1 critique submitted	04/09/14	07/01/14
	Primary Reviewer 2 critique submitted	04/20/14	07/01/14
	Primary Reviewer 3 critique submitted	04/15/14	07/01/14
	COI indicated by non-primary reviewer	NONE	07/01/14
	Preliminary Evaluation score summary sent to Chair	04/28/14	07/01/14
4. Peer Review: On-Site Meeting	Recommended for full review	YES	07/01/14
	Applicant notified of outcome	05/21/14	07/01/14
	Assigned to primary reviewers	05/07/14	07/01/14
	Primary Reviewer 1 COI signed	04/21/14	07/01/14
	Primary Reviewer 2 COI signed	04/24/14	07/01/14
	Primary Reviewer 3 COI signed	04/23/14	07/01/14
	Primary (Advocate) Reviewer 4 COI signed	04/29/14	07/01/14
	Primary Reviewer 1 critique submitted	05/28/14	07/01/14
	Primary Reviewer 2 critique submitted	05/25/14	07/01/14
	Primary Reviewer 3 critique submitted	05/27/14	07/01/14
	Primary (Advocate) Reviewer 4 critique submitted	06/02/14	07/01/14
	COI indicated by non-primary reviewer	NONE	07/01/14
	COI recused from participation	N/A	07/01/14
	Discussed at On-Site Meeting	YES	07/01/14
	Peer Review: On-Site Meeting	06/04/14 - 06/05/14	07/01/14
5. Final SRC Recommendation	Post review statements signed	06/05/14	07/01/14
	Third Party Observer Report	06/12/14	07/01/14
	Score report delivered to CSO	06/19/14	07/01/14
	COI indicated by SRCPDRC member	NONE	07/01/14
	COI recused from participation	N/A	07/01/14
	SRC Meeting	06/24/14	07/01/14
6. PIC Review	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/01/14
	SRC Chair Notification to PIC and OC	06/24/14	07/01/14
	COI indicated by PIC member	NONE	07/15/14
7. Oversight Committee Approval	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP140664
High-Impact/High-Risk Research Award

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *High-Impact/High-Risk Research Award* Request for Applications (RFA). CPRIT received 100 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Translational Cancer Research panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT’s grant review processes were followed by the review panel evaluating the applications in this grant cycle

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that one application was not recommended for a grant award that has the same score as an application that was recommended for a grant award. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score. The two applications were reviewed by different review panels.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

No individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a 3.5 score, another panel may decide based on the totality of factors that an application with a 3.5 score should not be recommended. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

This statement is true."

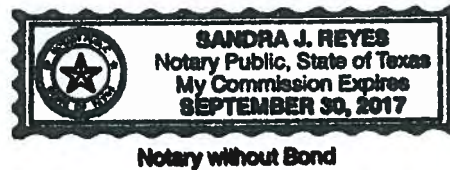
Wayne R. Roberts

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.

Sandra Reyes
Sandra Reyes
Notary Public, State of Texas



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

FY 2014
 CYCLE 1
 PROGRAM Research
 AWARD MECHANISM High-Impact/High-Risk Research Awards (HIHRRRA)
 APPLICATION ID RP140664
 APPLICATION TITLE Development of Therapeutic Antibodies Having both Fc[gamma] and Fc[Alpha] Effector Functions and Displaying Potent Cancer Cell Killing.
 APPLICANT NAME Georgiou, George
 ORGANIZATION The University of Texas at Austin
 PANEL NAME Translational Cancer Research (TCR)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	01/31/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	N/A	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	N/A	07/02/14
	Primary Reviewer 2 COI signed	N/A	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	N/A	07/02/14
	Primary Reviewer 1 critique submitted	N/A	07/02/14
	Primary Reviewer 2 critique submitted	N/A	07/02/14
	Primary Reviewer 3 critique submitted	N/A	07/02/14
	COI indicated by non-primary reviewer	N/A	07/02/14
	Preliminary Evaluation score summary sent to Chair	N/A	07/02/14
	Recommended for full review	N/A	07/02/14
	Applicant notified of outcome	N/A	07/02/14
4. Peer Review: On-Site Meeting	Assigned to primary reviewers	05/08/14	07/02/14
	Primary Reviewer 1 COI signed	04/26/14	07/02/14
	Primary Reviewer 2 COI signed	05/06/14	07/02/14
	Primary Reviewer 3 COI signed	04/21/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/27/14	07/02/14
	Primary Reviewer 1 critique submitted	05/21/14	07/02/14
	Primary Reviewer 2 critique submitted	05/31/14	07/02/14
	Primary Reviewer 3 critique submitted	05/19/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	06/04/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	06/06/14	07/02/14
	Post review statements signed	06/06/14	07/02/14
5. Final SRC Recommendation	Third Party Observer Report	06/12/14	07/02/14
	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRC/PDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
	Third Party Observer Report	07/07/14	07/08/14
6. PIC Review	Recommended for grant award	YES	07/02/14
	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
7. Oversight Committee Approval	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140672
Individual Investigator Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Basic Cancer Research Panel 2 for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

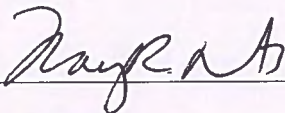
The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

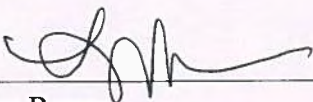
This statement is true."



Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research
AWARD MECHANISM Individual Investigator Research Awards (IIRA)
APPLICATION ID RP140672

APPLICATION TITLE Mutant KRAS Reprograms Lipid Metabolism Exposing Beta-Oxidation as a Novel Therapeutic Target in Lung Cancer

APPLICANT NAME Scaglioni, Pier Paolo
ORGANIZATION The University of Texas Southwestern Medical Center
PANEL NAME Basic Cancer Research-2 (BCR-2)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/01/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/01/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/01/14
	Date application submitted	02/02/14	07/01/14
	Method of submission	CARS	07/01/14
	Within receipt period	YES	07/01/14
	Appeal to submit application after CARS closed	N/A	07/01/14
2. Receipt, Referral, and Assignment	Appeal for late application submission accepted	N/A	07/01/14
	Administrative review notification	N/A	07/01/14
	Donation(s) made to CPRIT/foundation	NO	07/01/14
	Assigned to primary reviewers	03/31/14	07/01/14
	Applicant notified of review panel assignment	05/14/14	07/01/14
	Primary Reviewer 1 COI signed	04/21/14	07/01/14
	Primary Reviewer 2 COI signed	04/24/14	07/01/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	04/21/14	07/01/14
	Primary Reviewer 1 critique submitted	04/19/14	07/01/14
	Primary Reviewer 2 critique submitted	04/20/14	07/01/14
	Primary Reviewer 3 critique submitted	04/21/14	07/01/14
	COI indicated by non-primary reviewer	NONE	07/01/14
	Preliminary Evaluation score summary sent to Chair	04/28/14	07/01/14
	Recommended for full review	YES	07/01/14
4. Peer Review: On-Site Meeting	Applicant notified of outcome	05/21/14	07/01/14
	Assigned to primary reviewers	05/07/14	07/01/14
	Primary Reviewer 1 COI signed	04/21/14	07/01/14
	Primary Reviewer 2 COI signed	04/24/14	07/01/14
	Primary Reviewer 3 COI signed	04/21/14	07/01/14
	Primary (Advocate) Reviewer 4 COI signed	04/29/14	07/01/14
	Primary Reviewer 1 critique submitted	05/26/14	07/01/14
	Primary Reviewer 2 critique submitted	05/25/14	07/01/14
	Primary Reviewer 3 critique submitted	05/31/14	07/01/14
	Primary (Advocate) Reviewer 4 critique submitted	06/02/14	07/01/14
	COI indicated by non-primary reviewer	NONE	07/01/14
	COI recused from participation	N/A	07/01/14
	Discussed at On-Site Meeting	YES	07/01/14
	Peer Review: On-Site Meeting	06/04/14 - 06/05/14	07/01/14
	Post review statements signed	06/05/14	07/01/14
5. Final SRC Recommendation	Third Party Observer Report	06/12/14	07/01/14
	Score report delivered to CSO	06/19/14	07/01/14
	COI indicated by SRCPDRC member	NONE	07/01/14
	COI recused from participation	N/A	07/01/14
	SRC Meeting	06/24/14	07/01/14
	Third Party Observer Report	07/07/14	07/08/14
6. PIC Review	Recommended for grant award	YES	07/01/14
	SRC Chair Notification to PIC and OC	06/24/14	07/01/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
7. Oversight Committee Approval	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP140678
High-Impact/High-Risk Research Award

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *High-Impact/High-Risk Research Award* Request for Applications (RFA). CPRIT received 100 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Translational Cancer Research panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that one application was not recommended for a grant award that has the same score as an application that was recommended for a grant award. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score. The two applications were reviewed by different review panels.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

No individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a 3.5 score, another panel may decide based on the totality of factors that an application with a 3.5 score should not be recommended. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

This statement is true."

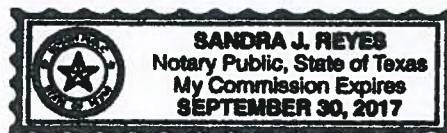
Wayne R. Roberts

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.

Sandra Reyes
Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research
AWARD MECHANISM High-Impact/High-Risk Research Awards (HIHRA)
APPLICATION ID RP140678
APPLICATION TITLE Novel, Humanized Single-Chain CD123xCD3 Bispecific Antibodies for Eliminating Leukemia Stem Cells and Leukemic Cells
APPLICANT NAME Woo, Jung
ORGANIZATION Scott & White Healthcare
PANEL NAME Translational Cancer Research (TCR)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	01/29/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	N/A	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	N/A	07/02/14
	Primary Reviewer 2 COI signed	N/A	07/02/14
	Primary Reviewer 3 COI signed	N/A	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 1 critique submitted	N/A	07/02/14
	Primary Reviewer 2 critique submitted	N/A	07/02/14
	Primary Reviewer 3 critique submitted	N/A	07/02/14
	COI indicated by non-primary reviewer	N/A	07/02/14
	Preliminary Evaluation score summary sent to Chair	N/A	07/02/14
	Recommended for full review	N/A	07/02/14
	Applicant notified of outcome	N/A	07/02/14
4. Peer Review: On-Site Meeting	Assigned to primary reviewers	05/08/14	07/02/14
	Primary Reviewer 1 COI signed	04/21/14	07/02/14
	Primary Reviewer 2 COI signed	04/24/14	07/02/14
	Primary Reviewer 3 COI signed	04/26/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/27/14	07/02/14
	Primary Reviewer 1 critique submitted	05/28/14	07/02/14
	Primary Reviewer 2 critique submitted	06/04/14	07/02/14
	Primary Reviewer 3 critique submitted	05/21/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	06/04/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	06/06/14	07/02/14
	Post review statements signed	06/06/14	07/02/14
	Third Party Observer Report	06/12/14	07/02/14
5. Final SRC Recommendation	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRCPDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/02/14
6. PIC Review	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
7. Oversight Committee Approval	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140685
Individual Investigator Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Clinical and Translational Cancer Research panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

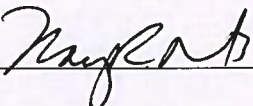
The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

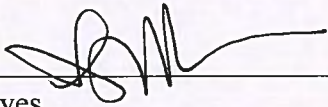
This statement is true."



Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research
AWARD MECHANISM Individual Investigator Research Awards (IIRA)
APPLICATION ID RP140685
APPLICATION TITLE Modulation of autophagy: Phase II Study of Vorinostat Plus Hydroxychloroquine vs. Regorafenib in Refractory Metastatic Colorectal Cancer (mCRC)
APPLICANT NAME Mahalingam, Devalingam
ORGANIZATION The University of Texas Health Science Center at San Antonio
PANEL NAME Clinical and Translational Cancer Research (CTCR)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	02/03/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	04/08/14	07/02/14
	Applicant notified of review panel assignment	05/15/14	07/02/14
	Primary Reviewer 1 COI signed	04/30/14	07/02/14
	Primary Reviewer 2 COI signed	05/02/14	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	05/05/14	07/02/14
	Primary Reviewer 1 critique submitted	04/21/14	07/02/14
	Primary Reviewer 2 critique submitted	04/28/14	07/02/14
	Primary Reviewer 3 critique submitted	04/22/14	07/02/14
	COI indicated by non-primary reviewer	Abu-Khalaf, Maysa	07/02/14
	Preliminary Evaluation score summary sent to Chair	05/01/14	07/02/14
4. Peer Review: On-Site Meeting	Recommended for full review	YES	07/02/14
	Applicant notified of outcome	05/21/14	07/02/14
	Assigned to primary reviewers	05/13/14	07/02/14
	Primary Reviewer 1 COI signed	04/30/14	07/02/14
	Primary Reviewer 2 COI signed	05/02/14	07/02/14
	Primary Reviewer 3 COI signed	05/05/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/29/14	07/02/14
	Primary Reviewer 1 critique submitted	05/30/14	07/02/14
	Primary Reviewer 2 critique submitted	06/04/14	07/02/14
	Primary Reviewer 3 critique submitted	05/30/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	06/08/14	07/02/14
	COI indicated by non-primary reviewer	Abu-Khalaf, Maysa	07/02/14
	COI recused from participation	YES	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	06/10/14	07/02/14
5. Final SRC Recommendation	Post review statements signed	07/03/14	07/07/14
	Third Party Observer Report	06/12/14	07/02/14
	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRCPDR member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
6. PIC Review	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/02/14
	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
7. Oversight Committee Approval	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP140767
Individual Investigator Research Award

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Cancer Prevention Research panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

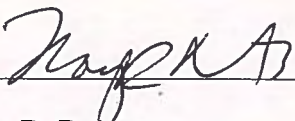
The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

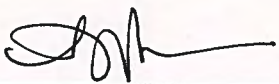
This statement is true."



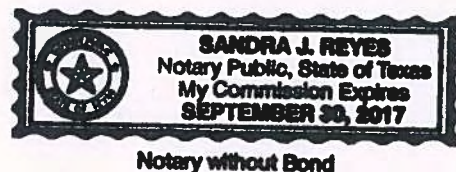
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research
AWARD MECHANISM Individual Investigator Research Awards (IIRA)
APPLICATION ID RP140767
APPLICATION TITLE Toll-like Receptors, Gut Microbiota, and Risk of Colorectal Adenoma
APPLICANT NAME Jiao, Li
ORGANIZATION Baylor College of Medicine
PANEL NAME Cancer Prevention Research (CPR)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	01/31/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
2. Receipt, Referral, and Assignment	Appeal for late application submission accepted	N/A	07/02/14
	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	03/16/14	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	04/09/14	07/02/14
	Primary Reviewer 2 COI signed	04/13/14	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	04/16/14	07/02/14
	Primary Reviewer 1 critique submitted	04/03/14	07/02/14
	Primary Reviewer 2 critique submitted	04/06/14	07/02/14
	Primary Reviewer 3 critique submitted	04/04/14	07/02/14
	COI indicated by non-primary reviewer	Mucci, Lorelei	07/02/14
	Preliminary Evaluation score summary sent to Chair	04/11/14	07/02/14
	Recommended for full review	YES	07/02/14
4. Peer Review: On-Site Meeting	Applicant notified of outcome	05/21/14	07/02/14
	Assigned to primary reviewers	04/23/14	07/02/14
	Primary Reviewer 1 COI signed	04/09/14	07/02/14
	Primary Reviewer 2 COI signed	04/13/14	07/02/14
	Primary Reviewer 3 COI signed	04/16/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/21/14	07/02/14
	Primary Reviewer 1 critique submitted	05/19/14	07/02/14
	Primary Reviewer 2 critique submitted	05/19/14	07/02/14
	Primary Reviewer 3 critique submitted	05/18/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	06/02/14	07/02/14
	COI indicated by non-primary reviewer	Martinez, Maria	07/02/14
	COI recused from participation	YES	07/02/14
	COI indicated by non-primary reviewer	Mucci, Lorelei	07/02/14
	COI recused from participation	YES	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
5. Final SRC Recommendation	Peer Review: On-Site Meeting	06/03/14-06/04/14	07/02/14
	Post review statements signed	06/04/14	07/02/14
	Third Party Observer Report	06/12/14	07/02/14
	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRCPDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
6. PIC Review	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/02/14
	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
7. Oversight Committee Approval	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140781
High-Impact/High-Risk Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *High-Impact/High-Risk Research Award* Request for Applications (RFA). CPRIT received 100 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Imaging Technology and Informatics panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT’s grant review processes were followed by the review panel evaluating the applications in this grant cycle

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that one application was not recommended for a grant award that has the same score as an application that was recommended for a grant award. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score. The two applications were reviewed by different review panels.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

No individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a 3.5 score, another panel may decide based on the totality of factors that an application with a 3.5 score should not be recommended. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

This statement is true."

Wayne R. Roberts

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.

Sandra Reyes
Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research
AWARD MECHANISM High-Impact/High-Risk Research Awards (HIHRA)
APPLICATION ID RP140781
APPLICATION TITLE High-Field Open MRI: Cost-Effective Screening for Early Detection of Breast Cancer
APPLICANT NAME McIntyre, Peter
ORGANIZATION Texas A&M University
PANEL NAME Imaging Technology and Informatics (ITI)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	02/03/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	N/A	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	N/A	07/02/14
	Primary Reviewer 2 COI signed	N/A	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	N/A	07/02/14
	Primary Reviewer 1 critique submitted	N/A	07/02/14
	Primary Reviewer 2 critique submitted	N/A	07/02/14
	Primary Reviewer 3 critique submitted	N/A	07/02/14
	COI indicated by non-primary reviewer	N/A	07/02/14
	Preliminary Evaluation score summary sent to Chair	N/A	07/02/14
	Recommended for full review	N/A	07/02/14
4. Peer Review: On-Site Meeting	Applicant notified of outcome	N/A	07/02/14
	Assigned to primary reviewers	04/25/14	07/02/14
	Primary Reviewer 1 COI signed	04/16/14	07/02/14
	Primary Reviewer 2 COI signed	04/14/14	07/02/14
	Primary Reviewer 3 COI signed	04/18/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/23/14	07/02/14
	Primary Reviewer 1 critique submitted	05/19/14	07/02/14
	Primary Reviewer 2 critique submitted	05/20/14	07/02/14
	Primary Reviewer 3 critique submitted	05/21/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	05/28/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	05/29/14-05/30/14	07/02/14
	Post review statements signed	05/30/14	07/02/14
	Third Party Observer Report	05/30/14	07/02/14
	Score report delivered to CSO	06/19/14	07/02/14
5. Final SRC Recommendation	COI indicated by SRCPDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/02/14
6. PIC Review	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
7. Oversight Committee Approval	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140784
Individual Investigator Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Cancer Prevention Research panel for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

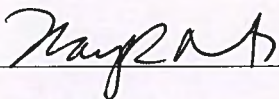
The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

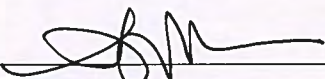
This statement is true."



Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

FY 2014
 CYCLE 1
 PROGRAM Research
 AWARD MECHANISM Individual Investigator Research Awards (IIRA)
 APPLICATION ID RP140784
 APPLICATION TITLE Next Generation Sequencing-Based Approaches for the Development of Epigenetic Biomarkers for Predicting Therapeutic Outcome in Patients with Colorectal Cancer
 APPLICANT NAME Goel, Ajay
 ORGANIZATION Baylor Research Institute
 PANEL NAME Cancer Prevention Research (CPR)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	02/03/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	NO	07/02/14
	Assigned to primary reviewers	03/16/14	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	04/09/14	07/02/14
	Primary Reviewer 2 COI signed	04/16/14	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	04/09/14	07/02/14
	Primary Reviewer 1 critique submitted	04/03/14	07/02/14
	Primary Reviewer 2 critique submitted	04/05/14	07/02/14
	Primary Reviewer 3 critique submitted	03/25/14	07/02/14
	COI indicated by non-primary reviewer	Petersen, Gloria	07/02/14
	Preliminary Evaluation score summary sent to Chair	4/11/2014	07/02/14
	Recommended for full review	YES	07/02/14
4. Peer Review: On-Site Meeting	Applicant notified of outcome	05/21/14	07/02/14
	Assigned to primary reviewers	04/23/14	07/02/14
	Primary Reviewer 1 COI signed	04/09/14	07/02/14
	Primary Reviewer 2 COI signed	04/13/14	07/02/14
	Primary Reviewer 3 COI signed	04/09/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/22/14	07/02/14
	Primary Reviewer 1 critique submitted	05/19/14	07/02/14
	Primary Reviewer 2 critique submitted	05/19/14	07/02/14
	Primary Reviewer 3 critique submitted	05/14/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	05/31/14	07/02/14
	COI indicated by non-primary reviewer	Petersen, Gloria	07/02/14
	COI recused from participation	YES	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	06/03/14-06/04/14	07/02/14
5. Final SRC Recommendation	Post review statements signed	06/04/14	07/02/14
	Third Party Observer Report	06/12/14	07/02/14
	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRCPDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
6. PIC Review	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/02/14
	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
7. Oversight Committee Approval	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
7. Oversight Committee Approval	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140800
Individual Investigator Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Basic Cancer Research Panel 2 for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

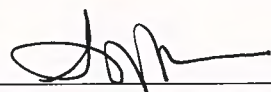
This statement is true."

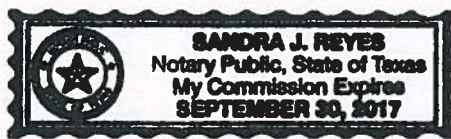


Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research
AWARD MECHANISM Individual Investigator Research Awards (IIRA)
APPLICATION ID RP140800
APPLICATION TITLE The Role of Alternative Polyadenylation in Glioblastoma Tumor Progression
APPLICANT NAME Wagner, Eric
ORGANIZATION The University of Texas Health Science Center at Houston
PANEL NAME Basic Cancer Research-2 (BCR-2)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/01/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/01/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/01/14
	Date application submitted	02/03/14	07/01/14
	Method of submission	CARS	07/01/14
	Within receipt period	YES	07/01/14
	Appeal to submit application after CARS closed	N/A	07/01/14
2. Receipt, Referral, and Assignment	Appeal for late application submission accepted	N/A	07/01/14
	Administrative review notification	N/A	07/01/14
	Donation(s) made to CPRIT/foundation	NO	07/01/14
	Assigned to primary reviewers	03/31/14	07/01/14
	Applicant notified of review panel assignment	05/14/14	07/01/14
	Primary Reviewer 1 COI signed	04/22/14	07/01/14
	Primary Reviewer 2 COI signed	04/21/14	07/01/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	03/11/14	07/01/14
	Primary Reviewer 1 critique submitted	04/16/14	07/01/14
	Primary Reviewer 2 critique submitted	04/04/14	07/01/14
	Primary Reviewer 3 critique submitted	04/21/14	07/01/14
	COI indicated by non-primary reviewer	NONE	07/01/14
	Preliminary Evaluation score summary sent to Chair	04/28/14	07/01/14
	Recommended for full review	YES	07/01/14
4. Peer Review: On-Site Meeting	Applicant notified of outcome	05/21/14	07/01/14
	Assigned to primary reviewers	05/07/14	07/01/14
	Primary Reviewer 1 COI signed	03/06/14	07/01/14
	Primary Reviewer 2 COI signed	04/22/14	07/01/14
	Primary Reviewer 3 COI signed	04/21/14	07/01/14
	Primary (Advocate) Reviewer 4 COI signed	04/29/14	07/01/14
	Primary Reviewer 1 critique submitted	05/29/14	07/01/14
	Primary Reviewer 2 critique submitted	05/15/14	07/01/14
	Primary Reviewer 3 critique submitted	05/26/14	07/01/14
	Primary (Advocate) Reviewer 4 critique submitted	06/02/14	07/01/14
	COI indicated by non-primary reviewer	NONE	07/01/14
	COI recused from participation	N/A	07/01/14
	Discussed at On-Site Meeting	YES	07/01/14
	Peer Review: On-Site Meeting	06/04/14 - 06/05/14	07/01/14
5. Final SRC Recommendation	Post review statements signed	06/05/14	07/01/14
	Third Party Observer Report	06/12/14	07/01/14
	Score report delivered to CSO	06/19/14	07/01/14
	COI indicated by SRCPDRC member	NONE	07/01/14
	COI recused from participation	N/A	07/01/14
	SRC Meeting	06/24/14	07/01/14
	Third Party Observer Report	07/07/14	07/08/14
6. PIC Review	Recommended for grant award	YES	07/01/14
	SRC Chair Notification to PIC and OC	06/24/14	07/01/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
7. Oversight Committee Approval	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RP140840
High-Impact/High-Risk Research Award

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *High-Impact/High-Risk Research Award* Request for Applications (RFA). CPRIT received 100 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Imaging Technology and Informatics panel for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT’s grant review processes were followed by the review panel evaluating the applications in this grant cycle

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that one application was not recommended for a grant award that has the same score as an application that was recommended for a grant award. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score. The two applications were reviewed by different review panels.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

No individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a 3.5 score, another panel may decide based on the totality of factors that an application with a 3.5 score should not be recommended. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

This statement is true."

Wayne R. Roberts

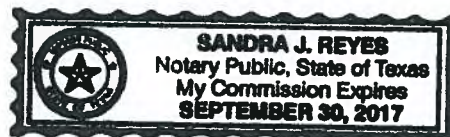
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.

Sandra Reyes

Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research
AWARD MECHANISM High-Impact/High-Risk Research Awards (HIHRA)
APPLICATION ID RP140840
APPLICATION TITLE New Technology for Ultra High Throughput Enumeration of Circulating Tumor Cells
APPLICANT NAME Vanapalli, Siva
ORGANIZATION Texas Tech University
PANEL NAME Imaging Technology and Informatics (ITI)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/02/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/02/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/02/14
	Date application submitted	02/03/14	07/02/14
	Method of submission	CARS	07/02/14
	Within receipt period	YES	07/02/14
	Appeal to submit application after CARS closed	N/A	07/02/14
	Appeal for late application submission accepted	N/A	07/02/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/02/14
	Donation(s) made to CPRIT/foundation	N/A	07/02/14
	Assigned to primary reviewers	N/A	07/02/14
	Applicant notified of review panel assignment	05/14/14	07/02/14
	Primary Reviewer 1 COI signed	N/A	07/02/14
	Primary Reviewer 2 COI signed	N/A	07/02/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	N/A	07/02/14
	Primary Reviewer 1 critique submitted	N/A	07/02/14
	Primary Reviewer 2 critique submitted	N/A	07/02/14
	Primary Reviewer 3 critique submitted	N/A	07/02/14
	COI indicated by non-primary reviewer	N/A	07/02/14
	Preliminary Evaluation score summary sent to Chair	N/A	07/02/14
	Recommended for full review	N/A	07/02/14
4. Peer Review: On-Site Meeting	Applicant notified of outcome	N/A	07/02/14
	Assigned to primary reviewers	04/25/14	07/02/14
	Primary Reviewer 1 COI signed	04/16/14	07/02/14
	Primary Reviewer 2 COI signed	04/10/14	07/02/14
	Primary Reviewer 3 COI signed	04/23/14	07/02/14
	Primary (Advocate) Reviewer 4 COI signed	04/24/14	07/02/14
	Primary Reviewer 1 critique submitted	05/04/14	07/02/14
	Primary Reviewer 2 critique submitted	05/18/14	07/02/14
	Primary Reviewer 3 critique submitted	05/20/14	07/02/14
	Primary (Advocate) Reviewer 4 critique submitted	05/28/14	07/02/14
	COI indicated by non-primary reviewer	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	Discussed at On-Site Meeting	YES	07/02/14
	Peer Review: On-Site Meeting	05/29/14-05/30/14	07/02/14
	Post review statements signed	05/30/14	07/02/14
5. Final SRC Recommendation	Third Party Observer Report	05/30/14	07/02/14
	Score report delivered to CSO	06/19/14	07/02/14
	COI indicated by SRCPDRC member	NONE	07/02/14
	COI recused from participation	N/A	07/02/14
	SRC Meeting	06/24/14	07/02/14
6. PIC Review	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/02/14
	SRC Chair Notification to PIC and OC	06/24/14	07/02/14
	COI indicated by PIC member	NONE	07/15/14
7. Oversight Committee Approval	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application RP140842
Individual Investigator Research Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *Individual Investigator Research Award* Request for Applications (RFA). CPRIT received 484 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Basic Cancer Research Panel 2 for review. As set forth in the RFA, a preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted

- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle
- Two lists of the de-identified overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle

The de-identified final scores for the applications that did not move past the preliminary review stage in this cycle are listed as "Final Scores for Preliminary Evaluations." The de-identified final scores for the applications that received full review are listed as "Final Scores for Fully Reviewed Applications."

- A final overall evaluation score and rank order score submitted by the SRPP committees for the grant applications recommended by the PIC in this cycle

I note that some applications that were not recommended for grant awards have scores that are equal to or more favorable than some applications that were recommended for grant awards. I conferred with CPRIT's Chief Scientific Officer about this issue. Dr. Kripke explained that each of CPRIT's seven scientific research review panels individually determines the applications that the panel forwards to the Scientific Review Council for grant award consideration. The panel's decision is based upon a number of factors, including the final score.

An application's score establishes its position relative to other applications reviewed by its assigned panel, but not relative to other panels. CPRIT has no policy that specifies a score that guarantees an application will or will not be recommended for funding. In this round, within each panel, no grant application with a less favorable score was recommended ahead of an application with a more favorable score.

The comprehensive list of de-identified application scores created for the purpose of this affidavit compiles the information for all seven panels into a single list. However, no individual panel was aware of the scores assigned by the other review panels. While one panel may determine that certain factors justify recommending an application for a grant award that has a score greater than 3.1, another panel may decide based on the totality of factors that an application with a score greater than 3.1 should not. I am satisfied that the individual panels followed CPRIT's review policies in creating the panel's list of recommended awards.

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict

of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

This statement is true."

Wayne R. Roberts

Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.

Sandra Reyes
Sandra Reyes
Notary Public, State of Texas



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Research
AWARD MECHANISM Individual Investigator Research Awards (IIRA)
APPLICATION ID RP140842
APPLICATION TITLE Determining the Functional Role of microRNAs in Viral Tumorigenesis.
APPLICANT NAME Sullivan, Christopher
ORGANIZATION The University of Texas at Austin
PANEL NAME Basic Cancer Research-2 (BCR-2)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	07/01/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	07/01/14
	CPRIT Application Receipt System (CARS) closed	02/03/14	07/01/14
	Date application submitted	02/03/14	07/01/14
	Method of submission	CARS	07/01/14
	Within receipt period	YES	07/01/14
	Appeal to submit application after CARS closed	N/A	07/01/14
	Appeal for late application submission accepted	N/A	07/01/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	07/01/14
	Donation(s) made to CPRIT/foundation	NO	07/01/14
	Assigned to primary reviewers	N/A	07/01/14
	Applicant notified of review panel assignment	05/14/14	07/01/14
	Primary Reviewer 1 COI signed	N/A	07/01/14
	Primary Reviewer 2 COI signed	N/A	07/01/14
3. Peer Review: Preliminary Evaluation	Primary Reviewer 3 COI signed	N/A	07/01/14
	Primary Reviewer 1 critique submitted	N/A	07/01/14
	Primary Reviewer 2 critique submitted	N/A	07/01/14
	Primary Reviewer 3 critique submitted	N/A	07/01/14
	COI indicated by non-primary reviewer	N/A	07/01/14
	Preliminary Evaluation score summary sent to Chair	N/A	07/01/14
	Recommended for full review	N/A	07/01/14
4. Peer Review: On-Site Meeting	Applicant notified of outcome	N/A	07/01/14
	Assigned to primary reviewers	05/07/14	07/01/14
	Primary Reviewer 1 COI signed	04/21/14	07/01/14
	Primary Reviewer 2 COI signed	03/06/14	07/01/14
	Primary Reviewer 3 COI signed	04/21/14	07/01/14
	Primary (Advocate) Reviewer 4 COI signed	04/29/14	07/01/14
	Primary Reviewer 1 critique submitted	05/27/14	07/01/14
	Primary Reviewer 2 critique submitted	06/02/14	07/01/14
	Primary Reviewer 3 critique submitted	05/30/14	07/01/14
	Primary (Advocate) Reviewer 4 critique submitted	06/02/14	07/01/14
	COI indicated by non-primary reviewer	NONE	07/01/14
	COI recused from participation	N/A	07/01/14
	Discussed at On-Site Meeting	YES	07/01/14
	Peer Review: On-Site Meeting	06/04/14 - 06/05/14	07/01/14
	Post review statements signed	06/05/14	07/01/14
	Third Party Observer Report	06/12/14	07/01/14
5. Final SRC Recommendation	Score report delivered to CSO	06/19/14	07/01/14
	COI indicated by SRCPDRC member	NONE	07/01/14
	COI recused from participation	N/A	07/01/14
	SRC Meeting	06/24/14	07/01/14
	Third Party Observer Report	07/07/14	07/08/14
	Recommended for grant award	YES	07/01/14
6. PIC Review	SRC Chair Notification to PIC and OC	06/24/14	07/01/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
7. Oversight Committee Approval	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

The identity of the attesting party is retained by CPRIT



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: THOMAS GOODMAN, PhD, CHIEF PRODUCT DEVELOPMENT OFFICER
SUBJECT: PRODUCT DEVELOPMENT PROGRAM OVERVIEW
DATE: AUGUST 11, 2014

Product Development Program activities since the last Oversight Committee meeting have focused on reconsidering the revenue sharing terms and conditions, finalizing contracts for several company awards that were announced at the February Oversight Committee meeting, reviewing applications submitted for FY2015 product development awards, and preparing two grant award recommendations for Oversight Committee approval.

- Reconsidering CPRIT's Revenue Sharing Terms. Some of the companies approved for CPRIT Product Development grants have contacted CPRIT with concerns about the standardized revenue sharing terms that were presented at the May 21st Oversight Committee meeting. Those communications and a memorandum summarizing CPRIT's proposed response were discussed with the Product Development Subcommittee.
- Contracts Finalized. CPRIT has executed award contracts with CerRx, DNATRIX, and ESSA Pharmaceuticals pursuant to terms that were approved by the Oversight Committee on May 21st. Any revenue sharing term modification approved by the Oversight Committee will be offered as contract amendments to these companies.
- Applications for FY2015 Product Development Awards. CPRIT's Product Development review panels met on July 15th and 16th to discuss 30 grant applications requesting in aggregate over \$280 million. Seventeen companies were chosen for in-person presentations to the full product development review panels held the week of August 12 – 15. FY2015 Cycle 1 Product Development award recommendations are expected to be presented for approval at the November 19th Oversight Committee meeting.

Earlier this year the Product Development program released a Request for Applications for Early Translational Research Applications (ETRA). Previously, the ETRA program was part of the scientific research portfolio. However, Dr. Kripke recommended and I agree that review of these early state translational research projects are best suited for the expertise of the Product Development review panels. CPRIT received 46 applications by the August 7 deadline. This cycle of applications is noteworthy in that, for the first time, CPRIT will require awardees to

prepare business plans as a condition of the grant. Review of the applications will take place August – October, with any grant recommendations coming before the Oversight Committee in November.

FY2015 Cycle 3 Product Development Request for Applications for Company Relocation, Established Company, and New Company product development awards were released on July 21st. CPRIT will accept applications from August 25th through September 29th. Any award recommendations from this cycle will be presented to the Oversight Committee for approval at its May 2015 meeting.

- Award Recommendations to the Oversight Committee. After scientific review and business and patent due diligence, two new company grant awards were recommended by the Product Development Review Council. These were approved by the PIC and are the subject of a memo available through CPRIT's secure portfolio until the grant awards are publicly announced. It is recommended that CPRIT be given contract negotiation authority for these two grants.
- New Nominations to the Review Council. The approval of the Oversight Committee is sought for the appointment of the following new members of the Review Council:

Stanton Gerson, MD - Case Comprehensive Cancer Center

Gail Eckhardt, MD - University of Colorado, Denver

Robert Figlin, MD - Cedars-Sinai Medical Center

Mark Moasser, MD - UCSF School of Medicine

Nora Cabine - Advocate Reviewer

Meryl Weinreb - Advocate Reviewer

Valerie Guild - Advocate Reviewer

Brenda Gavin - DVM, MBA - Founding Partner, Quaker Partners



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: DR. CRAIG ROSENFELD, PRODUCT DEVELOPMENT SUBCOMMITTEE CHAIR
SUBJECT: PROPOSED CHANGES TO CPRIT REVENUE SHARING TERMS AND CONDITIONS
DATE: AUGUST 15, 2014

The Product Development Subcommittee met and discussed the proposed changes to the economic terms referred to in Dr. Goodman's August 15 memo. After consideration and discussion, we recommend that the contract modifications described by Dr. Goodman in his memo be approved by the Oversight Committee.

The Product Development Subcommittee also discussed the two companies recommended for grant awards by the Program Integration Committee. The subcommittee recommends Oversight Committee approval for both companies and delegation of contract negotiation authority to CPRIT. Authority to execute a contract with each company will be contingent on the company's demonstration that it has rights in or adequate license to the technologies described in the grant application.



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: THOMAS C. GOODMAN, CHIEF PRODUCT DEVELOPMENT OFFICER
SUBJECT: PROPOSED CHANGES TO CPRIT REVENUE SHARING TERMS AND CONDITIONS
DATE: AUGUST 14, 2014

Summary and Recommendation:

Several companies approved for CPRIT Product Development grants have contacted CPRIT with concerns about the standard revenue sharing terms presented at the May 21st Oversight Committee meeting. After discussion with the Product Development Subcommittee, some issues raised by the companies were found to have merit. These can be addressed through the revisions CPRIT staff recommends here to the standard revenue sharing terms.

Background:

I presented Product Development Program Principles at the May 21, 2014, Oversight Committee meeting. One of the recommended principles requires that the rate of compensation expected from product development grantees should be uniform for similarly-sized grants and for companies at similar stages in their development. Another Program Principle holds that CPRIT's revenue sharing requirements should not weaken the recipient company or discourage future investments from private sources of capital. The Oversight Committee approved revenue sharing terms based on these Program Principles and reflected in the four-part matrix (see the attached) for five product development grantees.

CPRIT received a letter from three companies that have been approved for CPRIT grant awards. The letter raises objections to the revenue sharing terms that were earlier described to the Oversight Committee at its meeting on May 21, 2014. CPRIT also received an award declination letter from another company, ProNAi. Their letter describes some of the same concerns expressed by the three companies, though the fact that this company is currently located in the upper Midwest and raised almost \$60 million in private financing may have been the decisive factor in their electing not to take CPRIT funding and relocate to Texas.

CPRIT has already discussed with the companies the non-economic changes to the contract that they are seeking. CPRIT intends to accommodate as many of these as reasonable.

Proposed Changes to the Economic Terms

While it is not surprising that companies are seeking better economic terms, some of the points raised in the letters have merit and should be considered. Three primary contentions and proposed modifications to the revenue sharing conditions approved at the May 21st meeting are described below. I believe these modifications are adequate to address the core economic concerns raised by the companies.

1. Compression of the Matrix

It was argued that there should not be distinctions made between companies based on the size of the grant amount or degree to which companies had already accessed capital markets.

Given this, staff recommends the following change.

No differentiation between companies will be made on the basis of either the amount of the CPRIT grant award or the amount of professional investment the company has received. The values of “A” and “B”, which previously varied, will be the same for all companies and set at 4% and 2%, respectively.

2. Changes to the Buyout Clause

The availability of venture capital funding for early-stage, life sciences companies in Texas is problematic. The present terms of the buyout clause create potential negotiating problems with new investors in the future. For example, a company being pressed to pay off a grant award at the same time it is negotiating a new round of financing may be in a difficult position. Although the company was given three years to plan for the buyout (essentially the term of the CPRIT contract), this amount of time may be inadequate.

Given this, staff recommends the following change.

The buyout clause will be rewritten so that the company may buyout its revenue sharing requirement, at any time after the completion or termination of the contract, by repaying the amount of the grant award plus an interest rate of 9%, compounded quarterly, on any funds distributed to the company under the contract from the date of the distribution of those funds. Any revenue sharing paid by the company will be creditable against the buyout amount.

3. Accounting for Licensing Royalties

While the present contract allows for adjustment of the revenue sharing percentages as a result of other contributions to the development of the product, it does not consider potential licensing royalties that might have to be paid to allow product sales.

Staff recommends the addition of a stacking provision.

In addition to the adjustment clause (Section D4.02), the revenue sharing percentages may be reduced by 0.5% for every 1% of royalty that the company must pay to any third party in order to sell a product.

Royalty stacking, alone or when combined with any other allowed adjustment, shall not decrease the revenue sharing amounts by more than 50% of what they would otherwise be.

CPRIT will offer any company that is currently pending a final contract the option to proceed pursuant to the original (existing) terms for the contract. Assuming the approval of the above changes by the Oversight Committee, companies that were approved for contract execution at the May 21st Oversight Committee meeting and executed a contract thereafter will be offered the these newly approved terms as an amendment replacing the earlier terms.



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

August 4, 2014

Oversight Committee Members:

Pursuant to 25 T.A.C. § 703.7(j), I request that the Oversight Committee approve authority for CPRIT to advance grant funds upon execution of a grant contract for the two companies that will be considered for Product Development grant awards at the August 20, 2014, Oversight Committee meeting.

Although CPRIT disburses the majority of grant funds pursuant to requests for reimbursement, CPRIT may disburse grant funds in advance payments consistent with the General Appropriations Act, Article IX, § 4.03(a). Typically, the grant amount to be paid in advance is based upon the project year budget or tranche amount. All grant recipients, including those that receive advance payment of grant funds, are required to submit quarterly financial status reports that are reviewed and approved by CPRIT's financial staff. Failure to submit the financial status reports on a timely basis will result in forfeiture of reimbursement for expenses for the quarter and may result in grant termination and repayment of grant funds.

After consultation with Dr. Thomas Goodman, CPRIT's Chief Product Development Officer, one or more of the following reasons support advance payment of grant funds for the two companies to be considered for product development awards at the August meeting: 1) a larger amount of start-up funds is needed than can be advanced from cash on hand; 2) pre-clinical trial contracts will need to be entered into with substantial upfront payments; and/or 3) significant equipment purchases will be needed for work to begin.

Sincerely,

A handwritten signature in black ink, appearing to read "Wayne R. Roberts".

Wayne R. Roberts
Chief Executive Officer

Conflicts of Interest for Product Development Cycle 14.1 Applications
(Product Development Cycle 14.1 Awards Announced at August 2014 Oversight Committee Meeting)

The table below lists the conflicts of interest (COIs) identified by peer reviewers, Program Integration Committee (PIC) members, and Oversight Committee members on an application-by-application basis. All applications with at least one identified COI are listed below; applications with no COIs are not included. It should be noted that an individual is asked to identify COIs for only those applications that are to be considered by the individual at that particular stage in the review process. For example, Oversight Committee members identify COIs, if any, with only those applications that have been recommended for the grant awards by the PIC. COI information used for this table was collected by SRA International, CPRIT's third party grant administrator, and by CPRIT.

Grant ID	Applicant	Company	Conflict Noted
Applications considered by the PIC and Oversight Committee			
DP140072	Sumer, Baran	The University of Texas Southwestern Medical Center (OncoNano Medicine)	Montgomery, Will; Mitchell, Amy
Applications Not Recommended for PIC or Oversight Committee Consideration			
DP140018*	Palleiko, Ben	Cielo Therapeutics, Inc.	Saxberg, Bo
DP140021	Lenox, Mark	CVUS Clinical Trials, LLC	Cosan, Roy
DP140023	Andruss, Bernard	Asuragen, Inc.	Jones, Elaine
DP140028	Klemp, Walter	Moleculin, LLC	Jones, Elaine
DP140033*	Bearss, David	Tolero Pharmaceuticals, Inc.	Saxberg, Bo
DP140035	Burns, Lindsay	Pain Therapeutics, Inc.	Jones, Elaine
DP140039	Carney, Darrell	Chrysalis BioTherapeutics, Inc.	Jones, Elaine
DP140041*	Osborne, Nick	Avicin Therapeutics, Inc.	Clendeninn, Neil
DP140089	Paradiso, DVM, Linda	Boston Strategies Therapeutics Corporation	Saxberg, Bo
DP140011	Asaithambi, Arunkumar	Lantern Pharma, Inc.	Jones, Elaine
DP140036*	Szabo, Csaba	CBS Therapeutics, Inc.	DuBois, Ray
DP140086**	Lopez-Berestein, Gabriel	BINAFOR	DuBois, Ray

* = Not Discussed

**= Administratively Withdrawn



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CEO Affidavit Supporting Information

FY 2014 – Cycle 1
New Company Product Development Award

Request for Applications



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA C-14-NEWCO-1

New Company Product Development Awards

**Please also refer to the Instructions for Applicants document,
which will be posted December 23, 2013**

Application Receipt Opening Date: December 23, 2013

Application Receipt Closing Date: January 31, 2014

FY 2014

Fiscal Year Award Period

September 1, 2013–August 31, 2014

TABLE OF CONTENTS

1. KEY POINTS	5
2. ABOUT CPRIT	6
3. APPLICATION SURVEY	6
4. EXECUTIVE SUMMARY	7
5. MECHANISM OF SUPPORT.....	7
6. OBJECTIVES	7
7. FUNDING INFORMATION	8
8. KEY DATES.....	9
9. ELIGIBILITY	9
9.1. NEW APPLICATIONS	9
9.2. RESUBMISSION POLICY	11
9.3. RENEWAL POLICY	11
10. APPLICATION REVIEW	11
10.1. OVERVIEW	11
10.2. REVIEW PROCESS.....	12
10.2.1. Confidentiality of Review	13
10.3. REVIEW CRITERIA.....	14
10.3.1. Primary Criteria.....	14
10.3.2. Secondary Criteria	15
11. SUBMISSION GUIDELINES	16
11.1. ONLINE APPLICATION RECEIPT SYSTEM AND APPLICATION SUBMISSION DEADLINE	16
11.2. SUBMISSION DEADLINE EXTENSION	16
11.3. PRODUCT DEVELOPMENT REVIEW FEE	17
11.4. APPLICATION COMPONENTS	17
11.4.1. Layperson's Summary (1,500 characters)	17
11.4.2. Goals and Objectives.....	17
11.4.3. Timeline (One page).....	18
11.4.4. Resubmission Summary (One page).....	18
11.4.5. Executive Summary (One page)	18

11.4.6.	<i>Slide Presentation (Ten pages)</i>	18
11.4.7.	<i>Scientific Plan (Ten pages)</i>	19
11.4.8.	<i>Business Plan (Fifteen pages)</i>	19
11.4.9.	<i>Biographical Sketches of Key Scientific Personnel (Eight pages)</i>	21
11.4.10.	<i>Budget and Justification</i>	21
12.	AWARD ADMINISTRATION	22
13.	REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS	23
14.	CONTACT INFORMATION	23
14.1.	HELPDESK	23
14.2.	PROGRAMMATIC QUESTIONS	24

RFA VERSION HISTORY

Rev 12/9/13 RFA release

1. KEY POINTS

This New Company Product Development Award mechanism is governed by the following restrictions:

- Company applicants must be early-stage startup companies with no previous round of professional institutional investment (i.e., those that have not yet received Series A financing or a substantive equivalent). Companies at this early stage that are not currently located in Texas but intend to relocate to Texas should apply under this mechanism rather than the Company Relocation Awards mechanism.
- Recipient companies must currently have or must commit to the following: Headquarters or substantial business functions of the company in Texas; personnel sufficient to operate the Texas-based research and/or development activities of the company, along with appropriate management, relocated to or hired from within Texas.
- Of the total program budget, the Cancer Prevention and Research Institute of Texas (CPRIT) will contribute \$2.00 for every \$1.00 contributed, in matching funds, by the company. The demonstration of available matching funds must be made prior to the distribution of CPRIT grant funds, not at the time the application is submitted. CPRIT funds must, whenever possible, be spent in Texas. A company's matching funds must be targeted for the CPRIT-funded project but may be spent outside of Texas.
- Funding may be tranching and will be tied to the achievement of contract-specified milestones.
- Funding award contracts will include a revenue-sharing agreement or equity to be negotiated at contract execution and will require CPRIT to have input on any future patents, agreements, or other financial arrangements related to the products, services, services, or infrastructure supported by the CPRIT investment. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cpritch.state.tx.us.

2. ABOUT CPRIT

The State of Texas has established CPRIT, which may issue up to \$3 billion in general obligation bonds to fund grants for cancer research and prevention.

CPRIT is charged by the Texas Legislature to:

- Create and expedite innovation in the area of cancer research and product or service development, thereby enhancing the potential for a medical or scientific breakthrough in the prevention, treatment, and possible cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in the State of Texas; and
- Continue to develop and implement the Texas Cancer Plan by promoting the development and coordination of effective and efficient statewide public and private policies, programs, and services related to cancer and by encouraging cooperative, comprehensive, and complementary planning among the public, private, and volunteer sectors involved in cancer prevention, detection, treatment, and research.

CPRIT furthers cancer research in Texas by providing financial support for a wide variety of projects relevant to cancer research.

3. APPLICATION SURVEY

CPRIT will be administering a survey to determine the operational aspects of peer review. Company representatives that anticipate submitting an application are requested to complete the survey as soon as possible, but no later than January 13, 2014. Company representatives should provide the following information: applicant name, name of company, telephone number, email address, estimated award amount, and award mechanism. Please select only one award mechanism as only one application can be submitted per funding cycle. This information will be used for planning purposes only, and will not be used for evaluation of the application. The survey is available [here](#).

4. EXECUTIVE SUMMARY

CPRIT will foster the creation of high-quality new jobs in Texas by providing financial support for a wide variety of projects relevant to cancer. This Request for Applications (RFA) is designed to support the formation of oncology-focused companies in Texas. CPRIT expects outcomes of supported activities to directly and indirectly benefit subsequent cancer research efforts, cancer public health policy, or the continuum of cancer care—from prevention to treatment and cure. To fulfill this vision, applications may address any product development topic or issue related to cancer biology, causation, prevention, detection or screening, treatment, or cure. The overall goal of this award program is to improve outcomes of patients with cancer by increasing the availability of Food and Drug Administration (FDA)-approved therapeutic interventions with a primary focus on Texas-centric programs.

5. MECHANISM OF SUPPORT

The goal of the New Company Product Development Awards is to finance the research and development of innovative products, services, and infrastructure with significant potential impact on patient care. These investments will assist early-stage startup companies by providing the opportunity to further the research and development of new products for the diagnosis, treatment, supportive care, or prevention of cancer; to establish infrastructure that is critical to the development of a robust industry; or to fill a treatment, industry, or research gap. This award mechanism will support companies that intend to undertake product research and development in Texas with a strong presence of Texas-based employees. In determining eligibility for this award, CPRIT will evaluate whether applicants have a significant presence in Texas or are willing to relocate to Texas.

6. OBJECTIVES

The State of Texas seeks to attract industry partners in the field of cancer care to advance economic development and cancer care efforts in the State. The goal of this award mechanism is to support the formation and establishment of new startup companies in Texas that will develop products to significantly impact cancer care. These companies

must be Texas based or have personnel sufficient to operate the Texas-based research and/or development activities of the company, along with appropriate management, who are willing to relocate to or be hired and remain in Texas for a specified period after funding. Eligible products or services include—but are not limited to—therapeutics (e.g., small molecules and biologics), diagnostics, devices, and potential breakthrough technologies, including software and research discovery techniques. Eligible stages of research and development include translational research, proof-of-concept studies, preclinical studies, and Phase I or Phase II clinical trials. By exception, Phase III clinical trials and later stage product development projects will be considered where circumstances warrant CPRIT investment.

7. FUNDING INFORMATION

This is a 3-year funding program. Financial support will be awarded based upon the breadth and nature of the research and development program proposed. While requested funds must be well justified, there is no limit on the amount that may be requested. Funding will be milestone driven.

Funds may be used for salary and fringe benefits, research supplies, equipment, clinical trial expenses, intellectual property protection, external consultants and service providers, and other appropriate research and development costs, subject to certain limitations set forth by Texas State law. If a company is working on multiple projects, care should be taken to ensure that CPRIT funds are used to support activities directly related to the specific project being funded. Requests for funds to support construction and/or renovation may be considered under compelling circumstances for projects that require facilities that do not already exist in the State of Texas. Texas State law limits the amount of awarded funds that may be spent on indirect costs to no more than 5 percent of the total award amount (5.263 percent of the direct costs).

Consistent with statutory mandate, of the total program budget, CPRIT will contribute \$2.00 for every \$1.00 contributed, in matching funds, by the company. The demonstration of available matching funds must be made prior to the distribution of

CRPTI funds, not at the time the application is submitted. The matching funds commitment may be made on a year-by-year basis.

8. KEY DATES

RFA release	December 9, 2013
Online application opens	December 23, 2013, 7 a.m. Central Time
Applications due	January 31, 2014, 3 p.m. Central Time
Invitations to present sent	March 2014
Notifications sent if not invited	March 2014
Presentations to CPRIT*	April 2014

*All applicants who wish to be considered are requested to reserve these presentation dates until notified. Information on the timing of subsequent steps will be provided to applicants later in the process.

9. ELIGIBILITY

9.1. New Applications

- Early-stage startup companies are eligible. Such companies may have received seed funding from family, friends, and/or angel investors. However, only applicants with no previous round of professional institutional investment (i.e., those that have not yet received Series A financing or a substantive equivalent) are eligible. The inclusion of a complete and detailed capitalization table is required for assessment of eligibility.
- Recipient companies must commit to the following: Headquarters or substantial functions of the company in Texas; personnel sufficient to operate the Texas-based research and/or development activities of the company, along with appropriate management, relocated to or hired from within Texas who will remain in Texas for a specified period after funding; and use of Texas-based subcontractors and suppliers unless adequate justification is provided for the use of out-of-State entities. To the extent that Texas-based subcontractors or collaborators are not

available, non-Texas-based collaborators and subcontractors may be used.

However, non-Texas-based collaborators and subcontractors are not eligible to receive funds from CPRIT unless exceptional circumstances are demonstrated and approved by CPRIT.

- In general, a greater extent of commitment to establishing research and/or development functions in Texas will be viewed more favorably by CPRIT. However, it is left to the applicant's judgment to make a case for what they consider to be a sufficient extent of commitment to Texas.
- An applicant may submit only one application under this RFA during this funding cycle.
- A company applicant is eligible to receive a grant award only if the applicant certifies that the company, including the company representative, any senior member or key personnel listed on the application, any company officer or director (or any person related to one or more of these individuals within the second degree of consanguinity or affinity) have not made and will not make a contribution to CPRIT or to any foundation specifically created to benefit CPRIT.
- A company applicant is not eligible to receive CPRIT funding if the company representative, any senior member or key personnel listed on the application, and any company officer or director is related to a CPRIT Oversight Committee member.
- The company applicant must report whether the company, company representative, or other individuals who contribute to the execution of the proposed project in a substantive, measurable way, whether or not those individuals are slated to receive salary or compensation under the grant award, are currently ineligible to receive Federal grant funds, or have had a grant terminated for cause within 5 years prior to the submission date of the grant application.
- CPRIT grants will be awarded by contract to successful company applicants. Certain contractual requirements are mandated by Texas State law or by administrative rules. Although the company applicant need not demonstrate the ability to comply with these contractual requirements at the time the application is submitted, applicants should familiarize themselves with these standards before

submitting a grant application. Significant issues addressed by the CPRIT contract are listed in [Section 12](#) and [Section 13](#). All statutory provisions and relevant administrative rules can be found at www.cprit.state.tx.us.

9.2. Resubmission Policy

An application previously submitted to CPRIT but not funded may be resubmitted once and must follow all resubmission guidelines (see [Section 11.4.4](#)). More than one resubmission is not permitted. Applicants who choose to resubmit should carefully consider the reasons for lack of prior success. Applications that received overall numerical scores of 5 or higher are likely to need considerable attention. All resubmitted applications should be carefully reconstructed; a simple revision of the prior application with editorial or technical changes is not sufficient, and applicants are advised not to direct reviewers to such modest changes. A one-page summary of the approach to the resubmission should be included. Resubmitted applications may be assigned to reviewers who did not review the original submission. Reviewers of resubmissions are asked to assess whether the resubmission adequately addresses critiques from the previous review. **Applicants should note that addressing previous critiques is advisable; however, it does not guarantee the success of the resubmission.** All resubmitted applications must conform to the structure and guidelines outlined in this RFA.

9.3. Renewal Policy

Grant recipients that have previously received CPRIT grant funding may submit an application for competitive renewal under the Established Company Product Development Award RFA. Before submitting a renewal application, applicants must consult with the Product Development Programmatic Office (see [Section 14.2](#)) to determine whether it is appropriate for their company to seek renewal funding at this time.

10. APPLICATION REVIEW

10.1. Overview

Applications will be assessed based on evaluation of the quality of the company and the potential for continued product development. CPRIT requires the submission of a

comprehensive scientific plan (see [Section 11.4.7](#)) and a detailed business plan (see [Section 11.4.8](#)). The review will address the commercial viability, product feasibility, scientific merit, and therapeutic impact as detailed in the company's business and scientific plans. The plans will be reviewed by an integrated panel of individuals with biotechnology expertise and experience in translational and clinical research as well as in the business development/regulatory approval processes for therapeutics, devices, and diagnostics. In addition, advocate reviewers will participate in the review process.

Funding decisions are made by the review process described below.

10.2. Review Process

- 1. Product Development and Scientific Review:** Applications that pass initial administrative compliance review are assigned to independent CPRIT Product Development Peer Review Panel members for evaluation using the criteria listed below. Based on the initial evaluation and discussion by the Product Development Review Panel, a subset of company applicants may be invited to deliver in-person presentations to the review panel.
- 2. Due Diligence Review:** Following the in-person presentations, a subset of applications judged to be most meritorious by the Product Development Review Panels will be referred for additional in-depth due diligence, including—but not limited to—intellectual property, management, regulatory, manufacturing, and market assessments. Following the due diligence review, applications will be recommended for funding by the CPRIT Product Development Review Council based on the information set forth in the due diligence and intellectual property reviews, comparisons with applications from the Product Development Review Panels and programmatic priorities.
- 3. Program Integration Committee Review:** Applications recommended by the Product Development Review Council will be forwarded to the CPRIT Program Integration Committee (PIC) for review. The PIC will consider factors including program priorities set by the Oversight Committee, portfolio balance across programs, and available funding.

4. **Oversight Committee Approval:** The CPRIT Oversight Committee will vote to approve each grant award recommendation made by the PIC. The grant award recommendations will be presented at an open meeting of the Oversight Committee and must be approved by two-thirds of the Oversight Committee members present and eligible to vote.

The review process is described more fully in CPRIT's Administrative Rules, Chapter 703, Sections 703.6–703.8.

10.2.1. Confidentiality of Review

Each stage of application review is conducted confidentially, and all CPRIT Product Development Peer Review Panel members, Product Development Review Council members, Program Integration Committee members, CPRIT employees, and Oversight Committee members with access to grant application information are required to sign nondisclosure statements regarding the contents of the applications. All technological and scientific information included in the application is protected from public disclosure pursuant to Health and Safety Code §102.262(b).

Individuals directly involved with the review process operate under strict conflict of interest prohibitions. All CPRIT Product Development Peer Review Panel members and Product Development Review Council members are non-Texas residents.

An applicant will be notified regarding the peer review panel assigned to review the grant application. Peer review panel members are listed by panel on CPRIT's Web site. **By submitting a grant application, the applicant agrees and understands that the only basis for reconsideration of a grant application is limited to an undisclosed Conflict of Interest as set forth in CPRIT's Administrative Rules, Chapter 703, Section 703.9.**

Communication regarding the substance of a pending application is prohibited between the company applicant (or someone on the applicant's behalf) and the following individuals: an Oversight Committee member, a Program Integration Committee (PIC) member, a Product Development Review Panel member, or a Product Development

Review Council member. Applicants should note that the CPRIT PIC is comprised of the CPRIT Chief Executive Officer, the Chief Scientific Officer, the Chief Prevention Officer, the Chief Product Development Officer, and the Commissioner of State Health Services. The prohibition on communication begins on the first day that grant applications for the particular grant mechanism are accepted by CPRIT and extends until the grant applicant receives notice regarding a final decision on the grant application. Intentional, serious, or frequent violations of this rule may result in the disqualification of the grant application from further consideration for a grant award.

10.3. Review Criteria

Full peer review of applications will be based on primary scored criteria and secondary unscored criteria, listed below. Review committees will evaluate and score each primary criterion and subsequently assign a global score that reflects an overall assessment of the application. **The overall assessment will not be an average of the scores of the individual criteria; rather, it will reflect the reviewers' overall impression of the application. Evaluation of the scientific merit of each application is within the sole discretion of the peer reviewers.**

10.3.1. Primary Criteria

Primary criteria will evaluate the scientific merit and potential impact of the proposed work contained in the application. Concerns with any of these criteria potentially indicate a major flaw in the significance and/or design of the proposed study.

Primary criteria include:

Significance and Impact: Will the outcomes of this CPRIT-funded work result in the development of innovative products with significant product development potential? Will the outcome substantially impact the diagnosis, treatment, prevention of cancer, or supportive care for patients with cancer? How would competing products or services affect the value of the proposed offering?

Product: Is there demonstrated proof of relevance, and does the product fulfill a clear, unmet medical or infrastructure need? Has work been conducted that supports the advancement of the proposed product, service, or technology? Can the product be

produced or manufactured in a commercially viable fashion? Is there an appropriate basis for a reimbursement strategy?

Market Plan: Is there a realistic assessment of the market size and expected penetration? Has management adequately assessed potential competitors and described how the company's offering will successfully compete with them?

Development Plan and/or Regulatory Path: Is the development plan and/or regulatory path well characterized and appropriate? Is the plan milestone driven, and does it address both a positive and a negative outcome? Does the budget appropriately support the plan?

Scientific Plan: Is the proposed product, service, and/or infrastructure based on a feasible research framework, hypothesis, and/or goal? Are the methods appropriate, and are potential research and developmental obstacles and unexpected outcomes discussed?

Management and Staffing: Does the applicant have the appropriate level of management experience to execute the stated strategy in Texas, especially if the headquarters of the company are not in Texas? Would the proposed team have the needed experience or access to experienced external assistance, facilities, and resources to accomplish all aspects of the proposed plan?

10.3.2. Secondary Criteria

Secondary criteria contribute to the global score assigned to the application. Concerns with these criteria potentially question the feasibility of the proposed research and development activities.

Secondary criteria include:

Budget and Duration of Support: Are the budget and duration appropriate for the proposed work? Will the amount requested enable the applicant to reach appropriate milestones? Is the use of the funds requested in line with the stated objectives of the applicant and CPRIT? Is it clear how funds will be used? (For example: Is it clear that no CPRIT funds will be used outside of Texas without specific authorization by CPRIT? Is it clear that no CPRIT funds will be sent to the corporate headquarters if those headquarters remain outside of Texas?) Does the proposed investment fund the research and

development of the proposed product, service, or technology to a point where, if the results are positive, it is likely that the project will be able to attract further financial support outside of CPRIT?

11. SUBMISSION GUIDELINES

Applicants are advised to carefully review all instructions in this section to ensure the accurate and complete submission of all components of the application. Please refer to the *Instructions for Applicants* document for details that will be available when the application receipt system opens. Applications that are missing one or more components, exceed the specified page or word limits, or that do not meet the eligibility requirements listed above will be administratively withdrawn without review.

11.1. Online Application Receipt System and Application Submission Deadline

Applications must be submitted via the CPRIT Application Receipt System (CARS) (<https://CPRITGrants.org>). **Only applications submitted through this portal will be considered eligible for evaluation.** The applicant is eligible solely for the grant mechanism specified by the RFA under which the grant application was submitted. The company applicant must create a user account in the system to start and submit an application. The co-applicant, if applicable, must also create a user account to participate in the application. Furthermore, the Authorized Signing Official (ASO) (an individual authorized to sign and submit an application on behalf of the company applicant) must also create a user account in CARS. An application may not be submitted without ASO approval. Only the ASO is authorized to officially submit the application to CPRIT. Applications will be accepted beginning at 7 a.m. Central Time on December 23, 2013 and must be submitted by 3 p.m. Central Time on January 31, 2014. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

11.2. Submission Deadline Extension

The submission deadline may be extended for one or more grant applications upon a showing of good cause. All requests for extension of the submission deadline must be submitted via e-mail to the CPRIT HelpDesk. Submission deadline extensions, including

the reason for the extension, will be documented as part of the grant review process records.

11.3. Product Development Review Fee

All applicants must submit a fee of \$1,000 for product development review. Payment should be made by check or money order payable to CPRIT; electronic and credit card payments are not acceptable. The application ID and the name of the submitter must be indicated on the payment. All payments must be postmarked by the application submission deadline and mailed to:

Cancer Prevention and Research Institute of Texas
P.O. Box 12097
Austin, TX 78711

11.4. Application Components

11.4.1. Layperson's Summary (1,500 characters)

Provide an abbreviated summary for a lay audience using clear, nontechnical terms. Describe specifically how the proposed project would support CPRIT's mission (see [Section 2](#)). Would it fill a needed gap in patient care or in the development of a sustainable oncology industry in Texas? Would it synergize with Texas-based resources? Describe the overall goals of the work, the type(s) of cancer addressed, the potential significance of the results, and the impact of the work on advancing the fields of diagnosis, treatment, or prevention of cancer. Clearly address how the company's work, if successful, will have a major impact on the care of patients with cancer. The information provided in this summary will be made publicly available by CPRIT, particularly if the application is recommended for funding. The Layperson's Summary will be also used by advocate reviewers in evaluating the significance and impact of the proposed work. Do not include any proprietary information in this section.

11.4.2. Goals and Objectives

List specific goals and objectives for each year of the project. These goals and objectives will also be used during the submission and evaluation of progress reports and assessment of project success.

11.4.3. Timeline (One page)

Provide an outline of anticipated major milestones to be tracked. Timelines will be reviewed for reasonableness, and adherence to timelines will be a criterion for continued support of successful applications. If the application is approved for funding, this section will be included in the award contract. Applicants are advised not to include information that they consider confidential or proprietary when preparing this section.

11.4.4. Resubmission Summary (One page)

If this is a resubmission, upload a summary of the approach, including a summary of the applicant's response to previous feedback. Clearly indicate to reviewers how the application has been improved in response to the critiques. Refer the reviewers to specific sections of other documents in the application where further detail on the points in question may be found. When a resubmission is evaluated, responsiveness to previous critiques is assessed. If this is not a resubmission, then no summary is required.

Note: An application is a resubmission only if the previous application was finalized and submitted to CPRIT. However, an application that was submitted to CPRIT to be considered for FY2013 Cycle 3 awards and was returned by CPRIT due to the moratorium is not considered to be a resubmission.

11.4.5. Executive Summary (One page)

Provide an executive summary that clearly explains the product, service, technology, or infrastructure proposed; competition; market need and size; development or implementation plans; regulatory path; reimbursement strategy; and funding needs. Applicants must clearly describe the existing or proposed company infrastructure and personnel located in Texas for this endeavor.

11.4.6. Slide Presentation (Ten pages)

Provide a slide presentation summarizing the application. The presentation should be submitted in PDF format, with one slide filling each landscape-orientation page. The slides should succinctly capture all essential elements of the application and should stand alone.

11.4.7. Scientific Plan (Ten pages)

Present the rationale behind the proposed product or service, emphasizing the pressing problem in cancer care that will be addressed. Summarize the evidence gathered to date in support of the company's ideas. Describe the label claims that the company ultimately hopes to make, and describe the plan to gather evidence to support these claims. Outline the steps to be taken during the proposed period of the award, including the design of the translational or clinical research, methods, and anticipated results. Describe potential problems or pitfalls and alternative approaches. If clinical research is proposed, present a realistic plan to accrue a sufficient number of human subjects meeting the inclusion criteria within the proposed time period.

The scientific plan submitted must be of sufficient depth and quality to pass rigorous scrutiny by the highly qualified group of reviewers. To the extent possible, the scientific plan should be driven by data. In the past, applications that have been scored poorly have been criticized for assuming that assertions could be taken on faith. Convincing data are much preferred.

11.4.8. Business Plan (Fifteen pages)

Provide a business plan covering all of the topics below in the order shown. Successful applicants will make thoughtful, careful, and economical use of the limited space. Note that if the company is selected to undergo due diligence, information to support a full intellectual property review will be requested at that time. New Company Product Development Award applicants will be evaluated based not only on the current status of the components of the business plan but also on whether current weaknesses and gaps are acknowledged and whether plans to address them are outlined.

- A. Introduction:** Present the rationale behind the proposed project, emphasizing the pressing problem in cancer care that will be addressed. Describe the label claims that the company ultimately hopes to make, and briefly describe the plan to gather evidence to support these claims. Include the minimum level of detail required to provide a context for the rest of the business plan. Cross-reference sections in the scientific plan where further details may be found.

- B. Products and Markets:** Provide a brief description of the envisioned product and how the product will be administered to patients. Describe the initial market that will be targeted and how the envisioned product will fit within the standard of care.
- C. Regulatory Plans:** Provide a detailed regulatory plan, including preclinical and clinical activities, driven by interactions with the FDA, if possible. Summarize all interactions to date with the FDA.
- D. Risk Analysis:** Describe the specific risks inherent to the product plan and how they would be mitigated.
- E. Current and Pending Support:** Describe all funding sources. Provide a complete and detailed capitalization table, which should include all parties who have investments, stock, or rights in the company. The identities of all parties must be listed. It is not appropriate to list any funding source as anonymous.
- F. Financial Projections:** Provide a detailed source and use analysis of the development plan, focusing on the achievement of specific milestones.
- G. Resources Requested:** Include resources needed for research and product development and for any relocation expenses. The matching funds should be included in this section; however, this is the only section of the business plan that does not deal exclusively with CPRIT-requested funds.
- H. Scope of Work and Milestones:** Outline the specific goals of the project. Provide an outline of anticipated major milestones to be tracked. Timelines will be reviewed for reasonableness, and adherence to timelines will be a criterion for continued support of successful applications. If the application is approved for funding, this section will be included in the award contract.
- I. Key Personnel Located in Texas and Any Key Management Located Outside of Texas:** Present a plan for recruiting a senior management and scientific team, describing the types of expertise and skill sets that the project will require. For each key person currently on board, provide a paragraph briefly summarizing his or her

present title and position, prior industry experience, education, and any other information considered essential for evaluation of qualifications.

J. Organizational Commitment to Texas: Describe how CPRIT funding of the applicant's company would benefit the State of Texas. For example, describe how the company would create high-quality new jobs in the State and/or recruit out-of-State talent, and mention any Texas-based subcontractors and suppliers that would be used and any other unique, Texas-based resources that would be leveraged.

11.4.9. Biographical Sketches of Key Scientific Personnel (Eight pages)

Provide a biographical sketch for up to four key scientific personnel that describes their education and training, professional experience, awards and honors, and publications relevant to cancer research. Each biographical sketch must not exceed two pages and must use the "Product Development Programs: Biographical Sketch" template.

(In addition, information on the members of the senior management and scientific team should be included in the "Key Personnel" section of the Business Plan

[see [Section 11.4.8](#)]).

11.4.10. Budget and Justification

Provide a compelling justification of the budget for the entire proposed period of support, including salaries and benefits, supplies, equipment, patient care costs, animal care costs, and other expenses. The budget must be aligned with the proposed milestones. In preparing the requested budget, applicants should be aware of the following:

- Equipment having a useful life of more than 1 year and an acquisition cost of \$5,000 or more per unit must be specifically approved by CPRIT. An applicant does not need to seek this approval prior to submitting the application.
- Texas State law limits the amount of grant funds that may be spent on indirect costs to no more than 5 percent of the total award amount (5.263 percent of the direct costs). Guidance regarding indirect cost recovery can be found in CPRIT's Administrative Rules, which are available at www.cprit.state.tx.us.
- The annual salary that an individual may receive under a CPRIT award for FY 2014 is \$200,000. In other words, an individual may request salary proportional to the

percentage effort up to a maximum of \$200,000. Salary does not include fringe benefits. CPRIT FY 2014 is from September 1, 2013, through August 31, 2014.

12. AWARD ADMINISTRATION

Texas law requires that CPRIT awards be made by contract between the applicant and CPRIT. CPRIT grant awards are made to entities, not to individuals. Award contract negotiation and execution will commence once the CPRIT Oversight Committee has approved an application for a grant award. CPRIT may require, as a condition of receiving a grant award, that the grant recipient use CPRIT's electronic Grant Management System to exchange, execute, and verify legally binding grant contract documents and grant award reports. Such use shall be in accordance with CPRIT's electronic signature policy as set forth in Chapter 701, Section 701.25.

Texas law specifies several components that must be addressed by the award contract, including needed compliance and assurance documentation, budgetary review, progress and fiscal monitoring, and terms relating to revenue sharing and intellectual property rights. These contract provisions are specified in CPRIT's Administrative Rules, which are available at www.cprit.state.tx.us. Applicants are advised to review CPRIT's Administrative Rules related to contractual requirements associated with CPRIT grant awards and limitations related to the use of CPRIT grant awards as set forth in Chapter 703, Sections 703.10 - 703.12.

Prior to disbursement of grant award funds, the grant recipient organization must demonstrate that it has adopted and enforces a tobacco-free workplace policy consistent with the requirements set forth in CPRIT's Administrative Rules, Chapter 703, Section 703.20.

CPRIT requires award recipients to submit an annual progress report. These reports summarize the progress made toward the research goals and address plans for the upcoming year. In addition, fiscal reporting, human studies reporting, and vertebrate animal use reporting will be required as appropriate. Continuation of funding is contingent upon the timely receipt of these reports. Failure to provide timely and

complete reports may waive reimbursement of grant award costs, and may result in the termination of award contract. Forms and instructions will be made available at www.cpritis.state.tx.us.

Project Economics Sharing: Recipients should also be aware that the funding award contract will include a revenue-sharing agreement and will require CPRIT to have input on any future patents, agreements, or other financial arrangements related to the products, services, or infrastructure supported by the CPRIT investment. These contract provisions are specified in CPRIT’s Administrative Rules, which are available at www.cpritis.state.tx.us.

13. REQUIREMENT TO DEMONSTRATE AVAILABLE FUNDS

Texas State law requires that prior to disbursement of CPRIT grant funds, the award recipient demonstrate that it has \$1.00 in matching funds for every \$2.00 from CPRIT. Matching funds need not be in hand when the application is submitted. However, matching funds must be obtained before CPRIT funds will be released for use. CPRIT funds must, whenever possible, be spent in Texas. A company’s matching funds must be designated for the CPRIT-funded project but may be spent outside of Texas. Grant applicants are advised to consult CPRIT’s Administrative Rules, Chapter 703, Section 703.11 for specific requirements associated with demonstration of available funds.

14. CONTACT INFORMATION

14.1. HelpDesk

HelpDesk support is available for questions regarding user registration and online submission of applications. Queries submitted via e-mail will be answered within 1 business day. HelpDesk staff are not in a position to answer questions regarding scientific and commercialization aspects of applications. **Before contacting the HelpDesk, please refer to the “Instructions for Applicants” document, which provides a step-by-step guide on using the Application Receipt System.**

Dates of operation: December 23, 2013 to January 31, 2014 (excluding public holidays)

Hours of operation: Monday, Tuesday, Thursday, Friday, 7 a.m. to 4 p.m. Central Time
Wednesday, 8 a.m. to 4 p.m. Central Time

Tel: 866-941-7146

E-mail: Help@CPRITGrants.org

14.2. Programmatic Questions

Questions regarding the CPRIT Program, including questions regarding this or any other funding opportunity, should be directed to the CPRIT Product Development Program Director.

Tel: 512-305-8486

E-mail: Help@CPRITGrants.org

Web site: www.cprit.state.tx.us

Third Party Observer Report

CPRIT Product Development Panel Screening Review Report

Report #2014-05

Panel Name: Product Development Screening Review Meeting for Product Development – Part 1

Panel Date: February 27, 2014

Report Date: February 27, 2014

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized its out-sourced internal audit provider to function as a neutral third-party observer.

Introduction

The subject of this report is the Product Development Panel screening review chaired by David Shoemaker and held over the phone on February 27, 2014.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.

Observation Results Summary

Internal Audit participated in the Product Development Panel screening review meeting held telephonically on February 27, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Seventeen out of the twenty-two product development applications were discussed and evaluated by the Product Development Review Panel to determine which grants would be brought forth for further review. A cut-off was determined by the chair, and the applications discussed were based on their initial scores. However, the panel had the ability to champion an application, if requested.
- Twelve panel members, two advocate reviewers, four CPRIT staff members, and four SRA employees were present for the panel meeting over the phone.

- Ten conflict of interests were identified prior to or during the call. The panel members with the conflict of interests left the teleconference and did not participate in the review of the conflicted applications.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies. SRA program staff did not participate in the discussions around the merits of the applications. The panel members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include an evaluation of the appropriateness or rigor of the peer review panel's discussion of scientific, technical or programmatic aspects of the applications.

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Product Development Panel Screening Review Report

Report #2014-06

Panel Name: Product Development Panel Screening Review Meeting for Product Development Part 2

Panel Date: February 28, 2014

Report Date: February 28, 2014

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized its out-sourced internal audit provider to function as a neutral third-party observer.

Introduction

The subject of this report is the Product Development Panel screening review chaired by Jack Geltosky and held over the phone on February 28, 2014.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.

Observation Results Summary

Internal Audit participated in the Product Development Panel screening review meeting held telephonically on February 28, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Fourteen out of twenty product development applications were discussed and evaluated by the Product Development Review Panel to determine which grants would be brought forth for further review. A cut-off is determined by the chair, and the applications discussed were based on their initial scores. However, the panel had the ability to champion an application, if requested.

- Eleven members, two CPRIT staff members, and four SRA employees were present for the panel meeting over the phone.
- One conflict of interest were identified prior to or during the call. The panel member with the conflict of interest left the teleconference and did not participate in the review of the conflicted applications.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the peer review panel's discussion of scientific, technical or programmatic aspects of the applications.

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Product Development Panel Screening Review Report

Report #2014-07

Panel Name: Product Development Screening Review Panel - 1

Panel Date: March 31, 2014 – April 1, 2014

Report Date: April 1, 2014

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized its out-sourced internal audit provider to function as a neutral third-party observer.

Introduction

The subject of this report is the in-person Product Development Panel chaired by David Shoemaker and held March 31, 2014 – April 1, 2014.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.

Observation Results Summary

Internal Audit participated in the in-person Product Development Panel screening review meeting held March 31, 2014 – April 1, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Eleven product development applications were discussed and evaluated by the Product Development Review Panel to determine which grants would be brought forth for further review over the course of two days. A cut-off is determined by the panel as to which applications will move on further for due diligence.
- Twelve review panel members, four CPRIT staff members, and two SRA employees were present for the in-person panel meeting.

- Eight conflicts of interest were identified prior to or during the in-person review. Seven of the eight conflicts of interest panel members left the room and did not participate in the review of the conflicted applications. One panel member identified that they had a conflict of interest during the in-person presentation and notified a CPRIT staff member to confirm. The panel member participated in the review by asking a question to the applicants; however, the panel member's participation did not have an effect on the results of the scoring. Once the CPRIT staff confirmed the conflict of interest, the panel member left the room.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the peer review panel's discussion of scientific, technical or programmatic aspects of the applications.

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Product Development Review Panel Report

Report #2014-08

Panel Name: Product Development Review Panel - 2

Panel Date: March 31, 2014 – April 1, 2014

Report Date: April 1, 2014

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized its out-sourced internal audit provider to function as a neutral third-party observer.

Introduction

The subject of this report is the in-person Product Development Panel chaired by Jack Geltosky and held March 31, 2014 – April 1, 2014.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the telephone conference if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The peer review panel discussion is focused on the established scoring criteria.

Observation Results Summary

Internal Audit participated in the in-person Product Development Panel screening review meeting held March 31, 2014 – April 1, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Over the course of two days, seven product development applications were presented, discussed, and evaluated by the Product Development Review Panel to determine which grants would be recommended for due diligence review. A score cut-off is determined by the panel as to which applications will move on further for due diligence.
- Eleven review panel members, two advocate reviewers, four CPRIT staff members, and three SRA employees were present for the in-person panel meeting.

- One conflict of interest was identified prior to the meeting. The panel member with the conflict of interest left the meeting room and did not participate in the review of the conflicted application.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The panel members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the peer review panel's discussion of scientific, technical or programmatic aspects of the applications.

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

CPRIT Product Development Review Council Report

Report #2014-22

Panel Name: Product Development Review Council Meeting – Due Diligence (FY14.1 Product Development applications)

Panel Date: June 27, 2014

Report Date: July 7, 2014

Background

As part of CPRIT's on-going emphasis on continuous improvement in its grants review/management processes and to ensure that panel discussions are limited to the merits of the application and focused on the established evaluation criteria, CPRIT is implementing the use of a third-party observer at every in-person and telephone conference peer review meeting. CPRIT has authorized its out-sourced internal audit provider to function as a neutral third-party observer.

Introduction

The subject of this report is the Product Development Review Council review of Due Diligence evaluations for FY14.1 Product Development applications. The meeting was chaired by Jack Geltosky and David Shoemaker and held over the phone on June 27, 2014.

Panel Observation Objectives and Scope

The third-party observation was limited to observing whether the following objectives were met:

- CPRIT's established procedures for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers leave room or do not participate in the discussion if they have a conflict);
- CPRIT program staff participation is limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff do not engage in the panel's discussion on the merits of applications;
- The Council discussion is focused on the established scoring criteria.

Observation Results Summary

Internal Audit participated in the Product Development Review Council meeting held telephonically and chaired by Jack Geltosky and David Shoemaker on June 27, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Two product development applications were discussed and evaluated by the Product Development Review Council to determine whether the grants would receive CPRIT funding.

- Five panel members, three CPRIT staff members, and one SRA employee were present for the Council meeting over the phone.
- No conflict of interests were identified prior to the meeting.
- CPRIT program staff participation was limited to answering procedural questions and clarifying policies.
- SRA program staff did not participate in the discussions around the merits of the applications.
- The Council members' discussions were limited to the application evaluation criteria.

Disclaimer

The third-party observation did not include the following:

- An evaluation of the appropriateness or rigor of the Council's discussion of scientific, technical or programmatic aspects of the applications.

Internal Audit was not engaged to and did not conduct an examination or review, the objective of which would be the expression of an opinion or limited assurance on the accuracy of voting and scoring. Accordingly, we will not express such an opinion or limited assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported to you.

This report is intended solely for the information and use of CPRIT and its management and its Oversight Committee members and is not intended to be and should not be used by anyone other than these specified parties.

De-Identified Overall Evaluation Scores

New Company Product Development Award

Company ID	Final Overall Score
DP140072*	2.2
DP140034*	2.4
bb7	2.9
bb8	3.9
bb9	3.9
cc1	4.1
cc2	4.3
cc3	5.0
cc4	5.0
cc5	5.0
cc6	5.3
cc7	5.3
cc8	5.3
dd1	5.3
dd2	5.7
dd3	5.7
dd4	6.0
dd5	6.0
dd6	6.0
dd7	6.0
dd8	6.1
dd9	6.3
ee1	6.3
ee2	6.7
ee3	6.7
ee4	7.0

*=Recommended for Funding

Final Overall Evaluation Scores and Rank Order Scores

William Rice, M.D.
Oversight Committee Chair
Cancer Prevention and Research Institute of Texas
Via email to Bill.Rice@stdavids.com

Wayne R. Roberts
Chief Executive Officer
Cancer Prevention and Research Institute of Texas
Via email to wroberts@cprit.state.tx.us

Dear Mr. Roberts and Dr. Rice,

On behalf of the Product Development Review Council (PDRC), I am pleased to provide the PDRC's recommendations for CPRIT Established Company product development grant awards. The companies on the attached list submitted proposals in response to CPRIT requests for applications (RFA) released for the first review cycle of FY2014. Each recommendation reflects 50+ hours of individual review and panel discussion of the applicants' proposals as well as the PDRC's review of the due diligence reports.

The projects are numerically ranked in the order the PDRC recommends the applications be funded. Recommended funding amounts and the overall evaluation score are stated for each grant application. The PDRC did not make changes to the funding amount, goals, timelines, or project objectives requested by the applicants.

Our recommendations met the PDRC's standards for grant award funding. These standards include the companies' potential to 1.) expedite innovation and product development in cancer research and treatments; 2.) create and expand the number of high-quality new jobs in Texas; and 3.) make a return on CPRIT's investment in cancer research.

Sincerely,

/JG/

Chair, CPRIT Product Development Review Council

Attachment

Product Development Review Council Award Recommendations FY2014, Cycle 1, Part 2*

Rank	Application ID	Company Name	Project	Requested Budget	Overall Score
1	DP140072	OncoNano Medicine	OncoNano Medicine: Transforming Cancer Surgery by Tumor Illumination	\$6,000,000	2.2
2	DP140034	Curtana Pharmaceuticals, Inc	Preclinical Drug Discovery and Development of Novel, First-In-Class, Small Molecule Compounds that Directly Target Glioblastoma and Other Brain Cancers	\$7,580,185	2.4

* The first two product development proposals submitted in response to FY2014 Cycle 1 RFAs were approved by the Oversight Committee on May 21, 2014. The due diligence reviews for OncoNano and Curtana were not complete in time for the Oversight Committee's consideration at the May meeting.

High Level Summary of Due Diligence

Curtana Pharmaceuticals, Inc.

Summary of CPRIT Diligence and Recommendation for Funding

Curtana has presented an early stage development program for the identification of a lead candidate and its development in a new treatment paradigm utilizing a novel mechanism of action in brain cancers that currently have limited treatment options and poor prognosis. Curtana has mapped the screening and selection process for a lead candidate selection, preclinical mechanistic and IND-enabling studies, CMC development and initial clinical development.

The company is strongly positioned for this early development work, but further consideration of the optimal clinical program is warranted as are some of the risk aspects identified. Concerns were also noted on aspects of the funding spend and the current funding position. These elements should be further explored in the contract negotiation.

Notwithstanding these concerns, this program does have the opportunity to provide a novel treatment paradigm for cancers that currently have limited options. **The PDRC endorses funding for this application.**

OncoNano Medicine, Inc.

Summary of CPRIT Diligence and Recommendation for Funding

The proposed technology addresses a significant clinical need, and successful development would result in large cost savings and increased efficiency of care, as well as likely improvements in treatment efficacy.

The development plan is appropriate to take the technology through to an initial proof of concept and development should be relatively straightforward.

The management team is experienced and has the capability to manage this program through to proof of concept. Some licensing, regulatory, and budgetary issues were noted but these should be resolvable.

Overall the rationale behind the imaging product is compelling and the development program appropriate. **The PDRC endorses funding for this application.**



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application DP140034
New Company Product Development Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

"My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *New Company Product Development Award* Request for Applications (RFA). CPRIT received 43 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Product Development Panel-2 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT's third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT's grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT's third-party grants management vendor in my capacity as CPRIT's CEO to prepare this affidavit. Some information ("CEO Affidavit-Supporting Information") is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:


- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT's grant review processes were followed by the review panel evaluating the applications in this grant cycle

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the Scientific Research and Prevention Programs Committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

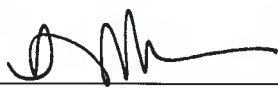
This statement is true."



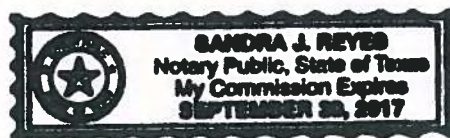
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Product Development
AWARD MECHANISM New Company Product Development Awards (NEWCO)
APPLICATION ID DP140034
APPLICATION TITLE Preclinical Drug Discovery and Development of Novel, First-In-Class, Small Molecule Compounds That Directly Target
APPLICANT NAME Stein, Gregory
ORGANIZATION Curtana Pharmaceuticals, Inc.
PANEL NAME Product Development Panel - 2 (PDP-2)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	05/12/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	05/12/14
	CPRIT Application Receipt System (CARS) closed	01/31/14	05/12/14
	Date application submitted	01/30/14	05/12/14
	Method of submission	CARS	05/12/14
	Within receipt period	YES	05/12/14
	Appeal to submit application after CARS closed	N/A	05/12/14
	Appeal for late application submission accepted	N/A	05/12/14
2. Receipt, Referral, and Assignment	Submission of application fee	YES	05/12/14
	Administrative review notification	N/A	05/12/14
	Donation(s) made to CPRIT/foundation	NO	05/12/14
	Assigned to primary reviewers	02/14/14	05/12/14
	Applicant notified of review panel assignment	02/26/14	05/12/14
	Primary Reviewer 1 COI signed	02/11/14	05/12/14
	Primary Reviewer 2 COI signed	02/19/14	05/12/14
	Primary Reviewer 3 COI signed	02/11/14	05/12/14
3. Peer Review: Screening Teleconference	Primary (Advocate) Reviewer 4 COI signed	02/11/14	05/12/14
	Primary (Advocate) Reviewer 5 COI signed	02/11/14	05/12/14
	Primary Reviewer 1 critique submitted	02/25/14	05/12/14
	Primary Reviewer 2 critique submitted	02/22/14	05/12/14
	Primary Reviewer 3 critique submitted	02/26/14	05/12/14
	COI indicated by non-primary reviewer	NONE	05/12/14
	COI recused from participation	N/A	05/12/14
	Peer Review: Screening Teleconference	02/28/14	05/12/14
4. Peer Review: On-Site Meeting	Post-Screening Teleconference score report	03/04/14	05/12/14
	Post review statements signed	04/06/14	05/12/14
	Third Party Observer Report	02/28/14	05/12/14
	Recommended for On-Site Meeting	YES	05/12/14
	Primary (Advocate) Reviewer 4 critique submitted	03/24/14	05/12/14
	Primary (Advocate) Reviewer 5 critique submitted	03/25/14	05/12/14
	COI indicated by non-primary reviewer	NONE	05/12/14
	COI recused from participation	N/A	05/12/14
5. Due Diligence and IP Review	Peer Review: On-Site Meeting	03/31/14 - 04/01/14	05/12/14
	Post review statements signed	04/01/14	05/12/14
	Third Party Observer Report	04/01/14	05/12/14
6. Final PDRC Recommendation	Score report delivered to CPDO	04/08/14	05/12/14
	Recommended for due diligence and IP review	YES	05/12/14
	Final due diligence review submitted to PDRC	06/12/14	07/09/14
	Intellectual Property conflict check	04/08/14	07/09/14
	Final intellectual property review submitted	06/24/14	07/09/14
	COI indicated by PDRC member	NONE	07/17/14
7. PIC Review	COI recused from participation	N/A	07/17/14
	Due Diligence Evaluation Meeting / PDRC Meeting	06/27/14	07/17/14
	Third Party Observer Report	07/07/14	07/17/14
	Recommended for grant award	YES	07/17/14
	PDRC Chair Notification to PIC and OC	06/30/14	07/17/14
8. Oversight Committee Approval	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
8. Oversight Committee Approval	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

identity of attesting party retained by CPRIT



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

**CEO AFFIDAVIT
Application DP140072
New Company Product Development Award**

THE STATE OF TEXAS

COUNTY OF TRAVIS

BEFORE ME, the undersigned authority, on this day personally appeared Wayne R. Roberts, who swore or affirmed to tell the truth, and stated as follows:

“My name is Wayne R. Roberts, the Chief Executive Officer (CEO) of the Cancer Prevention and Research Institute of Texas (CPRIT). I am of sound mind and capable of making this sworn statement. I submit this affidavit pursuant to the legal requirement imposed by V.T.C.A., Health & Safety Code § 102.251(c).

My affidavit addresses the grant review process for the application stated above that is recommended for a CPRIT grant award by the Program Integration Committee (PIC). This application was submitted pursuant to *New Company Product Development Award* Request for Applications (RFA). CPRIT received 43 applications for this RFA (including applications that may have been administratively withdrawn later). The application was assigned to the Product Development Panel-1 for review. A preliminary evaluation process as described by 25 T.A.C. § 703.6(e)(1) was not used for applications in this cycle.

CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and CPRIT’s third-party grants management vendor in my capacity as CPRIT’s CEO to prepare this affidavit. Some information (“CEO Affidavit-Supporting Information”) is applicable to all applications recommended for awards submitted pursuant to this RFA. The information listed below has been compiled as one packet and is incorporated herein by reference:

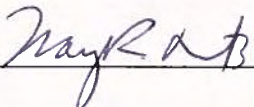
- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT’s grant review processes were followed by the review panel evaluating the applications in this grant cycle

- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
- A final overall evaluation score and rank order score submitted by the Scientific Research and Prevention Programs Committees for the grant applications recommended by the PIC in this cycle

In addition to the CEO Affidavit-Supporting Information that is applicable to all applications submitted pursuant to the applicable RFA and recommended for grant awards this cycle, I have also reviewed the application's grant pedigree. The grant pedigree for the application listed above has been attached to this affidavit. The application pedigree provides an overview of the conflict of interest process applicable to this application, including any conflicts of interest reported by the review panel or by the PIC. I note that Dr. Margaret Kripke, Chief Scientific Officer, and Dr. David Lakey, Department of State Health Services Commissioner, have conflict of interest waivers on file for FY2014 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3).

I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

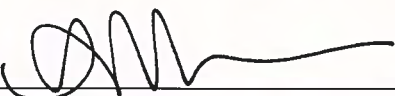
This statement is true."



Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 16th day of July, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2014
CYCLE 1
PROGRAM Product Development
AWARD MECHANISM New Company Product Development Awards (NEWCO)
APPLICATION ID DP140072
APPLICATION TITLE OncoNano Medicine: Transforming Cancer Surgery by Tumor Illumination
APPLICANT NAME Sumer, Baran
ORGANIZATION The University of Texas Southwestern Medical Center
PANEL NAME Product Development Panel - 1 (PDP-1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	12/20/13	05/12/14
	CPRIT Application Receipt System (CARS) opened	12/23/13	05/12/14
	CPRIT Application Receipt System (CARS) closed	01/31/14	05/12/14
	Date application submitted	01/31/14	05/12/14
	Method of submission	CARS	05/12/14
	Within receipt period	YES	05/12/14
	Appeal to submit application after CARS closed	N/A	05/12/14
	Appeal for late application submission accepted	N/A	05/12/14
	Submission of application fee	YES	05/12/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	05/12/14
	Donation(s) made to CPRIT/foundation	NO	05/12/14
	Assigned to primary reviewers	02/14/14	05/12/14
	Applicant notified of review panel assignment	02/26/14	05/12/14
	Primary Reviewer 1 COI signed	02/12/14	05/12/14
	Primary Reviewer 2 COI signed	02/12/14	05/12/14
	Primary Reviewer 3 COI signed	02/15/14	05/12/14
	Primary (Advocate) Reviewer 4 COI signed	02/12/14	05/12/14
3. Peer Review: Screening Teleconference	Primary (Advocate) Reviewer 5 COI signed	02/12/14	05/12/14
	Primary Reviewer 1 critique submitted	02/26/14	05/12/14
	Primary Reviewer 2 critique submitted	02/21/14	05/12/14
	Primary Reviewer 3 critique submitted	03/04/14	05/12/14
	COI indicated by non-primary reviewer	NONE	05/12/14
	COI recused from participation	N/A	05/12/14
	Peer Review: Screening Teleconference	02/27/14	05/12/14
	Post-Screening Teleconference score report	03/04/14	05/12/14
	Post review statements signed	03/19/14	05/12/14
4. Peer Review: On-Site Meeting	Third Party Observer Report	02/27/14	05/12/14
	Recommended for On-Site Meeting	YES	05/12/14
	Primary (Advocate) Reviewer 4 critique submitted	03/25/14	05/12/14
	Primary (Advocate) Reviewer 5 critique submitted	03/24/14	05/12/14
	COI indicated by non-primary reviewer	NONE	05/12/14
	COI recused from participation	N/A	05/12/14
	Peer Review: On-Site Meeting	03/31/14 - 04/01/14	05/12/14
	Post review statements signed	04/03/14	05/12/14
	Third Party Observer Report	04/01/14	05/12/14
5. Due Diligence and IP Review	Score report delivered to CPDO	04/08/14	05/12/14
	Recommended for due diligence and IP review	YES	05/12/14
	Final due diligence review submitted to PDRC	06/18/14	07/09/14
6. Final PDRC Recommendation	Intellectual Property conflict check	04/08/14	07/09/14
	Final intellectual property review submitted	06/24/14	07/09/14
	COI indicated by PDRC member	NONE	07/17/14
	COI recused from participation	N/A	07/17/14
	Due Diligence Evaluation Meeting / PDRC Meeting	06/27/14	07/17/14
	Third Party Observer Report	07/07/14	07/17/14
7. PIC Review	Recommended for grant award	YES	07/17/14
	PDRC Chair Notification to PIC and OC	06/30/14	07/17/14
	COI indicated by PIC member	NONE	07/15/14
	COI recused from participation	N/A	07/15/14
8. Oversight Committee Approval	PIC review meeting	07/15/14	07/15/14
	Recommended for grant award	YES	07/15/14
	CEO Notification to Oversight Committee	DATE	
	COI indicated by Oversight Committee member	NAME or NONE	
	COI recused from participation	YES/NO or N/A	
	Donation(s) made to CPRIT/foundation	YES/NO	
	Presented to CPRIT Oversight Committee	DATE	
	Award approved by Oversight Committee	YES/NO	
	Authority to advance funds requested	YES/NO	
	Advance authority approved by Oversight Committee	YES/NO	

identity of attesting party retained by CPRIT



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: THOMAS GOODMAN, PhD, CHIEF PRODUCT DEVELOPMENT OFFICER
KRISTEN DOYLE, GENERAL COUNSEL
SUBJECT: PROPOSED CONTRACT TERMS FOR PRODUCT DEVELOPMENT
AWARDS RATIFIED MAY 21, 2014
DATE: AUGUST 14, 2014

Summary and Recommendation

We recommend that the Oversight Committee delegate contract execution authority to CPRIT's CEO to execute grant award contracts consistent with the terms and conditions outlined in the Attachment below. Delegation of contract execution authority for two companies with awards ratified at the May 2014 meeting was contingent on the Oversight Committee's consideration of negotiated milestones, tranching, revenue sharing terms, and satisfaction of issues raised by the Product Development Review Council during the due diligence process.

It is Dr. Goodman's opinion that the deal terms and tranching presented in the Attachment are consistent with the proposals, appropriately mitigate risks, and provide an opportunity for return to the state of Texas while not unreasonably impacting the companies' ability to raise future funding.

Contract Process Overview

State law requires grant funding recommendations to be ratified by the Oversight Committee as the final step in the application review process. However, approval of the grant recommendation does not entitle an applicant to receive grant funds. The statute is clear that a grant is awarded by signing a written grant contract. Disbursement of grant funds is contingent upon a final contract.

The statutory bifurcation of the grant recommendation approval and award contract is meaningful. The statute lays out several issues that must be included and agreed to in the award contract, including revenue sharing terms. Therefore, it is possible that a project may be approved by the Oversight Committee for CPRIT grant funding, but the grant is never awarded (and grant funds are not disbursed) because the applicant cannot agree to CPRIT's contractual terms. If no agreement is reached, the contract is not executed, and grant funds set aside for the project are released.

The statute directs that, "the Oversight Committee shall negotiate on behalf of the state regarding awarding, by grant, money under this chapter." It has been the standard practice for the Committee to

approve a motion delegating contract negotiation authority to CPRIT's CEO and General Counsel and authorizing the CEO to execute the award contract following the ratification of the grant recommendations by the Oversight Committee.

Contract Process for Product Development

For Product Development grant projects, CPRIT ties the disbursement of grant funds to the achievement of defined milestones that are specified in the grant contract. Each slice of funding, commonly known as a tranche, and its associated objectives or deliverables are negotiated and included in the award contract.

Tranching adds complexity, both to contract negotiation and to contract monitoring, but it is an effective way to limit CPRIT's risk exposure. Although the total award amount for the project must be ratified by the Oversight Committee, the grantee receives only enough grant funds to accomplish the specified milestones within the particular tranche. The company must demonstrate successful completion through a written report detailing how the company has achieved the milestones tied to a specific tranche in order to access the next amount of grant funding. Expert reviewers assess the work done by the company and recommend the release of the next tranche of funding or that funding be terminated.

Tranches for the grant project are developed using deal-specific documentation, including:

- Information supplied by the applicant. Applicants are asked to provide specific goals and associated timelines for the proposed project in the application. The aims and timeline are evaluated during the review process, and the reviewers may indicate a change to be included in the contract or an issue to be negotiated.
- Information from the due diligence review. Icon, the company that performs due diligence reviews of CPRIT's Product Development applications, provides guidance on appropriate milestones to be achieved during the course of the project.
- Information from the intellectual property review. IP counsel may provide recommendations regarding specific steps to be taken regarding protecting IP, ensuring freedom to operate, or cleaning up problematic licensing agreements.

Icon, IP counsel, or the Review Council may identify an issue that, if not corrected or adequately addressed prior to contract, could be a reason for CPRIT not executing the contract. Although this is not technically a tranche recommendation, this information impacts the contract negotiations. For example, the IP and licensing review may identify an issue with the license agreement for the underlying technology that, if not resolved, is a deal breaker. CPRIT will direct the company to fix the underlying licensing issue (usually through renegotiation of the underlying licensing agreement) before contract negotiation with CPRIT can begin.

Two other important points are the agreed revenue sharing payments and revenue sharing buyout amount payable to CPRIT. These may be determined by the size of the grant and the commercial maturity of the company according to the schematic previously presented to the Oversight Committee at the May 21st meeting or by the new terms and conditions being recommended at the present meeting.

Oversight Committee Contract Review and Approval Prior to Final Execution

The Oversight Committee delegated contract negotiation authority to CPRIT staff to finalize deal terms for the two Product Development grant awards ratified at the May 21, 2014 meeting. Over the past months, Dr. Goodman has discussed and negotiated with representatives of the companies. We have reached terms that we believe to be satisfactory.

It is Dr. Goodman's opinion that the deal terms presented in the Attachment below are consistent with the applications, appropriately mitigate risks, and provide an opportunity for return to the state of Texas while not unreasonably impacting the companies' ability to raise future funding.

We recommend that the Oversight Committee delegate contract execution authority to CPRIT's CEO to execute a final award contract consistent with the terms and conditions outlined in the Attachment.

ATTACHMENT

1. AERase, Inc. - Established Company

Company and Project Summary (written by the company)

The mission of AERase, Inc. a recently established biopharmaceutical company located in Austin, TX, is to develop novel cancer treatments by exploiting the unique metabolism of cancer cells. Cancer cells, unlike normal cells, lack the ability to make certain amino acids (AA), the building blocks of proteins. Efforts have been made to exploit this vulnerability, seen in many different cancers, by depriving tumors of key AA using naturally occurring compounds. The use of these compounds has been complicated by poor activity, (human-derived drugs) and by the development of immune reactions, (microbe-derived drugs), nonetheless tumor shrinkage has been seen in several different cancer types, such as melanoma, and liver cancer. AERase, Inc. has developed a variation on a human molecule that promises to be effective in the depletion of a key AA and to be unlikely to cause an immune reaction. Before this compound can be used as a cancer treatment, it must be manufactured and tested in animals and humans. During drug development, AERase, Inc. will do cell and animal studies at contract laboratories in TX. The human trials proposed will include clinical sites in TX, and use contract research and other providers in TX. To guide product development the company has recruited key personnel to TX from companies in other states, and the company expects to grow from its current staff of 4 to a permanent staff of 10, based in TX, to support development of this novel cancer treatment.

Proposed Milestones and Tranching: The total award requested from CPRIT is \$19,806,146. The grants funds would be distributed in three tranches, contingent upon successful achievement of the milestones set forth below.

Tranche 1: \$5,026,687 CPRIT (matched with \$2,513,343 of other funding) - one year

AERase requests funding to initiate the first-in-human (FIH) Phase I trial of engineered hArg[Co+2]-PEG (AERase) in patients with advanced solid tumors. The following milestones will be achieved in the first year:

1. Complete manufacturing, characterization, and stability work on GMP material needed for IND and Phase I clinical trial program for AERase.
2. Establish assays for IND enabling studies and clinical pharmacology.
3. Establish pharmacokinetic, pharmacodynamic and efficacy profile of AERase in nonclinical studies.
4. Achieve FDA IND acceptance for FIH dose-escalation Phase I with AERase.

Tranche 2: \$6,349,653 CPRIT (matched with \$3,174,826 of other funding) - one year

During this tranche, AERase will expand the understanding of the product enzyme's activity in additional cancer types. The following milestones will be achieved in the second year:

1. Initiate enrollment in Phase I dose escalation trial in hematologic malignancies.
2. Complete enrollment in dose escalation portion of Phase I solid tumor trial.

Tranche 3: \$8,429,805 CPRIT (matched with \$4,214,902 of other funding) - one year

During this tranche, AERase will complete enrollment in the Phase I clinical program to establish a safe dose and regimen of AERase and a preliminary understanding of antitumor activity. The following milestones will be achieved in the third year:

1. Initiate enrollment in Phase I expansion portion of FIH trial.
2. Initiate enrollment in Phase Ib trial of AERase in combination with standard of care therapy in metastatic melanoma.

Proposed Revenue Sharing Terms: The revenue sharing terms in the contract shall read or be substantially equivalent to: (1) "For the purposes of the Contract, including this Attachment D, the RECIPIENT and INSTITUTE agree that the values of "A" and "B" in Section D4.01a above shall be 4.0 and 2.0, respectively, and that the value of "C" in Section D4.01b above shall be 0.9." or (2) those terms being presently recommended to the Oversight Committee in the attached memorandum.

Remaining Diligence Provisions: After AERase shall have developed and posted a company website, it will have satisfactorily responded to all diligence concerns raised by the Product Development Review Council and due diligence process.

Recommendation: We recommend that the Oversight Committee delegate contract execution authority to the CEO of CPRIT for this grant, subject to the Company's agreement to appropriate tranches and milestones and to CPRIT's standard revenue sharing terms for a grant of this size to a company of this commercial maturity.

2. Mirna Therapeutics - Established Company

Company and Project Summary (written by the company)

Mirna Therapeutics, Inc., is a Texas-based company developing a new class of cancer treatments that are based on naturally occurring tumor suppressor microRNAs. In April 2013, Mirna's lead product, a liposomal mimic of miR-34 (MRX34), entered a Phase I clinical trial for liver cancer. A key benefit of this therapy is the ability to simultaneously block multiple cancer processes which is important for the successful treatment of cancer that frequently originates from multiple mutations and thrives on multiple pathways. The ability to interfere with multiple cancer pathways is a new paradigm in cancer therapy that has the potential to create more effective cancer drugs. Because most cancer drugs are more effective in drug combinations, we propose here the preclinical and clinical development of one or more MRX34 combination therapies to maximize efficacy. The company's primary focus will be the MRX34+erlotinib (Tarceva[®]) combination in non-small cell lung cancer (NSCLC), the number one cause of cancer deaths in Texas. Preclinical data show strong synergy between the miR-34 therapy and erlotinib in erlotinib-resistant cancer cells. Because erlotinib alone, an FDA-approved drug to treat NSCLC, only benefits a limited fraction of patients, combining it with MRX34 is likely to maximize efficacy and broaden the base of patients that can be treated with this drug. Mirna will use Texas based resources and leverage relationships established with the ongoing clinical development of MRX34.

Proposed Milestones and Tranching: The total award approved by CPRIT is \$25,147,614. The grant funds would be distributed in three tranches, contingent upon successful achievement of the milestones set forth below.

Tranche 1: \$7,533,147 CPRIT (matched with \$3,766,574 of other funding) - one year

Mirna's primary goal in the first year will be to evaluate the MRX34+erlotinib combination and meet the following milestones:

- A. Demonstrate that the MRX34+erlotinib combination is more effective than the respective single agents in one or more well-established animal models of NSCLC.
- B. Demonstrate that the combination is safe at predicted therapeutic dose levels.

Alternatively, if the data from experimentation on the primary goal does not warrant advancing the MRX34+erlotinib combination to clinical development, or if a superior combination therapy is identified, then following milestones will pertain for the first year:

- A. Identify one or more novel, synergistic drug combinations with MRX34.
- B. Demonstrate superior activity of the MRX34+drug combination (in comparison to the respective single agents) in an animal model of cancer.
- C. Demonstrate that the combination is safe at predicted therapeutic dose levels.

Additionally, there shall be the milestones of:

1. Design and approval of the clinical study protocol.
2. Manufacturing of adequate drug supply.
3. Approval of the initiation of a Phase I trial by the FDA.
4. First Phase I patient enrolled.

Tranche 2: \$8,913,666 CPRIT (matched with \$4,456,833 of other funding) - one year

The goal of the second tranche will be to complete Phase I and initiate a Phase II clinical trial with the completion of the following milestones:

1. Determination of the recommended Phase II dose.
2. Determination of the eligibility criteria for Phase II patients.
3. Uninterrupted availability of drug supply.
4. Submission and approval of required regulatory documents.

Tranche 3: \$8,700,801 CPRIT (matched with \$4,350,401 of other funding) - one year

The goal of the final tranche will be to continue the Phase II clinical trial to completion with achievement of the following milestones:

1. Start of Phase II patient follow-up.
2. Analysis and top-line reporting of primary and secondary efficacy and safety data.

Proposed Revenue Sharing Terms: The revenue sharing terms in the contract shall read or be substantially equivalent to: (1) “For the purposes of the Contract, including this Attachment D, the RECIPIENT and INSTITUTE agree that the values of “A” and “B” in Section D4.01a above shall be 5.0 and 3.0, respectively, and that the value of “C” in Section D4.01b above shall be 1.6.” or (2) those terms being presently recommended to the Oversight Committee in the attached memorandum.

Remaining Diligence Provisions: Mirna has satisfactorily responded to all diligence concerns raised by the Product Development Review Council (PRDC) and due diligence process.

Recommendation: We recommend that the Oversight Committee delegate contract execution authority to the CEO of CPRIT for this grant, subject to the Company’s agreement to appropriate tranches and milestones and to CPRIT’s standard revenue sharing terms for a grant of this size to a company of this commercial maturity.



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

Nominations Subcommittee Meeting August 15, 2014

(CVs and Biosketches Attached)

Product Development Review Panel Members for Approval

- Nora Cabine - Advocate Reviewer
- Gail Eckhardt, M.D.
- Robert Figlin, M.D.
- Brenda Gavin – D.V.M., M.B.A.
- Stanton Gerson, M.D.
- Valerie Guild - Advocate Reviewer
- Mark Moasser, M.D.
- Meryl Weinreb - Advocate Reviewer

Scientific Research Review Panel Members for Approval

Basic Cancer Research-1 Panel

- David Houchens, Ph.D. – Advocate Reviewer
- Roxana Bellia, Ph.D. – Advocate Reviewer

Basic Cancer Research-2 Panel

- Margerie Manning, D.D.S. – Advocate Reviewer
- Sarah Wise Miller, M.B.A. – Advocate Reviewer

Cancer Biology Panel

- Ann Tonachel – Advocate Reviewer
- Carol Vallett, Ed.D. – Advocate Reviewer

Cancer Prevention Research Panel

- Michal-Judith Gillman – Advocate Reviewer
- Brian Booher – Advocate Reviewer

Clinical and Translational Cancer Research Panel

- Donna Niedzwiecki, Ph.D.
- Laura Porter, M.D. – Advocate Reviewer
- Robert Mesloh – Advocate Reviewer

Imaging Technology and Informatics Panel

- Ross Berbico, Ph.D.
- John Gore, Ph.D.
- Hossein Jadran, M.D., Ph.D., M.P.H., M.B.A.
- Stephanie Dunn Haney – Advocate Reviewer
- Jilda Nettleton, M.D., Ph.D. – Advocate Reviewer

Date: March 25, 2014

PERSONAL INFORMATION

NAME: Gerson, Stanton L., M.D.

Education

1973	A.B., Magna Cum Laude, Harvard College
1977	M.D., Cum Laude, Harvard Medical School
1977-80	Intern & Resident in Medicine, Hospital of the University of Pennsylvania
1980-83	Fellow in Hematology-Oncology, Hospital of the University of Pennsylvania

Contact Information

Office : Wearn Building Room 153
Case Western Reserve University
University Hospitals of Cleveland
11100 Euclid Avenue
Cleveland, Ohio 44106-5065
(216) 844-8562
FAX (216) 844-4975
Beeper: 33263
Email: slg5@po.cwru.edu

Home Address: 37995 Fairmount Blvd.,
Hunting Valley, Ohio 44022

PROFESSIONAL APPOINTMENTS

2004-present	Director, Case Comprehensive Cancer Center and Ireland Cancer Center now the Seidman Cancer Center
2003-present	Director, Center for Stem Cell and Regenerative Medicine
2003-present	Lecture Committee, Case Western Reserve University
1995-2004	Chief, Division of Hematology/Oncology Associate Director for Clinical Research NCI Designated Cancer Center at CWRU & University Hospitals of Cleveland

ACADEMIC APPOINTMENTS

2013-present	Distinguished University Professor, Case Western Reserve University
2005-present	Associate Dean for Oncology, Case Western Reserve University
2003-present	Lecture Committee, Case Western Reserve University
1997-present	Asa & Patricia Shiverick – Jane B. Shiverick (Tripp) Professor of Hematological Oncology
1985-present	Member, CWRU Cancer Research Center
1994-present	Professor of Medicine, Oncology & Environmental Health Sciences, CWRU
1991-1994	Associate Professor of Environmental Health Sciences, Case Western Reserve University (1991 with tenure)
1988-1991	Associate Professor of Medicine, Department of Medicine, Case Western Reserve University School of Medicine (1991 with tenure)
1983-88	Assistant Professor of Medicine and Oncology, Case Western Reserve University School of Medicine

CERTIFICATIOS AND LICENSURES

1983	Pennsylvania-MD 021822 Ohio-35049102
1980	American Board of Internal Medicine

1982	American Board of Internal Medicine, Hematology—076845
1983	American Board of Internal Medicine, Oncology—076845

HONORS AND AWARDS

1987	Edward Mallinckrodt Jr. Foundation Scholar
1997	Asa & Patricia Shiverick - Jane B. Shiverick (Tripp) Professor of Hematologic Oncology
2007	Mt Sinai Foundation, Cleveland, Maurice Salzman Award for Distinguished service with the Case Comprehensive Cancer Center
2008	American Cancer Society Heroes of Hope Award
2008	Honorary Alumnus of the Year Award, Medical Alumni Association, CWRU
2008-2013	Named one of Castle Connolly America's Top Doctors
2011	Dr. Rogers Prize in honor of Dr. Rogers from The Lotte & John Hecht Memorial Foundation in Canada. The Prize has been given to Dr. Gerson for his exceptional contributions in the field of Integrative Oncology. He gave the keynote address as the Dr. Rogers Prize Lecture at the 8 th International Conference of the Society for Integrative Oncology (11/10-12/11) titled "The Future of Integrative Oncology".
2012	Case Western Reserve Medal for Excellence in Health Science Innovation.
2013	CWRU Distinguished University Professor

MEMBERSHIPS IN PROFESSIONAL & SCIENTIFIC SOCIETIES

1977-78	International Grenfell Association
1979-84	Associate, American College of Physicians
1979-88	Society for Research in Primary Care
1990-93	Midwest Counselors
1984-present	American Federation of Clinical Research:
1985-present	American Society of Hematology
1987-present	American Association for Cancer Research
1988-present	Central Society for Clinical Research
1992-present	American Society for Clinical Oncology
1993-present	American Society for Clinical Investigation
1997-present	American Association of Physicians
1998-present	American Society of Gene Therapy
2002-present	International Society of Stem Cell Research

PROFESSIONAL SERVICES

Editorial Board:

- ◆ Stem Cells
- ◆ Stem Cells Translational Medicine
- ◆ Clinical Cancer Research
- ◆ Journal of Clinical Investigation

Manuscript And Abstract Reviews:

- ◆ Clinical Cancer Research, 1999- 2009
- ◆ Molecular Medicine, 1999-
- ◆ Blood, 2001- 2007, Editorial Board
- ◆ Stem Cells 2003-

Manuscript Reviewer:

Reviewer for the following journals:

- | | |
|---------------------------------|-----------------------------------|
| ◆ Annals of Internal Medicine | ◆ Carcinogenesis |
| ◆ Archives Internal Medicine | ◆ Experimental Therapeutics |
| ◆ Blood | ◆ International Journal of Cancer |
| ◆ British Journal of Cancer | ◆ JAMA |
| ◆ British Journal of Hematology | ◆ Journal of Biological Chemistry |

- | | |
|----------------------------------|-------------------------------------|
| ◆ Cancer Research | ◆ Journal of Clinical Investigation |
| ◆ Cancer Chemotherapy and | ◆ Journal of Clinical Oncology |
| ◆ Chemotherapeutics | ◆ Mutation Research |
| ◆ Cancer Communications | ◆ Oncology Research |
| ◆ Current Cancer Therapy Reviews | ◆ Nature |
| ◆ Oncogene | ◆ Nature Medicine |
| ◆ Cell Stem Cell | |
| ◆ Science | |
| ◆ Molecular Cancer Therapeutics | |

Reviewer of abstracts for national meetings of the following organizations:

- ◆ American Association for Cancer Research
- ◆ American Federation for Clinical Research
- ◆ American Society of Hematology
- ◆ American Society of Clinical Oncology
- ◆ American Society for Gene Therapy

Principal Investigator of active clinical trials

- | | |
|----------|--|
| CWRU2Y97 | Mutant MGMT Gene Transfer into Human Hematopoietic Progenitors To Protect Hematopoiesis During <i>O</i> ⁶ Benzylguanine and BCNU Therapy of Advanced Solid Tumors |
| CWRU1699 | A Phase II Trial of <i>O</i> ⁶ Benzylguanine and BCNU in Patients with Metastatic Melanoma |
| CWRU1A96 | Phase II Trial of <i>O</i> ⁶ Benzylguanine and BCNU in Patients with Multiple Myeloma |

COMMITTEE SERVICE

National

AACI

- | | |
|------------|--|
| 2006- 09 | Association of American Cancer Institutes Board of Directors |
| 2006, 2010 | Chair, Program Committee, National Meeting |

AACR

- | | |
|--------------|--|
| 1992-present | State Legislative Committee |
| 1997- 2000 | Program Committee, Gene Regulation Committee |
| 1999-present | Gene Therapy Committee |
| | Program Committee |
| | Abstract Review Committee |
| 2007-08 | Selection Committee for the Dorothy P. Landon-AACR Prize for Translational Cancer Research (Chairperson) |
| 2008-11 | Finance and Audit Committee |
| 2009-13 | Clinical and Translational Research Committee |
| 2009-14 | Continuing Medical Education Committee |
| 2009-12 | Science Policy and Legislative Affairs Committee |

ACS

- | | |
|--------------|--|
| 1993-present | Carcinogenesis & Nutrition Study Section |
| 1987-present | Cuyahoga Unit Pilot Grants |
| 1988-present | Chairman, Pilot Grant & Review Committee |
| | Medical Board Member |
| 2004-present | Member, Board of Trustees |

AHA, Cuyahoga

- | | |
|---------|----------------------------------|
| 1988-91 | Division Grants Review Committee |
|---------|----------------------------------|

ASH

- | | |
|---------|--|
| 1996-99 | American Society of Hematology, Subcommittee on Neoplasia, Chair |
|---------|--|

2000-present	Program Committee, Abstract Review Committee
2002-present	Publication Committee
2003-present	Scholar Review Committee
2006-09	Finance Committee
2011-present	Committee on Investment and Audit
<u>ASGT</u>	
2006-present	American Society of Gene Therapy
2008,9	Chair Program Committee annual meeting
<u>ECOG</u>	
1988-present	Eastern Cooperative Oncology Group (ECOG):
1990-present	Laboratory Committee
1994- 2005	Chair, Gene Therapy Committee
<u>FDA</u>	
2006-2011	Chair, Cellular, Tissue and Gene Therapies Advisory Committee (CTGTAG)
<u>ASCO</u>	
2000-2004	Program Committee, Abstract Review Committee
<u>NCI</u>	
1988-95	FDA Orphan Drugs (Oncology)
1990-present	Small Business Grants
1992-present	Gene Therapy Programs Review Committee
1993-present	Markers of Environmental Carcinogens Review Committee (RFA)
1995-2012	Special Review Committee (P30 Cancer Centers) Ad hoc
1996present	Clinical Research P01 Special Review Committee, Ad hoc
1994-99	Experimental Therapeutics II Study Section
1997-99	Chair of Experimental Therapeutics Study Section
2000	Ad Hoc Reviewer, Special Review Committee P30Grants, RO1Grants
2000	Manpower Review Committee Section G (K Series)
2003-2012	Parent Committee, Program Projects Grants Subcomm A
2005-present	Cancer Center Directors Working Group Steering Committee
2005-present	Early Detection Subcommittee
2007-2011	Cancer Centers Study Section, Chair 2010-2011
2011-present	Board of Scientific Counselors – Basic Science
2012-present	Board of Scientific Advisors
2012-present	Cancer Centers Working Group
2012- present	AIDS Malignancies Working Group
<u>NIEHS:</u>	
1993	Biomarkers Review Committee (RFA)
1994	Superfund Hazardous Substances (RFA)
2000	Directors Advisory Committee, Ad hoc
<u>National:</u>	
1987, 1988	VA Merit Grant Review Committee
1988	Bristol-Myers Drug Resistance
1991	NIMH Ad Hoc Special Review Committee
2005	NIDDK Board of Scientific Counselors Ad Hoc Committee
2009	Hematologic Malignancies Cancer Program Ad Hoc Committee at Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins
<u>International:</u>	
2004	CRUK Medical Oncology Unit Review, Weatherall Institute for Molecular Medicine, University of Oxford, London, UK
<u>Scientific Advisory Boards:</u>	
1994-1998	Ohio Edison Biotechnology, Athens, Ohio
1997	Novartis Lamisil Safety Board
1994-97	Osiris Therapeutics, Baltimore MD
1990-96	Sandoz (Novartis) Clozaril Board
1999	VIRxSYS Scientific Advisory Board
2000-08	Attenuon Scientific Advisory Board
2001	Stem Cell Transplant Program, U of Minnesota NCI Cancer Center

2001-06	Fox Chase NCI Comprehensive Cancer Center External Advisory Committee
2000 -08	Medical College of Virginia DNA Repair Therapeutics PPG
2002 -07	MD Anderson Gene Therapy PPG
2001 -14	Duke Cancer Center Stem Cell Transplant PPGs
2003 -09	Johns Hopkins Stem Cell Program
2005 -11	Sidney Kimmel Comprehensive Cancer Center External Advisory Board
2005 -present	Holden, Iowa Comprehensive Cancer Center External Advisory Board
2007 -present	Harvard Medical School Ad Hoc Search Review Committee
2008 -present	Herbert Irving Cancer Center ESAB Columbia University
2008 -present	University of Chicago Cancer Research Center External Advisory Committee
2009 -present	Lombardi Comprehensive Cancer Center Advisory Committee
2009-2014	University of Illinois External Advisory Board
2008, 2009	Moffitt Cancer Center Advisory Board
2008-present	Roswell Park Cancer Institute External Advisory Board
2010-present	Stanford Cancer Center External Scientific Advisory Board
2012-present	Medical College of Wisconsin Cancer Center External Scientific Advisory Board
2013- present	UT Southwestern Cancer Center
2012-present	Yale Smilow Cancer Center
2010-present	Tracon Pharmaceuticals
2014-present	Baylor College of Medicine Cancer Center
<u>OHIO:</u>	
2003	Governor's Council Third Frontier Technology
2006-present	Ohio Partners for Cancer Control Executive Board
<u>CWRU/UHC Service:</u>	
1985-93	Head, Programming Chair, Neoplastic Diseases Area of Concentration
1988-present	CWRU Medical School; Hematopoiesis
1987-95	Chairman, Infection Control Committee, Bone Marrow Transplant Service
1989-95	Internship Selection Committee, Department of Medicine
1990-present	House Staff Advisor, Department of Medicine
1991-94	Promotion & Tenure Committee, Department of Medicine
1991-present	Member, Environmental Health Sciences Training Program, CWRU
1992-present	Animal CWRU Users Committee, Case Western Reserve University
1992-present	Member, Pharmacology Training Program
1993-98	Co-Director, Gene Therapy Initiative, CWRU Cancer Center
1993-present	Member, Molecular Virology Training Program
1993-94	Member, Pharmacology Faculty Search Committee
1993-94	Member, Dermatology Chair Search Committee
1994-present	Member, CWRU Gene Therapy Steering Committee
1994-present	Member, Skin Disease Research Center Pilot Grant Committee
1994-97	Promotion & Tenure Committee, CWRU School of Medicine
1994-95	Member, Cancer Center Director Search Committee
1995-present	Biomedical Research Cleveland Member
1995	Member, Environmental Health Science Search Committee
1996	Member, Radiation Oncology Department Chair Search Committee
1996	Member Advisory Committee General Clinical Research Center
1998-present	Member, Microbiology & Molecular Biology, Chair, Search Committee
1998-present	Member, Pulmonary Medicine Chair, Search Committee
1999-present	Chair, Cancer Biology Curriculum Committee
1999-present	Director, Gene and Cell Therapy Facility, CWRU Cancer Center
2002-present	Biopark Advisory Committee
2003-present	Chair, Strategic Planning Committee (Interdisciplinary, Institutional, Chair) CWRU
2002	Member, Pathology Department Chair Search Committee
2003	Member, Hematology/Oncology Division Chief Search Committee
2004-present	Member, Research Committee, School of Medicine, CWRU
2004-present	Member, West Quad Scientific Program Planning Committee, CWRU

2008-present	Member, Pediatric Chair Search Committee
2007-present	Deans Extended Leadership Committee
2011-present	Deans Leadership Council
2012-present	Strategic Planning Committees
2004-present	Council of Chairs
2012-present	PWC working group for re-affiliation
<u>University Hospitals Case Medical Center</u>	
2003-present	Director, Ireland Cancer Center now Seidman Cancer Center
2004-present	Member, UHCMC Clinical Council
2005-present	Member, Chairs and Center Directors Committee
2008-present	Clinical Trials Task Force, UHMG
2006-present	CEO Ireland Cancer Center Advisory Group
2007-2011	Ireland Cancer Center Leadership Council
2011-present	Seidman Cancer Center Medical Leadership Council, Chair
2011-present	SCC Executive Quality Council
2012-present	Strategic Planning Committee
<u>Case Comprehensive Cancer Center:</u>	
1988-present	Executive Committee
1988-present	Program Leader Hematopoietic & Immune Cell Biology Program
1995-present	Program Leaders Committee
1995-2004	Associate Director, Clinical Research
1995-present	Senior Leadership Council
1997-present	CWRU General Clinical Research Center
	Executive Advisory Committee
2004-present	Director, Case Comprehensive Cancer Center

TEACHING ACTIVITIES

National & International Invited Lectures

05/16/87	Fourth Symposium on Advances in Neuroblastoma “ <i>In Vitro</i> Treatment of Bone Marrow” Philadelphia, Pennsylvania
06/06/89	Plenary Session Symposium: Atypical Neuroleptics and The Schizophrenic Patient “Agranulocytosis” Tufts University School of Medicine, Boston, MA
07/12/89	Invited Plenary “The Role of DNA Repair in the Carcinogenesis of N-nitroso Components” Environmental Mutagenesis Society International Conference, Cleveland, OH
09/18/89	Visiting Professor “Transgenic Mice Expressing Bacterial <i>O</i> ⁶ -alkylguanine-DNA Alkyltransferase” Frederick Cancer Research Center, Frederick, MD
02/09/90	Invited Lecturer “Clozapine-Associated Agranulocytosis” Plenary Session, French- American Clozaril Symposium, Robert Wood Johnson School of Medicine, East Hanover, NJ
03/15-16/90	Visiting Professor of Experimental Therapeutics “Drug Resistance in Colon Cancer” “Transgenic Mice Expressing Alkyltransferase Activity” Duke Cancer Center, Duke University School of Medicine, Durham, NC
04/17-18/90	International Clozapine Symposium “Clozapine-Induced Agranulocytosis” Cleveland, Ohio
07/11-18/90	Invited Lecturer “Overcoming Nitrosourea Resistance in Colon Cancer” Gordon Conference—Advances in Tumor Treatment, Plymouth, NH
08/28/90	Invited Lecturer “ <i>O</i> ⁶ -Methylguanine As A Sensitizing Agent for Nitrosoureas” National Institutes of Health, Division of Cancer Treatment, Bethesda, MD
10/9-11/90	Visiting Professor “Overcoming Nitrosourea Resistance” Department of Developmental Therapeutics, M.D. Anderson Cancer Center, Houston, TX
06/21-22/91	Visiting Professor “Mechanisms of Clozapine-Associated Agranulocytosis” Agranulocytosis Research Meeting, The Royal Free Hospital, London, England
06/25/91	Visiting Professor “The Role of Transgenic Expression of Alkyltransferase in Protection from Carcinogenesis” Patterson Cancer Research Foundation, University of Manchester, Manchester, England

07/09/91	Invited Plenary Lecturer “Repair of <i>O</i> ⁶ -Methylguanine DNA Adducts in the Liver and Kidney of Transgenic Mice Expressing the Bacterial <i>O</i> ⁶ -Alkylguanine DNA Alkyltransferase” International Congress of Radiation Research, Toronto, Ontario
12/20/91	Visiting Professor “Modulation of Nitrosourea Drug Resistance in Tumors” Department of Pharmacology, St. Jude Children’s Research Hospital, Memphis, TN
01/29/92	Invited Lecturer “Prospects for Gene Therapy in Cancer Patients” Eastern Cooperative Oncology Group Scientific Retreat, Phoenix, AZ
03/10/92	Visiting Professor “Mechanisms in Management of Clozapine-Induced Agranulocytosis” UCLA Harbor General Hospital, Department of Psychiatry and The Los Angeles County Mental Health Department, Los Angeles, CA
03/11/92	Visiting Professor “Transgenic Expression of Alkyltransferase” Department of Pathology and the Eppley Cancer Center, University of Omaha, Omaha, NE
04/17-20/93	Invited Plenary Lecturer “Protection from Thymic Lymphoma by the Transgenic Expression of Human <i>O</i> ⁶ -Alkylguanine-DNA-Alkyltransferase: Elucidation of the Role of DNA Repair in Carcinogenesis and Oncogene , Environmental Mutagenesis Society, Norfolk, VA
08/24-25/93	Visiting Professor “Transgenic Models of Carcinogen Protection” Indiana University Medical Center, Indianapolis, IN
10/19-20/93	Invited Speaker “Techniques and Applications of Gene Therapy for Cancer” Eastern Cooperative Oncology Group National Educational Symposium, Miami, Florida
11/12/93	Visiting Professor, “Protection from MNU Induced Lymphomas in Transgenic Mice” Sponsor: Dr. T. Ishikawa, Chairman of Pathology, Department of Pathology, University of Tokyo, Tokyo, Japan
11/15-16/93	Invited Speaker “The Role of <i>O</i> ⁶ -Benzylguanine in Overcoming Nitrosourea Resistance” Symposium: Current Progress on Drug Resistance Research, NCI-sponsored Japanese-American Scientific Symposium, Tokyo, Japan
12/10/93	Visiting Professor, Department of Carcinogenesis “Lessons Learned from Mice that Overexpress Alkyltransferase” American Health Institute, Valhalla, NY
02/07/94	Visiting Professor, Department of Molecular Biology “ <i>O</i> ⁶ -Alkylguanine-DNA-Alkyltransferase: A Drug Resistance Gene and A Protector from Carcinogenesis” Loyola University Medical Center, Chicago, IL
02/26/94	Visiting Lecturer “G-CSF and the Management of Clozapine-induced Agranulocytosis” Hillside Hospital/Long Island Jewish Medical Center, Glen Oaks, NY
03/02/94	Visiting Professor, Department of Hematology, “Transgenic Approaches to Carcinogenesis” Boston University School of Medicine, Boston, MA
04/09/94	Visiting Lecturer, Dept. of Psychiatry, Harvard Medical School “Clozapine: Hematologic Effects” McLean Hospital, Cambridge, MA
04/11/94	“DNA Repair Mediated Drug Resistance: The Paradigm of <i>O</i> ⁶ -Alkylguanine DNA Alkyltransferase” Symposium: Mechanisms and Circumvention of Drug Resistance American Association of Cancer Research, San Francisco, CA
05/15/94	Basic Science Symposium “Bringing Biochemical Modulation to the Clinic: Inhibition of <i>O</i> ⁶ -Alkylguanine DNA Alkyltransferase” American Society for Clinical Oncology, Dallas, TX
09/20/94	“Modulating Mutagenesis, Carcinogenesis & Drug Resistance with <i>O</i> ⁶ -Alkylguanine DNA Alkyltransferase” University of Pittsburgh, Department of Radiation Biology, Pittsburgh, PA
03/16/95	“Retroviral Gene Transfer of Drug Resistance” Columbia University Cancer Center
03/20/95	Invited Chair, AACR, Section of Molecular Biology/Transcription Regulation Toronto, Ontario
05/22/95	“Transgenic Models: A Tool for Translation to Clinical Application” NIEHS Advisory Council, Ken Olden, Director, NIH, Bethesda, MD.
10/17/95	“Developmental Therapeutics” Medical Grand Rounds
12/12-13/95	“Mesenchymal and Hematopoietic Gene Therapy” Department of Pediatric Oncology Johns Hopkins Cancer Center, Baltimore, MD
01/30-31/96	“Alkyltransferase Depletion Clinical Trials with Benzylguanine” Loyola University Cancer Center, Chicago, IL

02/12-14/96 “Gene Therapy of the Mesenchyme” Banbury Conference, Cold Spring Harbor Labs, Long Island, NY

06/12-14/96 “Gene therapy clinical trials: Developments and prospects” “Molecular diagnostics and therapeutics” Eastern Cooperative Oncology Group, Retreat on Laboratory Research and Clinical Trials, Boston, MA

06/21-22/96 “*O*⁶-benzylguanine in clinical trials and detection systems” Southwest Medical School, University of Texas, Dallas, TX

06/25/96 “Mesenchymal stem cell reconstitution during clinical transplantation” Johns Hopkins Medical Center, Baltimore, MD

10/3/96 “Use of MGMT Gene Therapy in Bone Marrow Transplantation” Am. Assoc. Cancer Research/Am. Soc. Bone Marrow Transplantation

10/25/96 “*O*⁶-alkylguanine DNA alkyltransferase as a Therapeutic Target” Division of Hematology/Oncology Retreat, Cleveland, OH San Diego, CA, National Meeting

11/5/96 “*O*⁶-benzylguanine to Sensitize Tumors in Clinical Trials” NCI Bethesda, Washington DC

11/6/96 “Temozolomide for the Treatment of Glioma, Melanoma and Colon Cancer” National Mount Sinai Conference “Innovative Chemotherapeutics”, NY

11/21/96 “Gene Therapy Approaches Using a Mutant MGMT” International Conference in Biotechnology, Dusseldorf, Germany

11/22/96 “Alkyltransferase as a Paradigm for DNA Repair Interventions” West German Cancer Center, Essen, Germany

11/25/96 “Transgenic Expression of MGMT in Carcinogenesis Studies” Netherlands Cancer Center, Amsterdam, Netherlands

11/6/96 “Overcoming Drug Resistance with Temozolomide in Gliomas and Melanomas” Chemotherapy Foundation, Symposium, Mt Sinai School of Medicine, New York City, NY

03/13/97 “Modulation of Alkylating Agent Resistance” Wadsworth Center, NY State Department of Health, Albany, NY

04/28/97 “Biochemical Modulation of Drug Resistance” Cancer Center, University of Illinois at Chicago, Chicago, IL

07/14/97 “*O*⁶-alkylguanine-alkyltransferase” Gordon Conference Chemotherapy of Experimental and Clinical Cancer
Colby-Sawyer College, New London, NY, July 13-18

10/07/97 “*O*⁶-benzylguanine Modulation of Drug Resistance” Duke University Medical Center, Raleigh, NC

10/21/97 “Drug Resistance Gene Transfer” Columbia University Hematology/Oncology Grand Rounds

10/31/97 “MGMT: A Novel Target for Drugs, Carcinogenesis, and Gene Therapy” NCI Extramural Advisory Board Committee, Rockville, MD

11/08/97 “Novel Chemotherapy Approaches to Melanoma” Perspectives in Melanoma, University of Pittsburgh

02/02/98 “DNA Repair-laboratory and translational approaches” University of Rochester Cancer Center, Rochester, NY

02/2-4/98 University of Indiana Department of Pediatrics

03/04-5/98 Gene Therapy Workshop NCI Experimental Therapeutics/Pathology B, Organization LaJolla, California

04/07/98 “Methylating Agent Potentiation of Lymphogenesis in PLUS-2 Knockout Mice and its Prevention by MTMT” NIEHS Transgenic Conference

06/02/98 “Selection of Stem Cells Using a DNA Repair Gene” Second Stem Cell Gene Transfer Conference, Seattle, WA

06/26/98 “Alkyltransferase Gene Therapy” Gene Technology For Malignant and Inherited Disease NATO Research Conference, Volga, Russia

01/21/99 “Educational Initiatives for Physicians in Environmental Health Sciences” Directives Retreat, NIEHS, Research Triangle Park

01/31-02/4/99 “Mouse Models of Cancer: DNA Repair Defects and Leukemogenesis” Invited Speaker at AACR Symposium, Keystone Conference, Colorado

03/10-11/99 “Educational Programs in Environmental Health Science” Invited Participant, Directives Retreat, NIEHS, Research Triangle Park

05/5-6/99 "MGMT Mutant Drug Resistance Gene Therapy" University of Chicago Retreat
NCI DNA Repair Meeting, Chicago

05/14-17/99 "Therapeutic Advances in Drug Resistance Gene Therapy" Chair, Educational Section,
Cancer Gene Therapy: Scientific Basis and Clinical Trials, ASCO, Atlanta
ASCO Review, McLaren Medical Center, Flint, Michigan

06/10/99 "Gene Therapy of Mesenchymal Tissues" Session Chair, American Society for Gene
Therapy/ECOG, Washington, DC/Baltimore

06/14/99 "Development of O⁶-Benzylguanine" NCI/CTEP, Bethesda

06/21-22/99 "O⁶-Benzylguanine, Phase I Trials" "Drug Resistance Gene Therapy"
University of Pittsburgh cancer Center Annual Retreat

09/09/99 "BG Clinical Trials" Harvard Medical School

10/11-12/99 "Mismatch Repair and Base Excision Repair as Chemotherapy Targets" NCDDG, Duke
Medical Center

11/15-18/00 "Stem Cell Therapeutics: Selection of Transduced cells" Stephen H Robinson MD
Lecturer, Division of Hematology/Oncology, Novel Mechanism Based Therapeutics
Medical Grand Rounds, Beth Israel Deaconess Hospital, Boston MA
Mt. Sinai Hospital, NY, NY

02/10/01 "Targeting DNA Repair for Therapeutics" Dept of Pharmacology and Cancer Center
University of Chicago

3/6/01 "Selective Pressure on Stem Cell Survival using Mutant MGMT Gene Transfer"
Dept of Experimental Pharmacology, Memorial Sloane Kettering Cancer Institute NY, NY

3/9/01 "Selective Stem Cell Survival in Preclinical Settings using Targeted DNA Repair"
University South Florida Cancer Center, Tampa, FL

5/01 Chair, ASCO Educational Session, Status and Future of Cancer Gene Therapy,
Chair, Young Investigators meeting, How to write a grant, ASCO meeting May 2001, San
Francisco

6/2-3/01 Therapeutic leads in DNA Repair, Keynote Speaker 3rd Annual DNA Repair Meeting
Indiana University Medical School, Indianapolis, IN

6/9/01 Gene Therapy Committee Chair, ECOG meeting, Pittsburgh, PA

7/14-19/01 Gordon Conference, Section Chair: DNA damage and repair: new opportunities
Colby College, NH

9/5/01 MD Anderson Cancer Center, Departmental of Experimental Therapeutics
"Repair of single base damage: therapeutic targets and clinical trials" Houston, TX

10/29-11/2/01 EORTC Meeting, Chair: Viral vector based therapeutic approaches
Talk: "Repopulating stem cells carrying chemotherapy resistance inducing genes"
Miami, FL

11/10/01 SBT Annual Meeting, NIH "Transplantation of stem cells: homing and selection with drug
resistance genes" NIH, Baltimore, MD

11/10/01 Chair: Gene Therapy of Cancer session, Drug Resistance gene transfer
Society of Biologic Response Modifiers, NIH

12/7-9/01 ASH Annual Meeting, Session: Hematopoiesis, Orlando, FL

1/17/02 Clinical development of BG, Investigators meeting. Access Oncology Forum, New York, NY

2/19/02 Targeting DNA damage response for drug development, Univ. North Carolina Cancer
Center Grand Rounds. Chapel Hill, NC

2/28/02 Development of Gleevec: a novel tyrosine kinase inhibitor for bcr-abl. Harvard Medical
School, Boston, MA
University South Florida Cancer Center Tampa, FL

3/21/02 Mutant MGMT for drug resistant stem cell gene transfer, Chair, drug resistance stem cell
gene therapy, Society for Stem Cell Gene therapy, Bethesda, MD

4/21/02 Plenary Speaker, MGMT as a drug selection genes, Southern Ohio Stem Cell Meeting,
Toronto, Ontario, Canada

4/26/02 Inhibition of AGT as a paradigm of targeted therapeutics, Harvard Medical School,
Boston, MA

5/18/02 ASCO meeting in May 2002, How to write a grant, Orlando, FL

6/8/02 Harvard Medical School 25th reunion Medical Symposium: "Novel advances in
therapeutics" , Harvard Medical School, Boston, Mass.

9/26-28/02 Mesenchymal and other nonhematopoietic stem cells and Annual conference, “Training stem cells to home to hematopoietic and nonhematopoietic organs using drug selection” St. Jude Cancer Center and Tulane Univ., New Orleans, LA

10/02/02 Using MGMT to select stem cells in hematopoietic and non-hematopoietic organs NCI Hematology Branch

10/11/02 Molecular Targets for Cancer Therapy: Second Biennial Meeting, Chair, Since Stem Cells Engraft, Will Drug Resistance Gene Transfer Help? St. Petersburg Beach, FL

10/13-15/02 Conference Organizer and Discussant, Section on “Novel Therapeutic Targets” and presentation: “Base Excision Repair a new cancer therapeutic Target” Molecular Therapeutics Conference, Univ. South Florida, Tampa, Florida

10/30/02 Department of Pathology Grand Rounds “Drug selection of stem cells *in vivo*: limits and opportunities” Univ. Washington, Seattle, Wash.

11/15/02 Univ. California at Davis, National Primate Center, Conference on Stem Cells and Gene Transfer “Selecting stem cells in large animals: Hematopoietic and mesenchymal cell therapy.”

2/15-16/03 University of Miami Leukemia Society Novel research in Leukemias, “Gene Therapy of Stem Cells”, Miami, FL

4/27-29/03 New Jersey Cancer Center, NJ Governor’s Scientific Advisory Retreat. “Training physician scientists in cancer”.

6/16/03 FDA Advisory Meeting “Clozaril white blood count monitoring”, Bethesda, Md

7/4/03 European Gene Therapy Society, Paris, France. “Stem cell selection using drug resistance”

7/13/03 AACR, Vion Pharmaceuticals Scientific Advisory Board. “Inhibition of AGT by VION 101M, Washington DC

7/27-31/03 Joint AACR/ASCO Methods in Clinical Research Workshop, Vail, Co. “Pharmacology development and monitoring of new drugs”

8/12/03 FDA Advisory Meeting, Bethesda, MD. “Neutropenia in children treated with modafinil”

9/12/03 U California, Davis, Primate Center/Dept of Pathology. “Stem Cell Selection and Solid Organ Transdifferentiation”

12/10/03 American Society of Hematology. Stem cell clonal intertions with gene therapy, San Diego, Ca.
“Clonal detection using quantitative PCR vs. LAM-PCR”

02/06/04 Memorial Sloan Kettering, New York, NY “Gene Therapy of Cancer”

09/22/04 The Cancer Institute of New Jersey, New Brunswick, NJ “Selecting Stem Cells as Cancer Therapy”.

10/19/04 Manchester, UK “In Vivo Stem Cell Selection with Mutant MGMT”

11/15/04 The Children’s Hospital of Philadelphia, PA “Stem Cell Selection by Chemotherapy Drug Resistance: Effective, But is it Safe?”

08/09/05 Manchester, UK “Clinical results with mutant MGMT: gene transfer modeling and application”.

10/25/05 Yale Cancer Center Grand Rounds, Hartford, CT “Drug resistance gene transfer: a potent approach to stem cell selection”.

9/16-20/06 Environmental Mutagen Society Annual Meeting, Vancouver, British Columbia Canada. “DNA Repair in Hematopoietic Stem Cells”.

11/7-10/06 18th EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics Prague, Czech Republic. “DNA Repair Modulators in Clinical Trials”.

11/14/06 Ludwig Boltzmann Insitute for Cancer Rsearch, Vienna, Austria. “DNA Repair in Defective Mice and their Cancer Prone and Stem Cell Failure Phenotype”.

11/15-17/06 Ernst Schering Foundation, Berlin, Germany-Cancer Stem Cells: Novel Concepts and Prospects for Tumor Therapy. “DNA Repair Defects in Stem Cells and Aging Tissues”.

6/13-17/07 MGMT and Alkylating Drug Resistance, Mainz, Germany “Overcoming Methylation Resistance: Developing Methoxyamine to Block Base Excision Repair”.

6/21-22/07 UPCI Retreat, Pittsburg, PA “The Aging Stem Cell”.

9/13-17/07 IVth Conference on Stem Cell Gene Therapy, Greece. “DNA Repair: an Essential Role in Stem Cell Maintenance”.

10/11/07	Ajou University School of Medicine, Seoul, Korea. "Targeting Base Excision Repair for Anti Cancer Therapy".
10/12/07	5 th Sino-US Symposium, Medicine in the 21 st Century, Shanghai International Convention Center, China. "DNA Repair as a Target for Chemotherapy".
10/14/07	Shanghai Insitute of Biochemistry and Cell Biology, China. "Stem Cells, DNA Repair and Aging".
05/28/08	Yale University, New Haven, CT. "Targeting DNA Repair from Discovery to Therapeutics".
05/29/08	ASGT 11 th Annual Meeting, Boston, Massachusettes. "Lentiviral Vectors for Stem Cell Therapy Glioblasoma".
09/2-5/08	DNA Repair 2008 Berlin – 10 th Biennual Meeting of the DGDR. "Stem Cell Aging: the Role of DNA Repair".
02/04/09	Roswell Park Cancer Institute Director's Conference, Buffalo, NY. "Base Excision Repair: A Target for Cancer Therapeutic Combinations".
02/06/09	Hollings Cancer Center 5 th Annual Hematologic Malignancies Symposium, Charleston, South Carolina. "Aging, DNA Damage and the Evolution and Treatment of Hematologic Malignancies".
03/05/09	TR3 2009 Meeting, Philadelphia, PA. "Selecting Stem Cells Using the MGMT Drug Resistance gene: Applications in Cancer and HIV".
03/06/09	Lombardi Comprehensive Cancer Center Grand Rounds, Washington DC. "Targeting DNA Repair for Cancer Therapy".
11/7/09-11/14/09	40 th Annual Interanational Symposium of the Princess Takamatsu Cancer Research Fund, Tokyo, Japan. "Decline in Stem Cell DNA Repair during Aging".
03/05/10	Harold Simmons Cancer Center Grand Rounds at UT Southwestern Medical Center at Dallas, TX. "Targeting Base Excision Repair in Cancer Therapy".
11/11/10	Dartmouth Hitchcock Norris Cotton Cancer Center Grand Rounds, Lebanon, New Hamshire. "Targeting DNA Repair for Cancer Therapeutics".
11/10/11-11/12/11	8 th International Conference of the Society for Integrative Oncology, Cleveland, Ohio. "The Future of Integrative Oncology".
11/16/11-11/18/11	10 th Annual Gene Therapy Symposium for Heart, Lung, and Blood Diseases: Cell Trafficking and the Niche. Univ. California at Davis, National Primate Center. "Mini-Workshon: <i>In vivo</i> Imaging".
01/19-20/12	Grand Rounds "Stem Cell Defects in DNA Repair" Fred Hutchinson Cancer Research Center, Seattle, Washington.

Regional & Local Invited Lectures

10/28/88	Invited Lecturer "DNA Repair and Its Role in Drug Resistance", Ohio American College of Physicians, Cleveland, OH
04/13/90	Visiting Professor of Experimental Radiation Biology, "DNA Repair in Transgenic Mice Expressing Bacterial Alkyltransferase", Ohio State College of Medicine, Department of Radiation Biology, Columbus, OH
07/14/94	"Transgenic Approaches to Carcinogenesis and Its Prevention", Medical College of Ohio, Department of Pathology, Toledo, OH
09/11-12/94	"Mechanism Based Modulation of Tumor Drug Resistance"
06/01/95	"Gene Therapy", Medical Grand Rounds, MetroHealth Medical Center, Cleveland, OH
05/27/97	"Protecting Bone Marrow by Drug Gene Therapy" Department of Cancer Biology, Cleveland Clinic Foundation, Cleveland, OH
09/25/97	"Chemotherapeutic Pathways of Cell Death" Case Western Reserve University, Ireland Cancer Center Retreat, Cleveland, OH
10/01/97	"Retroviral Mediated Gene Transfer into Stem Cells" Molecular Biology Seminar, Case Western Reserve University, Cleveland, OH
11/07/97	"Modulating DNA Repair: Molecular and Clinical Approaches" Molecular Medicine Seminar, Case Western Reserve University, Cleveland, OH
12/18/97	"Protecting the Stem Cell from DNA Damage" Asa Shiverick Chair Lecture, Case Western Reserve University, Cleveland, OH
07/27/98	"Gene Therapy in Cancer Hematology" Medical Grand Rounds, Department of Medicine, Meridia/Huron Hospital, Cleveland, OH

10/23/98 “Developmental and Experimental Therapeutics Retreat”
Chair, Division of Hematology/Oncology and Ireland Cancer Center
Case Western Reserve University, Squire Valeevue Farm, Cleveland, OH

02/15/99 “Transgenic Mouse Models of Defective DNA Repair” Department of Genetics and
Center for Human Genetics Lecture, Case Western Reserve University, Cleveland, OH

10/26/99 “Base Excision Repair”
Department of Pharmacology, Case Western Reserve University, Cleveland, OH

11/04/99 “Stem Cell Biology and Transplantation”
Division of General Internal Medicine, Frontier Lecture, Case Western Reserve
University, Cleveland, OH

11/19-20/99 Chair, Gene Therapy Committee, ECOG, St. Petersburg Beach, Florida

12/02-06/99 “Leukemogenesis Due to DNA Repair Defects”, Chair, Neoplasia Subcommittee, ASH,
New Orleans

12/12-13/99 AACR Program Committee, Philadelphia

01/05-07/00 “Developmental Therapeutics”, NCI Colon Cancer Consortium, San Francisco

10/04-6/00 Johns Hopkins Cancer Center: Reviewer site visit

10/12/00 “Protection and Selection of Stem Cell after Stem Cell Transplantation:
Drug Resistance Gene Transfer”, Department of Hematology

10/25-27/00 Mismatch Repair Defects in Hematopoiesis, Fanconi Anemia Foundation, Amsterdam
Netherlands

10/30-31/00 “Viral Based Therapeutic Applications” Chair of session and presenter
Molecular Targets and Cancer Therapeutics, AACR-EORTC International Conference
Miami FL

3/02/01 “Cancer Therapeutics: the Mechanism based Paradigm” Medical Grand Rounds, Ohio
State University Cancer Center

7/10/01 “Mechanism based therapeutics in cancer”, Medical Grand Rounds, University Hospitals of
Cleveland, Department of Medicine

8/10/01 Scientific Advisory Board Meeting, Edison Biotechnology, Columbus, OH

9/18/01 Novel Therapeutics and the future of Cancer, Department of Medicine, Case Western
Reserve University, Cleveland, OH

9/21/01 Cancer Genetics and Gene Therapy Meeting, Comprehensive Cancer Center of CWRU/UH
“The present and future of gene therapy” Cleveland, OH

10/16/01 Targeting DNA damage response for drug development. Dept of Pharmacology Lecture,
Case Western Reserve University, Cleveland, OH

10/19/01 Femur fragment transplantation: a new model for determining the normal biology of bone
marrow mesenchymal stem cells, Comprehensive Cancer Center Retreat, Toledo OH

4/18/02 Developing a Drug: Discovery, mechanism, preclinical models and clinical trials
Cancer Center Training Programs, Case Western Reserve University, Cleveland, OH

5/18/02 Developing a Drug: Discovery, mechanism, preclinical models and clinical trials
Cancer Center Training Programs, Case Western Reserve University, Cleveland, OH

5/29/02 Hematopoietic Stem Cells for Tissue Engineering
Stem Cell Engineering Course, Dept of Biology, CWRU, Cleveland, OH

5/31/02 Targeting base excision repair: imaging during preclinical development
Cancer Center Imaging Program, Case Western Reserve University, Cleveland, OH

9/18-20/02 Stem Cell Transplantation and Gene Therapy in Dogs , 2nd Annual Canine Cancer
Conference, Aurora, OH

5/27/03 International Cellular Engineering, Cleveland OH “Stem Cell Gene Therapy”
Cleveland OH. Stem Cell research – the new technology in cell therapy” Bioenterprise
Conference

10/23/03 State of Ohio Biotechnology Conference, Columbus, OH. :Center for Stem Cell and
Regenerative Medicine”

04/06/04 University Hospitals of Cleveland, Medical Grand Rounds “Stem Cells as Regenerative
Medicine” Department of Medicine, University Hospitals of Cleveland, Cleveland, OH

05/04/04 The Cleveland Clinic Foundation, Cleveland, OH “DNA Repair in Stem Cell
Maintenance”.

10/13/04 Case Western Reserve University- Mini Medical School: “Stem Cells: The Future of
Medicine”.

11/08/04 The City Club Youth Forum, Cleveland, OH “The Power of Stem Cells – Now and for the Future”

11/12/04 The Taussig Cancer Center Research Grand Rounds, Cleveland, OH. “Cancer Drug Discovery: DNA Repair as Target”.

04/21/05 The Cleveland Clinic Foundation Medical Grand Rounds, Cleveland, OH. “Stem Cells as Therapy: The National Center for Regenerative Medicine”

10/14/05 Case School of Medicine Alumni CME Event, Cleveland, OH. “The Science of Regenerative Medicine”.

04/20/06 Case Student Turning Point Society’s Exchanging Horizons Event, Keynote Speaker, Cleveland, Ohio.

09/28/06 An Evening of Science and Discovery, Keynote Speaker, Cleveland, Ohio.

11/27/06 In Town Club, Cleveland, Ohio “Stem Cell Therapy and Discovery”

05/14/07 The Franklin Club, Cleveland, Ohio “Stem Cells: Our Medical Future”.

11/06/07 Harvard Club of Cleveland, Cleveland, Ohio “Adult Stem Cells as Medicine Today; Bringing Embryonic Stem Cells to Medicine Tomorrow”.

12/14/07 Barrett Cancer Center, University of Cincinnati “Targeting DNA Repair for Cancer Therapy”.

05/01/08 University Hospitals Case Medical Center Rheumatology Grand Rounds, Cleveland, Ohio “Stem Cells: Origins, Biology, and Clinical Use”.

05/22/08 CTTE “Cell-Based Therapy and Tissue Engineering”, Cleveland, Ohio

07/15/08 Regenerative Medicine and Entrepreneurism/Intrapreneurism Executive Education Course, “FDA: Cell Therapy and Regenerative Medicine from Inside the Panel”, Cleveland, Ohio

09/26/08 Nano Meeting “Emerging Cancer Research”, Case Western Reserve University and University Hospitals, Cleveland, Ohio.

04/02/09 Senior Scholars Talk at the College Club, Cleveland, Ohio.

06/17-18/09 Harvard-Case Summer Course, Boston, MA

07/02/09 Talk to Trainees and Fellows

07/13-16/09 2nd Annual Business Executive Education Course “FDA: Cell-Therapy and Regenerative Medicine form Inside the Panel”, Cleveland, Ohio

07/17/09 Southwest General Health Center Grand Rounds, Cleveland, Ohio. “Update on Stem Cell Research”.

07/23/09 GCIC Seminar Series (Distinguished Panel Member), “Regulation of Biologics”, Cleveland, Ohio.

8/26/09 CWRU Hematology Course “Stem Cell Transplantation: Biology Behind the Experimental Success”, Cleveland, Ohio.

04/15/10 Guest Speaker at Cum Laude Ceremony at Hathaway Brown High School, Cleveland, Ohio.

07/15/10 The Business of Regenerative Medicine from Stem Cells to the Market Place, CWRU Adelbert Hall “FDA Cell-Therapy and Regenerative Medicine from Inside the Panel”, Cleveland, Ohio.

09/17/10 OSU Center for Regenerative Medicine and Cell-Based Therapies, Keynote Speaker on behalf of the NCRM – CSRM, Mohican State Park, Ohio.

09/25/10 Stem Cell Theory in Cancer: Current Understandings & Future Implications, Aultman Cancer Center, Akron, Ohio.

10/18/10 The 2010 NanoMedicine Summit, The InterContinental Hotel & Bank of America Conference Center, Cleveland, Ohio.

10/21/10 Cleveland Medical Mart Symposium, “Clinical Research and Delivery of Oncology Services, The Club, Marriott Key Center, Cleveland, Ohio

11/10/10 Molecular Genetics Cancer Course, “Hematopoietic Tumor Stem Cells”, CWRU, Cleveland, Ohio.

02/17/11 Is Cancer Curable? Executive Caterers Corporate Club at Landerhaven, Cleveland, Ohio.

03/16/11 Division of Hematology and Oncology Grand Rounds, “Stem Cells, DNA Repair and Aging”, University Hospitals Case Medical Center, Cleveland, Ohio.

07/11-14/11 Entrepreneurial Executive Educational Course in Regenerative Medicine. “FDA: Cell-Therapy and Regenerative Medicine from Inside the Panel”, Case Western Reserve University, Cleveland, Ohio.

12/06/11	Guest speaker for Hawken High School course “Our Witches, Our Cyborgs and Ourselves”. Howken School’s Gries Center in University Circle, Cleveland, Ohio.
05/22/12	Cell-Based Therapies and Tissue Engineering Course. “Stem Cells, DNA Repair and Longevity” Case Western Reserve University, Cleveland, Ohio.
07/16-19/12	Entrepreneurial Executive Educational Course in Regenerative Medicine. “FDA: Cell-Therapy and Regenerative Medicine from Inside the Panel”, Case Western Reserve University, Cleveland, Ohio.
05/21/13	Cell-Based Therapies and Tissue Engineering Course. “Stem Cells, DNA Repair and Longevity” Case Western Reserve University, Cleveland, Ohio.
04/02/14	International Society for Applied Cardiovascular Biology (ISACB) 14 th Biennial Satellite Meeting Program on Stem Cells for Disease Modeling and Regenerative Therapeutics. Speaker “When cells are safe: Validating potency and efficacy”, Cleveland, Ohio.
04/18/14	Keynote Speaker for Research ShowCASE, Veale Center, Case Western Reserve University, Cleveland, Ohio.

Trainees/Mentees

Student Name	Predoc/ Postdoc	Training Period	Degree	Year Awarded	Institution Degree Awarded	Title of Research Project	Current Position/Source of Support
Trey, J.	Postdoc H/O Fellow	1984-86	MD	1981	CWRU	Tumor Drug Resistance	Asst. Professor CWRU Hene Onc, METROHEALTH
Lim, I.K.	Postdoc	1987-88	MD/ PhD	1980	CWRU		Professor of Biochemistry – Ajou U. E Seoul, S. Korea
Benjamin, E.	Predoc	1987-88	MD	1988	CWRU	ACS Student Fellowship Award 1988	Instructor, Yale School of Medicine
Clapp, D.W.	Postdoc H/O Fellow	1987-90	MD		CWRU		Professor of Pediatrics, Indiana University
Warman, B.	Predoc	1987-90	MS	1990	CWRU	Retroviral Transfer	Researcher, Univ Argentina
Dumenco, L.	Postdoc	1988-92	MD	1986	Univ. of Wisconsin	Gene Therapy	Assoc Professor of Pathology; Brown University
Cowen, D.	Postdoc	1988-91	MD/Ph D	1994	CWRU	Myeloid Signaling	practice, Pulmonary Medicine
Dexter, B.	Predoc	1988-90	MD	1990	CWRU		Surgeon, Univ. of Iowa SOM
Minnick, D.	Predoc	1989-92				BCNU Mutagenesis	Senior Staff Scientist, NIEHS
Abboud, S.	Postdoc	1990-92	MD	1984	CWRU	TNF Effects on Hematopoiesis	Professor of Pathology University of Texas at San Antonio
Silvers, K.	Predoc	1991-93					Lost to followup
Brunschwig, E.	Predo	1991-96	BS	1991	Ohio State Univ.	Tumor Oncogeneity	Instructor

Zaidi, N.	Postdoc	1991-95	MD/Ph D	1991	Univ. of Manchester	Nitrosamine Carcinogenesis	Asst Prof of Pathology, Univ. of Kansas
Acre, C.	Predoc	1991-92	MD	1994	Med. College of Toledo		Asst. Professor, Peds, Loyola University, Chicago
Wolfman, J.	Postdoc	1991-92	PhD	1990	Univ. Rochester		Res. Associate CWRU
Allay, J.	Predoc	1991-96	BS	1990		Retroviral Gene Therapy	Senior Scientist, St Judes
Koc, O.	Postdoc H/O fellow	1992-9	MD	1989	Univ. of Istanbul	Gene Therapy	Assoc. Professor, Heme Onc, , CWRU
Ismail, M.	Predoc	2002-05	BS/MD		CASE	Retroviral Gene Therapy	
Phillips, W.	Predoc	1993-97	MS	1992	Univ. of North Carolina	Drug Resistance	Patent Lawyer, Denver
Liu, L.	Postdoc	1993-97	MD/Ph D	1991	Laval Univ.	Alkyltransferase Drug Resistance	Asst Prof of Heme Onc, CWRU
Cox, M.	Predoc	1993-95	MD	1996	CWRU		Medical Practice
Davis, B.	Predoc	1995-99	BS	1993	Binghamto n	Gene Therapy	Assoc Scientist, Wadsworth Res Inst Albany NY
Walker, S.	Predoc	1994-96	BS	1993	Cornell Univ. NY	Protein Kinase	Practice
Lee, K.	Postdoc	1995-98	PhD	1995	UC Davis	Transgenic Alkyltransferase	Staff Scientist, Biotech Company
Johnson, A.	Predoc	1996-99	BA	1995	Duke Univ.	Tumor Immunogenicity	CWRU, School of Medicine
Qin, X.	Postdoc	1996-99	MD/Ph D	1996	Univ. of Tokyo	Transgenic Mismatch Repair	Fellow in Heme Onc, Univ. of Maryland
Srinivasan, S.	Postdoc, H/O Fellow	1996-98	MD	1988	Stanley Medical College	Drug Resistance	Practice
Taverna, P.	Postdoc	1997-01	PhD	1994	“Mario Negri” Institute of Pharmacol ogical	Base Excision Repair	Chiron Corporation Cancer Pharmacology Dept.
Friebert, S.	Postdoc H/O fellow	1997-98	MD	1995	CWRU	Gene Therapy	Director of Ped. Palliative Care, Akron Children’s Hospital
Roth, Justin	Predoc	1998-07	BS	1997	Univ. of Missouri	Viral Envelope Mutagenesis	Post Doc, U Alabama
Ballas, Chris	Postdoc	1998-02	BA	1999	Vanderbilt	Stromal Cell Transplantation	Senior Scientist, Natl Gene Vector Lab, Indiana Univ
Spiro, T.	Postdoc	1998-00	MD	1984		BG/BCNU	Head, Molls Cancer Center, Cleveland
Zielski, Steven	Predoc	1999-03	BA,	1991	Gustavus	Lentiviral Gene	Instructor, Dept of Molec

			PhD		Adolphus College	Transfer	Biol, U. Michican
Wadhwa, P.	Postdoc	1999-01	MD	1992	BJ Medical College of Indiana	Retroviral Gene Transfer of phox91	Practice
Jaroscak, J.	Postdoc	1999-04	MD	1994	Ohio State Univ.	Placenta Stroma to Support Cord Blood	Asst Prof Univ N Carolina, Peds Heme Onc
Vollweiler, J.	H/O Fellow	2001-03	MD	1996	Northwestern Univ.	Stem Cell Transplantation	Instructor, CWRU, Southwest Hosp
Li, Yan	Predoc	2001-02	BS	1996	Univ. Istanbul	Neural stem cell gene transfer	MS, CWRU
Maisel, Christopher	H/O Fellow	2002-03	MD	1999	Univ. Pittsburgh	Myeloma	Asst Prof, Heme Onc, U. Baylor
Payne, Jennifer	H/O Fellow	2000-03	MD	1997	Univ. Pittsburgh	Hematologic malignancies	Instructor, Heme Onc NEOUCOM
Lin, Yuan	Predoc	2003-10	BS			Stem cell homing	Hematology Training Grant/CWRU
Park, Youngji	Postdoc	2002-06	PhD	2002		Stem cell DNA repair defects	Retired
Ozedmir, Aylin	Predoc	2003	BS	2001		Base excision repair	Res assoc, CWRU
Sweeney, Colin	Postdoc	2003-09	PhD	2003	Univ Minnesota	Stem cell gene transfer and insertional mutagenesis	NRSA; Hematology Training Grant/CWRU
Verees, Meg	Neurosurg Resident/Post Doc	2002-04	MD	1998		Glioma drug resistance	Asst Prof of Neurosurgery, MetroHealth
Kenyon, Jonathan	Predoc	2004-12	BS	2000	Michigan State U	DNA repair process	Aging and Training Grant
Qing, Yulan	Post Doc	2005-	PhD	2005	CWRU, Genetics	Stem Cell survival	
Yan, Yan	Predoc	2011-	BS	2009	Bejing U	Drug development	
Amar Desai	Predoc	2009-	BS	2007	Kenyon College	DNA repair and stem cells	T32, Molecular Pharm
Weeks, Lachelle	Predoc	2009-	BS	2007	Wellsley College	Drug development	F31
Fung, Hua	Post cos	2011-	PhD			Gene therapy	R42
Condie, Allison	Pre doc, Chemistry	2012-	BA	2010		Drug imaging	

RESEARCH SUPPORT

GRANT FUNDING

Active [PI unless noted]:

1991-2018	Case Comprehensive Cancer Center Support Grant (NCI) Gerson (PI) renewal score - 2012 - 20 5P30 CA043703-24 \$3.3M/DC/year \$5.1M/year Total Award: \$25.5M
1997-2018	Clinical Oncology Research Career Development Program 2K12 CA076917-11, PI \$668,751 renewal score -19 -2013
2008-2013	MGMT Methylation in Metastatic Cancers: Implications for Use of Alkylating Agent as Chemotherapeutic Agents STUDY P05037 Shering-Plough Inc \$314,369/year DC \$408,440/year
2003-2016	Center for Stem Cell & Regenerative Medicine (PARENT) TECH 06-063 BRCP, OhioALIVE PI Ohio General State Agency \$2,666,667/3 year DC \$2,666,667/3 year
2008-2014	Armed Forces Institute of Regenerative Medicine [AFIRM] Clinical Trials Core Facility, PI of Core \$274,000 DC
2010-2014	Lentiviral MGMT gene transfer into hematopoietic cells NCI 5R42 CA128269; PI of academic site, with Lentigen. 2,700,000 TC
2013-2017	NASA Heavy Ion Bombardment of Hematopoietic Stem Cells NNJ13ZSA001N ; NASA PI, 246,000 DC/y

Pending

2014-	R01- CA HSC Quiescence and Hematopoiesis SL Gerson PI PI, 4250,000 DC/y
-------	--

Past:

2005-2008	Clinical Lab Services Agreement Vion Pharm Inc \$ 38,462/year DC \$ 50,000/year
2005-2008	OES Stem Cell 04-06 Reinberger Foundation \$166,666/year DC \$166,666/year
2005-2009	Clinical Lab Services Agreement Vion Pharm Inc \$ 38,462/year DC \$ 50,000/year
2005-2009	OES Stem Cell 04-06 Reinberger Foundation \$166,666/year DC \$166,666/year
2006-2009	Multicenter Trial of O6BG and Topical BCNU for CTCLT PI Cooper 5R21 CA115057-02 \$185,947
2006-2010	National Center for Regenerative Medicine Capital Equipment DE-FG02-06CH11452 \$288,600/year DC \$288,600/year
2004-2009	Declining DNA Repair in Aging Hematopoietic Stem Cell 5R01 AG024916-05 \$199,783/year
2000-2010	Modulating Base Excision Repair in Tumor Drug Resistance 5R01 CA86357-08 (PI) \$138,398/year DC \$261,129/year IDC
2007-2009	Methoxyamine and Temozolomide: a Phase I trial PI Gerson R21 CA126149-02 \$193,607/year. DC \$298,114/year
2007-2011	Northeast Ohio Center for Cardiovascular Cell Therapy Research PI Ellis 5U1HL087314-02 \$299,802
2006-2007	Retroviral Insertional Mutagenesis in LM01 Stem Cells NIH (PI) NRSA to Colin Sweeney, Post Doc Trainee \$47,286/year DC
1998-2006	Hematology Training Grant PI Gerson \$318972/year DC \$21.064/year IDC PI transferred to Dr. Keith McCrae, 2006

	Total \$327,177		
1996-2007	Gene Transfer into Hematopoietic Progenitors (NCI)		
	5R01 CA73062-08 (PI)	\$200,250/year	\$96,699/year IDC
	\$1,001,250 total DC	\$483,495 total IDC	
2003-2006	SPECT imaging for in vivo Tracking of NIS Containing Stem Cells (DOE)		
	DOE # DE-FG02-03ER63597		
	PI – Lee; Co-PI – Gerson	\$66,668/year DC	\$35,332/year IDCO
	Total Award - \$306,000	\$200,004 total DC	\$105,996 total IDC
2003-2007	Wright Center of Innovation /Biomedical Research Technology Transfer		
	Center for Stem Cell and Regenerative Medicine Award [Consortium CCF, Athersys]		
	Gerson (PI)	Total award, \$19,476,864	
1994-2007	DNA Repair Defects Affecting Hematopoietic Stem Cells (NCI)		
	5R01 C63193-10 (PI)	\$175,000/year DC	\$92,750/year IDC
	Total \$875,000	\$463,750/year IDC	
2005-2006	OBR-OES Ohio Eminent Scholar Award		
	Ohio Board of Regents	Total award, \$1,231,500	\$500,000/year
1997-2007	Clinical Oncology Research Career Development Program (NCI)		
	5K12 CA076917-09	\$528,558/year	
2001-2004	Mutant MGMT Gene Transfer to Protect Hematopoietic Stem cells		
	NCI R21 CA09453 (PI)	\$225,000/yr	\$119,250/year IDC
		\$450,000 total DC	\$238,500 total IDC
2003-2004	Using NIS gene for monitoring stem cell therapies (NIH)		
	NIH # EB001847-01		
	PI – Lee; Co-PI – Gerson	\$150,000/year DC	\$79,500/year IDC
	Total Award - \$459,000	\$300,000 total DC	\$159,000 total IDC
1997-2003	NGVL Production of MFG-MGMT		
	NIH - subcontract	\$150,000 DC [to NGVL]	
1992-2004	Lymphomagenesis of <i>O</i> ⁶ -Methylguanine in Transgenic Mice		
	(NIEHS) RO1 ES06288-05 (PI)	\$199,548/year DC	\$105,680 – IDC
	Total \$1,938,132	\$1,027,211 - IDC	
1984-1989	Myeloid Cell Repair of Leukemogenic DNA Adducts (NIEHS)		
	1-ES00134 Physician Scientist Award		
	\$65,000/year	total \$325,000	
1986-1987	Measurement of Nitrosourea Exposure (NCI)		
	R03 CA43688	\$35,000/year	\$70,000 total
1987-1990	Prevention of Leukemogenesis in Hematopoietic Precursors (NCI)		
	R01 CA45609	\$123,200/year	\$369,000 total
1987-1992	Mallinckrodt Scholar		
		\$50,000/year	\$250,000 total
1990	Transgenic Mice Carrying a DNA Repair Gene (ACS)		
	RD314	\$105,000/year	\$105,000 total
1990-1995	Project 5. Modulation of O6-Alkylguanine Alkyltransferase to Potentiate Colon Cancer		
	Chemotherapy (NCI)		
	P01 CA51183	\$103,000/year	\$496,000 total
1991-1993	Mechanisms of Clozapine Induced Agranulocytosis (NIMH)		
	R03 MH47440	\$50,000/year	\$175,000 total
1991-1995	Blocking Leukemogenesis Through Gene Transfer (ACS)		
	CN-34	\$100,000/year	\$500,000 total
1993-1994	Transduction of Nitrosourea Resistance to Human Marrow		
	P30 CA43703 Special Pilot	\$50,000	\$50,000 total
	SL Gerson, PI, Special Pilot		
1992-1996	Inhibition of DNA Repair to Enhance Chemotherapy (NCDDG)		
	UO1 CA57725-04	\$97,860 (subcont)/year	\$390,000 total
	A Pegg, PI; S Gerson, PI Project 5		
	<i>Project 5: Selective Activity of Alkyltransferase Inhibitors</i>		
1991-1996	CWRU Cancer Center Hematopoietic Stem Cell Core Facility		
	P30 CA43703-07 S1	\$35,000/year	\$175,000 total
	Core Director and Program Leader		

1997-2001	Transgenic Approach to Oncogene and DNA Repair Imbalance (NCI) RO1 CA63193-06 (PI)	\$148,630/year DC	\$748,000 total
1995-1997	BCNU Modulation in Gliomas (FDA) M Gilbert, PI	\$100,000/year	
1996-1998	Immunodetection of alkyltransferase in gliomas ECOG supplement	\$55,000	
1996-1999	Immunodetection of alkyltransferase in gliomas ECOG pilot grant	\$15,000	
1995-1998	Institutional Pilot Grants, American Cancer Society Co-PI	\$60,000/year	
1994-1999	Developmental Program in Breast Cancer (NCI) R21 CA66221-03 C. Distelhorst, PI; S Gerson Project Leader	\$33,869 project 4 DC	\$136,000 total
1992-2001	Inhibition of DNA Repair to Enhance Chemotherapy (NCDDG) UO1 CA57725-09 (subcontract) /year A Pegg, PI; S Gerson, PI, Project 5	\$104,575 DC total \$523,000	\$55,425 IDC \$277,190 IDC
	<i>Project 5: Selective Activity of Alkyltransferase Inhibitor</i>		
1998-2001	Drug Resistance Gene Transfer with Mutant MGMT R21 CA76192 (PI)	\$100,000/year DC	\$53,000 IDC
1999-2001	Administrative Supplement to Gene Transfer into Hematopoietic Progenitors – NIH/CA R01 CA73062 Supplement	\$50,000/year	\$26,500/yr. IDC
2002-2003	Bioluminescence for in vivo stem cell tracking ICC/NIH		
	\$21,760/yr DC \$0 IDC		
2000-2006	RAID initiative NSC 3801, Methoxyamine approved support: IND directed toxicology and pharmacology, assay development, acquisition of bulk substance, production of radio labeled compound and additional validation in animal tumor models All support and effort at NCI-RAID and subcontractors		

Patents

1. Screening method for controlling agranulocytosis
#5,300,422 June 1995
2. Transduced mesenchymal stem cells
#5,591,625 January 7, 1997
3. Enhancing bone marrow engraftment using mesenchymal stem cells
#5,733,542 October 1998
4. Use of mutant alkyltransferases for gene therapy
#5,965,126 October 12, 1999
5. Methoxamine Potentiation of Temozolomide anti-cancer activity
#6,465,045 October 15, 2002
6. Methoxyamine combinations in the treatment of cancer
#6,635,677 October 21, 2003
7. In vitro maintenance of hematopoietic stem cells
#6,030,836 April 28, 2004
8. Genetic Markers in the CSF2RB Gene Associated with an Adverse Hematologic Response to Drugs
#11/351,371 February 9, 2006
9. Genetic Markers in the DRD1 Gene Associated with an Adverse Hematological Response to Drugs
#11/351,444 February 9, 2006
10. Genetic Markers in the HLA-C Gene Associated with an Adverse Hematological Response to Drugs
#11/351,601 February 10, 2006
11. Genetic Markers in the HLA-DQB1 Gene Associated with an Adverse Hematological Response to Drugs
#11/351,394 February 9, 2006
12. Genetic Markers in the NTSR1 Gene Associated with an Adverse Hematological Response to Drugs
#11/351,400 February 9, 2006

13. European Patent No. 0910246; Use of Mutant Alkyltransfers for Gene Therapy to Protect from Toxicity of Therapeutic Alkylating Agents; *Inventors:* Anthony Pegg and Stanton Gerson
Our Ref: 1996-0171 August 18, 2010.
14. Hematopoietic progenitor cell gene transduction
Inventors: Stanton L Gerson
#8,318,495, Nov 27, 2012
15. Alkylating agent combinations in the treatment of cancer
Inventors: Stanton L Gerson, Lili Liu
#8324282 December 4, 2012
16. Detection and quantitation of abasic siteformation in vivo
Inventors: Yanming Wang, Stanton Gerson, Lili Liu
#8367332 Feb 5, 2013

BIBLIOGRAPHY

Publications

Original Papers

1. Hagan DC, Gerson SL, Magasanik B. Isolation of super repressor mutants in the histidine utilization system of *S typhimurium*. *J Bacteriol* 121(2):583, 2/1975.
2. Gerson SL, Magasanik B. Regulation of the hut operons of *S typhimurium* and *K aerogene* by the heterologous hut repressors. *J Bacteriol* 124(3):1269, 12/1975.
3. Timmermans FJ, Gerson SL. Chronic granulomatous otitis media in bottle-fed Inuit children. *Can Med Assoc J* 122(5):545-7, 1980.
4. Gerson SL, Page PL, Hartwell B, Robinson SH. Altered growth characteristics of murine hematopoietic cells induced by cytotoxic drugs. *Stem Cells* 2:266-79, 1982.
5. Cassileth PA, Lusk EJ, Torri S, DiNubile N, Gerson SL. Antiemetic efficacy of dexamethasone therapy in patients receiving cancer chemotherapy. *Arch Int Med* 143(7):1347-51, 7/1983.*
6. Weiner MH, Talbot GH, Gerson SL, Filice G, Cassileth PA. Antigen-detection in the diagnosis of invasive aspergillosis - Utility in controlled, blinded trials. *Ann Intern Med* 99(6):777-82, 12/1983.*
7. Cassileth PA, Gerson SL, Bonner H, Neiman RS, Lusk EJ, Hurwitz S. Identification of early relapsing patients with adult acute nonlymphocytic leukemia by bone marrow biopsy after initial induction chemotherapy. *J Clin Oncol* 2(2):107-11, 2/1984.*
8. Gerson SL, Talbot GH, Lusk EJ, Strom B, Hurwitz S, Cassileth, PA. Prolonged granulocytopenia - The major risk factor for invasive pulmonary aspergillosis in patients with acute leukemia. *Ann Intern Med* 100(3):345-51, 3/1984.*
9. Gerson SL, Cooper RA. Release of granulocyte-specific colony-stimulating activity by human bone marrow exposed to phorbol esters. *Blood* 63(4):878-85, 4/1984.*
10. Cassileth PA, Lusk EJ, Torri S, Gerson, SL. Antiemetic efficacy of high-dose dexamethasone in induction therapy in acute nonlymphocytic leukemia. *Ann Int Med* 100(5):701-02, 5/1984.*
11. Gerson SL, Cooper RA. Myelopoiesis following phorbol ester exposure in human long term bone marrow cell culture. *Leukemia Res* 8(5):791-800, 1984.*
12. Albelda SM, Talbot GH, Gerson SL, Miller WT, Cassileth PA. Role of fiberoptic bronchoscopy in the diagnosis of invasive pulmonary aspergillosis in patients with acute leukemia. *Am J Med* 76(6):1027-34, 6/1984.*
13. Albelda SM, Talbot GH, Gerson SL, Miller WT, Cassileth PA. Pulmonary cavitation and massive hemoptysis in invasive pulmonary aspergillosis: Influence of bone marrow recovery in patients with acute leukemia. *Am Rev Resp Dis* 131(1):115-20, 1/1985.*
14. Gerson SL, Talbot GH, Hurwitz S, Lusk EJ, Strom B, Cassileth PA. Discriminant scorecard for diagnosis of invasive pulmonary aspergillosis in patients with acute leukemia. *Am J Med* 79(1):57-64, 7/1985.*
15. Gerson SL, Talbot GH, Lusk EJ, Hurwitz S, Strom B, Cassileth, PA. Invasive pulmonary aspergillosis in adult acute leukemia: Clinical clues to its diagnosis. *J Clin Oncol* 3(8):1109-16, 8/1985.*
16. Gerson SL, Friedman HM, Cines DB. Viral infection of vascular endothelial-cells alters production of colony-stimulating activity. *J Clin Invest* 76(4):1382-90, 10/1985.*
17. Saarinen UM, Coccia PF, Gerson SL, Pelley R, Cheung N-K. Eradication of neuroblastoma cells *in vitro* by monoclonal antibody and human complement: method for purging autologous bone marrow. *Cancer Res* 45(11 Pt2):5969-75, 11/1985.*

18. Gerson SL, Miller K, Berger NA. *O*⁶-alkylguanine-DNA alkyltransferase activity in human myeloid cells. *J Clin Invest* 76(6):2106-14, 12/1985.*
19. Geftter WB, Albelda SM, Talbot GH, Gerson SL, Cassileth PA, Miller WT. Invasive pulmonary aspergillosis and acute leukemia. Limitations in the diagnostic utility of the air crescent sign. *Radiology* 157(3):605-10 12/1985.*
20. Gerson SL, Trey J, Miller K, Berger NA. Comparison of *O*⁶-alkylguanine-DNA alkyltransferase activity based on cellular DNA content in human, rat and mouse tissues. *Carcinogenesis* 7(5):745-49, 5/1986.*
21. Weiner MH, Talbot GH, Gerson SL, Fetchick R, Andrews C, Peacock JE, Filice G, Cohen M, Provencher M, Cassileth P. Detection of fungal antigen in body fluids for diagnosis of invasive aspergillosis. *Zentralbl Bakteriol Hyg* 261(4):517-22, 7/1986.
22. Abrahm JL, Gerson SL, Hoxic JA, Tannenbaum SH, Cassileth PA, Cooper RA. Differential effects of phorbol esters on normal myeloid precursors and leukemic cells: Basis for autologous bone marrow reconstitution in acute nonlymphocytic leukemia using phorbol ester-treated bone marrow from patients in remission. *Cancer Res* 46(7):3711-16, 7/1986.*
23. Talbot GH, Weiner MH, Gerson SL, Provencher M, Hurwitz S. Serodiagnosis of invasive aspergillosis in patients with hematologic malignancy: Validation of the *Aspergillus fumigatus* antigen radioimmunoassay. *J Infect Dis* 155(1):12-27, 1/1987.
24. Gerson SL, Trey JE, Miller K, Benjamin E. Repair of *O*⁶-alkylguanine during DNA synthesis in murine bone marrow hematopoietic precursors. *Cancer Res* 47(1):89-95, 1/1987.*
25. Berger NA, Berger SJ, Gerson SL. DNA repair, ADP-ribosylation and pyridine nucleotide metabolism as targets for cancer chemotherapy. *Anti-Cancer Drug Des* 2(2):203-10, 10/1987.*
26. Abboud SL, Gerson SL, Berger NA. The effect of tumor-necrosis factor on normal human hematopoietic progenitors. *Cancer* 60(12):2965-70, 12/1987.*
27. Gerson SL, Trey JE, Miller K. Potentiation of nitrosourea cytotoxicity in human leukemic cells by inactivation of *O*⁶-alkylguanine-DNA alkyltransferase. *Cancer Res* 48:1521-27, 3/1988.*
28. Hull CC, Galloway P, Gordon N, Gerson SL, Hawkins N, Stellato TA. Splenectomy and the induction of murine colon cancer. *Arch Surg* 123(4):462-64, 4/1988.*
29. Gerson SL, Trey JE. Modulation of nitrosourea resistance in myeloid leukemias. *Blood* 71(5):1487-94, 5/1988.*
30. Gerson SL. Regeneration of *O*⁶-alkylguanine-DNA alkyltransferase in human lymphocytes after nitrosourea exposure. *Cancer Res* 48(18):5368-73, 9/1988.*
31. Trey JE, Gerson SL. The role of *O*⁶-alkylguanine DNA alkyltransferase in limiting nitrosourea-induced sister chromatid exchanges in proliferating human lymphocytes. *Cancer Res* 49(8):1899-1903, 4/1989.*
32. Clapp DW, Baley JE, Gerson SL. Gestational-age dependent changes in circulating hematopoietic stem-cells in newborn-infants. *J Lab Clin Med* 113(4):422-27, 4/1989.*
33. Gerson SL. Modulation of human-lymphocyte *O*⁶-alkylguanine-DNA alkyltransferase by streptozotocin *in vivo*. *Cancer Res* 49(11):3134-38, 6/1989.*
34. Dexter BU, Yamashita T, Donovan C, Gerson SL. Modulation of *O*⁶-alkylguanine-DNA alkyltransferase in rats following intravenous administration of *O*⁶-methylguanine. *Cancer Res* 49(13):3520-24, 7/1989.*
35. Dumenco LL, Warman B, Hatzoglou M, Lim IK, Abboud SL, Gerson SL. Increase in nitrosourea resistance in mammalian cells by retrovirally mediated gene transfer of bacterial *O*⁶-alkylguanine-DNA alkyltransferase. *Cancer Res* 49(21):6044-51, 11/1989.*
36. Escuro RS, Jacobs M, Gerson SL, Machicao AR, Lazarus HM. Prospective evaluation of a *candida* antigen detection test for invasive candidiasis in immunocompromised adult patients with cancer. *Am J Med* 87(6):621-27, 12/1989.*
37. Gerson SL, Lazarus HM. Hematopoietic emergencies. *Semin Oncol* 16(6):532-42, 12/1989.*
38. Lazarus HM, Creger RJ, Gerson SL. Infectious emergencies in oncology patients. *Semin Oncol* 16(6):543-60, 12/1989.*
39. Lim IK, Dumenco LL, Yun J, Donovan C, Warman B, Gorodetskaya N, Wagner TE, Clapp DW, Hanson RW, Gerson SL. High level, regulated expression of the chimeric P-enolpyruvate carboxykinase (GTP)-bacterial *O*⁶-alkylguanine-DNA alkyltransferase (*ada*) gene in transgenic mice. *Cancer Res* 50(6):1701-08, 3/1990.*
40. Dumenco LL, Donovan C, Warman B, Clapp DW, Lim IK, Yun J, Wagner T, Hanson RW, Gerson SL. Transgenic mice expressing the bacterial *O*⁶-alkylguanine-DNA alkyltransferase gene: An animal model

41. Lim IK, Dumenco LL, Hatzoglou M, Hanson RW, Gerson SL. Increased drug-resistance following retroviral gene-transfer of a chimeric *P*-enolpyruvate carboxykinase (GTP)-bacterial *O*⁶-alkylguanine-DNA alkyltransferase gene into NRK cells. *Carcinogenesis* 11(5):737-43, 5/1990.*
42. Gerson SL, Lieberman JA, Freidenberg WR, Lee D, Marx JJ Jr., Meltzer H. Polypharmacy in fatal clozapine-associated agranulocytosis (letter). *Lancet* 338(8761):262-63, 7/1991.
43. Clapp DW, Dumenco LL, Hatzoglou M, Gerson SL. Fetal liver hematopoietic stem cells as a target for in utero retroviral gene transfer. *Blood* 78(4):1132-39, 8/1991.
44. Lazarus HM, Andersen J, Chen MG, Variakojis D, Mansour EG, Oette D, Arce CA, Oken MM, Gerson SL. Recombinant granulocyte-macrophage colony-stimulating factor after autologous bone marrow transplantation for relapsed non-Hodgkin's lymphoma: Blood and bone marrow progenitor growth studies. A phase II Eastern Cooperative Oncology Group Trial. *Blood* 78(3):830-37, 8/1991.*
45. Dolan ME, Pegg AE, Dumenco LL, Moschel RC, Gerson SL. Comparison of the inactivation of mammalian and bacterial *O*⁶-alkylguanine-DNA alkyltransferase by *O*⁶-benzylguanine and *O*⁶-methylguanine. *Carcinogenesis* 12(12):2305-09, 12/1991.*
46. Gerson SL, Berger NA, Arce C, Petzold SJ, Willson JKV. Modulation of nitrosourea resistance in human colon cancer by *O*⁶-methylguanine. *Biochem Pharmacol* 43(5):1101-07, 3/1992.*
47. Gerson SL, Gullion G, Yeh H-S, Masor C. Granulocyte colony-stimulating factor for clozapine-induced agranulocytosis (letter). *Lancet* 340(8827):1097, 10/1992.*
48. Liu L, Castonguay A, Gerson SL. Lack of correlation between DNA methylation and hepatocarcinogenesis in rats and hamsters treated with 4-(m ethylnitrosamino)-1-(3-pyridyl)-1-butanone. *Carcinogenesis* 13(11):2137-40, 11/1992.*
49. Gerson SL, Dumenco LL. Carcinogenesis and DNA repair in transgenic mice. *Radiat Res. A 20th Century Prospective* 2:281-86, 1992.
50. Gerson SL, Meltzer H. Mechanisms of clozapine-induced agranulocytosis. *Drug Safety* 7(suppl 1):17-25, 1992.
51. Gerson SL, Zborowska E, Norton K, Gordon N, Willson JKV. Synergistic efficacy of *O*⁶-benzylguanine and 1,3-bis(2-chloroethyl)-1-nitrosourea (BCNU) in a human colon cancer xenograft completely resistant to BCNU alone. *Biochem Pharmacol* 45(2):483-91, 1/1993.*
52. Dumenco LL, Allay E, Norton K, Gerson SL. The prevention of thymic lymphomas in transgenic mice by human *O*⁶-alkylguanine-DNA alkyltransferase. *Science* 259(5092):219-22, 1/1993.*
53. Gerson SL. Molecular epidemiology of therapy-related leukemias. *Curr Opin Oncol* 5(1):136-44, 1/1993.
54. Minnick DT, Gerson SL, Dumenco LL, Veigl ML, Sedwick WD. Specificity of bischloroethylnitrosourea-induced mutation in a Chinese-hamster ovary cell-line transformed to express human *O*⁶-alkylguanine-DNA alkyltransferase. *Cancer Res* 53(5):997-1003, 3/1993.*
55. Gerson SL. Clozapine - Deciphering the risks (editorial). *N Engl J Med* 329(3):204-05, 7/1993.*
56. Gerson SL, Arce C, Meltzer HY. N-desmethyloclozapine - A clozapine metabolite that suppresses hematopoiesis. *Br J Haematol* 86(3):555-61, 3/1994.*
57. Koç ON, McFee M, Reed E, Gerson SL. Detection of platinum DNA-adducts in cord-blood lymphocytes following in-utero platinum exposure. *Eur J Cancer* 30A(5):716-17, 1994.*
58. Gerson SL, Parker P, Jacobs MR, Creger R, Lazarus H. Aspergillosis due to carpet contamination (letter). *Infect Control Hosp Epidemiol* 15(4 Pt 1):221-23, 4/1994.*
59. Gerson SL, Zaidi NH, Dumenco LL, Allay E, Fan CY, Liu L, O'Connor PJ. Alkyltrans-ferase transgenic mice: Probes of chemical carcinogenesis. *Mutat Res* 307(2):541-55, 6/1994.*
60. Gerson SL, Berger SJ, Varnes ME, Arce C. Combined depletion of *O*⁶-alkylguanine-DNA alkyltransferase and glutathione to modulate nitrosourea resistance in breast-cancer. *Biochem Pharmacol* 48(3):543-48, 8/1994.*
61. Liu L, Allay E, Dumenco LL, Gerson SL. Rapid repair of *O*⁶-methylguanine DNA adducts protects transgenic mice from MNU-induced thymic lymphomas. *Cancer Res* 54(17):4648-52, 9/1994.*
62. Gerson SL. G-CSF and the management of clozapine-induced agranulocytosis. *J Clin Psychiatry* 55(9):139-142 Suppl B 9/1994.*
63. Bardenstein DS, Haluschak J, Gerson S, Zaim T. Neutrophilic eccrine hidradenitis simulating orbital cellulitis. *Arch Ophthalmol* 112(11):1460-63, 11/1994.
64. Frankenburg FR, Stormberg D, Gerson SL. Unsuccessful reexposure to clozapine. *J Clin Psycho Pharmacol* 14(6):428-29, 12/1994.*

65. Zaidi NH, Pretlow TH, O'Riordan MA, Dumenco LL, Allay E, Gerson SL. Transgenic expression of human MGMT protects against azoxymethane-induced aberrant crypt foci and G to A mutations in the K-ras oncogene of mouse colon. *Carcinogenesis* 16(3):451-56, 3/1995.*
66. Zaidi NH, Allay E, Ayi TC, Li BFL, Dumenco LL, Sy MS, Gerson SL. The immature thymocyte is protected from N-methylnitrosourea-induced lymphoma by the human MGMT CD2 transgene. *Carcinogenesis* 16(5):1047-53, 5/1995.*
67. Gerson SL, Allay E, Vitantonio K, Dumenco LL. Determinants of O^6 -alkylguanine-DNA alkyltransferase activity in human colon cancer. *Clin Cancer Res* 1(5):519-25, 5/1995.*
68. Allay JA, Dumenco LL, Liu L, Gerson SL. Retroviral transduction and expression of the human alkyltransferase cDNA provides nitrosourea resistance to hematopoietic cells. *Blood* 85(11):3342-51, 6/1995.*
69. Clapp WD, Freie B, Srouf E, Yoder MC, Fortney K, Gerson SL. Myeloproliferative sarcoma-virus directed expression of β -galactosidase following retroviral transduction of murine hematopoietic cells. *Exp Hematol* 23(7):630-38, 7/1995.
70. Willson JKV, Haaga JR, Trey JE, Stellato TA, Gordon NH, Gerson SL. Modulation of O^6 -alkylguanine alkyltransferase directed DNA-repair in metastatic colon cancers. *J Clin Oncol* 13(9):2301-08, 9/1995.*
71. Lazarus HM, Haynesworth SE, Gerson SL, Rosenthal NS, Caplan AI. *Ex vivo* expansion & subsequent infusion of human bone marrow (BM)-derived stromal progenitor cells (mesenchymal stem cells [MSC]): Implications for therapeutic use. *Bone Marrow Transplantation* 16(4):557-64, 10/1995.
72. Berg SL, Gerson SL, Godwin K, Cole DE, Liu L, Balis FM. Plasma and cerebrospinal-fluid pharmacokinetics of O^6 -benzylguanine and time course of peripheral blood mononuclear cell methylguanine-DNA methyltransferase inhibition in the non-human primate. *Cancer Res* 55(20):4606-10, 10/1995.*
73. Mendelowitz AJ, Gerson SL, Alvir MJ, Lieberman JA. Clozapine-induced agranulocytosis – Risk-factors, monitoring and management. *CNS Drugs* 4(6):412-21, 12/1995.*
74. Wakazono Y, Kubota M, Furusho K, Liu L, Gerson SL. Thymidine kinase deficient cells with decreased TTP pools are hypersensitivity to DNA alkylating agents in. *Mutat Res* 362(1):119-25, 1/1996.*
75. Winter JN, Lazarus HM, Rademaker A, Villa M, Mangan C, Tallman M, Jahnke L, Gordon L, Newman S, Byrd K, Cooper BW, Horvath N, Crum E, Stadtmauer EA, Conklin E, Bauman A, Martin J, Goolsby C, Gerson SL, Bender J, O'Gorman M. Phase I/II study of combined granulocyte colony-stimulating factor and granulocyte-macrophage colony-stimulating factor administration for the mobilization of hematopoietic progenitor cells. *J Clin Oncol* 14(1):277-86, 1/1996.*
76. Koç ON, Allay JA, Lee K, Davis BM, Reese JS, Gerson SL. Transfer of drug resistance genes into hematopoietic progenitors to improve chemotherapy tolerance. *Semin Oncol* 23(1):46-65, 2/1996.
77. Gerson SL. DNA repair and the risk of secondary leukemias (letter). *J Clin Oncol* 14(2):681-2, 2/1996.*
78. Zaidi NH, Liu L, Gerson SL. Quantitative immunohistochemical estimates of O^6 -alkylguanine-DNA alkyltransferase expression in normal and malignant human colon. *Clin Cancer Res*, 2(3):577-84, 3/1996.*
79. Liu L, Lee K, Wassan E, Gerson SL. Differential sensitivity of human and mouse alkyltransferase to O^6 -benzylguanine utilizing a transgenic model. *Cancer Res* 56(8):1880-85, 4/1996.*
80. Stefan TL, Ingalls ST, Gerson SL, Willson JKV, Hoppel CL. Determination of O^6 -benzyl-guanine in human plasma by reversed-phase high-performance liquid chromatography. *J Chromatogr B Biomed Appl* 681(2):331-38, 6/1996.*
81. Roush GR, Rosenthal NS, Gerson SL, Toy EM, McCarthy P, Hirschler NV, Yomtovian R. An unusual case of autoimmune hemolytic anemia with reticulocytopenia, erythroid dysplasia, and an IgG2 autoanti-U. *Transfusion* 36(6):575-80, 6/1996.*
82. Smith DC, Gerson SL, Liu L, Donnelly S, Day R, Trump DL, Kirkwood JM. Carmustine and streptozocin in refractory melanoma: an attempt at modulation of O^6 -alkylguanine-DNA alkyltransferase. *Clin Cancer Res* 2(7):1129-34, 7/1996.*
83. Allay JA, Koç ON, Davis BM, Gerson SL. Retroviral-mediated gene transduction of human alkyltransferase complementary DNA confers nitrosourea resistance to human hematopoietic progenitors. *Clin Cancer Res* 2(8):1353-9, 8/1996.*
84. Gerson SL, Phillips W, Kastan M, Dumenco LL, Donovan C. Human CD34 hematopoietic progenitors have low, cytokine-unresponsive O^6 -alkylguanine-DNA alkyltransferase and are sensitive to O^6 -benzylguanine plus BCNU. *Blood* 88(5):1649-55, 9/1996.*

85. Ross AA, Layton TJ, Ostrander AB, Passos-Coelho JL, Davis JM, Huelskamp AM, Noga SJ, Davidson NE, Kennedy MJ, Cooper BW, Gerson SL et al. Comparative analysis of breast cancer contamination in mobilized and nonmobilized hematopoietic grafts. *J Hematother* 5(5):549-52 10/1996.
86. Reese JS, Koç ON, Lee K, Liu L, Allay JA, Phillips WP Jr., Gerson SL. Retroviral transduction of a mutant methylguanine DNA methyltransferase gene into human CD34 cells confers resistance to *O*⁶-benzylguanine plus 1,3-bis(2-chloroethyl)-1-nitrosourea. *PNAS* 93(24):14088-93, 11/1996.*
87. Davis BM, Koç ON, Lee K, Gerson SL. Current progress in the gene therapy of cancer. *Current Opinion in Oncology* 8(6):499-508, 11/1996.
88. Liu L, Markowitz S, Gerson SL. Mismatch repair mutations override alkyltransferase in conferring resistance to temozolomide but not 1,3 bis(2-chloroethyl)nitrosourea. *Cancer Research* 56(23):5375-79, 12/1996.*
89. Cooper BW, Mackay W, Gerson SL, Lazarus HM. Erythroid burst-forming units (BFU-E) predict hematopoietic recovery after peripheral blood progenitor cell transplantation in patients with advanced breast cancer. *Bone Marrow Transplantation* 19(11):1089-94, 6/1997.*
90. Allay JA, Dennis JE, Haynesworth SE, Majumdar MK, Clapp DW, Caplan AI, Gerson SL. LacZ and Interleukin-3 expression *in vivo* in retroviral transduction of marrow-derived human osteogenic mesenchymal progenitors. *Hum Gene Ther* 8(12):1417-27, 8/1997.*
91. Allay JA, Davis BM, Gerson SL. Human alkyltransferase-transduced murine myeloid progenitors are enriched *in vivo* by BCNU treatment of transplanted mice. *Exp Hematol* 25(10):1069-76, 9/1997.*
92. Allay E, Reese JS, McGuire EA, Koç ON, Sedransk N, Gerson SL. Potentiation of lymphomagenesis by methylnitrosourea in mice transgenic for LMO1 is blocked by *O*⁶-alkylguanine DNA-alkyltransferase. *Oncogene* 15(17):2127-32, 10/1997.*
93. Lazarus HM, Haynesworth SE, Gerson SL, Caplan AI. Human bone marrow-derived mesenchymal (stromal) progenitor cells (MPCs) cannot be recovered from peripheral blood progenitor cell collections. *J Hematother* 6(5):447-55, 10/1997.*
94. Raymond E, Izbicka E, Soda H, Gerson SL, Dugan M, Von Hoff DD. Activity of temozolomide against human tumor colony-forming units. *Clin Cancer Res* 3(10):1769-74, 10/1997.*
95. Phillips WP Jr., Willson JKV, Markowitz SD, Zborowska E, Zaidi NH, Liu L, Gordon NH, Gerson SL. MGMT transfectants of a 1,3-bis(2chloroethyl)-1-nitrosourea (BCNU)-sensitive colon cancer cell line selectively repopulate heterogeneous MGMT+/MGMT- xenografts after BCNU and *O*⁶-benzylguanine plus BCNU. *Cancer Res* 57(21):4817-23, 11/1997.*
96. Davis BM, Reese JS, Koç ON, Schupp JE, Gerson SL. Selection for G156A MGMT transduced hematopoietic progenitors and protection from lethality in mice treated with *O*⁶-benzylguanine and BCNU. *Cancer Res* 57(22):5093-99, 11/1997.*
97. Stefan TL, Ingalls ST, Minkler PE, Willson JKV, Gerson SL, Spiro TP, Hoppel CL. Simultaneous determination of *O*⁶-benzylguanine and 8-oxo-*O*⁶-benzylguanine in human plasma by reverse phase high-performance liquid chromatography. *J Chromatography B* 704(1-2):289-98, 12/1997.
98. Liu L, Lee K, Schupp J, Koç ON, Gerson SL. Heterogeneity of *O*⁶-alkylguanine-DNA-alkyltransferase measured by flow cytometric analysis in blood and bone marrow mononuclear cells. *Clin Cancer Res* 4(2):475-81, 2/1998.*
99. Koç ON, Gerson SL, Phillips GL, Cooper BW, Kutteh L, Van Zant G, Reece DE, Fox RM, Schupp JE, Tainer N, Lazarus HM. Autologous CD34(+) cell transplantation for patients with advanced lymphoma: effects of overnight storage on peripheral blood progenitor cell enrichment and engraftment. *Bone Marrow Transplant*, 21(4):337-43, 2/1998.*
100. Majumdar MK, Thiede MA, Mosca JD, Moorman M, Gerson SL. Phenotypic and functional comparison of cultures of marrow-derived mesenchymal stem cells (MSCs) and stromal cells. *J Cell Physiol* 176(1):57-66, 7/1998.*
101. Reese J, Davis B, Liu L, Gerson S. Simultaneous protection of G156A methylguanine DNA methyltransferase gene-transduced hematopoietic progenitors and sensitization of tumor cells using *O*⁶-benzylguanine and temozolomide. *Clin Cancer Res* 5(1):163-9, 1/1999.*
102. Liu L, Qin X, Gerson SL. Reduced lung tumorigenesis in human methylguanine DNA—methyltransferase transgenic mice achieved by expression of transgene within the target cell. *Carcinogenesis* 20(2):279-84, 2/1999.*
103. Dang CV, Gerson SL, Litwak M, Padarathsingh M. Gene therapy and translational cancer research. *Clin Cancer Res* 5(2):471-4, 2/1999.
104. Gerson SL, Schupp J, Liu L, Pegg A, Srinivasen S. Leukocyte *O*⁶-alkylguanine-DNA alkyltransferase from human donors is uniformly sensitive to *O*⁶-benzylguanine. *Clin Cancer Res* 5(3):521-4, 3/1999.*

105. Gerson SL. Mesenchymal stem cells: No longer second class marrow citizens. *Nature Med* 5(3):262-4, 3/1999.*
106. Koç ON, Reese JS, Davis BM, Liu L, Majczenko KJ, Gerson SL. Δ MGMT-transduced bone marrow infusion increases tolerance to O^6 -benzylguanine and 1,3-bis(2-chloroethyl)-1-nitrosourea and allows intensive therapy of 1,3-bis(2-chloroethyl)-1-nitrosourea-resistant human colon cancer xenografts. *Hum Gene Ther* 10(6):1021-30, 4/1999.*
107. Spiro TP, Gerson SL, Liu L, Majka S, Haaga J, Hoppel CL, Ingalls ST, Pluda JM, Willson JKV. O^6 -benzylguanine: a clinical trial establishing the biochemical modulatory dose in tumor tissue for alkyltransferase-directed DNA repair. *Cancer Res* 59(10):2402-10, 5/1999.*
108. Allay E, Veigl M, Gerson SL. Mice over-expressing human O^6 alkylguanine-DNA alkyltransferase selectively reduce O^6 methylguanine mediated carcinogenic mutations to threshold levels after N-methyl-N-nitrosourea. *Oncogene* 18(25):3783-7, 6/1999.*
109. Koç ON, Reese JS, Szekely EM, Gerson SL. Human long-term culture initiating cells are sensitive to benzylguanine and 1,3-bis(2-chloroethyl)-1-nitrosourea and protected after mutant (G156A) methylguanine methyltransferase gene transfer. *Cancer Gene Therapy* 6(4):340-8, 7-8/1999.*
110. Qin X, Liu L, Gerson SL. Mice defective in the DNA mismatch gene PMS2 are hypersensitive to MNU induced thymic lymphoma and are partially protected by transgenic expression of human MGMT. *Oncogene* 18(30):4394-400, 7/1999.*
111. Dumenco LL, Arce C, Norton K, Yun J, Wagner T, Gerson SL. Enhanced repair of O^6 -methylguanine DNA adducts in the liver of transgenic mice expressing the *ada* gene. *Cancer Res* 51(13):3391-98, 7/1999.*
112. Qin X, Zhou H, Liu L, Gerson SL. Transgenic expression of human MGMT blocks the hypersensitivity of PMS2-deficient mice to low dose MNU thymic lymphomagenesis. *Carcinogenesis*, 20(9):1667-73, 9/1999.*
113. Phillips WP Jr., Gerson SL. Acquired resistance to O^6 -benzylguanine plus chloroethylnitrosoureas in human breast cancer. *Cancer Chemother Pharmacol*, 44(4):319-26, 10/1999.*
114. Liu L, Taverna P, Whitacre CM, Chatterjee S, Gerson SL. Pharmacologic disruption of base excision repair sensitizes mismatch repair-deficient and -proficient colon cancer cells to methylating agents. *Clin Cancer Res* 5(10):2908-17, 10/1999.*
115. Reese J, Koç ON, Gerson SL. Human mesenchymal stem cells provide stromal support for efficient CD34⁺ transduction. *J Hematother Stem Cell Res*. 8(5):515-23, 10/1999.*
116. Davis BM, Roth JC, Liu L, Xu-Welliver M, Pegg AE, Gerson SL. Characterization of the P140K, PVP(138-140)MLK, and G156A O^6 -methylguanine-DNA methyltransferase mutants: implications for drug resistance gene therapy. *Hum Gene Ther* 10(17):2769-78 11/1999.*
117. Koç ON, Peters C, Aubourg P, Raghavan S, Dyhouse S, DeGasperi R, Kolodny EH, Yoseph YB, Gerson SL, Lazarus HM, Caplan AI, Watkins PA, Krivit W. Bone marrow-derived mesenchymal stem cells remain host-derived despite successful hematopoietic engraftment after allogeneic transplantation in patients with lysosomal and peroxisomal storage diseases. *Exp Hematol* 27(11):1675-81 11/1999.*
118. Koç ON, Gerson SL, Cooper BW, Dyhouse SM, Haynesworth SE, Caplan AI, Lazarus HM. Rapid hematopoietic recovery after coinfusion of autologous-blood stem cells and culture-expanded marrow mesenchymal stem cells in advanced breast cancer patients receiving high-dose chemotherapy. *J Clin Oncol* 18(2):307-16, 1/2000.*
119. Lazarus HM, Pecora AL, Shea TC, Koc ON, White JM, Gabriel DA, Cooper BW, Gerson SL, Krieger M, Sing AP. CD34(+) selection of hematopoietic blood cell collections and autotransplantation in lymphoma overnight storage of cells at 4 degrees C does not affect outcome. *Bone Marrow Transpl* 24(5):559-566 3/2000.*
120. Qin XS, Shibata D, Gerson SL. Heterozygous DNA mismatch repair gene PMS2-knockout mice are susceptible to intestinal tumor induction with N-methyl-N-nitrosourea. *Carcinogenesis* 21(4):833-838 4/2000.*
121. Koç ON, Gerson SL, Cooper BW, Laughlin M, Meyerson H, Kutteh L, Fox RM, Szekely EM, Tainer N, Lazarus HM. Randomized cross-over trial of progenitor-cell mobilization: high-dose cyclophosphamide plus granulocyte colony-stimulating factor (G-CSF) versus granulocyte-macrophage colony-stimulating factor plus G-CSF. *J Clin Oncol* 18(9):1824-30, 5/2000.*
122. Davis BM, Koç ON, Gerson SL. Limiting numbers of G156A O^6 methylguanine-DNA methyltransferase-transduced marrow progenitors repopulate nonmyeloablated mice after drug selection. *Blood* 95(10):3078-84, 5/2000.*

123. Chen R, Nagarajan S, Prince GM, Maheshwari U, Terstappen LWMM, Kaplan DR, Gerson SL, Albert JM, Dunn DE, Lazarus HM, Medof ME. Impaired growth and elevated Fas receptor expression in PIGA(+) stem cells in primary paroxysmal nocturnal hemoglobinuria. *J Clin Invest* 106(5):689-696 9/2000.
124. Spiro T, Liu L, Gerson SL. New Cytotoxic Agents for the Treatment of Metastatic Malignant Melanoma: Temozolomide and Related Combinations to Abrogate Drug Resistance. *Forum (Genova)* 10(3):274-85, 7-9/2000.
125. Taverna P, Liu L, Hanson AJ, Monks A, Gerson SL. Characterization of MLH1 and MSH2 DNA mismatch repair proteins in cell lines of the NCI anticancer drug screen. *Cancer Chemother Pharmacol* 46(6):507-16 12/2000.*
126. Majumdar MK, Thiede MK, Haynesworth SE, Bruder SP, Gerson SL. Human marrow-derived mesenchymal stem cells (MSCs) express hematopoietic cytokines and support long-term hematopoiesis when differentiated toward stromal and osteogenic lineages. *J Hematother Stem Cell Res* 9(6):841-8, 12/2000.*
127. Gerson SL. Drug resistance gene transfer: Stem cell protection and therapeutic efficacy. *Exp Hematol* 28(12): 1315-1324 12/2000.*
128. Reese JS, Qin X, Ballas C, Sekiguchi M, and Gerson SL. MGMT expression in murine bone marrow is a major determinant of animal survival after alkylating agent exposure. *J of Hematotherapy Stem Cell Res.* 10(1):115-23, 2/2001.*
129. Johnsen AK, France J, Nagy N, Askew D, Abdul-Karim FW, Gerson SL, Sy MS, Harding CV. Systemic deficits in transporter for antigen presentation (TAP)-1 or proteasome subunit Imp2 have little or no effect on tumor incidence. *Int J Cancer* 91(3):366-72, 2/2001.*
130. Davis BM, Encell LP, Zielske SP, Christians FC, Liu L, Friebert SE, Loeb LA, Gerson SL. Applied molecular evolution of O⁶-benzylguanine-resistant DNA alkyltransferases in human hematopoietic cells. *PNAS* 98(9):4950-54, 4/2001.*
131. Dowlati A, Hoppel C, Ingalls S, Majka S, Li X, Sedransk N, Spiro T, Gerson SL, Ivy p, Remick SC. Phase I clinical and pharmacokinetic study of rebeccamycin analog and NSC 655649 given daily for five consecutive days. *J of Clin Oncol.* 19(8):2309-18, 4/2001.*
132. Taverna P, Liu L, Hwang H, Hanson A, Kinsella T, Gerson SL. Methoxamine potentiates DNA single strand breaks and double strand breaks induced by temozolomide in colon cancer cells. *Mutation Research*, 485(4):269-81, 5/2001.*
133. Laughlin MJ, Barker J, Bambach B, Koç O, Rizzieri D, Wagner J, Gerson SL et al. Hematopoietic engraftment and survival in adult recipients of umbilical cord blood from unrelated donors. *New Engl J Med* 344(24):1815-22, 6/2001.*
134. Spiro TP, Liu L, Majka S, Haaga J, Willson JKV, Gerson SL. Temozolomide: the effect of once- and twice- a-day dosing on tumor tissue levels of the DNA repair protein O⁶ alkylguanine-DNA-alkyltransferase. *Clin Cancer Res* 7(8):2309-17, 8/2001.*
135. Liu L, Spiro TP, Qin X, Majka S, Haaga J, Schupp J, Willson JKV, Gerson SL. Differential degradation rates of inactivated alkyltransferase in blood mononuclear cells and tumors of patients receiving O⁶benzylguanine. *Clin Cancer Res*, 7(8):2318-24, 8/2001.*
136. Reese JS, Allay E, Gerson SL. Overexpression of human O⁶ alkylguanine DNA alkyltransferase (AGT) prevents MNU induced lymphomas in heterozygous p53 deficient mice. *Oncogene* 20: 5258-63, 8/2001.*
137. Zhou H, Chen W-D, Qin X, Lee K, Liu L, Markowitz S, Gerson SL. MMTV promoter hypomethylation is linked to spontaneous and MNU associated c-neu expression and mammary carcinogenesis in MMTV c-neu transgenic mice. *Oncogene* 20(42):6009-17, 9/2001.*
138. Lee K, Gerson SL, Maitra B, Koç ON. G156A MGMT-transduced human mesenchymal stem cells can be selectively enriched by O⁶-benzylguanine and BCNU. *J of Hemat* 10(5):691-701, 10/2001.*
139. Dowlati A, Haaga J, Remick SC, Spiro TP, Gerson SL, et al. Sequential tumor biopsies in early phase clinical trials of anti-cancer agents for pharmacodynamic evaluation. *Clin Can Res* 7(10); 2971-6, 10/2001.*
140. Zielske S, Gerson SL. Lentiviral transduction of P140K MGMT into human CD34⁺ hematopoietic progenitors at low multiplicity of infection confers significant resistance to BG/BCNU and allows selection *in vitro*. *Mol Ther.* 5(4):381-87, 4/2002.*
141. Liu LL, Schwartz S, Davis BM, Gerson SL. Chemotherapy-induced O-6-benzylguanine-resistant alkyltransferase mutations in mismatch-deficient colon cancer. *Cancer Res* 62(11): 3070-3076 6/2002.*

142. Gerson SL, Kaplan SL, Bruss JB, Le V, Arellano FM et al. Hematologic effects of linezolid: summary of clinical experience. *Antimicrobial Agents and Chemotherapy*. 46(8):2723-6, 8/2002.*
143. Koc ON, Day J, Nieder M, Gerson SL, Lazarus HM, Krivit W. Allogeneic mesenchymal stem cell infusion for treatment of metachromatic leukodystrophy (MLD) and Hurler syndrome (MPS-IH). *Bone Marrow Transpl* 30(4):215-222 8/2002.*
144. Gerson SL. Clinical Relevance of MGMT in the treatment of cancer. *J of Clin Onc* 20(38):2388-99, 8/2002.*
145. Liu L, Nakatsuru Y, Gerson SL. Base excision repair as a therapeutic target in colon cancer. *Clin Cancer Res*. 8(9):2985-91, 9/2002.*
146. Ballas CB, Zielske SP, Gerson SL. Adult bone marrow stem cells for cell and gene therapies: implications for greater use. *J of Cell Biochem Suppl* 38:20-28, 2002.*
147. Zhou H, Liu L, Lee K, Qin X, Grasso A, Kung H, Willis J, Kern J, Wagner T, Gerson SL. Lung tumorigenesis associated with erb-B-2 and erb-B-3 overexpression in human erb-B-3 transgenic mice is enhanced by methyl nitrosourea. *Oncogene* 21(57):8732-40, 12/2002.*
148. Cooper BW, Donaher E, Lazarus HM, Green SB, Gosky DM, Rosenthal NS, Berger SJ, Li X, Ingalls ST, Hoppel CL, Gerson SL. A phase I and pharmacodynamic study of sequential topotecan and etoposide in patients with relapsed or refractory acute myelogenous and lymphoblastic leukemia. *Leuk Res* 27(1):35-44, 1/2003.*
149. Zielske S, Gerson SL. Cytokines including SCF alone Enhance Lentiviral Transduction in Nondividing Human LTCIC and NODSCID Repopulating cells. *Molecular Therapy* 7(3):325-333 3/2003.
150. Tolcher AW, Gerson SL, Denis L, et al. Marked inactivation of O-6-alkylguanine-DNA alkyltransferase activity with protracted temozolomide schedules. *RIT J CANCER* 88(7):1004-1011 4/2003.*
151. Vollweiler JL, Zielske SP, Reese RS, Gerson SL. Hematopoietic stem cell gene therapy: progress toward therapeutic targets. *Bone Marrow Transplantation* 32(1):1-7 7/2003.*
152. Bowman JE, Reese JS, Lingas KT, Gerson SL. Myeloablation is not required to select and maintain expression of the drug-resistant gene, mutant MGMT, in primary and secondary recipients. *Molecular Therapy* 8(1):42-50 7/2003.*
153. Odago FO, Gerson SL. Telomerase inhibition and telomere erosion: a two-pronged strategy in cancer therapy *Trends in Pharmacological Sciences* 24(7):328-331 7/2003.*
154. Zielske SP, Gerson SL. SarCNU mediates selection of P140K methylguanine-DNA-methyltransferase transduced human CD34(+) cells in vitro *Blood Cells Molecules and Diseases* 31(1):48-50 7-8/2003.*
155. Davis BM, Reese JS, Lingas K, Gerson SL. Drug selection of mutant methylguanine methyltransferase from different oncoretroviral backbones results in multilineage hematopoietic transgene expression in primary and secondary recipients *Journal of Hematotherapy & Stem Cell Research* 12(4):375-387 8/2003.*
156. Tserng KY, Ingalls ST, Boczek EM, Spiro TP, Li XL, Majka S, Gerson SL, Willson JKV, Hoppel CL. Pharmacokinetics of O-6-benzylguanine (NSC637037) and its metabolite, 8-oxo-O-6-benzylguanine. *Journal of Clinical Pharmacology* 43(8):881-893 8/2003.*
157. Reese JS, Liu L, Gerson SL. Repopulating defect of mismatch repair-deficient hematopoietic stem cells. *Blood*, 102 (5): 1626-1633 9/2003.
158. Koc ON, Gerson SL. Akt helps stem cells heal the heart. *Nat Med* 9 (9): 1109-1110 9/2003.*
159. Richard E, Geronimi F, Lalanne M, Ged C, Redonnet-Vernhet I, Lamrissi-Garcia I, Gerson SL, de Verneuil H, Moreau-Gaudry F. A bicistronic SIN-lentiviral vector containing G156A MGMT allows selection and metabolic correction of hematopoietic protoporphyric cell lines *J Gene Med* 5(9):737-747 9/2003.*
160. Yang SM, Liu LL, Gerson SL, Xu Y. Measurement of anti-cancer agent methoxyamine in plasma by tandem mass spectrometry with on-line sample extraction *Journal of Chromatography B-Analytical Technologies in the Biomedical and Life Sciences* 795(2):295-307 10/2003.*
161. Liu LL, Yan L, Donze JR, Gerson SL. Blockage of abasic site repair * of 1,3-bis-(2-chloroethyl)-1-nitrosourea in colon tumor xenografts *Molecular Cancer Therapeutics* 2 (10):1061-1066 10/2003
162. Zielske SP, Reese JS, Lingas KT, Donze JR, Gerson SL. In vivo selection of MGMT(P140K) lentivirus-transduced human NOD/SCID repopulating cells without pretransplant irradiation conditioning *Journal of Clinical Investigation* 112 (10):1561-1570 11/2003.*
163. Dowlati A, Lazarus HM, Hartman P, Jaccobberger JW, Whitacre C, Gerson SL, Ksenich P, Cooper BW, Frisa PS, Gottlieb M, Murgu AJ, Remick SC. Phase I and correlative study of combination bryostatins 1 and vincristine in refractory B-cell malignancies. *Clin Cancer Res* 9(16 Pt 1): 5929-35, 12/2003.*

164. Zielske SP, Lingas KT, Li Y, Gerson SL. Limited Lentiviral Transgene Expression with Increasing Copy Number in an MGMT Selection Model: Lack of Copy Number Selection by Drug Treatment. *Molecular Therapy* 9: 923-931, 2004.
165. Gerson, SL MGMT: Its role in Cancer Aetiology and Cancer Therapeutics. *Nature Rev Cancer* 4: 296-307, 2004.
166. Liu L., Gerson SL. Therapeutic impact of methoxyamine: Blocking repair of abasic sites in the base excision repair pathway. *Current Opinion in Investigational Drugs* 5 (6):623-627 2004.
167. Hammond LA, Eckardt JR, Kuhn JG, Gerson SL, Johnson T, Smith L, Drengler RL, Campbell E, Weiss GR, Von Hoff DD, Rowinsky EK. A randomized phase I and pharmacological trial of sequences of 1,3-bis(2-chloroethyl)-1-nitrosourea and temozolomide in patients with advanced solid neoplasms. *Clin Cancer Res* 10:1645-1656, 2004.
168. Cooper BW, Veal GJ, Radivoyevitch T, Tilby MJ, Meyerson HJ, Lazarus HM, Koc ON, Creger RJ, Pearson G, Nowell GM, Gosky D, Ingalls ST, Hoppel CL, Gerson SL. A phase I and pharmacodynamic study of fludarabine, carboplatin, and topotecan in patients with relapsed, refractory, or high-risk acute leukemia. *Clin Cancer Res* 10:6830-6839, 2004.
169. Richard E, Robert E, Cario-Andre M, Ged C, Geronimi F, Gerson SL, De Verneuil H, Moreau-Gaudry F. HSC gene therapy of murine protoporphyria by methylguanine-DNA-methyltransferase-mediated *in vivo* drug selection. *Gene Ther* 11:1638-1647, 2004.
170. Wadhwa PD, Fu P, Koc ON, Cooper BW, Fox RM, Creger RJ, Bajor DL, Bedi T, Laughlin MJ, Payne J, Gerson SL, Lazarus HM. High-dose carmustine, etoposide, and cisplatin for autologous stem cell transplantation with or without involved-field radiation for relapsed/refractory lymphoma: An effective regimen with low morbidity and mortality. *Biol Blood Marrow Transplant* 11:13-22, 2005.
171. Park Y, Gerson SL. DNA repair defects in stem cell function and aging. *Annu Rev Med.* 56:495-508, 2005.
172. Bahlis NJ, Miao Y, Koc ON, Lee K, Boise LH, Gerson SL. N-Benzoylstauroporine (PKC412) inhibits Akt kinase inducing apoptosis in multiple myeloma cells. *Leuk Lymphoma* 46:899-908, 2005.
173. Lazarus HM, Koc ON, Devine SM, Curtin P, Maziarz RT, Holland HK, Shpall EJ, McCarthy P, Atkinson K, Cooper BW, Gerson SL, Laughlin MJ, Loberiza FR Jr, Moseley AB, Bacigalupo A. Cotransplantation of HLA-identical sibling culture-expanded mesenchymal stem cells and hematopoietic stem cells in hematologic malignancy patients. *Biol Blood Marrow Transplant* 11(5):389-98, May 2005.
174. Gajewski TF, Sosman J, Gerson SL, Liu L, Dolan E, Lin S, Vokes EE. Phase II trial of the 06-alkylguanine DNA alkyltransferase inhibitor 06-benzylguanine and 1, 3-bis(2-Chloroethyl)-1-nitrosourea in advanced melanoma. *Clin Cancer Res* 11;(21):7861-5, Nov 1, 2005.
175. Giles F, Verstovsek S, Thomas D, Gerson S, Cortes J, Faderl S, Ferrajoli A, Ravandi F, Kornblau S, Garcia-Manero G, Jabbour E, O'Brien S, Karsten V, Cahill A, Yee K, Albitar M, Sznol M, Kantarjian H. Phase I study of cloretazine (VNP40101M), a novel sulfonylhydrazine alkylating agent, combined with cytarabine in patients with refractory leukemia. *Clin Cancer Res* 11;(21):7817-24, Nov 1, 2005.
176. Lattime EC, Gerson SL editors and Introduction: gene therapy of cancer. *Semin Oncol* 32:535-36, 2005.
177. vanHeeckeren WJ, Vollweiler J, Fu P, Cooper BW, Meyerson H, Lazarus HM, Simic A, Laughlin MJ, Gerson, SL, Koc ON. Randomised comparison of two B-cell purging protocols for patients with B-cell non-Hodgkin lymphoma: *in vivo* purging with rituximab versus *ex vivo* purging with CliniMACS CD34+ cell enrichment device. *BJH* 132:42-55, 2005.
178. Fontes AM, Davis BM, Encell LP, Lingas K, Covas DT, Zago MA, Loeb LA, Pegg AE, Gerson SL. Differential competitive resistance to methylating versus chloroethylating agents among five 06-alkylguanine DNA alkyltransferases in human hematopoietic cells. *Mol Cancer Ther* 5(1):121-128, 2006.
179. Liu L, Gerson SL. Targeted modulation of MGMT: clinical implications. *Clin Cancer Res* 12:328-331, 2006.
180. An F-Q, Folarin HM, Compitello N, Roth J, Gerson SL, McCrae KR, Fakhari FD, Dittmer DP, Renne R. Long-term infected telomerase-immortalized endothelial cells: a model for Kaposi's sarcoma-associated herpesvirus latency *in vitro* and *in vivo*. *JVI* 80:4833-4846, 2006.
181. Yuksel M, Baron E, Camouse M, Cooper BW, Lazarus HM, Gerson SL, Laughlin MJ, Cooper KD, Gilliam A, Fu P, Stevens S, Koc ON. Peritransplant use of ultraviolet-B irradiation (UV-B) therapy is detrimental to allogeneic stem cell transplantation outcome. *Biol Blood Marrow Transplant* 12:665-671, 2006.

182. Fu P, Bagai RK, Meyerson H, Kane D, Fox RM, Creger RJ, Cooper BW, Gerson SL, Laughlin MJ, Koc ON, Lazarus HM. Pre-mobilization therapy blood CD34(+) cell count predicts the likelihood of successful hematopoietic stem cell mobilization. *Bone Marrow Transplant* 38:189-196, 2006.
183. Yan L, Bulgar A, Miao Y, Mahajan V, Donze JR, Gerson SL, Liu L. Combined treatment with temozolomide and methoxyamine: blocking apurinic/pyrimidinic site repair coupled with targeting topoisomerase II {alpha}. *Clin Cancer Res* 13:1532-1539, 2007.
184. Batts ED, Maisel C, Kane D, Liu L, Fu P, O'Brien T, Remick S, Bahlis N, Gerson SL. O(6)-benzylguanine and BCNU in multiple myeloma: a phase II trial. *Cancer Chemother Pharmacol.* 60:415-421, 2007.
183. Fu P, van Heeckeren WJ, Wadhwa PD, Bajor DJ, Creger RJ, Xu Z, Cooper BW, Laughlin MJ, Gerson SL, Koc ON, Lazarus HM. Time-dependent effect of non-Hodgkin's lymphoma grade on disease-free survival of relapsed/refractory patients treated with high-dose chemotherapy plus autotransplantation. *Contemporary Clinical Trials* Jul 19, 2007.
184. Love Z, Wang F, Dennis J, Awadallah A, Salem N, Molter J, Lin Y, Wiesenberger A, Majewski S, Gerson S, Lee Z. Imaging of mesenchymal stem cell transplant by bioluminescence and PET. *J Nucl Med*, Dec 148(12):2011-2020, 2007.
185. Gerson S, Kenyon J. Loss of DNA Damage Repair in Adult Stem Cells during Aging. Dec 26 NAR-01609-D-2007.R1.
186. Lin Y, Molter J, Lee Z, Gerson SL. Bioluminescence imaging of hematopoietic stem cell repopulation in murine models. *Methods Mol Biol* 430:295-306, 2008.
187. Gururangan S, Turner CD, Stewart CF, O'Shaughnessy M, Kocak M, Poussaint TY, Phillips PC, Goldman S, Packer R, Pollack IF, Blaney SM, Karsten V, Gerson SL, Boyett JM, Friedman HS, Kun LE. Phase I trial of VNP40101M (cloretazine) in children with recurrent brain tumors: a pediatric brain tumor consortium study. *Clin Cancer Res* 14:1124-1130, 2008.
188. Reese JS, Roth JC, Gerson SL. Bone marrow-derived cells exhibiting lung epithelial cell characteristics are enriched *in vivo* using methylguanine DNA methyltransferase-mediated drug resistance. *Stem Cells* 26:675-681, 2008.
189. Gao Y, Lobritz MA, Roth J, Abreha M, Nelson KN, Nankya I, Moore-Dudley DM, Abraha A, Gerson SL, Arts EJ. Targets of small interfering RNA restriction during human immunodeficiency virus type 1 replication. *J Virol* 82:2938-2951, 2008.
190. Fu P, van Heeckeren WJ, Wadhwa PD, Bajor DJ, Creger RJ, Xu Z, Cooper BW, Laughlin MJ, Gerson SL, Koc ON, Lazarus HM. Time-dependent effect of non-Hodgkin's lymphoma grade on disease-free survival of relapsed/refractory patients treated with high-dose chemotherapy plus autotransplantation. *Contemp Clin Trials* 29:157-164, 2008.
191. Wald DN, Vermaat HM, Zang S, Lavik A, Kang Z, Peleg G, Gerson LS, Bunting KD, Agarwal ML, Roth BL, Tse W. Identification of 6-benzylthioinosine as a myeloid leukemia differentiation-inducing compound. *Cancer Res* 68:4369-4376, 2008.
192. Lee Z, Dennis JE, Gerson SL. Imaging stem cell implant for cellular-based therapies. *Exp Biol Med* (Maywood) 233:930-940, 2008.
193. Tang Z, Du R, Jiang S, Wu C, Barkauskas DS, Richey J, Molter J, Lam M, Flask C, Gerson S, Dowlati A, Liu L, Lee Z, Halmos B, Wang Y, Kern JA, Ma PC. Dual MET-EGFR combinatorial inhibition against T790M-EGFR-mediated erlotinib-resistant lung cancer. *Br J Cancer* 99:911-922, 2008.
194. Wang F, Dennis JE, Awadallah A, Solchaga LA, Molter J, Kuang Y, Salem N, Lin Y, Tian H, Kolthammer JA, Kim Y, Love ZB, Gerson SL, Lee Z. Transcriptional profiling of human mesenchymal stem cells transduced with reporter genes for imaging. *Physiol Genomics* 37:23-34, 2009.
195. Strunk CJ, Platzbecker U, Thiede C, Schaich M, Illmer T, Kang Z, Leahy P, Li C, Xie X, Laughlin MJ, Lazarus HM, Gerson SL, Bunting KD, Ehninger G, Tse W. Elevated AF1q expression is a poor prognostic marker for adult acute myeloid leukemia patients with normal cytogenetics. *Am J Hematol* 84:308-309, 2009.
196. Barr PM, Fu P, Lazarus HM, Horvath N, Gerson SL, Koc ON, Bahlis NJ, Snell MR, Dowlati A, Cooper BW. Phase I trial of fludarabine, Bortezomib and Rituximab for relapsed and refractory indolent and mantle cell non-Hodgkin lymphoma. *Br J Haematol* 147(1):89-96, 2009.
197. Wang Y, Gerson SL. Direct Detection and Quantification of Abasic Sites for In Vivo Studies of DNA Damage and Repair. *Nuc Med Biol*, Nov;36(8):975-83, 2009.
198. Yan Q, Yao D, Wei LL, Huang Y, Myers J, Zhang L, Xin W, Shim J, Man Y, Petryniak B, Gerson S, Lowe J, and Zhou L 'O-fucose Modulates Notch-Controlled Blood Lineage Commitment, *A J Path.* 2010 176(6):2921-34. Epub 2010 Apr 2. PMID: 20363915.
199. Bulgar AD, Snell M, Donze JR, Kirkland EB, Li L, Yang S, Xu Y, Gerson SL, Liu L. Targeting base

- excision repair suggests a new therapeutic strategy of fludarabine for the treatment of chronic lymphocytic leukemia. *Leukemia*. 2010 Oct;24(10):1795-9. Epub PMID: 20811400.
200. Rizzieri D, LoRusso S, Tse W, Khan K, Advani A, Moore J, Karsten V, Cahill A, Gerson SL. Phase I study of temozolomide and laromustine (VNP40101M) in patients with relapsed or refractory leukemia. *Clin Lymphoma Myeloma Leuk*. 2010 Jun;10(3):211-6. PMID: 20511167.
 201. Kundu S, Fan K, Cao M, Lindner DJ, Tuthill R, Liu L, Gerson S, Borden E, Yi T. Tyrosine phosphatase inhibitor-3 sensitizes melanoma and colon cancer to biotherapeutics and chemotherapeutics. *Mol Cancer Ther*. 2010 Aug;9(8):2287-96. Epub 2010 Aug 3.
 202. Anthanasiou MC, Dettling M, Cascorbi I, Mosyagin I, Salisbury BA, Pierz KA, Zou W, Whalen H, Malhotra AK, Lencz T, Gerson SL, Kane JM, Reed CR. Candidate gene analysis identifies a polymorphism I HLA-DQB1 associated with Clozapine-induced agranulocytosis. *J Clin Psychiatry* 72:458-463, 2011.
 203. Kindwall-Keller TL, Hegerfeldt Y, Myerson HJ, Margevicius S, Fu P, van Heeckeren W, Lazarus HM, Cooper BW, Gerson SL, Barr P, Tse WW, Curtis C, Fanning LR, Creger RJ, Carlson-Barko JM, Laughlin MJ. Bone Marrow Transplant. 2011 Oct 17. doi: 10.1038/bmt.2011.195, in press. PMID: 22002488.
 204. Lin Y, Cheung P, Roth JC, Wilson DL, Gerson SL. Imaging stem cell derived persistent foci after in vivo selection of lentiviral MGMT-P140K transformed murine bone marrow cells. *Mol Ther*. 2011 Jul;19(7):1342-52. PMID:21304493.
 205. Lazarus HM, Sommers SR, Arfons LM, Fu P, Ataergin SA, Kaye NM, Liu F, Kindwall-Keller TL, Cooper BW, Laughlin MJ, Creger RJ, Barr PM, Gerson SL, Kaplan D. Spontaneous autologous graft-versus-host disease in plasma cell myeloma autograft recipients: Flow cytometric analysis of hematopoietic progenitor cell grafts. *Biol Blood Marrow Transplant*. 2011 Jul;17(7):970-8. PMID: 21440080.
 206. Yao D, Huang Y, Huang X, Wang W, Yan Q, Wei L, Xin W, Gerson S, Stanley P, Lowe JB, Zhou L. Protein O-fucosyltransferase 1 (Pofut1) regulates lymphoid and myeloid homeostasis through modulation of notch receptor ligand interactions. *Blood* 117:5652-5662, 2011. PMID: 21464368.
 207. Xu D, Liu X, Yu WM, Meyerson HJ, Guo C, Gerson SL, Qu CK. Non-lineage/stage restricted effects of a gain-of-function mutation in tyrosine phosphatase Ptpnll (Shp2) on malignant transformation of hematopoietic cells. *Jrn Exp Med*. 2011 Sep 26;208(10):1977-88. PMID: 21930766.
 208. Qing Y, Lin Y, Gerson SL. An intrinsic BM hematopoietic niche occupancy defect of HSC in *scid* mice facilitates exogenous HSC engraftment. *Blood* 2012 Feb 16; 119(7):1768-71. PMID: 22147896.
 209. Apisarnthanarax N, Wood GS, Steven SR, Carlson S, Chan D, Liu L, Szabo SK, Fu P, Gilliam AC, Gerson SL, Remick SC, Cooper KD. Phase I clinical trial of O⁶Benzylguanine and topical BCNU in the treatment of cutaneous T-cell lymphoma, mycosis fungoides-type. *Arch Dermatol*, DER11-0722R. In press, 2012. PMID: 22250189.
 210. Bulgar AD, Weeks LD, Miao Y, Yang S, Xu Y, Guo C, Markowitz S, Oleinick N, Gerson SL, Liu L. Removal of uracil by uracil DNA glycosylase limits pemetrexed cytotoxicity: overriding the limit with methoxyamine to inhibit base excision repair. *Cell Death Dis* Jan 12;3:e252, 2012. PMID 22237209.
 211. Fontes AM, Melo FUF, Greene LJ, Feca VM, Lin Y, Gerson SL, Covas DT. Production of human factor VIII-FL in 293T cells using the bicistronic MGMT (P140K)-retroviral vector. *Genet Mol Res* 11(1): 775-789, 2012. PMID: 22576836.
 212. Alberti MO, Roth JC, Ismail M, Tsuruta Y, Abraham E, Bereboeva L, Gerson SL, Curiel DT. Derivation of a myeloid cell-binding adenovirus for gene therapy of inflammation. *PLoS One*. 2012;7(5):e37812. Epub 2012 May 18. PMID: 22624065.
 213. Roth JC, Ismail M, Reese JS, Lingas KT, Ferrari G, Gerson SL. Co-transduction with MGMT and ubiquitous or erythroid-specific GFP lentiviruses allows enrichment of dual-positive hematopoietic progenitor cells in vivo. *ISRN Hematol*. 2012;2012:212586. Epub 2012 Jul 19. PMID:22888445.
 214. Falahati R, Zhang J, Flebbe-Rehwaltd L, Shi Y, Gerson SL, Gaensler KML. Chemoselection of allogeneic HSC after murine neonatal transplantation without myeloablation or post-transplant immunosuppression. *Mol Ther* (2012); Nov;20(11):2180-9. doi: 10.1038/mt.2012.136. Epub 2012 Aug 7. PMID:22871662.
 215. Yang S, Savvides P, Liu L, Gerson S, Xu Y. Development and validation of an LC-MS/MS method for pharmacokinetic study of methoxyamine in phase I clinical trial. *J Chromatogr B Analyt Technol Biomed Life Sci*. 2012 Jul 15;901:25-33. doi: 10.1016/j.jchromb.2012.05.036. Epub 2012 Jun 6. PMID:22743337.
 216. Kindwall-Keller TL, Hegerfeldt Y, Meyerson HJ, Margevicius S, Fu P, van Heeckeren W, Lazarus HM,

- Cooper BW, Gerson SL, Barr P, Tse WW, Curtis C, Fanning LR, Creger RJ, Carlson-Barko JM, Laughlin MJ. Prospective study of one- vs two-unit umbilical cord blood transplantation following reduced intensity conditioning in adults with hematological malignancies. *Bone Marrow Transplant* 47:924-933, 2012. PMID: PMC3262108.
217. Kenyon J, Fu P, Lingas K, Thomas E, Saurastri A, Santos Guasch G, Wald D, Gerson SL. Humans accumulate microsatellite instability with acquired loss of MLH1 protein in hematopoietic stem and progenitor cells as a function of age. *Blood*. 2012 Oct 18;120(16):3229-36. doi: 10.1182/blood-2011-12-401950. Epub 2012 Jun 26. PMID: 22740444.
 218. Condie AG, Gerson SL, Miller RH, Wang Y. Two-proton fluorescent Imaging of myelination in the spinal cord. *ChemMedChem*. 2012 Nov 7. doi: 10.1002/cmdc.201200343 PMID: 23136014.
 219. Gordon MS, Rosen LS, Mendelson D, Ramanathan RK, Goldman J, Liu L, Xu Y, Gerson SL, Anthony SP, Figg WD, Spencer S, Adams BJ, Theuer CP, Leigh BR, Weiss GJ. A phase 1 study of TRC102, an inhibitor of base excision repair, and pemetrexed in patients with advanced solid tumors. *Invest New Drugs*. 2012 Sep 29. PMID: 23054206.
 220. Zhou G, Hamik A, Nayak L, Tian H, Shi H, Lu Y, Sharma N, Liao X, Hale A, Boerboom L, Feaver RE, Gao H, Desai A, Schmaier A, Gerson SL, Wang Y, Atkins GB, Blackman BR, Simon DI, Jain MK. Endothelial Kruppel-like factor 4 protects against atherothrombosis in mice. *J Clin Invest*. 2012 Dec 3;122(12):4727-31. doi: 10.1172/JCI66056. Epub 2012 Nov 19. PMID: 23160196.
 221. Yu WM, Liu X, Shen J, Jovanovic O, Pohl E, Gerson SL, Finkel T, Broxmeyer HE, Qu CK. Metabolic Regulation by the mitochondrial phosphatase PTPM1 is required for hematopoietic stem cell differentiation. *Cell Stem Cell* 2013, 12: 62-74, <http://dx.doi.org/10.1016/j.stem.2012.11.022>. See editorial, Warr, Passegue *Cell Stem Cell* 2013, 12: 62-74.
 222. Weeks LD, Fu P, Gerson SL. Uracil DNA glycosylase expression determines human lung cancer cell sensitivity to pemetrexed. *Mol Cancer Ther*. 2013 Jul 19. PMID: 2387385.
 223. Corn DJ, Kim Y, Krebs MD, Mounts T, Molter J, Gerson S, Alsberg E, Dennis JE, Lee Z. Imaging early stage osteogenic differentiation of mesenchymal stem cells. *J Orthop Res*. 2013 Jun;31(6):871-9. doi: 10.1002/jor.22328. Epub 2013 Feb 25. PMID: 23440976.
 224. Weeks L, Zentner G, Scacheri P, Gerson SL. Uracil DNA glycosylase (UNG) loss enhances DNA double strand break formation in human cancer cells exposed to pemetrexed. *Cell Death and Dis* 2014 Feb 6;5e1045. doi: 10.1038/cddos.2013.477.
 225. Desai A, Qing Y, Gerson SL. Exonuclease 1 is a Critical Mediator of Survival During DNA Double Strand Break Repair in Nonquiescent Hematopoietic Stem and Progenitor Cells. *Stem Cells* 32(2):582-93, Feb 2014. PMID: 24420907
 226. Desai A, Webb B, Gerson SL. CD133+ cells contribute to radioresistance via altered regulation of DNA repair genes in human lung cancer cells. *Radiother Oncol* 2014 Jan 16. (Epub ahead of print) PMID 24440048.
 227. Desai A, Gerson SL. Exo1 Independent DNA Mismatch Repair Involves Multiple Compensatory Nucleases. *DNA Repair*, 2014.
 228. Qing Y, Wang Z, Bunting KD, Gerson SL. Bcl2 Overexpression Rescues the Hematopoietic Stem Cell Defects in Ku70-deficient Mice by Restoration of Quiescence. *Blood* 2014, in press. PMID: 24394664

Chapters, Books, Reviews

1. Gerson SL, Schreiber AD. Complications of transfusion in surgical patients. In: *The Medical Care of the Surgical Patient*, D Goldman et al., ed., Lippincott, Philadelphia, 1982, pp 427-41.
2. Gerson SL. Testicular Cancer. In: EA Mortimer Jr, ed., *Primary Care of Cancer: Recommendations for Screening, Diagnosis and Management*, 1987.
3. Stein J, Strandjord S, Saarinen U, Warkentin P, Gerson S, Lazarus H, VonHoff D, Coccia P, Cheung N-K. *In vitro* treatment of autologous bone marrow for neuroblastoma patients with anti C-D2 monoclonal antibody and human complement: a pilot study. Evans AE, ed., *Prog Clin Biol Res. Adv Neuroblastoma Res*, New York: Alan R Liss Inc, 1987.
4. Gerson SL. Molecular epidemiology of therapy related leukemias. *Curr Opin Oncol* 5:136-44, 1993.
5. Gerson SL, Berger NA. Genetic and molecular approaches to the protection of normal and hematopoietic cells from the nitrosoureas. *Cancer Bull* 45(2):125-30, 1993.
6. Gerson SL, Willson JKV. *O*⁶ alkylguanine-DNA alkyltransferase. A target for the modulation of drug resistance. *Hematology/Oncology Clinics of North America* 9(2):431-50, 4/1995.*
7. Lattime EC, Gerson SL. Genes, oncogenes, and gene therapy strategies for cancer - Introduction. *Semin Oncol* 22(1):1-3, 2/1996.*

8. Koç ON, Davis BM, Lee K, Gerson SL. Gene Therapy of cancer: current progress. *Curr Opin Oncol*, in press, 1996.
9. Koc ON, Phillips WP Jr, Lee K, Liu L, Zaidi NH, Allay JA, Gerson SL. Role of DNA repair in resistance to drugs that alkylate O6 of guanine. *Cancer Treat Res*. 87:123-46, 1996
10. Lattime EC, Gerson SL. *Cancer Gene Therapy*, Academic Press, 1998.
11. Gerson SL. Alkylating Agents. In: *Current Cancer Therapeutics*, Churchill Livingstone, NY, 1998, pp 1-37.
12. Bhalla K, Gerson SL, Sullivan D. Chemotherapeutic Agents. In: *Hematology*, ER Hoffman, E Benz, S Shattell, B Fine eds., 1998.
13. Davis B, Koç O, Reese J, Gerson SL. *O*⁶-benzylguanine-resistant mutant genes improve hematopoietic cell tolerance to alkylating agents. *Prog Exp Tumor Res* 36:65-81, 1999.
14. Koç O, Davis B, Reese J, Friebert S, Gerson S. Transfer of drug resistance genes into hematopoietic progenitors. In: *Gene Therapy of Cancer*, E Lattime, S Gerson eds., Associated Press, 1999, pp 177-203.
15. Gerson SL, Koç ON, Davis BM, Reese JS. Transfer of chemotherapeutic resistance genes into hematopoietic stem cells. In: *Progress in Growth Factors* 5(1):3-6, 1999.
16. Gerson SL. *Cancer Gene Therapy: Clinical Trials and their Scientific Basis*. In: *ASCO Educational Session*, ASCO Publications, 1999, pp 132-40.
17. Davis BM, Koç ON, Reese JS, Gerson SL. *O*⁶ benzylguanine resistant mutant MGMT genes improve hematopoietic cell tolerance to alkylating agents. In: *Marrow Protection: Transduction of Hematopoietic Cells with Drug Resistance Genes*, Karger NY, 1999, pp 65-81.
18. Gerson SL. Therapeutic Development of *O*⁶ benzylguanine: targeting DNA repair and drug resistance, 2000.
19. Gerson SL. Progress in stem cell drug resistance gene therapy: current and future applications. In: *ASCO Educational Book*, ASCO Publications, 2001.
20. Koç ON, Gerson SL. Mesenchymal Stem Cells in Allogeneic Transplantation. In: *Allogeneic Stem Cell Transplantation*. Eds. HM Lazarus, MJ Laughlin.
21. Wadhwa P, Zielske S, Roth J, Ballas C, Bowman J, Gerson SL. *Cancer Gene Therapy: Scientific Basis*. *Annual Review of Medicine* 53:437-52, 2002.*
22. Gerson SL. Progress in Stem Cell Drug Resistance Gene Therapy: Current and Future Applications. *ASCO Educational Book*, 2001, 542-51.
23. Lattime N, Gerson S. eds., *Gene Therapy of Cancer*, 2nd edition, 2002.
24. Koç O, Zielske S, Roth J, Reese J, Gerson S. Transfer of drug resistance genes in hematopoietic progenitors. *Gene Therapy of Cancer*, 2nd edition, 2002.
25. Roth JC, Zielske SP, Wadhwa PD, Ballas CB, Bowman JE, Reese JS, Gerson SL. *Cancer Gene Therapy Models*. In: *Cancer Handbook*, chap 69; McMillan Nature Publications, 1069-80, 2001 eds Malcolm R. Alison.
26. Gerson, SL, Bhalla K, R Creger, S Grant, Naturian K, DeRimer, D. Pharmacology and MlecularMechanisms of antineoplastic ag Elsevier, ents for hematologic diseases In: *Hematology*, ER Hoffman, E Benz, S Shattell, B Fine eds., 2009.
27. Young N, Gerson, SL, High, K, eds, *Clinical Hematology*, Elsevier, 2006.
28. Lattime N, Gerson S. eds., *Gene Therapy of Cancer*, 3rd edition, 2013.
29. Gerson, SL, Bhalla K, Caimi P, Capagnaro E, Creger R.,, Pharmacology and MlecularMechanisms of antineoplastic agents for hematologic diseases . In: *Hematology*, ER Hoffman, E Benz, S Shattell, B Fine eds., Elsevier, 2013.

Theses

1. Gerson SL. Regulation of the histidine utilization operons in *S typhimurium* and *K aerogenes* by the hut repressor. Senior Thesis, Harvard College, Widner Library, Harvard University, 1973.
2. Gerson SL. The effects of prior cytotoxic therapy on granulopoiesis. Honors Thesis, Harvard Medical School Countway Library, Harvard Medical School, 1977.

Abstracts:

1. Gerson SL, Page PL, Hartwell BL, Robinson SH. Altered proliferative capacity of hematopoietic cells after cytoxic perturbation. *Blood* 50:147a, 1977.
2. Page PL, Gerson SL, Hartwell BL, Robinson SH. Chemotherapy induced alterations in proliferative capacity of marrow stem cells. *Clin Res* 26:537A, 1978.

3. Gerson SL, Gerson DF. Digital simulation of the population dynamics of granulopoietic stem cells in diffusion chamber culture. Proc 10th Ann Conf on Models & Simulation, pp 105-10, 1979, Pittsburgh, PA..
4. Cassileth P, Lusk E, Torri S, Dinubile N, Gerson, SL. A randomized double-blind study of the antiemetic efficacy of high dose dexamethasone (Hexadrol) in chemotherapy. Clin Res 30:415A, 1982.
5. Gerson SL, Talbot GH, Lusk E, Hurwitz S, Skros M, Strom B, Cassileth PA. Invasive pulmonary aspergillosis - A case control study of risk factors in adult acute leukemia. Clin Res 30:367A, 1982.*
6. Weiner MH, Talbot GH, Gerson SL, Felice G, Cassileth PA. Diagnosis of invasive aspergillosis - Utility of fungal antigen-detection in controlled, blinded trials. Clin Res 30:381A, 1982.*
7. Talbot GH, Gerson SL, Provencher M, Cassileth PA. Limited utility of fungal nasal surveillance cultures in invasive pulmonary aspergillosis. 22nd ICAAC 9, 1982.
8. Gerson SL, Cooper RA. Production of granulocyte-specific colony stimulating activity by phorbol ester-treated human bone marrow cells. Blood 60:97A, 1982.
9. Cassileth PA, Gerson SL, Bonner H, Neiman R, Lusk E, Hurwitz S. Identification of early relapsing patients with adult acute nonlymphocytic leukemia (ANLL) by bone marrow biopsy after initial induction chemotherapy. Proc ASCO 2:184, 1983.
10. Gerson SL, Talbot GH, Strom BL, Lusk E, Hurwitz S, Alavi J, Cassileth PA. Prolonged granulocytopenia - A major risk factor for invasive pulmonary aspergillosis in patients with acute leukemia. Proc ASCO 2:96, 1983.
11. Gerson SL, Friedman H, Cines DB. Production of colony stimulating activity by endothelial cells during viral infection. Blood 62:135a, 1983.
12. Albelda S, Talbot G, Gerson S, Miller W, Cassileth P. Pulmonary cavitation and massive hemoptysis in invasive pulmonary aspergillosis: Influence of marrow recovery in patients with acute leukemia. Am Rev Respir Dis 129, 1984.
13. Albelda S, Talbot G, Gerson S, Miller W, Cassileth P. The role of fiberoptic bronchoscopy in the diagnosis of invasive pulmonary aspergillosis in patients with acute leukemia. Am Rev Respir Dis 129, 1984.
14. Saarinen UM, Coccia PF, Gerson S, Pelley R, Donovan D, Cheung KVN. In vitro eradication of neuroblastoma (NB) cells by monoclonal antibody (Mab) and human complement ©: A method for purging autologous bone marrow (BM). Proc AACR 23:291, 1985.
15. Gerson SL, Ray K, Berger NA. O⁶-alkylguanine alkyltransferase in human myeloid precursors. Proc AACR 23:102, 3/1985.*
16. Trey J, Miller K, Benjamin E, Gerson SL. Role of DNA repair enzymes in susceptibility of bone marrow to leukemogenic effects of nitrosoureas. Blood 66(suppl):123a, 1985.
17. Abraham J, Gerson S, Hoxie J, Tannenbaum S, Cassileth P, Cooper R. Advanced acute myelogenous leukemia (AML) treated by autologous reconstitution using marrow exposed to 12-O-tetradecanoyl phorbol 13 acetate (TPA). Proc ASCO 4:170, 1985.
18. Abboud S, Gerson SL, Berger NA. The effect of recombinant human tissue necrosis factor (TNF) on normal progenitor cells. Blood 66(suppl):124a, 1985.
19. Trey JE, Benjamin E, Gerson SL. Deficient repair of O⁶-alkylguanine during bone marrow precursor proliferation following nitrosourea exposure. Proc AACR 27:106, 3/1986.*
20. Gerson SL, Trey JE, Miller K. O⁶-methylguanine can overcome nitrosourea resistance of tumor cells. Clin Res 34(2):563A, 4/1986.*
21. Gerson SL, Trey JE, Miller K. Modulation of nitrosourea resistance in myeloid leukemias. Blood 68(suppl):223a, 1986.
22. Zwick D, Ruymann F, Gerson S, Perussia B, Barson W, Munn D, Jacobs D, Mulne A, Newton W, Grossman N, Maddux H. Mechanisms of bone marrow failure and histiocytic activity in neonatal viral associated hemophagocytic syndrome with large granular lymphocytosis (LGL). Proc Soc Ped Res, 1987.
23. Trey JE, Gerson SL. Enhanced induction of sister chromatid exchanges (SCE) in resting vs. proliferating lymphocytes after inactivation of O⁶-alkylguanine-DNA alkyltransferase by O⁶-methylguanine. Proc AACR 28:118, 3/1987.*
24. Clapp DW, Baley J, Gerson SL. Preterm neonates have more circulating hematopoietic stem cells than term infants. Proc Soc Ped Res 407A, 4/1987.*
25. Hatzoglou M, Gerson SL, Winchaw-Boris A, Hanson RW. Use of a retroviral vector containing the hormonally regulated promoter for the phosphoenolpyruvate carboxykinase (PEPCK) gene. Proc Am Soc Biol Chem, 5/1987.*

26. Spitzer T, Gerson S, Lazarus H. Prolonged disease-free survival in refractory acute nonlymphocytic leukemia using mitoxantrone. *Leukemia* 1(11):786-787, 11/1987.
27. Clapp DW, Baley JE, Gerson SL. Effect of recombinant human granulocyte macrophage colony stimulating factor (rh GM-CSF) on circulating stem cells in infants. *Proc Soc Ped Res* 23:462A, 1988.
28. Gerson SL, Dumenco LL, Hatzoglou M, Kessen S, Trey JE. Retroviral gene transfer of the E coli ada gene results in high level expression of *O*⁶-alkylguanine-DNA alkyltransferase in mammalian cells. *Proc AACR* 29:136, 3/1988.*
29. Uy B, Gerson SL. Inactivation of *O*⁶-alkylguanine-DNA alkyltransferase in rat-tissues following intravenous infusion of *O*⁶-methylguanine. *Clin Res* 36:501a, 4/1988.*
30. Weiner MH, Talbot GH, Gerson SL, Fetchick R, Andrews C, Peacock JE, Filice G, Cohen M. Detection of fungal antigen in body fluids for diagnosis of invasive aspergillosis. *Zentralbl Bakteriol Mikrobiol Hyg [A]* 261:517-522, 7/1988.*
31. Gerson SL, Clapp DW, Donovan C. Effect of GM-CSF and IL-3 on DNA repair and nitrosourea sensitivity in proliferating hematopoietic cells. *Blood* 72:117a, 1988.
32. Gerson SL, Kessen S, Marnocha P, Willson JKV. Inactivation of *O*⁶-alkylguanine-DNA alkyltransferase in human colon cancer: A model for biochemical modulation of tumor drug resistance. *Proc AACR* 30:571, 1989.
33. Lim IK, Yun J, Kessen S, Gorodetskaya N, Wagner T, Hanson RW, Gerson SL. Transgenic mice containing the E coli ada gene express increased *O*⁶-alkylguanine-DNA alkyltransferase activity. *Proc AACR* 30:18, 1989.
34. Clapp DW, Dumenco LL, Hatzoglou M, Gerson SL. Proviral integration occurs in multiple fetal tissues following retroviral gene transfer *in vivo*. *Ped Res* 25:268A, 4/1989.*
35. Dumenco LL, Clapp DW, Lim IK, Kessen S, Donovan C, Warman B, Gorodetskaya N, Yun J, Wagner T, Hanson RW, Gerson SL. Transgenic animals expressing the bacterial *O*⁶-alkylguanine-DNA alkyltransferase gene: A model to study the role of DNA repair in the carcinogenesis of N-nitroso compounds. *Env Mol Mutagen* 14(Suppl 15):53, 1989.
36. Clapp DW, Dumenco LL, Gerson SL. Fetal liver hematopoietic stem cells as a target for retroviral gene transfer *in vivo*. *Blood* 74(Suppl 1):242a, 8/1989.*
37. Dumenco LL, Donovan C, Warman B, Yun J, Lim IK, Gerson SL. Rapid regeneration of *O*⁶-alkylguanine-DNA alkyltransferase after DNA damage in transgenic mice expressing the bacterial alkyltransferase. *Proc AACR* 31:105, 1990.
38. Lazarus H, Andersen J, Oette D, Donovan C, Gerson S, Beschoner W, Chen M, Oken M. Phase II ECOG Trial of recombinant granulocyte-macrophage colony stimulating factor (rhGM-CSF) after autologous bone marrow transplant (AuBMT) for relapsed non-Hodgkin's lymphoma (NHL). *Proc ASCO* 9:15, 1990.
39. Clapp DW, Dumenco LL, Gerson SL. Successful retroviral mediated gene transfer into early hematopoietic progenitors following fetal liver injection *in vivo*. *Ped Res* 27:130A, 4/1990.*
40. Gerson SL, Zborowska E, Norton K, Willson, JKV. Inactivation of alkyltransferase by *O*⁶-benzylguanine reverses BCNU resistance in a human colon cancer xenograft. *Proc AACR* 32:2233, 1991.
41. Gerson SL, Dumenco LL, Arce C, Norton K, Johnson K. Enhanced repair of *O*⁶-methylguanine DNA adducts in liver and kidney of transgenic mice expressing bacterial *O*⁶-alkylguanine-DNA alkyltransferase. *Proc AACR* 32:653, 1991.
42. Weber MC, Gerson SL, Tykocinski ML. Use of episomal vectors for antisense RNA-mediated inhibition of GM-CSF in human bone marrow stromal cells. *UCLA Symposia Leukemia Advances in Biological Therapy*, 1991.
43. Gerson SL, Dumenco LL, Norton K, Arce C, Johnson K. Repair of *O*⁶-methylguanine DNA adducts in the liver and kidney of transgenic mice expressing the bacterial *O*⁶-alkylguanine DNA alkyltransferase. *Radiat Res* 1:18, 1991.
44. Gerson SL, Arce C, Meltzer H. Identification of a metabolite potentially responsible for clozapine associated agranulocytosis. *Blood* 78(suppl):417a, 1991.
45. Dumenco LL, Allay E, Wolfman JC, Norton K, Gerson SL. A transgenic model to test the role of DNA repair in prevention of nitrosourea induced T-cell leukemia/lymphoma. *Blood* 78(43a), 1991.
46. Gerson SL, Kastan M, Dumenco LL, Arce C. Human hematopoietic progenitors maintain low *O*⁶-alkylguanine-DNA alkyltransferase during growth factor stimulation. *Proc AACR* 33:8, 1992.
47. Dumenco LL, Allay E, Norton K, Gerson SL. Transgenic expression of human *O*⁶-alkylguanine-DNA alkyltransferase prevents nitrosourea-induced lymphoma in mice. *Proc AACR* 33:182, 1992.

48. Willson J, Gerson S, Haaga J, Berger S, Berger N. Biochemical modulation of drug resistance in colon cancers. *Proc AACR* 33:236, 1992.
49. Minnick DT, Veigl ML, Gerson SL, Sedwick WD. Probable structural determinants of BCNU-induced mutations in mammalian cells. *Proc AACR* 33:144, 1992.
50. Clapp DW, Donovan CA, Freie B, Gerson SL. Expression of the retroviral marker lacZ in hematopoietic progenitor CFU-GM. *Clin Res* 40:350A, 4/1992.*
51. Minnick DT, Dumenco L, Veigl ML, Gerson SL. Dissection of the chemical specificity of BCNU-induced base substitutions through alteration of mutational specificity by *O*⁶-alkylguanine DNA alkyltransferase. *Env Mol Mutagen* 19:43a, 1992.
52. Clapp DW, Freie B, Doerschuk CM, Srour EF, Yoder M, Fortney K, Gerson SL. *In vivo* expression of the retroviral marker lacZ in mouse and rat hematopoietic precursors. *Blood* 80(suppl):239a, 1992.
53. Allay E, Dumenco LL, Beecher S, Gerson SL. Prevention of K-ras activation and nitrosourea-induced lymphoma by a DNA repair gene in transgenic mice. *Blood* 80(suppl):356c, 1992.
54. Lazarus HM, Haynesworth SE, Gerson SL, Caplan AI. Marrow-derived stromal progenitors [mesenchymal stem cells]: A phase I clinical trial. *Blood* 80(suppl):243, 1992.
55. Zaidi NH, Beecher S, Allay E, Dumenco LL, Gerson SL. T-cell lymphoma derived from an immature (J11d+) thymocyte is prevented by Transgenic MGMT expression. *Proc AACR* 34:146, 1993.
56. Gerson SL, Markowitz SD, Willson JKV. Induction of BCNU resistance in a sensitive colon cancer xenograft by transfection of alkyltransferase MGMT: A model for tumor drug resistance heterogeneity. *Proc AACR* 34:271, 1993.
57. Liu L, Allay E, Dumenco LL, Gerson SL. Early efficient repair of *O*⁶-methylguanine-DNA adducts prevents MNU-induced lymphoma in MGMT+ transgenic mice. *Proc AACR* 34:142, 1993.
58. Gerson SL, Allay E, Millie E, Beecher S, Dumenco LL. Transgenic MGMT expression prevents nitrosourea-induced K-ras mutations and thymic lymphoma. *Proc AACR* 34:122, 1993.
59. Gerson SL, Allay E, Liu L, Zaidi NH, Beecher S, Millie E, Dumenco LL. Protection from thymic lymphoma by transgenic expression of the human *O*⁶-alkylguanine-DNA alkyltransferase MGMT: Elucidation of the role of DNA repair in carcinogenesis and oncogene activation. *J Env Mutagen Soc* 21:23, 1993.
60. Allay J, Dennis J, Haynesworth S, Clapp DW, Lazarus HM, Caplan AI, Gerson SL. Retroviral transduction of marrow-derived mesenchymal precursors. *Blood* 82(suppl 10):477a, 11/1993.*
61. Ciobanu N, Lazarus HM, Debellis R, Ascensao J, Sparano JA, Gucalp R, Dutcher J, Fox RM, Creger RJ, Cooper BW, Gerson SL, Nese M, Bello L, Wiemik PH. Autologous bone-marrow transplantation (ABMT) using ex-vivo etoposide (VP-16) purged marrow in patients (pts) with poor-risk lymphomas (LY) and acute leukemias (Leuk). *Blood* 82(10):a629 Suppl 1, 11/1993.*
62. Gerson SL, Allay E, Ma J, Bradley D, Heist A, Sy M-S. Transgenic expression of the DNA-repair protein *O*⁶-alkylguanine DNA-alkyltransferase fails to protect mice from thymic lymphomas induced by ethylnitrosourea (ENU). *Blood* 82(10):a45 Suppl 1, 11/1993.*
63. Allay JA, Dumenco LL, Gerson SL. Retroviral transduction and persistence of the human alkyltransferase gene into hematopoietic cells. *J Cellular Biochem Suppl* 18a:236, 1/1994.*
64. Liu L, Dumenco LL, Allay E, Gerson SL. Transgenic MGMT gene overexpression in lung, a new model to study NNK-induced carcinogenesis. *Proc AACR* 35:182, 1994.
65. Phillips WP, Gerson SL, Zborowska E, Zaidi NH, Liu L, Li BFL, Ayi TC, Willson JKV. Effects of *O*⁶-benzylguanine on the BCNU resistance of MGMT transduced colon cancer xenografts. *Proc AACR* 35:395 1994.
66. Allay E, Koç ON, Gerson SL. MNU-induced mutation frequency is significantly reduced in Big Blue (lacI+) mice overexpressing the MGMT DNA repair gene. *Proc AACR* 35:115, 1994.
67. Zaidi NH, Dumenco LL, Liu L, Allay E, Gerson SL. Transgenic expression of high levels of hMGMT in mouse liver results in enhanced repair of N-Nitrosodimethylamine induced *O*⁶-methylguanine. *Proc AACR* 35:539, 1994.
68. Zaidi NH, Pretlow TP, O'Riordan MA, Dumenco LL, Gerson SL. High incidence of K-ras mutation in aberrant crypt foci and normal mucosa of mice given azoxymethane. *Proc AACR* 35:98, 1994.
69. Cooper B, Gerson S, Ross A, Lazarus H. Erythroid burst-forming units (BFU-E) predict hematopoietic recovery in patients with advanced breast cancer. *Proc ASCO* 35:74, 1994.
70. Allay JA, Dumenco LL, Gerson SL. Induction of nitrosourea resistance by retroviral transduction of the human alkyltransferase gene into hematopoietic-cells. *Exp Hematol* 22(3):698 8/1994.*

71. Gerson SL, Liu L, Phillips WP, Zaidi NH, Heist A, Markowitz S, Willson JKV. Drug resistance mediated by DNA repair: The paradigm of O^6 -alkylguanine DNA alkyltransferase. *Proc AACR* 35: 699, 1994.
72. Page JG, Giles HD, Phillips W, Gerson SL, Smith AC, Tomaszewski JE. Preclinical toxicology study of O^6 -benzylguanine (NSC-637037) and BCNU (carmustine, NSC-409962) in male and female Beagle dogs. *Proc AACR* 36:328, 1994.
73. Allay JJ, Dumenco LL, Liu L, Gerson SL. Retroviral transduction of the human alkyltransferase gene into hematopoietic cells lead to high expression and increased nitrosourea resistance *in vivo*. *Blood* 84(10):A346 Suppl 1 11/1994.*
74. Dennis JE, Steckley J, Allay J, Gerson S, Caplan A. Osteogenic and stromagenic potential of conditionally immortalized mesenchymal progenitor cells. Combined Orthopaedic Research Societies Meeting, 12/6-8/95, San Diego, California.
75. Zaidi NH, Liu L, Gerson SL. Cell-type and tissue heterogeneity of O^6 -alkylguanine-DNA alkyltransferase expression in normal and malignant human colon. *Proc AACR* 36:356(A-2119), 1995.
76. Liu L, Allay E, Gerson SL. Efficient protection of human MGMT transgenic mice from NNK induced lung tumors. *Proc AACR* 36:147(A-872), 1995.
77. Liu L, Corey DA, Zaidi NH, Gerson SL. Flow cytometry and western blot of alkyltransferase protein correlates well with biochemical assay, but not O^6 -benzylguanine depletion of activity. *Proc AACR* 36:356(A-2120), 1995.
78. Allay E, McGuire EA, Koç ON, Marko DA, Pincus E, Gerson SL. Transgenic human O^6 -alkylguanine-DNA alkyltransferase decreases incidence and increases latency of MNU-induced thymic lymphomas in Ttg-1 transgenic mice. *Proc AACR* 36:188(A-1122), 1995.
79. Smith DC, Gerson SL, Liu L, Donnelly S, Trump DL, Kirkwood JM. Phase II trial of carmustine (BCNU) and streptozocin (STZ) in refractory melanoma. *Proc ASCO* 14:182(A-410), 1995.
80. Majumdar MP, Haynesworth SE, Thiede MA, Marshak DR, Caplan AI, Gerson SL. Culture-expanded human mesenchymal stem cells (MSCs) express cytokines and support hematopoiesis *in vitro*. *Blood* 86(10):1966, 11/1995.*
81. Thiede MA, Majumdar MP, Miller S, Longin K, Hardy W, Gerson SL, Marshak R, Storb R, Sandmaier BM. Reinfusion of *ex vivo* - Expanded, retrovirus-transduced, autologous mesenchymal stem cells (MSCs) into irradiated dogs. *Blood* 86:112a, 1995.*
82. Winter JN, Lazarus HM, Rademaker AF, Bauman A, Cooper B, Thomas R, Gordon LI, Tallman MS, Rubin H, Gerson S, Miller LL. Comparison of PIXY321 and GM-CSF for mobilization of peripheral blood progenitor cells (PBPC) in advanced breast cancer. *Blood* 86(10):3929 Suppl 1, 11/1995.*
83. Koç O, Gerson SL, Fox RM, Schupp JE, Marko DA, Steckley JA, Lazarus HM. Infusion of CD34 enriched peripheral blood progenitor cells result in rapid engraftment after high-dose chemotherapy in patients with advanced lymphoma. *Blood* 86(10):917 Suppl 1, 11/1995.*
84. Allay JA, Davis BM, Gerson SL. MGMT expression in murine hematopoietic progenitors can serve as a dominant selectable marker *in vivo*. *Blood* 86:113a, 1995.*
85. Allay JA, Koç ON, Davis BM, Gerson SL. Induction of nitrosourea resistance in human hematopoietic progenitors by MGMT retroviral transduction. *Blood* 86(10):1848 Suppl 11/1995.*
86. Koç ON, Lazarus HM, Cooper BW, Steckley JA, Gerson SL. Progenitor content and CD34+ cells in peripheral blood progenitor cell (PBPC) collections are better predictors of hematopoietic recovery than total mononuclear cell (MNC) count. *Blood* 86:985a, 1995.
87. Reese JS, Schupp JE, Pincus EL, Gerson SL. T-cell receptor rearrangement is required for lymphomagenesis in immunodeficient mice. *Proc AACR* 37:547, 1996.
88. Reese JS, Lee KM, Allay JA, Koç ON, Liu L, Gerson SL. Retroviral expression of mutant human alkyltransferase provides O^6 -benzylguanine resistance in human hematopoietic progenitors. *Proc AACR* 37:334, 1996.
89. Liu L, Markowitz S, Willson JKV, Gerson SL. Mismatch repair mutator phenotype confers resistance to temozolomide in human colon cancer cell lines. *Proc AACR* 37:365, 1996.
90. Liu L, Zaidi NH, Spiro TP, Majka S, Willson JKV, Gerson SL. Differential degradation rates of inactivated alkyl transferase in lymphocytes and tumors of patients after treatment with O^6 -benzylguanine. *Proc AACR* 37:380, 1996.
91. Gerson SL, Spiro TP, Reidenberg P, Schupp J, Liu L, Haaga J, Majka S, Statkevich P, Batra V, Dugan M, Willson JKV. Rapid depletion of O^6 -alkylguanine DNA alkyltransferase with twice daily oral temozolomide (SCH 52365) in patients with advanced cancer. *Proc ASCO* 15:188a, 1996.

92. Cooper BW, Lazarus HM, McGloin B, Creger R, Gosky DM, Willson JKV, Hoppel CL, Berger SJ, Berger NA, Gerson SL. A phase I and pharmacodynamic study of sequential topotecan and etoposide (TE) in adult patients with refractory/relapsed acute leukemia (RAL). Proc ASCO 15:486a, 1996.
93. Spiro TP, Willson JKV, Haaga J, Hoppel CL, Liu L, Majka S, Gerson SL. *O*⁶-benzylguanine and BCNU: Establishing the biochemical modulatory dose in tumor tissue for *O*⁶-alkylguanine DNA alkyltransferase directed DNA repair. Proc ASCO 15:187a, 1996.
94. Phillips WP, Gerson SL. Acquired resistance to *O*⁶-benzylguanine and BCNU in MCF-7. Proc AACR 37:333, 1996.
95. Lee KM, Zaidi N, Liu L, Gerson SL. Overexpression of *O*⁶-alkylguanine DNA alkyltransferase by the MMTV promoter in mouse mammary glands: A new model to prevent mammary carcinogenesis. Mole Biology/Bioch, 1996.
96. Myeloma plasma cells: A target for *O*⁶-benzylguanine (BG) & BCNU therapy. Proc AACR 37:535, 1996.
97. Gerson SL. Overcoming drug resistance with temozolomide in gliomas and melanomas. Cancer Invest 15(1):9, 1996.
98. Koç ON, Reese JS, Szekely EM, Lee KM, Gerson SL. FLT3-dependent human peripheral blood (PB) long term culture initiating cell (LTCIC) expansion leads to retroviral transduction with mutant MGMT and resistance to *O*⁶-benzylguanine & BCNU. Blood 88:274a, 11/1996.*
99. Davis BM, Koç ON, Lee KM, Reese JS, Schupp JE, Gerson SL. Enrichment for BCNU and *O*⁶-benzylguanine resistant cells after transplant of G156A MGMT transduced bone marrow progenitors in mice. Blood 88:431a, 11/1996.*
100. Reese JS, Koç ON, Liu L, Gerson SL. *O*⁶-benzylguanine (BG) plus temozolomide is an effective strategy to select for retrovirally transduced human CD34 cells containing BG resistant G156A MGMT. Proc AACR 38:522, 1997.
101. O'Brien T, Koç O, Qin X, Liu L, Gerson SL. Elevated *O*⁶-alkylguanine-DNA alkyltransferase activity in myeloma plasma cells: A target for *O*⁶-benzylguanine (BG) & BCNU therapy. Proc AACR 38:313, 1997.
102. Reese JS, Allay E, Koç ON, Gerson SL. Transgenic expression of human *O*⁶-alkyltransferase (AGT) prevents MNU induced lymphomas in heterozygote p53 deficient mice. Proc AACR 38:450, 1997.
103. Liu L, Chatterjee S, Gerson SL. Blockade of base excision repair appears to mediate cytotoxicity of temozolomide in mismatch repair deficient tumor cells. Proc AACR 38:228, 1997.
104. Kyshtoobayeva A, Gerson SL, VonPalffy S, Brem H, Fruehauf JP. MGMT expression by glioblastoma confers *in vitro* BCNU resistance. Proc AACR 38:432, 1997.
105. Liu L, Phillips WP Jr., Gerson SL. Resistance to *O*⁶bG+BCNU is mediated by either AGT dependent or independent mechanisms in human colon cancer cells. Proc AACR 38:522, 1997.
106. Davis BM, Koç ON, Gerson SL. Detection of long term hematopoiesis by G156A MGMT transduced progenitors in non-myeloablated mice after enrichment with *O*⁶-benzylguanine and BCNU. Blood 90:554a, 11/1997.*
107. Qin X, Liu L, Liskay M, Gerson SL. Mice defective in the DNA mismatch gene PMS2 are hypersensitive to MNU induced thymic lymphoma and are partially protected by transgenic expression of human MGMT. Blood 90:414a, 11/1997.*
108. Koç ON, Dyhouse SM, Gerson SL, Haynesworth SE, Cooper BW, Kutteh L, Caplan A, Lazarus HM. Culture-expanded autologous human mesenchymal stem cells (MSCs) circulate in blood and retain proliferative capacity following IV infusion into breast cancer patients. Blood 90:367a, 11/1997.*
109. Koç ON, Davis BM, Reese JS, Liu L, Gerson SL. ΔMGMT transduced bone marrow infusion increases tolerance to *O*⁶-benzylguanine and BCNU and allows intensive therapy of BCNU resistant xenografts in nude mice. Blood 90:243a, 11/1997.*
110. Koc ON, Davis BM, Reese JS, Liu L, Gerson SL. Delta MGMT transduced bone marrow infusion increases tolerance to O-6 benzylguanine and BCNU and allows intensive therapy of BCNU resistant xenografts in nude mice. Blood 90(10):1066 Part 1 Suppl 1 Nov 1997.
111. Qin X, Liu L, Liskay RM, Gerson SL. Heterozygous DNA mismatch repair gene PMS2-knockout mice are susceptible to intestinal and splenic tumors following MNU treatment. Proc AACR 39:461, 1998
112. Liu L, Taverna P, Gerson SL. Identification of the role of base excision repair in cytotoxicity of methylating agents by blocking AP sites in colon cancer cells. Proc AACR 39:631, 1998.
113. Taverna P, Phillips WP Jr., Liu L, Gerson SL. Resistance to *O*⁶bG + BCNU is mediated by increased removal of BCNU-induced DNA interstrand-crosslinks in human breast cancer cells. Proc AACR 39:219, 1998.

114. Taverna P, Liu L, Gerson SL. Base excision repair (BER) activity in colon cancer cells. *Proc AACR* 39:307, 1998.
115. Davis BM, Roth JC, Liu L, Freibert SE, Schupp JE, Neumann A, Xu-Welliver M, Pegg AE, Gerson SL. Novel mutant alkyltransferase proteins protect hematopoietic cells from *O*⁶-benzylguanine (BG) & BCNU and remain active after high dose BG. *Blood* 92(10):466a, 11/1998.*
116. Davis BM, Koç ON, Gerson SL. Bone marrow repopulation by limited numbers of G156A MGMT transduced hematopoietic cells in non-myeloablated mice after *O*⁶-benzylguanine and BCNU mediated selection. *Blood* 92(10):691a, 11/1998.*
117. Reese JS, Qin X, Sekiguchi M, Gerson SL. MGMT expression in bone marrow is the major determinant of survival after methylating agent exposure. *Blood* 92(10):265a, 11/1998.*
118. Donaher E, Berger S, Hoppel C, Lazarus H, Gerson S, Cooper B. A phase I and pharmacodynamic study of sequential topotecan and etoposide (TE) in adult patients with refractory/relapsed acute leukemia (RAL). *Blood* 92(10):234a, 1998.
119. Koç ON, Gerson SL, Cooper BW, Dyhouse SM, Haynesworth SE, Caplan A, Tainer N, Lazarus H.M. Rapid hematopoietic recovery after co-infusion of autologous culture-expanded human mesenchymal stem cells (hMSCs) and PBPCs in breast cancer patients receiving high dose chemotherapy. *Blood* 92(10):274a, 11/1998.*
120. Koç ON, Gerson SL, Cooper BW, Kutteh L, Meyerson H, Fox RM, Szekely EM, Tainer N, Lazarus HM. High dose cyclophosphamide (CTX) + G-CSF is a better progenitor cell mobilization regimen than G-CSF + GM-CSF when compared directly in the same patient in a randomized cross-over clinical trial. *Blood* 92(10):724a, 11/1998.*
121. Koç ON, Lee KM, Majcenko K, Davis BM, Dyhouse SM, Gerson SL. GFP and MGMT transduced human mesenchymal stem cells (hMSCs) can be selectively enriched with *O*⁶-benzylguanine (BG) and BCNU. *Blood* 92(10):148a, 1998.
122. Spiro TP, Gerson SL, Hoppel CL, Liu L, Schupp J, Majka S, Haaga J, Willson JKV. *O*⁶-benzylguanine totally depletes alkylguanine DNA alkyltransferase in tumor tissue: A phase I pharmacokinetic/pharmacodynamic study. *Proc ASCO* 17:212a, 1998.
123. Whitacre CM, Gerson S. Topoisomerase I and II Inhibitors: Scheduling combination therapy. *Cancer Therapeutics* 1(5), 11-12/1998.
124. Nakatsuru Y, Davis BM, Qin X, Liu L, Gerson SL. Resistance to temozolomide (TMZ) plus *O*⁶-benzylguanine (BG) in mismatch DNA repair (MMR) knockout mouse hematopoietic progenitors. *Proc AACR* 40:296, 1999.
125. Maruo N, Liu L, Schupp J, Chatterjee S, Gerson SL. Cellular localization of MGMT enhancer binding protein in normal human tissues. *Proc AACR* 40:153, 1999.
126. Gerson SL, Koç ON, Davis BM, Reese JS. Transfer of chemotherapeutic resistance genes into hematopoietic stem cells. *Progress in Growth Factors* 5(1):3-6, 1999.
127. Qin X, Zhou H, Liu Lm, Gerson SL. PMS2-deficient mice are hypersensitive to GI tumor induction by azoxymethane and protected by MGMT overexpression. *Proc AACR* 40:57, 1999.
128. Zhou H, Lee K, Qin X, Gerson SL. c-neu transgenic mice are hypersensitive to MNU breast tumor induction. *Proc AACR* 40:371, 1999.
129. Taverna P, Liu L, Lomas D, Gerson SL. Deficiency in DNA mismatch repair (MMR) correlates with novel agents resistance but not with drug resistance mechanisms in cell lines from the NCI anticancer drug screen. *Proc AACR* 40:139, 1999.
130. Davis BM, Encell LP, Freibert SE, Loeb LA, Gerson SL. A mammalian cell selection strategy to identify mutant human MGMT sequences mediated *O*⁶-benzylguanine & BCNU resistance. *Proc AACR* 40:700, 1999.
131. Liu L, Davis BM, Gerson SL. MMR deficient colon cancer cells acquire BG-resistant mutations in AGT during treatment with BG plus BCNU. *Proc AACR* 40:139, 1999.
132. Spiro TP, Gerson SL, Hoppel CL, Liu L, Schupp J, Majka S, Haaga J, Pluda J, Willson JKV. *O*⁶-benzylguanine and BCNU: Kinetics, efficacy, & safety. *Proc ASCO* 18:184a, 1999.
133. Dowlati A, Remick SC, Majka S, Ingalls S, Hoppel C, Spiro T, Gerson S, Willson JKV. A phase I clinical and pharmacokinetic study of rebeccamycin analog (NSC 655649) given daily for five consecutive days. *Proc ASCO* 18:181a, 1999.
134. Remick SC, Dowlati A, Ingalls ST, Hoppel C, Spiro T, Gerson S, Willson JKV. A phase I pharmacokinetic study of declopramide in combination with cisplatin patients with advanced cancer. *Proc ASCO* 18:169a, 1999.

135. Gerson S, Koç O, Davis B, Reese J, Pavlus J. G156A MGMT gene transfer with *in vivo* selection using *O*⁶-benzylguanine and BCNU: preclinical basis for a clinical trial in patients with advanced malignancies. Proc Am Soc Gene Therapy, 1999.
136. Koç ON, Majczenko K, Brewer F, Keunmyoung L, Gerson SL. ΔMGMT mediated selection strategy for human mesenchymal stem cells in NOD-SCID mice using *O*⁶-benzylguanine (BG) and BCNU. Proc Am Soc Gene Therapy, 1999.
137. Davis BM, Pavlus JE, Gerson SL. MFG-P140K MGMT transduction and expression protects hematopoietic cells from toxicity by methylating and chloroethylating agents plus *O*⁶-benzylguanine. Proc Am Soc Gene Therapy, 1999.
138. Koç ON, Peters C, Gerson SL, Lazarus HM, Brewer F, Krivit W. Allogeneic mesenchymal stem cell transplantation in patients with genetic diseases. Blood 94(10):132a, 1999.
139. Koç ON, Laughlin MJ, Szekeley E, Rizk M, Gerson SL. Mesenchymal stem cells potentiate *ex vivo* survival and growth factor mediated expansion of peripheral blood CD34+ cells. Blood 94(10):558a, 11/1999.*
140. Davis BM, Encell LP, Zielske SP, Christians F, Liu L, Loeb LA, Gerson SL. Gene transfer of novel *O*⁶-methylguanine-DNA methyltransferases (MGMT) obtained by directed evolution protect hematopoietic cells from *O*⁶-benzylguanine & BCNU. Blood 94(10):360a, 1999.
141. Ballas CB, Reese JS, Dennis JE, Gerson SL. Transplantation, engraftment and selection for donor murine stromal cells *in vivo*. Blood 94(10):162b, 11/1999.*
142. Pavlus JE, Davis BM, Reese JS, Gerson SL. Comparison of *in vivo* selection for MFG-P140K MGMT and MFG-G156A MGMT transduced murine progenitors using *O*⁶-benzylguanine and BCNU. Blood 94(10):420b, 11/1999.*
143. Davis BM, Encell LP, Zielske SP, Christians F, Liu L, Loeb LA, Gerson SL. Gene transfer of novel *O*⁶-methylguanine-DNA methyltransferases (MGMT) obtained by directed evolution protect hematopoietic cells from *O*⁶-benzylguanine & BCNU. Blood 94(10):1610 Part 1 Suppl 1 Nov 1999.
144. Koc ON< Laughlin MJ, Szekely E, Rizk M, Gerson SL. Mesenchymal Stem Cells potentiate *ex vivo* survival and growth factor mediated expansion of peripheral blood CD34+ cells. Blood 94(10):2495 Part 1 Suppl 1 Nov 1999.
145. Ballas CB, Reese JS, Dennis JE, Gerson SL. Transplantation, engraftment and selection for donor murine stromal cells *in vivo*. Blood 94(10):3901 Part 2 Suppl. 1 Nov 1999.
146. Gerson SL. DNA repair defects: Pathways to murine lymphomas and treatment-related leukemias. Blood 94(10):63-64 Part 1 Suppl. 1, 11/1999.*
147. Pavlus JE, Davis BM, Reese JS, Gerson SL. Comparison of *in vivo* selection for MFG-P140K mgmt and MG-G156A mgmt transduced murine progenitors using *O*⁶-benzylguanine and BCNU. Blood 94(10):5105 Part 2 Suppl 1 Nov 1999.
148. Koc ON, Peters C, Gerson SL, Lazarus HM, Brewer F, Krivit W. Allogeneic mesenchymal stem cell transplantation in patients with genetic diseases. Blood 94(10):581 Part 1 S. 11/1999.*
149. Davis BM, Encell LP, Zielske SP, Christians F, Liu L, Loeb LA, Gerson SL. Gene transfer of novel *O*⁶-methylguanine-DNA methyltransferases (MGMT) obtained by directed evolution protect hematopoietic cells from *O*⁶-benzylguanine & BCNU. Blood 94(10):1610 Part 1 S 11/1999.*
150. Szabo SK, Spiro T, Stevens SR, Horvath N, Liu L, Cooper KD, Gerson S, and Wood GS. Phase I Clinical Trial of *O*⁶-benzylguanine and BCNU in Cutaneous T Cell Lymphoma; SID Society for Investigative Dermatology Poster, 2000.
151. Dowlati A, Robertson K, Ksenich P, Jacobberger J, Whitacre C, Schnur G, Cooper B, Spiro T, Lazarus H, Gerson S. et al. Phase I trial of combination bryostatin-1 and vincristine in B-cell malignancies. ASCO 2000.
152. Tolcher A, Felton S, Gerson SL, et al. Persistent and marked inactivation of *O*⁶-alkylguanine DNA alkyltransferase AGAT a mechanism of resistance to alkylators with protracted low dose oral schedules of temozolomide. ASCO 2000.
153. Jaroscek J, Smith T, Haynesworth S, Laughlin MJ, Kurtzberg J, Gerson SL. Preliminary characterization of the surface staining of placental derived adherent cells: A potential new source of stroma for umbilical cord blood (UCB) expansion. Blood 96(11): 4349 Part 2, 11/2000.*
154. Jaroscek J, Mandel D, Meyerson HJ, Fu P, Greenspan NS, DeJelo C, Lazarus H, Gerson SL, Koc O, Stevens C, Rubinstein P, Stewart CC, Laughlin MJ. Effect of umbilical cord blood (UCB) graft lymphocyte and CD34+populations on survival and engraftment of adult recipients. Blood 96(11):5044 Part 2, 11/2000.*

155. Wadhwa PD, Roth JC, Davis BM, Dinanuer MC, Gerson SL. Selection for gp91PHOX-transduce murine hematopoietic progenitors by mutant mgmt (P140K) mediated resistance to BG and BCNU using a bicistronic retroviral vector. *Blood* 96(11):292 Part 1, 11/2000.*
156. Reese JS, Liu L, Gerson SL. Mismatch repair deficient hematopoietic stem cells have an early selection advantage *in vivo* but experience late exhaustion after methylating agent exposure. *Blood* 96(11):292 Part 1, 11/2000.*
157. Koc ON, Day J, Brown D, Andrews P, Peters C, Nieder M, Gerson SL, Lazarus HM, Caplan AI, Laughlin MJ, Raghavan S, Kolodny EH, Krivit W. Results of a phase I clinical trial of allogeneic mesenchymal stem cell (MSC) transplantation in patients with Hurler disease and metachromatic leukodystrophy (MLD). *Blood* 96(11):732 Part 1, 11/2000.*
158. Bowman JE, Davis BM, Gerson SL. Competitive *in vivo* selection for MFG-P140K MGMT and MFG-G156A4 MGMT transduced murine progenitors in secondary recipient mice using O-6-benzylguanine and BCNU. *Blood* 96(11):908 Part 1, 11/2000.*
159. Zielske SP, Gerson SL. Drug resistance of human hematopoietic stem cells transduced with MGMT P140K using a lentiviral vector at low multiplicity of infection. *Blood* 96(11):923 Part 1, 11/2000.*
160. Laughlin MJ, Barker J, Bambach B, Koc ON, Rizzieri DA, Wagner JE, Gerson SL, Lazarus HM, Cairo M, Stevens CE, Rubinstein P, Kurtzberg J. Hematopoietic engraftment and survival after unrelated donor umbilical cord blood (UCB) transplantation in adult recipients. *Blood* 96(11):2520 Part 1, 11/2000.*
161. Cooper B, Ksenich P, Koç O, Lazarus H, Creger R, Berger S, Ingall S, Hoppel C, Reed E, Gerson S. A phase I and pharmacodynamic study of fludarabine, carboplatin, and topotecan (FCT) for relapsed/refractory acute leukemia (RAL) and advanced myelodysplastic syndromes (MDS). *ASCO* 2001.
162. Zielske S, Li Y, Bhakta S, Gerson SL. The expression efficiency of P140K MGMT in lentiviral vector transduced human hematopoietic cells is sufficient for high level drug resistance and *in vitro* selection. *Blood* 98(11):887 Part 1 11/2001.*
163. Reese JS, Gerson SL. Bone marrow failure is associated with genomic instability in transplanted mismatch repair deficient hematopoietic stem cells after exposure to temozolomide. *Blood* 98(11):1152 Part 1 11/2001.*
164. Jaroscek J, Gerson SL, Laughlin MJ. Engraftment competition between umbilical cord blood (UCB) units in NOD/SCID mice. *Blood* 98(11):2704 Part 1, 11/2001.*
165. Simic A, Meyerson H, Cooper B, Fox R, Gerson SL *et al.* Efficient B-lymphocyte purging of PBPCs in B-cell HNL can be achieved by either *in-vivo* Rituximab therapy or *ex-vivo* CD34+ cell enrichment using CliniMACS device. *Blood* 98(11):3076 Part 1 11/2001.*
166. Jaroscek J, Fu P, Meyerson H, Mandel D, Koç ON, Lazarus HM, Gerson SL, Laughlin MJ. Clinical results in adults transplanted with unrelated HLA-mismatched umbilical cord blood: graft lymphocyte populations, engraftment, and survival. *Blood* 98(11):5316 Part 2 11/2001.*
167. Gerson SL, Koç ON, Reese J, Davis B, Roth J, Zielske S. Repopulating Stem Cells Carrying Chemotherapy Resistance-inducing Genes. *Clin Cancer Res* 7(11):W834 Suppl. S 11/2001.*
168. Ballas C, Gerson SL. Enrichment of retrovirally transduced rat mesenchymal stem cells *in vitro* by resistance to BCNU. *ASGT* 2001, Seattle WA.
169. Fontes A, Davis B, Loeb L, Gerson SL. Directed molecular evolution of DNA alkyltransferases coupled to selection with O⁶ benzylguanine plus BCNU and O⁶ benzylguanine plus temozolomide in human hematopoietic cells. *AACR Annual Meeting*, New Orleans LA, 2001, Pg. 32.
170. Liu L, Gerson SL. Upregulation of anti-apoptosis genes and decreased G2 arrest contributes to the acquired resistance to BG and BCNU observed in MMR deficient cells harboring Bg-resistance K165 mutant AGT. *AACR Annual Meeting*, New Orleans LA, 2001, Pg. 645.
171. Ballas C, Gerson SL. Femur fragment transplantation: a new model for determining the normal biology of bone marrow mesenchymal stem cells. *CWRU Cancer Center Retreat*, Oct 2001.
172. Liu L, Donze JR, Gerson SL. Methoxamine enhances antitumor efficacy of BCNU in colon tumor xenografts. *AACR proc.* 2002, Pg. 794.
173. Liu L, Yan L, Gerson SL. Prolonged exposure to MX after TMZ increases cell death mediated by persistent AP site and increased DNA breakage. *AACR proc.* 2002, Pg. 836.
174. Ozdemir A, Liu L, Reese J, Gerson SL. Selective protection of bone marrow from cytotoxicity of MX combined with TMZ due to low levels of topoisomerases and II. *AACR proc.* 2002.

175. Ke M, Szabo S, Liu L, Gilliam A, Gerson S, Wood G, Stevens S. Update of the Phase I Clinical Trial of *O*⁶ benzylguanine (BG) and carmustine (BCNU) in the treatment of cutaneous T-cell lymphoma. *J Invest Dermatol* 119(1):844 Part 2 Jul 2002.
176. Ozdemir A, Liu L, Reese J, Gerson S. Low topoisomerase I and II protects bone marrow from MX potentiation of TMZ toxicity. *AACR proc.* 2002, Pg. 794.
177. Vangilder JG, Gerson S. Cerebellar toxicity due to BCNU in MGMT knockout mice is prevented by overexpression of MGMT. *AACR proc.* 2002, Pg. 595.
178. Hang Z, Liu L, Keumyoung L, Qin X, Grasso AW, Kung H, Willis JE, Kern HJ, Gerson SL. Mice transgenic for erbB3 develop lung cancer that is potentiated by methylnitrosourea. *AACR proc.* 2002, Pg. 486.
179. Zielske SP, Gerson SL. Cytokine stimulation is necessary for high level lentiviral transduction of human repopulating hematopoietic stem cells. *Am Soc Gene Therapy*, 2002, Pg. S310.
180. Roth, JC, Gerson SL. Screening mutant ecotropic MLV envelope libraries for altered host range. *Am Soc Gene Therapy* :S176 2002.
181. Gerson SL, Zielske S, Reese J, Roth J, Vollweiler J. Mutant MGMTs confer significant stem cell survival, enrichment, and organ-repopulating advantage. *Blood Cell Mol Dis* 28(3):20 May-Jun 2002.*
182. Ke MS, Szabo SK, Liu L, Gilliam AC, Gerson SL, Wood GS, Stevens SR. Update of the phase I clinical trial of *O*⁶ benzylguanine (BG) and carmustine (BCNU) in the treatment of cutaneous T cell lymphoma. *J Investigative Dermatology* 119(1):844 part 2 7/2002.*
183. Zielske SP, Gerson SL. HIV vpr protein in a lentiviral vector does not promote transduction of minimally stimulated human hematopoietic progenitors. *Blood* 100(11):5549 Part 2 Nov 2002.*
184. Bhakta S, Gerson SL. Lentivirus-mediated gene transfer of methylguanine methyltransferase into human hematopoietic stem cells: a model for gene therapy. *Amer Coll Physicians – Amer Soc Int Med*, 2002.
185. Richard E, Geronimi, F, Lalanne M, Ged C, Redonnet-Vernhet I, Lamrissi-Garcia I, Gerson S, de Verneuil H, Moreau-Gaudry F. A bicistronic SIN-lentiviral vector containing G156A MGMT allows selection and metabolic correction of hematopoietic protoporphyric cell lines. *Blood* 100(11):1697 Part 1 Nov 2002.*
186. Richard E, Lalanne M, Cario-Andre M, Geronimi F, Gerson SL, de Verneuil H, Moreau-Gaudry F. A bicistronic SIN-lentiviral vector containing G156A MGMT allows selection and metabolic correction of protoporphyric mice without myeloablation. *Mol Ther* 7(5):1053 Part 2 5/2003.*
187. Zielske SP, Reese JS, Lingas KT, Donze, J, Gerson SL, et al. Human NOD/SCID repopulating cells lentivirus-transduced with P140K MGMT have a selective advantage and are enriched in vivo after BG/BCNU treatment without pre-transplant irradiation conditioning. *Mol Ther* 7(5):1054 Part 2 5/2003.*
188. Zielske SP, Lingas KT, Arts EJ, Gerson SL. High level lentiviral transduction of low-dose SDF-1-exposed human hematopoietic progenitors under conditions of reduced proliferation. *Mol Ther* 7(5):1066 Part 2 5/2003.*
189. Roth JC, Lin Y, Ismail M, et al. Co-transduction with a marker/therapeutic and mutant MGMT lentivirus allows selective enrichment of dual-vector expressing cells. *Mol Ther* 7(5):1069 Part 2 5/2003.*
190. Bahlis NJ, Liu L, Cooper B, Laughlin M, O'Brien T, Gerson S. Phase II study of *O*⁶benzylguanine (*O*⁶-BG) and BCNU in multiple myeloma. *ASCO #2420a(22):602* 5-6/2003.
191. Apisarnthanarax N, Ke MS, Szabo SK, Liu L, Fu P, Gilliam AC, Gerson SL, Wood GS, Stevens SR. Phase I clinical trial of *O*⁶ benzylguanine and topical BCNU in the treatment of cutaneous T-cell lymphoma. *ASCO #2295a(22):571*, 5-6/2003.
192. Yan L, Gerson SL, Liu L. Human tumor cells expressing AGT undergo permanent growth arrest after exposure to BG and BCNU. *AACR #692*, 44(2)a:132, 7/2003.
193. Xu Y, Yang S, Liu L, Gerson SL. A tandem mass spectrometry method for the measurement of methoxyamine in plasma samples. *AACR #5335*, 44(2)a:1058, 7/2003.
194. Liu L, Yan L, Mahajan V, Donze JR, Gerson SL. Inhibition of AP site repair coupled with action of topoisomerase II poison: A potential strategy to enhance efficacy of chemotherapeutic alkylating agents. *AACR #6543*, 44(2)a: 1309, 7/2003.
195. Maisel CM, Miao Y, Kharfan-Dabaja MA, Gerson SL, Bahlis NJ. The Proteasome Inhibitor MG-132 Combined with the Heat Shock Protein Inhibitor 17-AAG Synergistically Induces Cell Death in Myeloma Cell Line U266. *Blood* 102(11):254a 11/2003.

196. Hamza NS, Fanning L, Tary-Lehmann M, Jaroscak J, Koc ON, Lazarus HM, Cooper B, Gerson SL, et al. High rate of graft failure after infusion of multiple (3-5) umbilical cord blood (UCB) units in adults with hematologic disorders: Role of HLA disparity and UCB graft T cell cross immune reactivation. *Blood* 102(11):680a 11/2003.
197. Bahlis NJ, Miao Y, Koc ON, Gerson SL. PKC δ inhibition restores PTEN function to suppress P13K/AKT signaling in myeloma cells. *Blood* 102(11):379a 11/2003.
198. Kane D, Fu P, Meyerson H, Fox RM, Cooper BW, Gerson SL, Laughlin MJ, et al. Pre-Mobilization therapy blood CD43+ cell number is the most important discriminator in the classification and regression tree (CART) algorithm to predict mobilization outcome in cancer patients and normal donors. *Blood* 102(11):3566a 11/2003.
199. Wadhwa P, Fu P, Koc ON, Cooper BW, Fox RM, Creger RJ, Bajor DL, Bedi T, Laughlin MJ, Gerson SL, et al. High-dose carmustine, etoposide, cisplatin, autologous stem cell transplant and involved-field radiotherapy for relapsed/refractory lymphoma: an effective regimen with low mortality. *Blood* 102(11):2721a 11/2003.
200. Reese JS, Fine A, Gerson SL. Hematopoietic stem cell-derived alveolar epithelial cells are enriched *in vivo* using P140K-MGMT gene transfer. *Blood* 102(11):1225a 11/2003.
201. Park Y, Lin Y, Gerson SL. Murine *scid* hematopoietic stem cells have a transplant repopulation defect. *Blood* 102(11):1176a 11/2003.
202. Fanning L, Hamza N, Fu P, Meyerson H, Fox R, Jaroscak J, Lazarus H, Koc O, Gerson S, et al. HLA disparity, graft lymphocyte and CD34+ Populations, and CMV serostatus influence umbilical cord blood transplant (UCBT) engraftment rate and event free survival (EFS) in adults. *Blood* 102(11):1689a 11/2003.
203. Vollweiler J, van Heeckeren W, Meyerson H, Fu P, Fox R, Cooper BW, Laughlin MJ, Gerson SL, et al. Delayed B-cell recovery after in-vivo rituximab purging vs. delayed myeloid engraftment after ex-vivo CD34+ cell enrichment: Interim analysis of a randomized phase II trial of B-lymphocyte purging of autologous PBPCs in NHL. *Blood* 102(11):3586a 11/2003.
204. Jaroscak J, Schwartz S, Laughlin J, Gerson SL. Peripheral blood and bone marrow chimerism results in recipients of multiple umbilical cord blood transplant using short tandem repeat assays. *Blood* 102(11):1751a 11/2003.
205. Lee Z, Koc O.N., Wojtkiewicz G.R., et al. Imagine Mesenchymal Stem Cell Transplantation on Small Animal Models. *The Journal of Nuclear Medicine* 45:196 2004.
206. Giles FJ, Verstovsek S, Cortes J, Faderl S, Garcia-Manero G, Ravandi-Kashani F, Kornblau S, Gerson S, Sznol M, Kantarjian H. Phase I study of VNP40101M (101M) and AraC in patients (pts) with refractory leukemia. *J Clin Oncol, ASCO* 22(14S): 6617, 2004.
207. Murren J, Gerson S, Kummur S, Davies M, Remick S, Chu E, Karsten V, Sznol M. A phase I trial of the sulfonylhydrazine alkylator, VNP4010M (101M), administered weekly in patients (pts) with metastatic cancer. *J Clin Oncol, ASCO* 22(14S): 2060, 2004.
208. Gajewski TF, Sosman J, Peterson AC, Gerson S, Dolan E, Vokes E. Phase II trial of O⁶-benzylguanine (O⁶BG) and BCNU in patients with advanced melanoma. *J Clin Oncol, ASCO* 22(14S): 7524, 2004.
209. Lin Y, Cheung P, Wilson DL, Gerson SL. Dynamic patterns of migration and expansion of Hematopoiesis during MGMT mediated drug selection. *Blood* 104(11): 156, 2004.
210. Fu P, van Heeckeren WJ, Wadhwa PD, Bajor DJ, Creger RJ, Cooper BW, Laughlin MJ, Lazarus HM, Gerson SL, Koc ON. Time-dependent effect of non-Hodgkin's lymphoma grade on disease free survival (DSF) of relapsed/refractory patients treated with high-dose chemotherapy (HDC) plus autologous hematopoietic stem cell transplant (AHSCT). *Blood* 104(11): 917, 2004.
211. Maisel C, Bahlis N, Miao Y, Liu L, Gerson S. Depletion of the intracellular Akt kinase, and its downstream signaling, mediates synergy between the proteasome inhibitor MG-132 and the heat shock protein 90 inhibitor 170-AAG in the multiple Myeloma cell line U266. *Blood* 104(11): 3364, 2004.
212. Reese JS, Roth JC, Gerson SL. Drug selection enrichment of type II pneumocytes following transplant of P140K MGMT lentiviral transduced hematopoietic stem cells. *Blood* 104(11): 3594, 2004.
213. Roth JC, Ismail M, Ferrari G, Gerson SL. Mutant MGMT Lentivirus co-transduction with a marker lentivirus efficiently enriches for dual-vector expressing cells in vivo. AGST poster #914, 2004.
214. Reese J, Lingas K, Ksenich P, Sweeney C, Koc O, Gerson S. Preliminary results of a phase I trial using retroviral gene transfer of G156A MGMT to protect Hematopoiesis during BG and BCNU therapy of advanced malignancies. AGST poster #1006, 2004.

215. Yuksel M, Baron E, Cooper BW, Lazarus HM, Gerson SL, Laughlin MJ, Cooper KD, Gilliam A, Koc ON. Peritransplant use of ultraviolet-B (UVB) phototherapy is detrimental to outcome of allogeneic stem cell transplantation. *Blood* 104(11): 1843, 2004.
216. Park Y, Luo G, Gerson S. Repopulation advantage of Blm^{-/-} cells in the primary recipients can be reversed by cisplatin treatment. *Blood* 104(11):2683, 2004.
217. Park Y, Lin Y, Gerson SL. Lack of functional DNA-PKcs and DNA double-strand break repair leads to a repopulating stem cell defect in *Scid* mice. *Blood* 104(11):2684, 2004.
218. Snell MR, Liu L, Gerson SL. Enhanced sensitivity to fludarabine in colon cancer cells co-treated with methoxyamine. AACR poster #1501, 2004.
219. Liu L, Donze J, Bulgar A, Gerson SL. Apoptotic death induced by TMZ and MX is due to apoptotic signals emanating from mitochondria DNA damage. AACR poster #1540.
220. Verees M, Liu L, Gerson SL. Interruption of base excision repair selectively enhances temozolamide and 1,3-bis(2-chloroethyl)-nitrosourea cytotoxicity in treatment of adult human malignant glioma cell lines. AACR poster #1548, 2004.
221. Mirsalis J, Schindler-Horvat J, Bakke J, Swezey R, Fairchild D, Iyer L, Newman R, Gerson S, Schweikart K, Covey J, Tomaszewski JT. Preclinical toxicity studies of methoxyamine (MX) and temozolamide (TMZ). AACR poster #2118, 2004.
222. Liu L, Xu Y, Mahajan V, Donze J, Gerson SL. Potentiation of chemotherapeutic alkylating agents by targeting abasic lesion in DNA. AACR poster #3037, 2004.
223. Bahlis NJ, Miao Y, Koc ON, Gerson S. N-benzoylstauroporine (PKC412) inhibits Akt kinase inducing apoptosis in multiple myeloma cells. ASCO abstract #6503, 2005.
224. Gerson SL, O'Brien S, Donze J, Karsten V, Karp J, Rizzieri D, Verhoef G, Daenen S, Sznol M, Giles F. Analysis of pre-treatment 06-alkylguanine transferase (AGT) levels in patients (pts) with hematologic malignancies receiving VNP40101M (101M). ASCO abstract #6542, 2005.
224. Koc ON, Bahlis NJ, Liu L, Lazarus HM, Cooper BW, Gerson SL, Laughlin MJ, Jacobberger JW, Horvath N, Remick S. A phase I trial of bortezomib in combination with fludarabine in patients with lymphoproliferative neoplasms. ASCO abstract #6647, 2005.
225. Savvides P, Egorin MJ, Gerson S, Ramanathan RK, Berger NA, Ramalingam S, Hoppel C, Belani CP, Remick S, Chatta GS. Analysis of elderly (=65 yrs) patients' participation on early phase I clinical trials at two NCI-designated comprehensive cancer centers. ASCO abstract #8133, 2005.
226. Bulgar AD, Liu L, Xu Y, Gerson SL. Mitochondrial mediated cell death induced by fludarabine combined with methoxyamine due to blockage of base excision repair pathway. *Proc Amer Assoc Cancer Res* 2005;46:Abstract #3326.
227. Donze JR, Yan L, Miao Y, Gerson SL, Liu L. Using gene expression profiling to identify molecular mechanisms involved in acquired drug-resistance development in MMR deficient tumor cells. *Proc Amer Assoc Cancer Res* 2005;46:Abstract #5941.
228. Sweeney CL, Reese JS, Lingas K, Flick S, Gerson SL. Retrovirus insertion site analysis following *in vivo* drug selection in a phase I clinical trial utilizing G156A MGMT stem cell transduction in advanced malignancies. *Blood*, 106(11 Part 1): 853a. Abstracts from the 47th Annual Meeting of the American Society of Hematology (2005).
229. Snell M, Koc ON, Bahlis NJ, Liu L, Lazarus HM, Gerson SL, Laughlin MJ, Jacobberger J, Horvath N, Remick S, Cooper BW. A phase I trial of PS-341 and fludarabine for relapsed and refractory indolent non-Hodgkin's lymphoma and chronic lymphocytic leukemia. *J Clin Oncol*, ASCO 24(18S): 7850, 2006.
230. Lin Y, Gerson SL. Monitoring dynamic transgene expression in murine bone marrow transplant model and enhancement of transgene expression by drug selection with bioluminescence imaging. The Fifth Annual Meeting of the Society of Molecular Imaging (2006).
231. Athanasiou M, Dettling M, Dain B, Lachowicz M, Malhotra A, Gerson S, Kane J, Cascorbi I, Reed C. Replication of genetic markers associated with clozapine-induced agranulocytosis. World Congress of Psych Genetics, CARING abstract WCPG (2006).
232. Gerson SL, Lin Y. Bioluminescence imaging reveals that hematopoietic reconstitution is a dynamic process perturbed by drug selection using MGMT gene transfer in the mouse. 5th Annual Gene Therapy Symposium for Heart, Lung, and Blood Disease (Nov 2006).
233. Roth JC, Alberti MO, Pereboeva L, Komarova S, Gerson SL, Curier DT. Engineering a recombinant adenovirus for targeted transduction of neutrophils for use as anti-inflammatory cell vehicles. *AGST* (2007).

- 234.Liu L, Bulgar A, Donze J, Adams BJ, Theuer CP, Gerson SL. Prevention of base excision repair by TRC102 (methoxyamine) potentiates the anti-tumor activity of premetrexed in vitro and in vivo. *J Clin Oncol*, ASCO 25(18S):13005, 2007.
- 235.Reese JS, Lingas KT, Sweeney CL, Brell JM, Gerson SL. Safety of MGMT gene transfer into hematopoietic progenitors: A phase I clinical trial using retroviral gene transfer of G156A MGMT to protect hematopoiesis during BG plus alkylating agent treatment of advanced malignancies. *Blood*, Nov 2007; 110:500.
- 236.Kenyon J, Tomas E, Lingas K, Gerson SL. Differential hMLH1 gene expression after temozolomide selection linked to microsatellite instability in a subset of hematopoietic stem/progenitor cells in old versus young and cancer versus normal patient samples. *Blood*, Nov 2007; 110:509.
- 237.Wald DN, Vermaat H, Kang Z, Gerson SL, Bunting K, Tse W. Indication and characterization of 6-benzylthioinosine as a novel myeloid differentiation-inducing compound. *Blood*, Nov 2007; 110:905.
- 238.Sweeney CL, Lin Y, Gerson SL. Retroviral insertion and Temozolomide selection promote T-cell lymphomas in tumor-prone mice. *Blood*, Nov 2007; 110:2593.
- 239.Reese JS, Solchaga LA, Lingas KT, Lazarus HM, Gerson SL. Improved culture expansion of human mesenchymal stem cells (MSCs) using fibroblastic growth factor-2 for the treatment of graft versus host disease (GVHD). *Blood*, Nov 2007; 110:1207.
- 240.Qing Y, Gerson SL. Loss of Ku70 results in a HSC repopulating defect. *Blood*, Nov 2007; 110:1256.
- 241.Lin Y, Gerson SL. In vivo imaging of drug selected MGMT lentiviral transduced hematopoiesis reveals distinct persistent and stable clonal engraftment sites. *Molecular Therapy* 16(1) May 2008. Abstract #1034.
- 242.Tarantal AF, Lee CCI, Cowan MJ, Gerson SL, Kohn DB. Prenatal transplant and postnatal in vivo imaging of transduced human peripheral blood stem cells expressing firefly luciferase and drug resistance gene in rhesus monkeys. *Molecular Therapy* 16(1) May 2008. Abstract #1035.
- 243.Weeks LD, Bulgar AD, Donae JR, Miao YL, Liu L, Gerson SL. Induction of uracil DNA glycosylase (UDG) in human cancer cells in response to antimetabolites combined with Methoxyamine. *Proc Amer Assoc Cancer Res* 2009;50:Abstract #3765.
- 244.Wang Y, Liu L, Wu C, Somoza E, Wang C, Zhu W, Gerson SL. In vivo imaging of abasic sites induced by DNA-targeted chemotherapies. *Proc Amer Assoc Cancer Res* 2009;50:Abstract #5017.
- 245.Savvides PS, Xu Y, Liu L, Gerson S. Unexpected prolonged half life of the base-excision repair inhibitor Methoxyamine (MX) given with Temozolomide (TMZ) in the first in human phase I clinical trial. *Proc Amer Assoc Cancer Res* 2009;50:Abstract #5433.
- 246.Bulgar AD, Miao Y, Borden E, Gerson SL, Liu L. Enhancement of decitabine cytotoxicity by Methoxyamine via inhibition of base excision repair. *Proc Amer Assoc Cancer Res* 2009;50:Abstract #5547.
- 247.Miao Y, Bulgar AD, Tuthill R, Borden E, Gerson SL, Liu L. The impact of expression of BER proteins on therapeutic effect of combining Temozolomide with Methoxyamine in melanoma cells. *Proc Amer Assoc Cancer Res* 2009;50:Abstract #5551.
- 248.Qing Y, Lin Y, Park Y, Gerson SL. Self-renewal and BM niche occupancy defects in NHEJ deficient HSCs. *Blood (ASH Annual Meeting Abstracts)*, Nov 2010; 116: 1455.
- 249.Weiss GJ, Gordon MS, Rosen LS, Savvides P, Adams BJ, Alvarez D, Liu L, Xu Y, Gerson SL, Leigh BR, Piper VG. Final results from a phase I study of oral TRC102 (methoxyamine HCl), an inhibitor of base-excision repair, to potentiate the activity of premetrexed in patients with refractory cancer. *J Clin Oncol* 28:15s, 2010 (suppl; abstr 2576).
- 250.Savvides P, Xu Y, Liu L, Bokar JA, Silverman P, Dowlati A, Gerson SL. Pharmacokinetic profile of the base-excision repair inhibitor methoxyamine-HCl (TRC102; MX) given as an one-hour intravenous infusion with temozolomide (TMZ) in the first-in-human phase I clinical trial. *J Clin Oncol* 28, 2010 (suppl; abstr e13662).
- 251.Savvides PS, Xu Y, Liu L, Rogers L, Bokar J, Silverman P, Dowlati A, Gerson SL. Phase I clinical trial of the base-excision repair inhibitor Methoxyamine-HCl (TRC102;MX) in combination with Temozolomide (TMZ) in patients with solid tumors. *Proc Amer Assoc Cancer Res* 2012;53: Abstract #1743.
- 252.Savvides PS, Xu Y, Liu L, Rogers L, Krishnamurthi S, Dowlati A, Gerson SL. Pharmacokinetic profile of the base-excision repair inhibitor methoxyamine-HCl (TRC102; MX) given as an one-hour intravenous infusion with temozolomide (TMZ) in the first in human phase I clinical trial. *Proc Amer Assoc Cancer Res* 2012;53: Abstract #753.

253. Weeks LD, Gerson SL, Liu L. Expression of the DNA repair protein UNG predicts lung cancer sensitivity to pemetrexed. Proc Amer Assoc Cancer Res 2012;53: Abstract #4696.
254. Tacastacas J, Chan D, Dowlati A, Gerson S, Honda K, Lu K, Fu P, Cooper K. Phase I/II clinical trial of O⁶benzylguanine (O⁶BG)-potentiated topical carmustine (BCNU) in the treatment of cutaneous T-cell lymphoma (CTCL). The Late-Breaking Research Symposium, American Academy of Dermatology's 70th Annual Meeting, 3/16/2012, San Diego, CA.
255. Desai A, Gerson, SL, and Yulan Qing Y ; hematopoietic Stem Cells Are Dependent On Homologous Recombination Only During Active Cell Cycle in Nuclease-Mutant Exonuclease1mut mice. ASH 2012
256. Qing Y, Wang, Z, Matsuyama, S Bunting, KD and Stanton L. Gerson, SL. Rescue of the HSC Maintenance Defects in Ku70-Deficient Mice by Overexpression of Bcl2 Reveals a Novel Role of Bcl2 in HSC". ASH 2012.

S. Gail Eckhardt, M.D.

CURRICULUM VITAE

HOME ADDRESS

2958 6th St.
Boulder, CO 80304
Telephone: (720) 560-2436 (cell)

BUSINESS ADDRESS

12801 E. 17th Avenue, L18-8124
Campus Box 8117
Aurora, CO 80045
Phone: (303) 724-3850
Fax: (303) 724-3892
Email: gail.eckhardt@ucdenver.edu

PERSONAL DATA

Place of Birth: Houston, Texas
Citizenship: U.S.A.
Marital Status: Married
Name of Spouse & Children: Steven G. Britt, M.D., Blair (1990), Byron (1992)

EDUCATION

1981 B.S., Stephen F. Austin State University
1985 M.D., University of Texas Medical Branch, Galveston, TX

TRAINING

1985-1988 Internship and Residency, Internal Medicine, University of Virginia Medical Center, Charlottesville, VA
1988-1990 Research Fellowship, Experimental and Molecular Medicine, Scripps Clinic and Research Foundation, La Jolla, CA
1990-1992 Fellowship, Medical Oncology, University of California, San Diego, CA
1991-1992 Research Fellowship, Medicine and Biology, University of California, San Diego, CA

FACULTY APPOINTMENTS

1992-1999: Clinical Faculty, Department of Medicine, Division of Medical Oncology, University of Texas Health Science Center at San Antonio, TX
1992-1995: Assistant Member, Cancer Therapy and Research Center, Institute for Drug Development, San Antonio, TX
1995-1999: Associate Director of Clinical Research, Cancer Therapy and Research Center, Institute for Drug Development, San Antonio, TX
1995-1999: Director, Drug Development Fellowship Training Program, Cancer Therapy and Research Center, Institute for Drug Development, San Antonio, TX
1999-2002: Associate Professor of Medicine and Director of Phase I Program, Division of Medical Oncology, University of Colorado Denver, Aurora, CO
1999-present: Director, Phase I Program, University of Colorado Cancer Center, Aurora, CO
2000-2007: Director, GI Malignancies Program, Division of Medical Oncology, University of Colorado Denver, Aurora, CO
2001-present: Director, Developmental Therapeutics/ Phase I Fellowship Program (GME approved), Division of Medical Oncology, University of Colorado Denver, Aurora, CO
2002-present: Professor of Medicine, University of Colorado Denver, Aurora, CO
2004-present: Professor of Medicine with Tenure, University of Colorado Denver, Aurora, CO
2004-present: Leader (2004-2010) and Co-Leader (2010-present), Developmental Therapeutics Program, University of Colorado Cancer Center, Aurora, CO
2006-present: Head, Division of Medical Oncology; University of Colorado Anschutz Medical Campus, Aurora, CO; Co-Head (2012)
2010-present Senior Associate Director Translational and Collaborative Research, University of Colorado Cancer Center

MAJOR PROFESSIONAL SOCIETIES

American Society of Clinical Oncology
American Association of Cancer Research
European Society for Medical Oncology

LICENSURE AND BOARD CERTIFICATION

Colorado, 1999
Internal Medicine, 1988
Medical Oncology, 1993, 2007

HONORS/AWARDS

1976 Alpha Chi
1981 Gamma Sigma Epsilon
1985 Alpha Omega Alpha
2008 ASCO Statesman Award
2011 University of Colorado Technology Transfer Office Business Advisor of the Year
2012 Fellow of the American Society of Clinical Oncology

SERVICE

Local and National Committees, Study Sections, Boards

2014-present	Damon Runyon Clinical Investigator Grant Review Committee
2014-present	Member, NCI Investigational Drug Steering Committee
2013-present	Indiana University Cancer Center External Advisory Board
2013-present	Oregon Health Sciences University Knight Cancer Institute External Advisory Board
2012-present	MD Anderson Vice Provost Advisory Council on Clinical Research
2012-present	AACR Scientific Review Committee for Fight Colorectal Cancer-AACR Career Development Award
2012	Cancer Research UK Programme Review Panel
2012-present	Baylor Daniel L. Duncan Cancer Center External Advisory Board
2010-2015	Member, NCI IRG-A, Cancer Centers Study Section
2011-present	Faculty, ASCO/AACR/NCI Clinical Research Methods Workshop, Vail, CO
2011-present	Georgetown Lombardi Cancer Center External Advisory Board
2010	Member, AACR 2011 Scientific Program Committee
2010-present	Member, NCI Colorectal Cancer Task Force
2010-present	Member, The Cancer Genome Atlas CRC Disease Working Group
2009-2010	Chair, FDA Oncology Drugs Advisory Committee
2007-present	Faculty, ASCO/AACR/NCI Clinical Research Methods Workshop, Vail, CO
2006-2010	Program Committee and Course Director, ASCO/AACR/NCI Clinical Research Methods Workshop, Vail, CO
2009-present	Member, ESMO Translational Research Working Group
2009	Member, Colorectal Cancer Coalition Grants Review Committee, AACR
2006-2010	Member, NCI GI Steering Committee
2005-2009	Member, UCHSC Department of Medicine Professor Promotions Review Committee
2006-2009	Steering Committee, ASCO GI Malignancies Symposium
2006-2009	Member, Deans Strategic Initiative Review Committee
2006-2009	Steering Committee, NCI/ESMO, Targeted Anticancer Therapy Symposium
2006-2007	Member, NCI Clinical Trials Working Group (CTWG) Evaluation Committee
2006-2007	Member, NIH/NCI Developmental Therapeutics Study Section
2005-2009	Member, FDA Oncology Drugs Advisory Committee
2005-2008	Member, NCI Investigational Drug Steering Committee
2005-2006	Co-Chair, ASCO Translational Research Working Group
2005-2006	Board Liaison, ASCO Clinical Research Committee
2004-2008	MOGA/ASCO/AACR, Faculty, Australia and Asia Pacific Clinical Oncology Research Development Workshop

2004-2007	Board of Directors, ASCO
2004	Co-Chair, Phase I Clinical Trials/ Pharmacology/Pharmacogenomics/ Experimental and Molecular Therapy Committees, AACR Annual Meeting
2004	Steering Committee, ASCO GI Malignancies Symposium
2003	Faculty, NIH Clinical Research Roadmap Workshop, January
2003	Chair, ASCO Scientific Program Committee
2002-2005	Member, ASCO Publications Committee
2002-present	Member, EORTC Phase I/II Review Panel
2002	Steering Committee, ASCO Molecular Therapeutics Symposium, November
2002-2006	Scientific Committee, International Symposium on Signal Transduction Modulators in Cancer Therapy, September
2002	Vice Chair, ASCO Scientific Program Committee
2001	Faculty, NCI Pre-clinical Angiogenesis Imaging Models Working Group
2001-present	Member, COMIRB
2001-2004	Member, GI Steering Committee, Southwest Oncology Group (SWOG)
2001	Reviewer, Experimental Therapeutics (ET-1) Study section, NCI/NIH
2001	Member, American Society of Clinical Oncology (ASCO) Molecular Oncology Task Force
2001-2003	Program Committee, ASCO/AACR/FECS Clinical Research Methods Workshop, Flims, Switzerland
2000-2003	Faculty, ASCO/NCI/AACR Clinical Research Methods Workshop, Vail, CO
2000	Member, Molecular Markers Study Section, NCI, September
2000	Faculty, NCI Lung Cancer State of the Science Meeting
2000-present	External Reviewer, Drug Development Group, National Cancer Institute
2000	Co-Chair, Angiogenesis Symposium, American Association for Cancer Research 91 st Annual Meeting
2000	Member, American Association for Cancer Research Cain Memorial Award Selection Committee
1999-present	Member, UCCC Protocol Review and Monitoring Committee
1999	Moderator, California Breast Cancer Research Symposium, 1999.
1999-2001	Member, University of California Breast Cancer Research Program: Innovative Treatment Modalities study section
1998-present	Member, Angiogenesis Working Group, National Cancer Institute
1998-2000	Member, RAID study section, National Cancer Institute
1995-1999	Member, Committee on Graduate Studies, UTHSCSA Cellular and Structural Biology Dept.

Journal Review/Editorial Boards

Journal of Clinical Oncology- Associate Editor 2002-2005
Oncogene
Investigational New Drugs -Associate Editor
Cancer Research
Clinical Cancer Research –Editorial Board 2004-2007
Cancer Chemotherapy and Pharmacology
Journal of the National Cancer Institute

GRANT SUPPORT

Peer-reviewed, Current

- 2P30 CA46934-24 Theodorescu (PI) 08/01/1988 to 07/30/2017
NCI: University of Colorado Cancer Center Support Grant
The major goal of this grant is to provide developmental and infrastructure support of cancer-related programs and core (shared) services.
Role: Developmental Therapeutics Program Leader/ Senior Associate Director Translational and Collaborative Research
- DOD/Idea Award (Eckhardt/Tan) 09/15/11-9/14/14
Title: Collaborative Model for Acceleration of Individualized Therapy of Colon Cancer

Goals: The overall goal of this Idea Award is enhance the efficiency and speed of developing novel and individualized therapy for patients with KRAS mutant colorectal cancer (CRC) using a comprehensive bioinformatics approach and novel preclinical models of human CRC.

Role: PI

3. 1UM1CA186688-01 (Eckhardt)

03/14/2014 to 01/31/2019

Title: Southwest Early Clinical Trials Consortium

The overall goal of this project is to participate as a site (with MDACC) in the NCI Experimental Therapeutics Clinical Trials Network for the development of novel agents.

Role: PI (Co-PIs at MDACC: Meric-Bernstam, Yao)

Pharmaceutical (non-peer reviewed)

1. MLN/Takeda

06/01/10-12/01/12

Laboratory funding for development of predictive biomarkers for a MLN4924 and TAK733 in melanoma models including human tumor explants.

PI: Eckhardt

2. Genentech

07/01/10-06/30/13

Funding for Developmental Therapeutics GME-approved Fellowship

PI: Eckhardt

3. AstraZeneca

07/01/10-04/01/14

Phase I Trial of the JAK2 inhibitor, AZD1480, in patients with advanced solid tumors.

PI: Eckhardt

4. Millennium/Takeda

09/01/11-09/01/14

Phase I trial of the oral hedgehog inhibitor, TAK441, in patients with advanced solid tumors.

PI: Eckhardt

5. Millennium/Takeda

06/07/11-05/31/13

Assessment of activity and combination effects with standard chemotherapy of the PLK-1 and AurA inhibitors, TAK960 and MLN8237, respectively, against CRC models *in vitro* and *in vivo*.

PI: Eckhardt

6. Millennium/Takeda

06/07/11-05/31/13

Assessment of comprehensive combination effects of MEK, RAF, AKT, and AurA inhibitors, against CRC models *in vitro* and *in vivo*.

PI: Eckhardt

Completed in Last 5 Years

1. AACR/Littlefield Grant : Development of Individualized Therapy for IGF-1R Inhibition in Colorectal Cancer

PI: Eckhardt 7/1/08-6/30/11

2. NIH/NCI, T32 CA079446-06A1: Training In Pharmacology Of Antineoplastic Agents.

PI: Eckhardt 7/1/05-6/30/10

3. NIH/NCI, K24 CA106349: Development Of Mechanism-Based Anticancer Therapy.

PI: Eckhardt 3/1/05-2/28/10

4. NIH/NCI, U01 CA099176: Early Clinical Trials with Phase I Emphasis.

PI: Eckhardt 04/07/03 - 02/28/08

5. NIH/NCI, R21 CA101716: Overcoming Age Barriers to Enrollment in Early Clinical Trials of Novel Anticancer Agents.

PI: Eckhardt 05/1/03 – 06/30/06

PUBLICATIONS

Peer-Reviewed Manuscripts

1. **Eckhardt, S. G.**, Milich, D. R. and McLachlan, A. Hepatitis B virus core antigen has two nuclear localization sequences in the arginine-rich carboxy terminus. *Journal of Virology*, February, V65 N2:575-582, 1991.

2. **Eckhardt, S. G.**, Dai, A., Davidson, K.K., Forseth, B., Wahl, G., Von Hoff, D.D. Induction of differentiation in HL60 cells by the reduction of extrachromosomally amplified *c-myc*. *Proc Natl Acad Sci* 91:6674-6678, 1994.
3. Eckardt, J., **Eckhardt, G.**, Villalona-Calero, M., Drengler, R., Von Hoff, D.D. New anticancer agents in clinical development (Part 1,2). *Oncology* 9(11):1191-1199; 1321-1326, 1995.
4. Rothenberg, M.L., Eckardt, J.R., Kuhn, J.G., Burris, H.A., III, Nelson, J., Hilsenbeck, S.G., Rodriguez, G.I., Weiss, G.R., Thurman, A.M, Smith, L.S., **Eckhardt, S.G.**, Weiss, G.R., Elfring, G.L., Rinaldi, D.A., Schaaf, L.J., Von Hoff, D.D. Phase II trial of irinotecan in patients with progressive or rapidly recurrent colorectal cancer. *J Clin Oncol* 14(4):1128-1135, 1996.
5. **Eckhardt, S.G.**, Burris, H.A., Eckardt, J.R., Weiss, G., Rodriguez, G., Rothenberg, M., Rinaldi, D., Barrington, R., Kuhn, J.G., Fields, S., Smetzer, L., Von Hoff, D.D. A phase I clinical and pharmacokinetic study of the angiogenesis inhibitor, Tecogalan Sodium. *Annals of Oncology* 7: 491-496, 1996.
6. **Eckhardt, S.G.**, Pluda, J., guest editors. Development of Angiogenesis Inhibitors for Cancer Therapy. *Investigational New Drugs* 15: 1-86, 1997.
7. **Eckhardt, S.G.**, Baker, S.D., Eckardt, J.R., Burke, T.G., Warner, D.L., Kuhn, J.G., Rodriguez, G., Fields, S., Thurman, A., Smith, L., Rothenberg, M.L., White, L., Wissel, P., Kunka, R., DePee, S., Littlefield, D., Burris, H.A., Von Hoff, D.D., Rowinsky, E.K. A Phase I and Pharmacokinetic Study of GI147211, a Water Soluble Camptothecin Analog, Administered for Five Consecutive Days Every Three Weeks. *Clin Can Res* 4 (3): 595-604, 1998.
8. Hammond, L.A., Eckardt, J.R., Ganapathi, R., Burris, H., Rodriguez, G., **Eckhardt, S.G.**, Rothenberg, M.L., Weiss, G.R., Kuhn, J.G., Hodges, S., Von Hoff, D.D., Rowinsky, E.K. A Phase I and Translational Study of Sequential Administration of the Topoisomerase I and II Inhibitors Topotecan and Etoposide. *Clin Can Res* 4 (6): 1459-1468, 1998.
9. **Eckhardt, S.G.** Irinotecan: A Review of the Initial Phase I Trials. *Oncology* 12 (8), 31-38, 1998.
10. Rothenberg ML, Kuhn JG, Schaaf LJ, Drengler RL, **Eckhardt SG**, Villalona-Calero MA, Hammond L, Mill LL, Petit RG, Rowinsky EK, Von Hoff DD. Alternative Dosing Schedules for Irinotecan. *Oncology* 12 (8), 68-71, 1998.
11. De Vore, R., Johnson, D., Crawford, J., Dimery, I., Eckardt, J., **Eckhardt, S.G.** Irinotecan plus cisplatin in patients with advanced non-small-cell lung cancer. *Oncology* 12 (8), 79-83, 1998.
12. Villalona-Calero, M.A., Baker, Sharyn D., Hammond, L., Ayelsworth, C., **Eckhardt, S.G.**, Kraynak, M., Fram, R., Fischkoff, S., Velagapudi, R., Toppmeyer, D., Razvillas, B., Jakimowicz, K., Von Hoff, D.D., Rowinsky, E.K. Phase I and Pharmacokinetic Study of the Water Soluble Dolastatin 15 Analog LU103793. *J Clin Oncol* 16 (8): 2770-2779, 1998.
13. Rowinsky, E.K., Smith, L., Yow-Ming, W., Chaturvedi, P., Villalona, M., Campbell, E., Ayelsworth, C., **Eckhardt, S.G.**, Hammond, L., Kraynak, M., Drengler, R., Stephenson, J., Harding, M.W., Von Hoff, D.D. Phase I and Pharmacokinetic Study of Paclitaxel in Combination with VX-710, a Novel Agent that Reverses Multidrug Resistance Conferred by Overexpression of both MDR1 and MRP. *J Clin Oncol* 16(9), 2964-76, 1998.
14. Siu, L.L., Von Hoff, D.D., Rephaeli, A., Rowinsky, E., **Eckhardt, S.G.** Activity of Pivaloyloxymethyl Butyrate, a Novel Anticancer Agent, on Primary Human Tumor Colony-Forming Units. *Investigational New Drugs* 16(2), 113-9, 1998.
15. Izbicka, E., Lawrence, R., Raymond, E., **Eckhardt, G.**, Faircloth, G., Jimeno, J., Clark, G., Von Hoff, D. In Vitro Antitumor Activity of the Novel Marine Agent, Ecteinascidin (ET-743, NSC 648766) Against Human Tumors Explanted from Patients. *Annals of Oncology* 9: 981-7, 1998.
16. Rothenberg, M.L., Sharma, A., Weiss, G.R., Villalona-Calero, M.A., Eckardt, J.R., Ayelsworth, C., Kraynak, M.A., Rinaldi, D.R., Rodriguez, G.I., Burris, H.A., **Eckhardt, S.G.**, Stephens, C.D., Forral, K., Nichol, S., Von Hoff, D.D.: Phase I Trial of Paclitaxel and Gemcitabine Administered Every 2 Weeks in Patients with Refractory Solid Tumors. *Annals of Oncology* 9 (7), 733-738, 1998.
17. Diab SG, Baker SD, Joshi A, Burris HA, Cobb PW, Villalona-Calero M, **Eckhardt SG**, Weiss GR, Rodriguez GI, Drengler R, Kraynak M, Hammond L, Finizio M, Von Hoff DD, and Rowinsky EK. A Phase I and Pharmacokinetic Study of Losoxantrone and Paclitaxel in Patients with Advanced Solid Tumors. *Clin Can Res* 5(2), 299-308, 1999.
18. **Eckhardt, S.G.** Angiogenesis Inhibitors as Anticancer Therapy. *Hosp Pract* 34(1), 63-68, 1999.
19. Villalona-Calero MA, Weiss GR, Burris HA, Rodriguez G, Drengler RL, **Eckhardt SG**, Reigner B, Moczygamba J, Burger HU, Griffin T, Von Hoff DD, Rowinsky EK. Phase I and Pharmacokinetic Study of the Oral Fluoropyrimidine Capecitabine in Combination with Paclitaxel In Patients with Advanced Solid Malignancies. *J Clin Oncol* 17 (6), 1915-1925, 1999.

20. + **Eckhardt SG**, Rizzo J, Sweeney KR, Cropp G, Baker S, Kraynak M, Kuhn JG, Villalona-Calero MA, Hammond L, Weiss G, Thurman A, Smith L, Drengler R, Eckardt J, Moczygemba J, Hannah AL, Von Hoff DD, Rowinsky EK. A Phase I and Pharmacologic Study of the Tyrosine Kinase Inhibitor SU101 in Patients with Advanced Solid Tumors. *J Clin Oncol* 17(4), 1095-1104, 1999.
21. Britten CD, Hilsenbeck SG, **Eckhardt SG**, Marty J, Mangold G, MacDonald J, Rowinsky EK, Von Hoff DD, Weitman S. Enhanced antitumor activity of 6-hydroxymethylacylfulvene in combination with irinotecan and 5-fluorouracil in the HT29 human colon tumor xenograft model. *Can Res* 59(5), 1049-53, 1999.
22. Hammond LA, Eckardt JR, Baker SD, **Eckhardt SG**, Reidenberg P, Statkevich P, Weiss GR, Rinaldi DA, Von Hoff DD, Rowinsky EK. Phase I and pharmacokinetic study of temozolomide on a daily-times-five schedule in patients with advanced solid malignancies. *J Clin Oncol* 17(8), 2604-2613, 1999.
23. Britten, C, Rowinsky, E.K. Atkins, Y., Agarwala, S.S., Eckardt, J., Diab, S., Dugan, M., Reidenberg, P., Statkevich, P., Forral, K., Kraynak, M., Von Hoff, D.D., **Eckhardt, S.G** . A phase I study of temozolomide combined with cisplatin (CDDP) in patients with advanced cancer. *Clin Can Res* (5), 1629-1637, 1999.
24. Hidalgo M, Izbicka E, **Eckhardt SG**, MacDonald J, Cerna C, Gomez L, Rowinsky EK, Weitman SD, Von Hoff DD. Antitumor Activity of 6-hydroxymethylacylfulvene, a semisynthetic derivative of Illudin S, against adult and pediatric human tumor colony forming units. *Anticancer Drugs* 10:837-844, 2000.
25. Nemunaitis, J., Von Hoff, D.D., Holmlund, J., Dorr, A., **Eckhardt, S.G.** Phase I/pharmacokinetic (PK) trial of a protein kinase α -antisense oligonucleotide, Isis 3521 (CGP 64128A), administered thrice weekly. *J Clin Oncol*; 17:3586-3595, 1999 .
26. Hidalgo, M., Villalona-Calero, M.A., **Eckhardt, S.G.**, Drengler, R.L., Rodriguez, G.I., Hammond, L.A., Diab, S., Weiss, G., Garner, A.M., Campbell, E., Davidson, K., Louie, A., O'Neil, J., Von Hoff, D.D., Rowinsky. A Phase I and Pharmacologic Study of PN401 and 5-Fluorouracil in Patients with Advanced Solid Malignancies. *J Clin Oncol* 18: 167-177, 2000.
27. Miguel A. Villalona-Calero, Thierry Petit, John Kuhn, Patrick Cobb, Maura Kraynak, **S. Gail Eckhardt**, Ronald Drengler, Cecelia Simmons, Pedro Santabarbara, Daniel D. Von Hoff , and Eric K. Rowinsky. A Phase I and Pharmacologic Study of Protracted Infusions of Crisnatol Mesylate in Patients with Solid Malignancies. *Clin Can Res* 5: 3369-3378, 1999.
28. + Rowinsky, E., Hammond, L., Ayelsworth, C., Humphrey, R., Siu, L., Smith, L., Thurman, A., Rodriguez, G., Sorensen, M., Von Hoff, D., **Eckhardt, S.G.** Prolonged administration of BAY 12-9566, an oral non peptidic biphenyl matrix metalloproteinase (MMP) inhibitor: a phase I and pharmacokinetic (PK) study. *J Clin Oncol* 18:178-186, 2000.
29. Devore, R.F., Johnson, D.H., Crawford, J., Garst, J., Dimery, I.W., Eckardt, J., **Eckhardt, S.G.**, Efring, G., Schaaf, L.J., Hanover, C.K., Miller, L.L. Phase II Study of Irinotecan Plus Cisplatin in Patients with Advanced Non-Small Cell Lung Cancer. *J Clin Oncol* 17:2710-2715, 1999.
30. + Britten CD, Rowinsky EK, Baker SD, LeMaistre CF, Weiss GR, Smith LA, Stephenson J, Hammond L, Rothenberg M, Smetzer L, Collins W, Von Hoff DD, **Eckhardt SG**. A Phase I and Pharmacokinetic Study of the Mitochondrial-Specific Rhodacyanine Dye Analog MKT 077. *Clin Can Res* 6:42-29, 2000.
31. Rinaldi DA, Kuhn JG, Burris HA, Dorr FA, Rodriguez G, **Eckhardt SG**, Fields SM, Woodworth JR, Langley C, Clark G, Abraham T, Von Hoff DD. A Phase I Evaluation Of LY231514, A Novel Multi-Targeted Antifolate, Administered Every 21 Days, Utilizing The Modified Continual Reassessment Method For Dose Escalation. *Cancer Chemotherapy and Pharmacology* 44:372-380, 1999.
32. Honghui Z, Choi L, Lau H, Brunsch U, DeVries EG, **Eckhardt SG**, Van Oosterom A, Verweij J, Schran H, Barbet N, Linnarz R, Capdeville R. Population pharmacokinetics/toxicokinetics (PK/TD) relationship of SAM486A in phase I studies in patients with advanced cancers. *J Clin Pharmacol* 40:275-283, 2000.
33. Ganly I., Kirn D., **Eckhardt SG**, Rodriguez GI, Soutar D, Otto R, Robertos AG, Park O, Gulley ML, Heise C, Von Hoff DD, Kaye SB. First Evidence of Biological Activity of ONYX-015, an E1B Attenuated Adenovirus, in Patients with Recurrent p53 Overexpressing Head and Neck Cancer. *Clin Cancer Res* 6: 798-806, 2000.
34. Zucker S, **Eckhardt SG**, Rowinsky EK. Plasma MMPs as surrogates of BAY 12-9566. *J Clin Oncol*; 18(8):1805-6. No abstract available. 2000
35. Hammond LA, Hilsenbeck SG, **Eckhardt SG**, Marty J, Mangold G, MacDonald J, Rowinsky EK, Von Hoff DD, Weitman S. Enhanced Antitumor Activity of 6-Hydroxymethylacylfulvene in Combination with Topotecan or Taxol in the MV522 Lung Carcinoma Xenograft Model. *Eur J Can* 36: 2430-6, 2000.
36. Rowinsky EK, Johnson TR, Geyer CE, Drengler R, **Eckhardt SG**, Hammond LA, Smetzer L, Coyle J, Rizzo J, Schwartz G, Tolcher A, DeJager RL. DX-8951F (Exatecan Mesylate), a hexacyclic camptothecin analog on a daily x 5 schedule: A phase I and pharmacokinetic study in patients with advanced solid malignancies. *J Clin Oncol* 18: 3151-63, 2000.

37. + **Eckhardt SG**, Baker SD, Britten CD, Hidalgo M, Siu L, Hammond L, Weiss G, Villalona-Calero MA, Felton S, Drengler R, Kuhn JG, Garner A, Smith L, Rothenberg ML, Smith SL, MacDonald J, Weitman S, Moczygamba J, Von Hoff DD, Rowinsky EK. A Phase I and Pharmacokinetic Study of MGI 114, a Novel Mushroom-derived Cytotoxin Administered for Five Consecutive Days Every Four Weeks. *J Clin Oncol* 18: 4086-97, 2000.
38. + Amita Patnaik, Eric K. Rowinsky, Brinda K. Tammara, Manuel Hidalgo, Ronald L. Drengler, Allison M. Thurman, Lillian L. Siu, Lisa A. Hammond, Sally Felton, Suresh Mallikaarjun, Daniel D. Von Hoff, and **S. Gail Eckhardt**. A phase I and pharmacokinetic (pk) study of the differentiating agent, vesnarinone, in combination with gemcitabine in patients with advanced cancer. *J Clin Oncol* 18: 3974-85, 2000.
39. Vonderheide RH, Dutcher JP, Anderson JE, **Eckhardt SG**, Stephens KF, Razvillas B, Garl S, Butine MD, Perry VP, Armitage RJ, Ghalie R, Caron DA, Gribben JG. Phase I study of recombinant human CD40 ligand in cancer patients. *J Clin Oncol*;19(13):3280-7, 2001
40. Hidalgo M, Siu LL, Nemunaitis J, Rizzo J, Hammond LA, Takimoto C, **Eckhardt SG**, Tolcher A, Britten CD, Denis L, Ferrante K, Von Hoff DD, Silberman S, Rowinsky EK. Phase I and pharmacologic study of OSI-774, an epidermal growth factor receptor tyrosine kinase inhibitor, in patients with advanced solid malignancies. *J Clin Oncol*;19(13):3267-79, 2001
41. + Tolcher AW, **Eckhardt SG**, Kuhn J, Hammond L, Weiss G, Rizzo J, Aylesworth C, Hidalgo M, Patnaik A, Schwartz G, Felton S, Campbell E, Rowinsky EK. Phase I and pharmacokinetic study of NSC 655649, a rebeccamycin analog with topoisomerase inhibitory properties. *J Clin Oncol*;19(11):2937-47, 2001
42. Hidalgo M, **Eckhardt SG**. Matrix metalloproteinase inhibitors: how can we optimize their development? *Ann Oncol*; 12(3):285-7, 2001
43. Hidalgo M, **Eckhardt SG**. Development of matrix metalloproteinase inhibitors in cancer therapy. *J Natl Cancer Inst*. 7;93(3):178-93, 2001 Review.
44. Herbst RS, Hidalgo M, Pierson AS, Holden SN, Bergen M, **Eckhardt SG**. Angiogenesis inhibitors in clinical development for lung cancer. *Semin Oncol* ;29(1 Suppl 4):66-77, 2002
45. Rothenberg ML, Kuhn JG, Schaaf LJ, Rodriguez GI, **Eckhardt SG**, Villalona-Calero MA, Rinaldi DA, Hammond LA, Hodges S, Sharma A, Elfring GL, Petit RG, Locker PK, Miller LL, Von Hoff DD. Phase I dose-finding and pharmacokinetic trial of irinotecan (CPT-11) administered every two weeks. *Ann Oncol*;12(11):1631-41. 2001
46. Villalona-Calero MA, Eckhardt SG, Weiss G, Hidalgo M, Beijnen JH, van Kesteren C, Rosing H, Campbell E, Kraynak M, Lopez-Lazaro L, Guzman C, Von Hoff DD, Jimeno J, Rowinsky EK. A phase I and pharmacokinetic study of Ecteinascidin-743 on a daily x 5 schedule in patients with solid malignancies. *Clin Cancer Res*; 8(1):75-85 2002
47. + LL Siu, EK Rowinsky, LA Hammond, GR Weiss, M Hidalgo, GM Clark, J Moczygamba, L Choi, R Linnartz, NC Barbet, IT Sklenar, R Capdeville, CW Porter, DD Von Hoff, **SG Eckhardt**. A Phase I and Pharmacokinetic Study of SAM486A, a Novel Polyamine Biosynthesis Inhibitor, Administered on a Daily-Times-Five Every-Three-Week Schedule in Patients with Advanced Solid Malignancies. *Clin Cancer Res*; 8(7):2157-66, 2002
48. + Amita Patnaik, Eric K. Rowinsky, Sally A. Felton, Miguel A. Villalona, Lisa A. Hammond, Carolyn D. Britten, Lillian L. Siu, A Goetz, Susan Burton, Harold Keer, and **S. Gail Eckhardt**. A phase I study of the differentiating agent, AN-9; a prodrug of butyric acid, in patients with advanced cancer. *Clin Cancer Res*; 8(7):2142-8, 2002
49. Pierson AS, Gibbs P, Richards J, Russ P, **Eckhardt SG**, Gonzalez R. A phase II study of Irofulven (MGI 114) in patients with stage IV melanoma. *Invest New Drugs*; 20(3):357-62, 2002
50. +Hao D, Hammond LA, **Eckhardt SG**, Patnaik A, Takimoto CH, Schwartz GH, Goetz AD, Tolcher AW, McCreery HA, Mamun K, Williams JI, Holroyd KJ, Rowinsky EK. A Phase I and pharmacokinetic study of squalamine, an aminosterol angiogenesis inhibitor. *Clin Cancer Res*; 9(7):2465-71, 2003
51. Gustafson DL, Long ME, Zirrolli JA, Duncan MW, Holden SN, Pierson AS, **Eckhardt SG**. Analysis of docetaxel pharmacokinetics in humans with the inclusion of later sampling time-points afforded by the use of a sensitive tandem LCMS assay. *Cancer Chemother Pharmacol*; 52(2):159-66, 2003
52. +Patnaik A, **Eckhardt SG**, Izbicka E, Tolcher AA, Hammond LA, Takimoto CH, Schwartz G, McCreery H, Goetz A, Mori M, Terada K, Gentner L, Rybak ME, Richards H, Zhang S, Rowinsky EK. A phase I, pharmacokinetic, and biological study of the farnesyltransferase inhibitor tipifarnib in combination with gemcitabine in patients with advanced malignancies. *Clin Cancer Res*; 15;9(13):4761-71, 2003
53. +Syed S, Takimoto C, Hidalgo M, Rizzo J, Kuhn JG, Hammond LA, Schwartz G, Tolcher A, Patnaik A, **Eckhardt SG**, Rowinsky EK. A phase I and pharmacokinetic study of Col-3 (Metastat), an oral tetracycline derivative with potent matrix metalloproteinase and antitumor properties. *Clin Cancer Res*; 10(19):6512-21, 2004

54. Gottschalk S, Anderson N, Hainz C, **Eckhardt SG**, Serkova NJ. Imatinib (STI571)-mediated changes in glucose metabolism in human leukemia BCR-ABL-positive cells. *Clin Cancer Res.*; 10(19):6661-8, 2004
55. Ratain MJ, **Eckhardt SG**. Phase II studies of modern drugs directed against new targets: if you are fazed, too, then resist RECIST. *J Clin Oncol.*; 22(22):4442-5, 2004
56. + Witta SE, Gustafson DL, Pierson AS, Menter A, Holden SN, Basche M, Persky M, O'Bryant CL, Zeng C, Baron A, Long ME, Gibbs A, Kelly K, Bunn PA Jr, Chan DC, Pallansch P, **Eckhardt SG**. A phase I and pharmacokinetic study of exisulind and docetaxel in patients with advanced solid tumors. *Clin Cancer Res.*; 10(21):7229-37, 2004
57. + Ramnath N, Hamm J, Schwartz G, Holden S, **Eckhardt SG**, Vredenburg MR, Bernacki RJ, Lathia C, Kanter P, Creaven PJ. A phase I and pharmacokinetic study of BAY59: a novel taxane. *Oncology.*;67(2):123-9, 2004
58. de Bono JS, Rha SY, Stephenson J, Schultes BC, Monroe P, **Eckhardt SG**, Hammond LA, Whiteside TL, Nicodemus CF, Cermak JM, Rowinsky EK, Tolcher AW. Phase I trial of a murine antibody to MUC1 in patients with metastatic cancer: evidence for the activation of humoral and cellular antitumor immunity. *Ann Oncol.*; 15(12):1825-33, 2004
59. +Hiroyuki Kobayashi , **S. Gail Eckhardt**, Jennifer A. Lockridge, Mace L. Rothenberg, Alan B. Sandler, Cindy L. O'Bryant, Wendy Cooper, Scott N. Holden, RogerD. Aitchison, Nassim Usman, Maurice Wolin, and Michele L. Basche. Safety and pharmacokinetic study of RPI.4610 (ANGIOZYME®), an anti-VEGFR-1 ribozyme, in combination with carboplatin and paclitaxel in patients with advanced solid tumors. *Cancer Chemother Pharmacol* 56(4):329-36, 2005.
60. +Scott N Holden, **S Gail Eckhardt**, Russell Bassar, Richard de Boer, Danny Rischin, Michael Green, Mark A Rosenthal, Catherine Wheeler, Alan Barge, Herbert I Hurwitz Clinical evaluation of ZD6474, an orally active inhibitor of VEGF receptor signaling, in patients with solid, malignant tumors. *Ann Oncol.* 16(8):1391-7, 2005.
61. Maria Pia Morelli, Tina Cascone, Teresa Troiani, Ferdinando De Vita, Michele Orditura, Gianluca Laus, **S. Gail Eckhardt**, Stefano Pepe, Giampaolo Tortora, Fortunato Ciardiello. Sequence-dependent antiproliferative effects of cytotoxic drugs and epidermal growth factor receptor inhibitors. *Ann Oncol* 4:61-68, 2005.
62. Abou-Alfa GK, Rowinsky EK, Patt YZ, Schwartz GK, Kelsen DP, Sharma S, Siegel E, Becerra CR, **Eckhardt SG**, Feit K, De Jager R, O'Reilly EM. A Phase II study of intravenous exatecan administered daily for 5 days, every 3 weeks to patients with biliary tract cancers. *Am J Clin Oncol.*; 28(4):334-9, 2005
63. Tolcher AW, Hao D, de Bono J, Miller A, Patnaik A, Hammond LA, Smetzer L, Van Wart Hood J, Merritt J, Rowinsky EK, Takimoto C, Von Hoff D, **Eckhardt SG**. Phase I, pharmacokinetic, and pharmacodynamic study of intravenously administered Ad5CMV-p53, an adenoviral vector containing the wild-type p53 gene, in patients with advanced cancer. *J Clin Oncol.*; 1;24(13):2052-8, 2006.
64. Morelli MP, Cascone T, Troiani T, Tuccillo C, Bianco R, Normanno N, Romano M, Veneziani BM, Fontanini G, **Eckhardt SG**, De Pacido S, Tortora G, Ciardiello F. Anti-tumor activity of the combination of cetuximab, an anti-EGFR blocking monoclonal antibody and ZD6474, an inhibitor of VEGFR and EGFR tyrosine kinases. *J Cell Physiol*; 208(2):344-53, 2006.
65. Bianco C, Giovannetti E, Ciardiello F, Mey V, Nannizzi S, Tortora G, Troiani T, Pasqualetti F, **Eckhardt G**, de Liguoro M, Ricciardi S, Del Tacca M, Raben D, Cionini L, Danesi R. Synergistic antitumor activity of ZD6474, an inhibitor of vascular endothelial growth factor receptor and epidermal growth factor receptor signaling, with gemcitabine and ionizing radiation against pancreatic cancer. *Clin Cancer Res.*; 12(23):7099-107, 2006
66. Teresa Troiani, Owen Lockerbie, Mark Morrow, Fortunato Ciardiello' **S.Gail Eckhardt**. Sequence-Dependent Inhibition of Human Colon Cancer Cell Growth and of Pro-Survival Pathways by Oxaliplatin in combination with ZD6474 (ZACTIMA™), an inhibitor of VEGFR and EGFR Tyrosine Kinases *Molecular Cancer Therapeutics* 5(7):1883-94, 2006
67. Lisa J. Green, Philip Marder, Chad Ray, Carolyn A. Cook, Susan Jaken, Luna C Musib,Roy S. Herbst, Michael Carducci, Carolyn D. Britten, Michele Basche, **S. Gail Eckhardt**, and Donald Thornton. Development and Validation of a Drug Activity Biomarker that Demonstrates Target Inhibition in Cancer Patients Receiving Enzastaurin, a Novel Phospho-Kinase C-β Inhibitor. *Clin Cancer Res* 12(11): 3408-3415, 2006.
68. + Michele Basche, Daniel L Gustafson, Scott N. Holden, Cindy L. O'Bryant, Lia Gore, Samir Witta, Mary Kay Schultz, Mark Morrow, Adrah Levin, Brian R. Creese, Michael Kangas, Kaye Roberts, Thu Nguyen, Kat Davis, Russell S. Addison, Jane C. Moore, **S. Gail Eckhardt**. A Phase I Biologic and Pharmacologic Study of the Heparanase Inhibitor PI-88 in Patients with Advanced Solid Tumors. *Clin Cancer Res*; 12(18):5471-80, 2006
69. Ramaswamy B, Elias AD, Kelbick NT, Dodley A, Morrow M, Hauger M, Allen J, Rhoades C, Kendra K, Chen HX, **Eckhardt SG**, Shapiro CL. Phase II trial of bevacizumab in combination with weekly docetaxel in metastatic breast cancer patients. *Clin Cancer Res* 12(10):3124-9, 2006.

70. + Lia Gore, Scott N. Holden, Roger B. Cohen, Mark Morrow, A. Scott Pierson, Cindy L. O'Bryant, Martha Persky, Daniel Gustafson, Christine Mikule, Susan Fisher, Stephen Zhang, Peter A. Palmer, **S. Gail Eckhardt**. A Phase I Safety, Pharmacological, and Biological Study of the Farnesyl Protein Transferase Inhibitor, Tipifarnib, and Capecitabine in Advanced Solid Tumors. *Annals of Oncology* 17(11):1709-17, 2006.
71. Abou-Alfa GK, Letourneau R, Harker G, Modiano M, Hurwitz H, Tchekmedyian NS, Feit K, Ackerman J, De Jager RL, **Eckhardt SG**, O'Reilly EM. Randomized Phase III Study of Exatecan and Gemcitabine Compared With Gemcitabine Alone in Untreated Advanced Pancreatic Cancer. *J Clin Oncol* 24(27):4441-7, 2006.
72. Medeiros BC, Landau HJ, Morrow M, Lockerbie RO, Pitts T, **Eckhardt SG**. The farnesyl transferase inhibitor, tipifarnib, is a potent inhibitor of the MDR1 gene product, P-glycoprotein, and demonstrates significant cytotoxic synergism against human leukemia cell lines. *Leukemia*; 21(4):739-46, 2007.
73. Messersmith WA, Hidalgo M, Carducci M, **Eckhardt SG**. Novel targets in solid tumors: MEK inhibitors. *Clin Adv Hematol Oncol* 4(11):831-6, 2006.
74. Camidge, D.R., **Eckhardt, S.G.**, Gore, L., Dynamic and modern: bringing the ethics of phase I trials up to date. *J Clin Oncol.* 10; 24 (32):5179-80, 2006
75. Chow LQM, **Eckhardt SG**. Sunitinib: From Rational Design to Clinical Efficacy. *J Clin Oncol* 25(7):884-96, 2007
76. + S Hariharan, D Gustafson, S Holden, D McConkey, D Davis, M Morrow, M Basche, L Gore, C Zang, CL O'Bryant, A Baron, D Gallemann, D Colevas & **SG Eckhardt**. Assessment of the biological and pharmacological effects of the $\alpha \beta_3$ and $\alpha \beta_5$ Integrin Receptor Antagonist, cilengitide (EMD 121974), in patients with advanced solid tumors. *Ann Oncol*; 18(8):1400-7, 2007
77. O'Dwyer PJ, **Eckhardt SG**, Haller DG, Tepper J, Ahnen D, Hamilton S, Benson AB 3rd, Rothenberg M, Petrelli N, Lenz HJ, Diasio R, DuBois R, Sargent D, Sloan J, Johnson CD, Comis RL, O'Connell MJ; Gastrointestinal Scientific Leadership Council of the Coalition of Cancer Cooperative Groups. Priorities in colorectal cancer research: recommendations from the Gastrointestinal Scientific Leadership Council of the Coalition of Cancer Cooperative Groups. *J Clin Oncol*; 25(16):2313-21, 2007
78. Bradshaw-Pierce EL, **Eckhardt SG**, Gustafson DL. A physiologically based pharmacokinetic model of docetaxel disposition: from mouse to man. *Clin Cancer Res*;13(9):2768-76, 2007
79. + Chiappori AA, **Eckhardt SG**, Bukowski R, Sullivan DM, Ikeda M, Yano Y, Yamada-Sawada T, Kambayashi Y, Tanaka K, Javle MM, Mekhail T, O'Bryant CL, Creaven PJ. A phase I pharmacokinetic and pharmacodynamic study of S-3304, a novel matrix metalloproteinase inhibitor, in patients with advanced and refractory solid tumors. *Clin Cancer Res*;13(7):2091-9, 2007
80. Teresa Troiani, Natalie J. Serkova, Daniel L. Gustafson, Thomas K. Henthorn, Owen Lockerbie, Andrea Merz, Michael Long, Mark Morrow, Fortunato Ciardiello, **S.Gail Eckhardt**. Investigation of Two Dosing Schedules of Vandetanib (ZD6474), an Inhibitor of VEGFR and EGFR Signaling, in Combination with Irinotecan in a Human Colon Cancer Xenograft Model. *Clin Cancer Res* 13(21): 6450-6458, 2007
81. Serkova NJ, Spratlin JL, **Eckhardt SG**. NMR-based metabolomics: Translational application and treatment of cancer. *Curr Opin Mol Ther* 9(6):572-85, 2007
82. Patt YZ, Lee FC, Liebmann JE, Diamandidis D, **Eckhardt, SG**, Javle M, Justice GR, Keiser W, Salvatore JR, Bexon A., Lin E. Capecitabine plus 3-weekly irinotecan (XELIRI regimen) as first-line chemotherapy for metastatic colorectal cancer: phase II trial results. *Am J Clin Oncol.*; 30(4):350-7, 2007
83. Saltz LB, Rosen LS, Marshall JL, Belt RJ, Hurwitz HI, **Eckhardt SG**, Bergsland EK, Haller DG, Lockhart AC, Rocha, Lima CM, Huang X., DePrimo SE, Chow-Maneval E, Chao RC, Lenz HJ. Phase II trial of sunitinib in patients with metastatic colorectal cancer after failure of standard therapy. *J Clin Oncol.*; 25(30):4793-9, 2007
84. Chen C, Kan M, Song J, Campana J, Raben A, Hu K, Harrison L, Quon H, Dancey J, Baron A, Said S, **Eckhardt SG**, Raben D. Phase I trial of gefitinib in combination with radiation or chemoradiation for patients with locally advanced squamous cell head and neck cancer. *J Clin Oncol.*; 1;25(31):4880-6, 2007
85. Zerbe LK, Dwyer-Nield LD, Fritz JM, Redente EF, Shroyer RJ, Conklin E, Kane S, Tucker C, **Eckhardt SG**, Gustafson DL, Iwata KK, Malkinson AM. Inhibition by erlotinib of primary lung adenocarcinoma at an early stage in male mice. *Cancer Chemother Pharmacol.* 62(4):605-20, 2007
86. + Lia Gore, Mace L. Rothenberg, Cindy L. O'Bryant, Dan Gustafson, Mary Kay Schultz, Candice McCoy, Astrid Schott, Catherine Scholz, and **S. Gail Eckhardt**. A Phase I and Pharmacokinetic Study of the Oral Histone Deacetylase Inhibitor, MS-275, in Patients with Refractory Solid Tumors and Lymphomas. *Clin Cancer Res* 14(14):4517-25, 2008
87. + Alex A Adjei, Roger B Cohen, Wilbur Franklin, Clive Morris, David Wilson, Julian R Molina, Lorelei J Hanson, Lia Gore, Laura Chow, Stephen Leong, Lara Maloney, Gilad Gordon, Heidi Simmons, Allison Marlow, Kevin Litwiler, Suzy Brown, Gregory Poch, Katie Kane, Jerry Haney, and **S. Gail Eckhardt**. A Phase I

- Pharmacokinetic and Pharmacodynamic Study of the Oral, Small-Molecule MEK1/2 Inhibitor AZD6244 (ARRY-142886) in Patients with Advanced Cancers. *J Clin Oncol*; 26(13):2139-46, 2008
88. + Chow LQ, Gustafson DL, O'Bryant CL, Gore L, Basche M, Holden SN, Morrow MC, Grolnic S, Creese BR, Roberts KL, Davis K, Addison R, **Eckhardt SG**. A phase I pharmacological and biological study of PI-88 and docetaxel in patients with advanced malignancies. *Cancer Chemother Pharmacol*. Dec;63(1):65-74. Mar 5. Epub, 2008
 89. + Chow LQ, **Eckhardt SG**, O'Bryant CL, Schultz MK, Morrow M, Grolnic S, Basche M, Gore L. A phase I safety, pharmacological, and biological study of the farnesyl protein transferase inhibitor, lonafarnib (SCH 663366), in combination with cisplatin and gemcitabine in patients with advanced solid tumors. *Cancer Chemother Pharmacol*; 62(4):631-46, 2008
 90. Ashkenazi A, Holland P, **Eckhardt SG**. Ligand-Based Targeting of Apoptosis in Cancer: The Potential of Recombinant Human Apoptosis Ligand 2/Tumor Necrosis Factor-Related Apoptosis-Inducing Ligand (rhApo2L/TRAIL). *J Clin Oncol*; 26(21):3621-30, 2008
 91. + Lieu C, Chow L, Pierson AS, **Eckhardt SG**, O'Bryant CL, Morrow M, Tran ZV, Wright JJ, Gore L. A phase I study of bortezomib, etoposide and carboplatin in patients with advanced solid tumors refractory to standard therapy. *Invest New Drugs*. 2009 Feb;27(1):53-62. Epub 2008 Jul 11
 92. + O'Bryant CL, Lieu CH, Leong S, Boinpally R, Basche M, Gore L, Leonardi K, Schultz MK, Hariharan S, Chow L, Diab S, Gibbs A, **Eckhardt SG**. A dose-ranging study of the pharmacokinetics and pharmacodynamics of the selective apoptotic antineoplastic drug (SAAND), OSI-461, in patients with advanced cancer, in the fasted and fed state. *Cancer Chemother Pharmacol*. 2009 Feb; 63(3):477-89. Epub 2008 May 29
 93. Chen RW, Bemis LT, Amato CM, Myint H, Tran H, Birks DK, **Eckhardt SG**, Robinson WA. Truncation in CCND1 mRNA alters miR-16-1 regulation in mantle cell lymphoma. *Blood*. Aug 1;112(3):822-9. May 15. Epub, 2008
 94. Spratlin J, Serkova N, **Eckhardt SG**. Clinical Applications of Metabolomics in Oncology – A Review, CCR-08-1059R. *Clin Can Res* 2009 Jan 15;15(2):431-40
 95. Call JA, **Eckhardt SG**, Camidge DR. Targeted manipulation of apoptosis in cancer treatment. *Lancet Oncol*. 2008 Oct; 9(10):1002-11. Epub 2008 Aug 27
 96. **Eckhardt SG**, De Porre P, Smith D, Maurel J, Steward WP, Bouche O, van de Velde H, Michiels B, Bugat R. Patient-Reported Outcomes as a Component of the Primary Endpoint in a Double-Blind, Placebo-Controlled Trial in Advanced Pancreatic Cancer. *J Pain Symptom Manage*. 2009 Feb;37(2): 135-43. Epub 2008 Aug 23
 97. +Lam ET, O'Bryant CL, Basche M, Gustafson DL, Serkova N, Baron A, Holden SN, Dancey J, **Eckhardt SG**, Gore L. A phase I study of gefitinib, capecitabine, and celecoxib in patients with advanced solid tumors. *Mol Cancer Ther*. 2008 Dec;7(12):3685-94.
 98. Jimeno A, Messersmith WA, Hirsch FR, Franklin WA, **Eckhardt SG**. KRAS Mutations and Sensitivity to Epidermal Growth Factor Receptor Inhibitors in Colorectal Cancer: Practical Application of Patient Selection. *J Clin Oncol*. 2009 Mar 1;27(7):1130-6. Epub 2009 Jan 5
 99. Spratlin JL, Serkova NJ, **Eckhardt SG**. Clinical applications of metabolomics in oncology: a review. *Clin Cancer Res*. 2009 Jan 15;15(2):431-40.
 100. Pitts, TM, Morrow M., Kaufman, SA, Tentler, JJ, **Eckhardt, SG**. Vorinostat and bortezomib exert synergistic anti-proliferative and pro-apoptotic effects in colon cancer cell models. *Mol Cancer Ther*, 2009 Feb;8(2):342-9. Epub 2009 Jan 27
 101. Klawitter J, Anderson, N, Christians U, Leibfritz D, **Eckhardt SG**, Serkova NJ. Time-dependent effects of imatinib in human leukemia cells: A kinetic NMR-profiling study. *Br J Cancer*, 2009 Mar 24;100(6):923-31. Epub 2009 Mar 3
 102. +Stephen Leong, Roger B Cohen, Daniel L Gustafson, Corey J Langer, D Ross Camidge, Kristin Padavic, Lia Gore, Margaret Smith, Laura Quan Man Chow, Margaret von Mehren, Cindy OBryant, Sujatha Hariharan, Sami Diab, Norma Lynn Fox, Renee Miceli, and **S Gail Eckhardt**. Mapatumumab, an Antibody Targeting TRAIL-R1, in Combination with Paclitaxel and Carboplatin in Patients with Advanced Solid Malignancies: Results of a Phase 1 and Pharmacokinetic Study. *J Clin Oncol*. 2009 Sep 10;27(26):4413-21. Epub 2009 Aug 3.
 103. M. Pia Morelli, Amy M. Brown, Todd M. Pitts, John J. Tentler, Fortunato Ciardiello, Anderson Ryan, Juliane M. Jürgensmeier and **S. Gail Eckhardt**. Targeting Vascular Endothelial Growth Factor Receptor-1 and -3 With Cediranib (AZD2171): Effects on Migration and Invasion of GI Cancer Cell Lines. *Mol Cancer Ther* 2009 Sep;8(9):2546-58. Epub 2009 Sep 15.

104. Klawitter J, Anderson N, Klawitter J, Christians U, Leibfritz D, **Eckhardt SG**, Serkova NJ. Time-dependent effects of imatinib in human leukaemia cells: a kinetic NMR-profiling study. *Br J Cancer*. 2009 Mar 24;100(6):923-31. Epub 2009 Mar 3. PMID: 19259085
105. Olsen CC, Schefter TE, Chen H, Kane M, Leong S, McCarter MD, Chen Y, Mack P, **Eckhardt SG**, Stiegmann G, Raben D. Results of a phase I trial of 12 patients with locally advanced pancreatic carcinoma combining gefitinib, paclitaxel, and 3-dimensional conformal radiation: report of toxicity and evaluation of circulating K-ras as a potential biomarker of response to therapy. *Am J Clin Oncol*. 2009 Apr;32(2):115-21.
106. Jimeno A, Messersmith WA, Hirsch FR, Franklin WA, **Eckhardt SG**. KRAS mutations and susceptibility to cetuximab and panitumumab in colorectal cancer *Cancer J*. 2009 Mar-Apr;15(2):110-3. Review. PMID: 19390304.
107. Kominsky DJ, Klawitter J, Brown JL, Boros LG, Melo JV, **Eckhardt SG**, Serkova NJ. Abnormalities in glucose uptake and metabolism in imatinib-resistant human BCR-ABL-positive cells. *Clin Cancer Res*. 2009 May 15;15(10):3442-50. Epub 2009 Apr 28. PMID: 19401345
108. Philip PA, Mooney M, Jaffe D, **Eckhardt G**, Moore M, Meropol N, Emens L, O'Reilly E, Korc M, Ellis L, Benedetti J, Rothenberg M, Willett C, Tempero M, Lowy A, Abbruzzese J, Simeone D, Hingorani S, Berlin J, Tepper J. Consensus report of the national cancer institute clinical trials planning meeting on pancreas cancer treatment. *J Clin Oncol*. 2009 Nov 20;27(33):5660-9. Epub 2009 Oct 26. Review.
109. Hudachek SF, **Eckhardt SG**, Hicks B, Gustafson DL. Population pharmacokinetic model of PI-88, a heparanase inhibitor. *Cancer Chemother Pharmacol*. 2010 Mar;65(4):743-53. Epub 2009 Jul 25.
110. +Jennifer L. Spratlin, Roger B. Cohen, Matthew Eadens, Lia Gore, D. Ross Camidge, Sami Diab, Stephen Leong, Cindy O'Bryant, Laura Q.M. Chow, Natalie J. Serkova, Neal J. Meropol, Nancy L. Lewis, E. Gabriela Chiorean, Floyd Fox, Hagop Youssoufian, Eric K. Rowinsky, and **S. Gail Eckhardt**. Phase I Pharmacologic and Biologic Study of Ramucirumab (IMC-1121B), a Fully Human Immunoglobulin G1 Monoclonal Antibody Targeting the Vascular Endothelial Growth Factor Receptor-2. *J Clin Oncol* 2010 Feb 10;28(5):780-7. Epub 2010 Jan 4.
111. + Michael S. Gordon, Christopher S. Sweeney, David S. Mendelson, **S. Gail Eckhardt**, Abraham Anderson, Darrin Beaupre, Daniel Branstetter, Teresa L. Burgess, Angela Coxon, Hongjie Deng, Paula Kaplan-Lefko, Ian Leitch, Kelly Oliner, Lucy Yan, Min Zhu, Lia Gore. Safety, Pharmacokinetics, and Pharmacodynamics of AMG 102, a Fully Human Hepatocyte Growth Factor–Neutralizing Monoclonal Antibody, in a First-in-Human Study of Patients With Advanced Solid Tumors. *Clin Cancer Res*. 2010 Jan 15;16(2):699-710. Epub 2010 Jan 12.
112. Zhou Q, Gustafson D, Nallapareddy S, Diab S, Leong S, Lewis K, Gore L, Messersmith WA, Treston AM, **Eckhardt SG**, Sidor C, Camidge DR. A phase I dose-escalation, safety and pharmacokinetic study of the 2-methoxyestradiol analog ENMD-1198 administered orally to patients with advanced cancer. *Invest New Drugs*. 2010 Jan 19. [Epub ahead of print]
113. Pugh TJ, Chen C, Rabinovitch R, **Eckhardt SG**, Rusthoven KE, Swing R, Raben D. Phase I Trial of Bortezomib and Concurrent External Beam Radiation in Patients with Advanced Solid Malignancies. *Int J Radiat Oncol Biol Phys*. 2010 Feb 2. [Epub ahead of print]
114. Diamond JR, Borges VF, **Eckhardt SG**, Jimeno A. BRCA in breast cancer: from risk assessment to therapeutic prediction. *Drug News Perspect*. 2009 Dec;22(10):603-8. Review.
115. + Camidge DR, Herbst RS, Gordon MS, **Eckhardt SG**, Kurzrock R, Durbin B, Ing J, Tohny TM, Sager J, Ashkenazi A, Bray G, Mendelson D. A phase I safety and pharmacokinetic study of the death receptor 5 agonistic antibody PRO95780 in patients with advanced malignancies. *Clin Cancer Res*. 2010 Feb 15;16(4):1256-63. Epub 2010 Feb 9.
116. Banerji U, Camidge DR, Verheul HM, Agarwal R, Sarker D, Kaye SB, Desai IM, Timmer-Bonte JN, **Eckhardt SG**, Lewis KD, Brown KH, Cantarini MV, Morris C, George SM, Smith PD, van Herpen CM. The first-in-human study of the hydrogen sulfate (Hyd-sulfate) capsule of the MEK1/2 inhibitor AZD6244 (ARRY-142886): a phase I open-label multicenter trial in patients with advanced cancer. *Clin Cancer Res*. 2010 Mar 1;16(5):1613-23. Epub 2010 Feb 23.
117. + Kurzrock R, Patnaik A, Aisner J, Warren T, Leong S, Benjamin R, **Eckhardt SG**, Eid JE, Greig G, Habben K, McCarthy CD, Gore L. A phase I study of weekly R1507, a human monoclonal antibody insulin-like growth factor-I receptor antagonist, in patients with advanced solid tumors. *Clin Cancer Res*. 2010 Apr 15;16(8):2458-65. Epub 2010 Apr 6.
118. John J. Tentler, Erica L. Bradshaw-Pierce, Natalie J. Serkova, Kendra M. Hasebroock, Todd M. Pitts, Jennifer R. Diamond, Graham C. Fletcher, Mark R. Bray and **S. Gail Eckhardt**. Assessment of the *In Vivo* Antitumor Effects of ENMD-2076, A Novel Multi-Targeted Kinase Inhibitor, Against Primary and Cell Line-Derived Human Colorectal Cancer Xenograft Models. *Clin Cancer Res* 2010 Apr 20. [Epub ahead of print]

119. Herbst RS, **Eckhardt SG**, Kurzrock R, Ebbinghaus S, O'Dwyer PJ, Gordon MS, Novotny W, Goldwasser MA, Tohny TM, Lum BL, Ashkenazi A, Jubb AM, Mendelson DS. Phase I dose-escalation study of recombinant human Apo2L/TRAIL, a dual proapoptotic receptor agonist, in patients with advanced cancer. *J Clin Oncol*. 2010 Jun 10;28(17):2839-46. Epub 2010 May 10.
120. Leong S, Messersmith WA, Tan AC, **Eckhardt SG**. Novel agents in the treatment of metastatic colorectal cancer. *Cancer J*. 2010 May-Jun;16(3):273-82.
121. Todd M. Pitts, Aik Choon Tan, Gillian N. Kulikowski, John J. Tentler, Amy M. Brown, Sara A. Flanigan, Stephen Leong, Christopher D. Coldren, Fred R. Hirsch, Marileila Varella-Garcia, Christopher Korch, and **S. Gail Eckhardt**. Development of an Integrated Genomic Classifier for a Novel Agent in Colorectal Cancer: Approach to Individualized Therapy in Early Development. *Clin Cancer Res*. 2010 Jun15;16(12):3193-204. Epub 2010 Jun 8.
122. John J. Arcaroli, Basel M. Touban, Aik Choon Tan, Marileila Varella-Garcia, Rebecca W. Powell, **S. Gail Eckhardt**, Paul Elvin, Dexiang Gao, Wells A. Messersmith. Gene Array and FISH Biomarkers of Activity of Saracatinib (AZD0530), a Src Inhibitor, in a Preclinical Model of Colorectal Cancer. *Clin Cancer Res*. 2010;16(16):4165-77.
123. John J. Tentler, Aik Choon Tan, Sujatha Nallapareddy, Anna Spreafico, Todd M. Pitts, M. Pia Morelli Heather M. Selby, Maria I. Kachaeva, Sara A. Flanigan, Gillian N. Kulikowski, Stephen Leong, John J. Arcaroli, Wells A. Messersmith and **S. Gail Eckhardt**. Identification of Predictive Markers of Response to the MEK1/2 Inhibitor Selumetinib (AZD6244) in KRAS-Mutated Colorectal Cancer. *Mol Cancer Ther* 2010 Dec;9(12):3351-62. Epub 2010 Oct 5.
124. Flanigan SA, Pitts TM, **Eckhardt SG**, Tentler JJ, Tan AC, Thorburn A, Leong S. The insulin-like growth factor I receptor/insulin receptor tyrosine kinase inhibitor PQIP exhibits enhanced antitumor effects in combination with chemotherapy against colorectal cancer models. *Clin Cancer Res*. 2010 Nov 15;16(22):5436-46. Epub 2010 Oct 13.
125. Martinelli E, Troiani T, Morgillo F, Rodolico G, Vitagliano D, Morelli MP, Tuccillo C, Vecchione L, Capasso A, Orditura M, De Vita F, **Eckhardt SG**, Santoro M, Berrino L, Ciardiello F. Synergistic antitumor activity of sorafenib in combination with epidermal growth factor receptor inhibitors in colorectal and lung cancer cells. *Clin Cancer Res*. 2010 Oct 15;16(20):4990-5001. Epub 2010 Sep 1.
126. Diamond JR, Bastos BR, Hansen RJ, Gustafson DL, **Eckhardt SG**, Kwak E, Pandya SS, Fletcher GC, Pitts TM, Kulikowski GN, Morrow M, Arnott J, Bray MR, Sidor CF, Messersmith WA, Shapiro GI. Phase I Safety, Pharmacokinetic and Pharmacodynamic Study of ENMD-2076, a Novel Angiogenic and Aurora Kinase Inhibitor, in Patients with Advanced Solid Tumors. *Clin Cancer Res*. 2011 Feb 15;17(4):849-60. Epub 2010 Dec 3.2010
127. J.L. Spratlin, T.M. Pitts, G.N. Kulikowski, M.P. Morelli, J.J. Tentler, N.J. Serkova and **S.G. Eckhardt**. Synergistic Activity of Histone Deacetylase and Proteasome Inhibition Against Pancreatic and Hepatocellular Cancer Cell Lines. *Anticancer Res* 2011 Apr;31(4):1093-103.
128. Niedzwiecki D, Bertagnolli MM, Warren RS, Compton CC, Kemeny NE, Benson AB 3rd, **Eckhardt SG**, Alberts S, Porjosh GN, Kerr DJ, Fields A, Rougier P, Pipas JM, Schwartz JH, Atkins J, O'Rourke M, Perry MC, Goldberg RM, Mayer RJ, Colacchio TA. Documenting the Natural History of Patients With Resected Stage II Adenocarcinoma of the Colon After Random Assignment to Adjuvant Treatment With Edrecolomab or Observation: Results From CALGB 9581. *J Clin Oncol*. 2011 Aug 10;29(23):3146-52. Epub 2011 Jul 11.
129. + Infante JR, Kurzrock R, Spratlin J, Burris HA, **Eckhardt SG**, Li J, Wu K, Skolnik JM, Hylander-Gans L, Osmukhina A, Huszar D, Herbst RS. A Phase I study to assess the safety, tolerability, and pharmacokinetics of AZD4877, an intravenous Eg5 inhibitor in patients with advanced solid tumors. *Cancer Chemother Pharmacol*. 2011 Jun 3. [Epub ahead of print]
130. + Jänne PA, Boss DS, Camidge DR, Britten CD, Engelman JA, Garon EB, Guo F, Wong S, Liang J, Letrent S, Millham R, Taylor I, **Eckhardt SG**, Schellens JH. Phase I dose-escalation study of the pan-HER inhibitor, PF299804, in patients with advanced malignant solid tumors. *Clin Cancer Res*. 2011 Mar 1;17(5):1131-9. Epub 2011 Jan 10.
131. + Gore L, Rivera E, Basche M, Moulder-Thompson SL, Li J, Eppers S, Grolnic S, O'Bryant C, Cleere D, Elsayed YA, **Eckhardt SG**. Phase I combination study of trabectedin and capecitabine in patients with advanced malignancies. *Invest New Drugs*. 2011 Sep 20. [Epub ahead of print]
132. Pan Y, Xu R, Peach M, Huang CP, Branstetter D, Novotny W, Herbst RS, **Eckhardt SG**, Holland PM. Evaluation of pharmacodynamic biomarkers in a Phase 1a trial of dulanermin (rhApo2L/TRAIL) in patients with advanced tumours. *Br J Cancer*. 2011 Dec 6;105(12):1830-8. doi: 10.1038/bjc.2011.456. Epub 2011 Oct 27.

133. Morelli MP, Tentler JJ, Kulikowski GN, Tan AC, Bradshaw-Pierce EL, Pitts TM, Brown AM, Nallapareddy S, Arcaroli JJ, Serkova NJ, Hidalgo M, Ciardiello F, **Eckhardt SG**. Preclinical Activity of the Rational Combination of Selumetinib (AZD6244) in Combination with Vorinostat in KRAS-Mutant Colorectal Cancer Models. *Clin Cancer Res* 18(4):1051-62. Epub 2011 Dec 15.
134. Ma WW, Messersmith WA, Dy GK, Weekes CD, Whitworth A, Ren C, Maniar M, Wilhelm F, **Eckhardt SG**, Adjei AA, Jimeno A. Phase I study of Rigosertib, an inhibitor of the phosphatidylinositol 3-kinase and Polo-like kinase 1 pathways, combined with gemcitabine in patients with solid tumors and pancreatic cancer. *Clin Cancer Res*. 2012 Apr 1;18(7):2048-55. Epub 2012 Feb 14.
135. Hong DS, Bowles DW, Falchook GS, Messersmith WA, George GC, O'Bryant CL, Vo AC, Klucher K, Herbst RS, **Eckhardt SG**, Peterson S, Hausman DF, Kuzrock R, Jimeno A. A Multicenter Phase 1 Trial of PX-866, an Oral Irreversible Phosphatidylinositol 3-Kinase Inhibitor, in Patients with Advanced Solid Tumors. *Clin Cancer Res*. 2012 Jun 12. [Epub ahead of print]
136. Sullivan KD, Padilla-Just N, Henry RE, Porter CC, Kim J, Tentler JJ, **Eckhardt SG**, Tan AC, Degregori J, Espinosa JM. ATM and MET kinases are synthetic lethal with nongenotoxic activation of p53. *Nat Chem Biol*. 2012 Jun 3. doi: 10.1038/nchembio.965. [Epub ahead of print]
137. + Leong S, **Eckhardt SG**, Chan E, Messersmith WA, Spratlin J, Camidge DR, Diab S, Khosravan R, Lin X, Chow Maneval E, Lockhart AC. A phase I study of sunitinib combined with modified FOLFOX6 in patients with advanced solid tumors. *Cancer Chemother Pharmacol*. 2012 Jul;70(1):65-74. Epub 2012 May 24.
138. Arcaroli JJ, Quackenbush KS, Powell RW, Pitts TM, Spreatico A, Varella-Garcia M, Bemis L, Tan AC, Reinemann JM, Touban BM, Dasari A, **Eckhardt SG**, Messersmith WA. Common PIK3CA mutants and a novel 3' UTR mutation are associated with increased sensitivity to saracatinib. *Clin Cancer Res*. 2012 May 1;18(9):2704-14.
139. Flygare JA, Beresini M, Budha N, Chan H, Chan IT, Cheeti S, Cohen F, Deshayes K, Doerner K, **Eckhardt SG**, Elliott LO, Feng B, Franklin MC, Reisner SF, Gazzard L, Halladay J, Hymowitz SG, La H, LoRusso P, Maurer B, Murray L, Plise E, Quan C, Stephan JP, Young SG, Tom J, Tsui V, Um J, Varfolomeev E, Vucic D, Wagner AJ, Wallweber HJ, Wang L, Ware J, Wen Z, Wong H, Wong JM, Wong M, Wong S, Yu R, Zobel K, Fairbrother WJ. Discovery of a potent small-molecule antagonist of inhibitor of apoptosis (IAP) proteins and clinical candidate for the treatment of cancer (GDC-0152). *J Med Chem*. 2012 May 10;55(9):4101-13. Epub 2012 Mar 28.
140. Wong H, Budha NR, West K, Blackwood E, Ware JA, Yu R, Darbonne WC, Gould SE, Steigerwalt R, Erickson R, Hop CE, LoRusso P, **Eckhardt SG**, Wagner A, Chan IT, Mamounas M, Flygare JA, Fairbrother WJ. Dogs are more sensitive to antagonists of inhibitor of apoptosis proteins than rats and humans: a translational toxicokinetic/toxicodynamic analysis. *Toxicol Sci*. 2012 Nov;130(1):205-13. doi: 10.1093/toxsci/kfs235. Epub 2012 Jul 28.
141. Dy GK, Infante JR, **Eckhardt SG**, Novello S, Ma WW, Jones SF, Huff A, Wang Q, Suttle AB, Ottesen LH, Adjei AA, Burris HA 3rd. Phase Ib trial of the oral angiogenesis inhibitor pazopanib administered concurrently with erlotinib. *Invest New Drugs*. 2012 Nov 8. [Epub ahead of print]
142. Diamond JR, **Eckhardt SG**, Tan AC, Newton TP, Selby HM, Brunkow KL, Kachaeva MI, Varella-Garcia M, Pitts TM, Bray MR, Fletcher GC, Tentler JJ. Predictive biomarkers of sensitivity to the aurora and angiogenic kinase inhibitor ENMD-2076 in preclinical breast cancer models. *Clin Cancer Res*. 2013 Jan 1;19(1):291-303. doi: 10.1158/1078-0432.CCR-12-1611. Epub 2012 Nov 7.
143. Tentler J, Weekes C, Leong S, Jimeno A, Messersmith W, Pitts T, Tan AC, Arcaroli J, **Eckhardt SG**. Patient-derived tumor explant models. *Nat. Rev. Clin. Oncol*. 9, 338–350 (2012)
144. + Micel LN, Tentler JJ, Smith PG, **Eckhardt SG**. Role of Ubiquitin Ligases and the Proteasome in Oncogenesis: Novel Targets for Anticancer Therapies. *J Clin Oncol*. 2013 Jan 28. [Epub ahead of print]
145. Yap TA, Arkenau HT, Camidge DR, George S, Serkova NJ, Gwyther SJ, Spratlin JL, Lal R, Spicer J, Desouza NM, Leach MO, Chick J, Poondru S, Boinpally R, Gedrich R, Brock K, Stephens A, **Eckhardt SG**, Kaye SB, Demetri G, Scurr M. First-in-human phase I trial of two schedules of OSI-930, a novel multikinase inhibitor, incorporating translational proof-of-mechanism studies. *Clin Cancer Res*. 2013 Feb 15;19(4):909-19. doi: 10.1158/1078-0432.CCR-12-2258. Epub 2013 Feb 12.
146. Weekes CD, Von Hoff DD, Adjei AA, Leffingwell DP, **Eckhardt SG**, Gore L, Lewis KD, Weiss GJ, Ramanathan RK, Dy GK, Ma WW, Sheedy B, Iverson C, Miner JN, Shen Z, Yeh LT, Dubowy RL, Jeffers M, Rajagopalan P, Clendeninn NJ. Multicenter phase I trial of the mitogen-activated protein kinase 1/2 inhibitor BAY 86-9766 in patients with advanced cancer. *Clin Cancer Res*. 2013 Mar 1;19(5):1232-43. doi: 10.1158/1078-0432.CCR-12-3529. Epub 2013 Feb 22.
147. + Bradshaw-Pierce EL, Pitts TM, Kulikowski G, Selby H, Merz AL, Gustafson DL, Serkova NJ, **Eckhardt SG**, Weekes CD. Utilization of quantitative in vivo pharmacology approaches to assess combination effects of

- everolimus and irinotecan in mouse xenograft models of colorectal cancer. PLoS One. 2013;8(3):e58089. doi: 10.1371/journal.pone.0058089. Epub 2013 Mar 8.
148. + Bradshaw-Pierce EL, Pitts TM, Tan AC, McPhillips K, West M, Gustafson DL, Halsey C, Nguyen L, Lee NV, Kan JL, Murray BW, **Eckhardt SG**. Tumor P-Glycoprotein Correlates with Efficacy of PF-3758309 in in vitro and in vivo Models of Colorectal Cancer. Front Pharmacol. 2013;4:22. doi: 10.3389/fphar.2013.00022. Epub 2013 Mar 22.
 149. + Pitts TM, Kulikowski GN, Tan AC, Murray BW, Arcaroli JJ, Tentler JJ, Spreafico A, Selby HM, Kachaeva MI, McPhillips KL, Britt BC, Bradshaw-Pierce EL, Messersmith WA, Varella-Garcia M, **Eckhardt SG**. Association of the epithelial-to-mesenchymal transition phenotype with responsiveness to the p21-activated kinase inhibitor, PF-3758309, in colon cancer models. Front Pharmacol. 2013;4:35. doi: 10.3389/fphar.2013.00035. Epub 2013 Mar 28.
 150. Schlegel J, Sambade MJ, Sather S, Moschos SJ, Tan AC, Winges A, Deryckere D, Carson CC, Trembath DG, Tentler JJ, **Eckhardt SG**, Kuan PF, Hamilton RL, Duncan LM, Miller CR, Nikolaishvili-Feinberg N, Midkiff BR, Liu J, Zhang W, Yang C, Wang X, Frye SV, Earp HS, Shields JM, Graham DK. MERTK receptor tyrosine kinase is a therapeutic target in melanoma. J Clin Invest. 2013 Apr 15. doi:pii: 67816. 10.1172/JCI67816. [Epub ahead of print]
 151. + Spreafico A, Tentler JJ, Pitts TM, Tan AC, Gregory MA, Arcaroli JJ, Klauck PJ, McManus MC, Hansen RJ, Kim J, Micel LN, Selby HM, Newton TP, McPhillips KL, Gustafson DL, Degregori JV, Messersmith WA, Winn RA, **Eckhardt SG**. Rational Combination of a MEK Inhibitor, Selumetinib, and the Wnt/Calcium Pathway Modulator, Cyclosporin A, in Preclinical Models of Colorectal Cancer. Clin Cancer Res. 2013 Aug 1;19(15):4149-62. doi: 10.1158/1078-0432.CCR-12-3140. Epub 2013 Jun 11.
 152. + Lieu CH, Tan AC, Leong S, Diamond JR, **Eckhardt SG**. From Bench to Bedside: Lessons Learned in Translating Preclinical Studies in Cancer Drug Development. J Natl Cancer Inst. 2013 Sep 19. [Epub ahead of print]
 153. Arcaroli JJ, Quackenbush KS, Purkey A, Powell RW, Pitts TM, Bagby S, Tan AC, Cross B, McPhillips K, Song EK, Tai WM, Winn RA, Bikkavilli K, Vanscoyk M, **Eckhardt SG**, Messersmith WA. Tumours with elevated levels of the Notch and Wnt pathways exhibit efficacy to PF-03084014, a γ -secretase inhibitor, in a preclinical colorectal explant model. Br J Cancer. 2013 Aug 6;109(3):667-75. doi: 10.1038/bjc.2013.361. Epub 2013 Jul 18.

+ Denotes studies where Dr. Eckhardt was the P.I. and/or mentored junior faculty/fellows/residents (underlined) on the manuscript. Dr. Eckhardt's laboratory or clinical trainees are underlined.

Books/Book Chapters

1. Weiss, G.R., Eckardt, J.R., **Eckhardt, S.G.**, Fields, S.A., Rothenberg, M., Rodriguez, G.I., Valley, A., Burris, H.A.: New anticancer agents. In: *Cancer Chemotherapy and Biological Response Modifiers Annual 16*. H.M. Pinedo, D.L. Longo and B.A. Chabner (eds.), Elsevier Science Publishers B.V., Amsterdam, 1995.
2. Weiss, G.R., Burris H.A., **Eckhardt, S.G.**, Rodriguez, G.I., Sharma, S., Valley, A.: New anticancer agents. In: *Cancer Chemotherapy and Biological Response Modifiers Annual 17*. H.M. Pinedo, D.L. Longo and B.A. Chabner (eds.), Elsevier Science Publishers B.V., Amsterdam, 1997.
3. Hidalgo, M, Pierson AS, Holden SN, Bergen M, **Eckhardt SG**. Angiogenesis Inhibitors as Anticancer Therapy. In: *Advances in Internal Medicine Volume 47*. Dzau V. Mosby, Inc. St. Louis, MO, 2001.
4. Anthony J. Murgo, Janet Dancey, **S. Gail Eckhardt**, Manuel Hidalgo, Susan G. Arbuck, Kenn Zerivitz and Barbara A. Blaylock. New targets for cancer chemotherapy. In: *Cancer Chemotherapy and Biological Response Modifiers, Annual 20*. G. Giaccone, R. Schilsky and P. Sordel (Eds.), Chapter 11: 1-34, 2002.
5. Hidalgo M., Garrett-Mayer E., Clendeninn N., **Eckhardt S.G.** (eds): *Principals of Anticancer Drug Development*. Springer, New York, NY. 2011.
6. Aik-Choon Tan, Stephen Leong, Todd M. Pitts, John J. Tentler, **S. Gail Eckhardt**. New Approaches to Integration of Personalized Medicine in Early Cancer Drug Development. In: *Principles of Molecular Diagnostics and Personalized Cancer Medicine* Dongfeng Tan, MD and Henry T Lynch, MD (eds), Lippincott Williams & Wilkins, Philadelphia, PA, 2012 (in press)

Published Abstracts

1. **Eckhardt, S.G.**, McGill, J., Davidson, K., Von Hoff, D.: Low concentrations of hydroxyurea cause loss of extrachromosomal DNA and differentiation in HL60 cells. *Am Assoc Cancer Res*, 34:389, 1993.

2. **Eckhardt, S.G.**, McGill, J., Davidson, K., Von Hoff, D.D.: Low concentrations of ydroxyurea cause loss of extrachromosomal DNA and differentiation in HL60 cells. 3rd Annual Symposium on Cancer Research in San Antonio, p. 15, 1993.
3. Rothenberg, M.L., Kuhn, J.G., Burris, H.A., III, Nelson, J., Eckardt, J.R., Chen, S.-F., Rodriquez, G.I., Weiss, G.R., Smith, L.S., Thurman, A.M., **Eckhardt, S.G.**, Hilsenbeck, S.G., Clark, G.M., Fields, S.M., Perez, E., Von Hoff, D.D.: Phase II trial of CPT-11 in patients with 5-FU-refractory colorectal cancer. Eighth NCI-EORTC Symposium on New Drugs in Cancer Therapy. 5(Suppl 5):190, Amsterdam, The Netherlands, March 15-18, 1994.
4. **Eckhardt, G.**, Burris, H., III, Eckardt, J., Fields, S., Kuhn, J., Smetzer, L., Marcus, S., Masuo, K., Sobel, R., Von Hoff, D.: Initial phase I assessment of the novel angiogenesis inhibitor DS4152. Eighth NCI-EORTC Symposium on New Drugs in Cancer Therapy. 5(Suppl 5):72, Amsterdam, The Netherlands, March 15-18, 1994.
5. **Eckhardt, S.G.**, Burris, H.A., Eckardt, J.R., Weiss, G., Rinaldi, D., Barrington, R., Smith, L., Fields, S., Kuhn, J., Smith, S., Smetzer, L., Marcus, S., Masuo, K., Sobel, R. Von Hoff, D.D.: Phase I assessment of the novel angiogenesis inhibitor DS4152 (Tecogalan sodium). *Proc Am Soc Clin Oncol* 13:55, 1994.
6. Rothenberg, M.L., Eckardt, J.R., Burris, H.A., III, Nelson, J., Kuhn, J.G., Chen, S.F., Hilsenbeck, S.G., Clark, G.M., Fields, S.M., Rodriguez, G.I., Weiss, G.R., Smith, L.S., Thurman, A.M., **Eckhardt, S.G.**, Rinaldi, D.A., Perez, E., Von Hoff, D.D.: Irinotecan (CPT-11) as second-line therapy for patients with 5-FU-refractory colorectal cancer. *Proc Am Soc Clin Oncol* 13:198, 1994.
7. Van Den Berg, C.L., Mattern, V.L., **Eckhardt, G.**, Beitzel, B.F., Sakaguchi, A.Y., McGill, J.R. Double minutes of a colon cancer cell line localize to 14q13. 4th Annual Symposium on Cancer Research in San Antonio, p 28, 1994.
8. **Eckhardt, S.G.**, Eckardt, J.R., Weiss, G., Rinaldi, D., Barrington, R., Rodriguez, G., Smith, L., Fields, S., Kuhn, J., Smith, S., Smetzer, L., Marcus, S., Masuo, K., Sobel, R., Von Hoff, D.D., Burris, H.A.: Phase I assessment of the novel angiogenesis inhibitor DS4152 (Tecogalan sodium). 4th Annual Symposium on Cancer Research in San Antonio, p 40, 1994.
9. **Eckhardt, S.G.**, Eckardt, J.R., Weiss, G., Rinaldi, D., Barrington, R., Rodriguez, G., Smith, L., Fields, S., Kuhn, J., Smith, S., Smetzer, L., Marcus, S., Masuo, K., Sobel, R., Von Hoff, D.D., Burris H.A.: Phase I Assessment of the Novel Angiogenesis Inhibitor Tecogalan Sodium. *Breast Cancer Research and Treatment* 32 (Suppl):35, 1994.
10. **Eckhardt, S.G.**, Eckardt, J.R., Weiss, G., Rinaldi, D., Rodriguez, G., Fields, S., Kuhn, J., Smetzer, L., Higashi, L., Von Hoff, D.D., Burris, H.A. : Results of a phase I trial of the novel angiogenesis inhibitor, tecogalan sodium. *Am Assoc Cancer Res* 36:105, 1995.
11. McGill, J.R., Mattern, V., Van Den Berg, C.L., Beitzel, B.F., Chang, D., Dai, A., Hodge, J. and **Eckhardt, S.G.**: Mapping and characterization of a microdissected colon cancer double minute chromosome. *Am Assoc Cancer Res* 36:540, 1995.
12. **Eckhardt, S.G.**, Mattern, V., Beitzel, B., Chang, D., Dai, A., Hodge, J., Trent, J., Von Hoff, D.D. and McGill, J. Documentation of genomic instability in human ovarian cancer cells using microdissected DNA probes. *Am Assoc Cancer Res* 36:543, 1995.
13. **Eckhardt, S.G.**, Pulte, D.E., Hilsenbeck, S., Von Hoff, D.D., Eckardt J.R.: Response to Chemotherapy in Smoking and Non-Smoking Patients with Non-Small Cell Lung Cancer. *Proc Am Soc Clin Oncol* 14:26, 1995.
14. Kolesar, J., Rizzo, J., **Eckhardt, G.**, Eckardt, J., Rodriguez, G., Moyer, M., Stauffer, J., Rothenberg, M., Burris, H., Von Hoff, D., Kuhn, J.: Detection of NQ01 Gene in Patients with Colon Cancer and Normal Volunteers by Reverse Transcriptase-PCR and Capillary Electrophoresis. *Proc Am Soc Clin Oncol* 14:9, 1995.
15. **Eckhardt, S.G.**, Rephaeli, A., Degen, D.R., Ortiz, V., Von Hoff D.D.: Activity of pivaloyloxymethyl butyrate, a novel anticancer agent, on primary human tumor colony-forming units. 9th NCI-EORTC Symposium on New Drugs in Cancer Therapy. *Annals of Oncology* 7(Suppl 1):64, 1996.
16. Reidenberg, P., Villanona, M., **Eckhardt, G.**, Rodriguez, G, Burris, H., Von Hoff, D.: Phase I clinical and pharmacokinetic study of temozolomide (Temodal®) in advanced cancer patients stratified by extent of prior therapy. 9th NCI-EORTC Symposium on New Drugs in Cancer Therapy. *Annals of Oncology* 7(Suppl 1):99, 1996.
17. Villalona-Calero, M., Jakimowicz, K., Razvillas, B., Rinaldi, D., **Eckhardt, G.**, Aylesworth, C., Fischkoff S., Von Hoff, D.: LU103793: A phase I study of a novel dolastatin. 9th NCI-EORTC Symposium on New Drugs

- in Cancer Therapy. *Annals of Oncology* 7(Suppl 1):100, 1996.
18. **Eckhardt, S.G.**, Degen, D., Tohgo, A., Von Hoff, D.D.: Activity of DX-8951f, a water-soluble camptothecin derivative, on primary human tumor colony-forming units. 9th NCI-EORTC Symposium on New Drugs in Cancer Therapy. *Annals of Oncology* 7(Suppl 1):126, 1996.
19. McGill, J., Mattern, V., Beitzel, B., Leach, R., Morrow, M., Hodge, J., Johnson-Pais, T., Von Hoff, D., **Eckhardt, G.**: Microdissected double minute DNA facilitates discovery of genomic alterations in human ovarian cancer. *Proc Am Assoc Cancer Res* 37:126, 1996.
20. **Eckhardt, S.G.**, Degen, D., Faircloth, G.T., Jimeno, J., Von Hoff, D.D.: Activity of ecteinascidin, a novel marine cytotoxic, against primary human tumor colony-forming units. *Proc Am Assoc Cancer Res* 37:409, 1996.
21. Kolesar, J., Villalona-Calero, M., **Eckhardt, G.**, Rodriguez, G., Rinaldi, D., Von Hoff, D., Kuhn, J. Detection of a point mutation and the alternative splice NQ01 gene in patients with colon cancer. *Proc Am Soc Clin Oncol* 15:189, 1996.
22. Rinaldi, D.A., Burris, H.A., Dorr, F.A., Rodriguez, G., **Eckhardt, S.G.**, Fields, S.M., Woodworth, J.R., Kuhn, J.G., Langley, C., Clark, G., Lu, P., Von Hoff, D.D.: A phase I evaluation of LY231514, a novel multitargeted antifolate administered every 21 days. *Proc Am Soc Clin Oncol* 15:489, 1996.
23. Drengler, R., Burris, H., Dietz, A., Eckhardt, J., **Eckhardt, G.**, Hodges, S., Kraynak, M., Kuhn, J., Peacock, N., Rinaldi, D., Rizzo, J., Rodriguez, G., Schaaf, L., Smith, L., Thurman, A., Von Hoff, D.: A phase I trial to evaluate orally administered irinotecan HCl (CPT-11) given daily x 5 every 3 weeks in patients with refractory malignancies. *Proc Am Soc Clin Oncol* 15:489, 1996.
24. Rothenberg, M.L., Rinaldi, D.A., Smith, L.S., Schaaf, L.J., Hodges, S., Thurman, A.M., Ichhpurani, N.K., **Eckhardt, S.G.**, Rodriguez, G.I., Villalona, M., Drengler, R., Dietz, A.J., Murphy, T.C., Burris, H.A. III, Von Hoff, D.D.: Every other week irinotecan (CPT-11): Results of a phase I and pharmacokinetic (PK) study. *Proc Am Soc Clin Oncol* 15:489, 1996.
25. **Eckhardt, S.G.**, Degen, D., MacDonald, J.R., Von Hoff, D.D.: Activity of the novel semi-synthetic agent MGI 114 against primary human tumor colony-forming units. 6th Annual Symposium on Cancer Research in San Antonio, July 1996.
26. Mattern, V.L., Beitzel, B.F., Leach, R.J., Morrow, M., Hodge, J., Johnson-Pais, T., Von Hoff, D.D., McGill, J.R., **Eckhardt, S.G.**: Genomic alterations in human ovarian cancer discovered by Microdissected amplified DNA. 6th Annual Symposium on Cancer Research in San Antonio, July 1996.
27. **Eckhardt, S.G.**, Degen, D., Ortiz, V., Faircloth, G.T., Jimeno, J., Von Hoff D.D.: *In vitro* studies of a novel marine cytotoxic, ecteinascidin (ET-743). European Society for Medical Oncology 21st Congress, Vienna, Austria, November 1-5, 1996.
28. **Eckhardt, S.G.**, Weiss, G.R., Kraynak, M., Kuhn, J.G., MacDonald, J.R., Hanna, J., De Moor, C., Moczygemba, J., Von Hoff, D.D., Rowinsky, E.K.: MGI 114 - a novel mushroom-derived cytotoxin: a phase I and pharmacokinetic (PK) study in patients with advanced cancer. *Proc Am Assoc Cancer Res* 38: 306, 1997.
29. Wick, M., Mangold, G., Dexter, D., Perkins, W., **Eckhardt, G.**, Von Hoff, D.D.: Combination drug study with sodium phenylacetate and gemcitabine against the MiaPaca human pancreatic cancer xenograft. *Proc Am Assoc Cancer Res* 38: 87, 1997.
30. Villalona-Calero, M., Von Hoff, D., **Eckhardt, G.**, Aylesworth, C., Hammond, L., Drengler, R., Razvillas, B., Kraynak, M., Jakimowicz, K., Fram, R., Velagapudi, R., Rowinsky, E.: Phase I and pharmacokinetic (PK) study of LU 103793, a water soluble analog of Dolastatin-15 on a daily x 5 schedule. . *Proc Am Soc Clin Oncol* 16: 233a, 1997.
31. DeVore, R., Crawford, J., Dimery, I., Eckhardt, J., **Eckhardt, G.**, Kasunic, D., Demke, D., Gorris, G.: Phase II trial of Irinotecan (CPT-11) plus Cisplatin (CDDP) in Advanced NSCLC. *Proc Am Soc Clin Oncol* 16: 466a, 1997.
32. Rowinsky, E., Smith, L., Chaturvedi, P., Wang, Y.M.C., Campbell, E., Hatch, S., Harding, M., Aylesworth, C., **Eckhardt, G.**, Villalona, M., Drengler, R., Kraynak, M., Von Hoff, D.: Pharmacokinetic (PK) and toxicologic interactions between the multidrug resistance (MDR) reversal agent VX-710 and Paclitaxel (P) in cancer patients. *Proc Am Soc Clin Oncol* : 218a, 1997.
33. Ganly, I., Kirn, D., Rodriguez, G.I., Soutar, D., **Eckhardt, G.**, Otto, R., Robertson, A.G., Park, O., Gulley, M.L., Kraynak, M., Heise, C., Maack, C., Trown, P.W., Kaye, S., Von Hoff, D.D.: Phase I trial of intratumoral injection with an E1B-attenuated adenovirus, Onxy-015 in patients with recurrent p53(-) head and neck cancer. *Proc Am Soc Clin Oncol* 16: 382a, 1997.
34. **Eckhardt, S.G.**, Rizzo, J., Hammond, L., Hannah, A., Alexander, J., Moczygemba, J., Kraynak, M., Forral,

- K., Von Hoff, D.D., Rowinsky, E.K.: A Phase I and pharmacokinetic (PK) study of the tyrosine kinase inhibitor SU101 in patients with advanced solid tumors. *Proc Am Soc Clin Oncol* 16: 225a, 1997.
35. **Eckhardt, S.G.**, Sharma, S., Kuhn, J., Rizzo, J., Campbell, E., Ho, P., Weiss, G., Hammond, L., Kraynak, M., Von Hoff, D.D., Rowinsky, E.K.: A Phase I and pharmacokinetic (PK) study of the rebeccamycin analog NSC 655649 in patients with advanced cancer. *Proc Am Soc Clin Oncol* 16: 216a, 1997.
36. Ayelworth, C., Von Hoff, D., **Eckhardt, G.**, Rinaldi, D., Weiss, G., Kuhn, J., Campbell, E., Rowinsky, E.: A phase I trial of rhizoxin (NSC 332598) administered as a 72-hour continuous intravenous infusion every three weeks. *Proc Am Soc Clin Oncol* 16: 230a, 1997.
37. Nemunaitis, J., **Eckhardt, G.**, Dorr, A., Pribble, J., Smith, R., Bruce, N., Ognoskie, D., Von Hoff, D.: Phase I evaluation of CGP 64128A, an antisense inhibitor of protein kinase Ca (PKC α) in patients with refractory cancer. *Proc Am Soc Clin Oncol* 16: 246a, 1997.
38. **Eckhardt, S.G.**, Atkins, Y., Agarwala, S.S., Eckhardt, J., Diab, S., Dugan, M., Reidenberg, P., Statkevich, P., Forral, K., Kraynak, M., Von Hoff, D.D., Rowinsky, E.K. A phase I study of temozolomide combined with cisplatin (CDDP) in patients with advanced cancer. *Proc Am Soc Clin Oncol* 16: 236a, 1997.
39. Siu, L.L., Rowinsky, E.K., Weiss, G.R., Hammond, L., Kraynak, M., Moczygemba, J., Choi, L., Barbet, N.C., DeMoor, C., Von Hoff, D.D., **Eckhardt, S.G.** A phase I and pharmacokinetic (PK) study of the polyamine biosynthesis inhibitor CGP 48664 in patients with advanced cancer. *Proc Am Soc Clin Oncol*, 17: 735a, 1998.
40. Sharma, S., Rowinsky, E.K., Thurman, A., Drengler, R., Kraynak, M., Siu, L., Hidalgo, M., Ayelworth, C., Hanham, A., Fisher, E., Von Hoff, D.D., **Eckhardt, S.G.** A phase I and pharmacologic (PK) study of vesnarinone, an inducer of differentiation and apoptosis, in combination with gemcitabine. *Proc Am Soc Clin Oncol* 17: 803a, 1998.
41. **Eckhardt, S.G.**, Baker, S.D., Weiss, G.R., Kraynak, M., Britten, C., Siu, L., MacDonald, J.R., Smith, S., DeMoor, C., Moczygemba, J., Von Hoff, D.D., and Rowinsky, E.K. A phase I and pharmacokinetic (PK) study of the novel mushroom-derived cytotoxin, MGI 114, in patients with advanced cancer. *Proc Am Soc Clin Oncol* : 894a, 1998.
42. Britten, C.D., Rowinsky, E.K., Baker, S.D., LeMaistre, C.F., Weiss, G.R., Kraynak, M., Collins, W., Smetzer, L., Von Hoff, D.D., **Eckhardt, S.G.** A phase I and pharmacokinetic (PK) study of the rhodacyanine dye analog MKT 077. *Proc Am Soc Clin Oncol* : 886a, 1998.
43. Rowinsky, E., Hammond, L., Ayelworth, C., Humphrey, R., Siu, L., Smith, L., Thurman, A., Rodriguez, G., Sorensen, M., Von Hoff, D., **Eckhardt, S.G.** Prolonged administration of BAY 12-9566, an oral non peptidic biphenyl matrix metalloproteinase (MMP) inhibitor: a phase I and pharmacokinetic (PK) study. *Proc Am Soc Clin Oncol* : 836a, 1998.
44. Jimeno, J., Villalona-Calero, M., **Eckhardt, G.**, Weiss, G., Campbell, E., Hidalgo, M., Siu, L., Britten, C., Kraynak, M., Beijnen, J., Von Hoff, D., Rowinsky, E. Phase I and pharmacokinetic (PK) study of ET-743, a novel minor groove binder of marine origin on a daily x 5 schedule. *Proc Am Soc Clin Oncol*, 17: 737a, 1998.
45. Hammond, L., Villalona-Calero, M., **Eckhardt, S.G.**, Drengler, R., Ayelworth, C., Johnson, T., Hidalgo, M., Rodriguez, G., Diab, S., Monroe, P., Thornton, D., Von Hoff, D., Rowinsky, E. A phase I and pharmacokinetic (PK) study of the multitargeted antifol (MTA) LY231514 with folic acid. *Proc Am Soc Clin Oncol* : 866a, 1998.
46. Johnson, T., Geyer, C., De Jager, R., **Eckhardt, S.G.**, Smetzer, L., Coyle, J., Drengler, R., Von Hoff, D. and Rowinsky, E. Phase I and pharmacokinetic (PK) study of DX-9051f, a novel hexacyclic Camptothecin (CPT) analog, on a 30 minute infusion daily for 5 day every 3 week schedule. *Proc Am Soc Clin Oncol* : 756a, 1998.
47. Baker, S.D., Ravdin, P., Ayelworth, C., Smetzer, L., Bruno, R., Vernillet, L., Pazdur, R., Doyle, G., Hammershaimb, L., Hooker, E., Burris, H., **Eckhardt, G.**, Johnson, T., Kraynak, M., Hammond, L., Rodriguez, G., Weiss, G., Von Hoff, D., Rowinsky, E. A phase I and pharmacokinetic (PK) study of docetaxel in cancer patients (PTS) with liver dysfunction due to malignancies. *Proc Am Soc Clin Oncol* : 739a, 1998.
48. Diab, S., Britten, C., **Eckhardt, G.**, Hammond, L., Elledge, R., Siu, L., Sharma, S., Hidalgo, M., Ayelworth, C., Razvillas, B., Kraynak, M., Baker, S., Smith, R., Averbuch, S., Von Hoff, D., Rowinsky, D. Phase I and pharmacokinetic (PK) study of the nonpolyglutamated thymidylate synthase (TS) inhibitor ZD9331 given as a 30 minute infusion every 3 weeks. *Proc Am Soc Clin Oncol* : 869a, 1998.
49. Nemunaitis, J., Von Hoff, D.D., Holmlund, J., Dorr, A., **Eckhardt, S. G.** Phase I/pharmacokinetic (PK) trial of a protein kinase c- α antisense oligonucleotide, Isis 3521 (CGP 64128A), administered thrice weekly. *Proc Am Soc Clin Oncol* : 812a 1998.

50. Siu, L.L., Rowinsky, E.K., Clark, G.M., DeMoor, C., Ayelsworth, C., Von Hoff, D.D., **Eckhardt, S.G.** Dose escalation using the modified continual reassessment method (MCRM) in phase I clinical trials: A review of the San Antonio experience. 10th NCI-Symposium of New Drugs in Cancer Therapy. *Annals of Oncology* 9(Suppl 2):127, 1998.
51. Porter, C.W., Siu, L., Kramer, D.L., Mett, H., Barbet, N., Linnartz, R., **Eckhardt, S.G.** Pharmacodynamic confirmation of CGP-48664 as an inhibitor of the polyamine biosynthetic enzyme S-deno-sylmethionine decarboxylase (SAMDC) in an advanced melanoma patient. 10th NCI-Symposium of New Drugs in Cancer Therapy. *Annals of Oncology* 9(Suppl 2):128, 1998.
52. Diab, S., Britten, C., Smith, R., **Eckhardt, S.G.**, Baker, S., Hammond, L., Siu, L., Sharma, S., Hidalgo, M., Ayelsworth, C., Young, R., Wong, L., Razvillas, B., Kraynak, M., Douglass, E., Von Hoff, D., Rowinsky, E. A phase I and pharmacokinetic (PK) study of ZD9331, a novel long-acting thymidylate synthetase (TS) inhibitor, on a single dosing every 3 weeks schedule. 10th NCI-Symposium of New Drugs in Cancer Therapy. *Annals of Oncology* 9(Suppl 2):160, 1998.
53. Hammond, L., Baker, S.D., Villalona-Calero, M., **Eckhardt, S.G.**, Drengler, R., Ayelsworth, C., Johnson, T., Hidalgo, M., Rodriguez, G., Diab, S., Monroe, P., Thornton, D., Johnson, R., Von Hoff, D., Rowinsky, E. A phase I and pharmacokinetic (PK) study of the multitargeted antifol (MTA) LY231514 with folic acid (FA). 10th NCI-Symposium of New Drugs in Cancer Therapy. *Annals of Oncology* 9(Suppl 2):160, 1998.
54. Hannah, A., Malkin, M., Rosen, L., Lopez, A.M., Marshall, J., Lombardi, C.C., **Eckhardt, S.G.** An overview of phase I/II studies of SU101, a tyrosine kinase inhibitor, in patients with recurrent malignant glioma and advanced solid tumors. 10th NCI-EORTC Symposium of New Drugs in Cancer Therapy. *Annals of Oncology* 9(Suppl 2):18, 1998.
55. Rizzo, J., Renouf, J., **Eckhardt, S.G.**, Weitman, S., Rowinsky, E., Kuhn, J. Cytochrome P-450 metabolism of the rebeccamycin analog NSC655649. 10th NCI-EORTC Symposium of New Drugs in Cancer Therapy. *Annals of Oncology* 9(Suppl 2):61, 1998.
56. Rothenberg, M.L., Kuhn, J.G., Schaaf, L.J., **Eckhardt, S.G.**, Villalona-Calero, M.A., Petit, R.G., Miller, L.L., Elfring, G.L., Murphy, T.C., Von Hoff, D.D. Phase I and pharmacokinetic study of intravenous irinotecan (CPT-11) administered once every 2 weeks +/-G-CSF. 10th NCI-Symposium of New Drugs in Cancer Therapy. *Annals of Oncology* 9 (Suppl 2):63, 1998.
57. Johnson, T., Geyer, C., De Jager, R., **Eckhardt, S.G.**, Smetzer, L., Clark, G., Coyle, J., Drengler, R., Von Hoff, D., Rowinsky, E. A phase I and pharmacokinetic (PK) study of DX-8951f, a novel hexacyclic camptothecin (CPT) analog, on a 30 minute infusion daily for 5 days every 3 week schedule. 10th NCI-Symposium of New Drugs in Cancer Therapy. *Annals of Oncology* 9(Suppl 2):64, 1998.
58. **Eckhardt, S.G.**, Kuhn, J., Rizzo, J., Sharma, S., Campbell, E., Ivey, P., Weiss, G., Hammond, L., Kraynak, M., Von Hoff, D.D., Rowinsky, E. A phase I and pharmacokinetic (PK) study of the rebeccamycin analog NSC 655649 in patients with advanced cancer. 10th NCI-Symposium of New Drugs in Cancer Therapy. *Annals of Oncology* 9(Suppl 2):66, 1998.
59. Rowinsky, E., Hammond, L., Ayelsworth, C., Humphrey, R., Smetzer, L., Siu, L., Weiss, G., Smith, L., Thurman, A., Rodriguez, G., Sorensen, M., Von Hoff, D., **Eckhardt, S.G.** Prolonged administration of BAY 12-9566, an oral nonpeptidic biphenyl matrix: A phase I and Pharmacologic study. 10th NCI-Symposium of New Drugs in Cancer Therapy. *Annals of Oncology* 9(Suppl 2):76, 1998.
60. **Eckhardt, S.G.**, Villalona, M.A., Kraynak, M., Moczygamba, J., Von Hoff, D.D., Rowinsky, E.K. A phase I study of AN-9 (pivaloyloxymethylbutyrate, Pivanex), a lipophilic butyric acid analog, in patients with advanced solid tumors. 10th NCI-Symposium of New Drugs in Cancer Therapy. *Annals of Oncology* 9(Suppl 2):84, 1998.
61. Baker, S.D., Ravdin, P., Ayelsworth, C., Smetzer, L., Bruno, R., Vernillet, L., Pazdur, R., Doyle, G., Hammershaimb, L., Hooker, E., Burris, H.A., **Eckhardt, S.G.**, Johnson, T., Kraynak, M., Hammond, L., Rodriguez, G., Weiss, G., Rowinsky, E. A phase I and pharmacokinetic (PK) study of docetaxel in cancer patients with liver dysfunction due to malignancies. 10th NCI-Symposium of New Drugs in Cancer Therapy. *Annals of Oncology* 9(Suppl 2):102, 1998.
62. Cropp, G.F., Hannah, A.L., Malkin, M., **Eckhardt, S.G.**, Marshall, J., Lombardi, C.C., Rosen, L., Lopez, A.M., Sweeney, K. Pharmacokinetics of SU101, a PDGF-R signal transduction inhibitor, and metabolite, SU0020. 10th NCI-Symposium of New Drugs in Cancer Therapy. *Annals of Oncology* 9(Suppl 2):110, 1998.
63. Diab, S., Baker, S.D., Hammond, L., Villalona, M., **Eckhardt, S.G.**, Tinu, C., Weiss, G., Kraynak, M., Ayelsworth, C., Smith, L., Rodriguez, G., Drengler, R., Patil, R., Siu, L., Rothenberg, M., Smetzer, L., Nyhart, E., Storniolo, A.M., Von Hoff, D., Rowinsky, E. Phase I and pharmacokinetic (PK) study of the diaryl-sulfonylurea LY295501 administered as a single oral dose weekly for 3 weeks every 4 weeks. 10th NCI-

- Symposium of New Drugs in Cancer Therapy. *Annals of Oncology* 9(Suppl 2):115, 1998.
64. Britten, C.D., Rowinsky, E.K., Agarwala, S.S., Baker, S.D., Eckardt, J., Diab, S., Dugan, M., Reidenberg, P., Statkevich, P., Marco, A., Loomba, A., Forral, K., Kraynak, M., Von Hoff, D.D., **Eckhardt, S.G.** A phase I safety and pharmacokinetic (PK) study of temozolomide in combination with cisplatin. 10th NCI-Symposium of New Drugs in Cancer Therapy. *Annals of Oncology* 9(Suppl 2):116, 1998.
 65. Siu, L.L., Rowinsky, E.K., Weiss, G.R., Hammond, L., Kraynak, M., Moczygemba, J., Choi, L., Linnartz, R., Porter, C., DeMoor, C., Von Hoff, D.D., **Eckhardt, S.G.** A phase I and pharmacokinetic (PK) study of the polyamine biosynthesis inhibitor CGP 48664 in patients with advance cancer. 10th NCI-Symposium of New Drugs in Cancer Therapy. *Annals of Oncology* 9(Suppl 2):116, 1998.
 66. Villalona-Calero, M., **Eckhardt, S.G.**, Weiss, G., Campbell, E., Hidalgo, M., Kraynak, M., Beijnen, J., Jimeno, J., Von Hoff, D., Rowinsky, E. A phase I and pharmacokinetic study of ET-743, a novel DNA minor groove binder of marine origin, administered as a 1-hour infusion daily x 5 days. 10th NCI-Symposium of New Drugs in Cancer Therapy. *Annals of Oncology* 9(Suppl 2):118, 1998.
 67. **Eckhardt, S.G.**, Baker, S.D., Moczygemba, J., MacDonald, J.R., Smith, S., Von Hoff, D.D., Rowinsky, E.K. A phase I and pharmacokinetic (PK) study of the novel mushroom-derived cytotoxin, MGI 114, in patients with advanced cancer. 10th NCI-Symposium of New Drugs in Cancer Therapy. *Annals of Oncology* 9(Suppl 2):123, 1998.
 68. **Eckhardt, S.G.**, Thurman, A., Kraynak, M., Hidalgo, M., Hanham, A., Von Hoff, D.D., Rowinsky, E.K. A phase I and pharmacologic (PK) study of vesnarinone, an inducer of dirrerentiation and apoptosis, in combination with gemcitabine. 10th NCI-Symposium of New Drugs in Cancer Therapy. *Annals of Oncology* 9(Suppl 2):125, 1998.
 69. Seymour, L., Grochow, L., **Eckhardt, G.**, Erlichman, C., Hirte, H., Goel, R., Humphrey, R., Elias, I. Clinical and pharmacokinetic (PK) results of 4 phase I studies of the second generation matrix metalloprotease (MMP) inhibitor bay 12-9566, a non-peptidic biphenyl inhibitor of MMPs 2, 3 & 9. *Annals of Oncology* 9(Suppl 4):125, 1998.
 70. Siu, L., Paoletti, X., O'Quigley, J., Rowinsky, E.K., Clark, G.M., Von Hoff, D.D., **Eckhardt, S.G.** Strategies for improvement in dose escalation using the continual reassessment method (CRM) in phase I clinical trials. *Annals of Oncology* 9(Suppl 4):126, 1998.
 71. Hidalgo, M., Villalona-Calero, M.A., **Eckhardt, S.G.**, Weiss, G., Campbell, E., Kraynak, M., Beijnen, J., Jimeno, J., Von Hoff, D., Rowinsky, E. A phase I and pharmacokinetic (PK) study of ET-743, a novel minor groove binder of marine origin administered on a daily x 5 schedule. *Annals of Oncology* 9(Suppl 4):127, 1998
 72. **Eckhardt, S.G.**, Rizzo, J., Britten, C., Siu, L., Humphrey, R., Smetzer, L., Sorensen, M., Sundaresan, P., Von Hoff, D.D., Rowinsky, E.K. A phase I and pharmacologic study of the oral matrix metalloproteinase inhibitor, BAY 12-9566, in combination with paclitaxel and Carboplatin. *Annals of Oncology* 9(Suppl 4):128, 1998.
 73. Hammond, L., Villalona-Calero, M., **Eckhardt, S.G.**, Siu, L., Hidalgo, M., Thornton, D., Walling, J., Baker, S., Coltman, C., Von Hoff, D., Rowinsky, E. A phase I and pharmacokinetic (PK) study of the multitargeted antifolate (MTA, LY231514) with folic acid (FA). *Annals of Oncology* 9(Suppl 4):129, 1998.
 74. Britten, C.D., Rowinsky, E., Yao, S-L, Soignet, S., Rosen, N., **Eckhardt, S.G.**, Drengler, R., Hammond, L., Siu, L.L., Smith, L., McCreery, H., Pezzulli, S., Lee, Y., Lobell, R., Deutsch, P., Von Hoff, D., Spriggs, D. The Farnesyl Protein Transferase (FPTase) Inhibitor L-778, 123 in Patients with Solid Cancers. *Proc Am Soc Clin Oncol* 155a, 1999.
 75. Tolcher, A., Rowinsky, E.K., Rizzo, J., Britten, C., Siu, L., Humphrey, R., Smetzer, L., Sorenson, M., Von Hoff, D.D., **Eckhardt, S.G.** A Phase I and Pharmacokinetic Study of the Oral Matrix Metalloproteinase Inhibitor Bay 12-9566 in Combination with Paclitaxel and Carboplatin. *Proc Am Soc Clin Oncol* 160a, 1999.
 76. Patnaik, A., Rowinsky, E., Hammond, L., Thurman, A., Hidalgo, M., Siu, L., Moczygemba, J., Williams, J., Holroyd, K., Nelson, K., Von Hoff, D.D., **Eckhardt, S.G.** A Phase I and Pharmacokinetic (PK) Study of the Unique Angiogenesis Inhibitor. Squalamine Lactate (MSI-1256F). *Proc Am Soc Clin Oncol* 162a, 1999.
 77. Rowinsky, E., Johnson, T., Geyer, C., **Eckhardt, S.G.**, Smetzer, L., Coyle, J., Drengler, R., Diab, S., De Jager, R., Von Hoff, D. DX-8951f, a Hexacyclic Camptothecin (CPT) Analog on A Daily x 5 Day Schedule: A Phase I and Pharmacokinetic (PK) Study. *Proc Am Soc Clin Oncol* 164a, 1999.
 78. Hidalgo, M., Aylesworth, C., Ferrante, K., Weiss, G., Britten, C., Stephenson, J., Johnson, T., Smith, L., Molpus, K., LaCreta, F., Kadow, J., Healey, D., **Eckhardt, G.**, Von Hoff, D., Rowinsky, E. Phase I and Pharmacokinetic (PK) Study of BMS 184476, a Potent and Soluble Taxane Analog, as A 1-Hour Infusion Every 3 Weeks. *Proc Am Soc Clin Oncol* 168a, 1999.
 79. Rha, S.Y., Diab, S.G., Britten, C., Baker, S.D., Smith, R., **Eckhardt, S.G.**, Hammond, L., Hidalgo, M.,

- Young, R., Johnson, T., Stephenson, J., Newman, A., Douglass, E., Smith, M., Averbuch, S., Von Hoff, D., Rowinsky, E. Determination of the Variables Affecting the Clearance (CL) of the Novel Thymidylate Synthase (TS) Inhibitor, ZD9331. *Proc Am Soc Clin Oncol* 171a, 1999.
80. Johnson, T., Hammond, L., Johnson, R., Drengler, R., **Eckhardt, S.G.**, Neumanitis, J., Villalona, M., Williams, T.T., Diab, S., Walling, J., Simmon, C., Von Hoff, D., Rowinsky, E. Phase I and Pharmacokinetic Study (PK) of The Multitargeted Antifol LY231514 (MTA) in Combination with Irinotecan (CPT-11). *Proc Am Soc Clin Oncol* 172a, 1999.
81. Tin-U, C., Diab, S.G., Smith, L., Hammond, L., Baker, S.D., Villalona-Calero, M., **Eckhardt, S.G.**, Weiss, G., Smetzer, L., Thornton, D.D., Rowinsky, E., Von Hoff, D. Phase I and Pharmacokinetic (PK) Study of the Diarylsulfonylurea LY295501 Administered Orally Weekly for 3 Weeks Every 4 Weeks. *Proc Am Soc Clin Oncol* 179a, 1999.
82. Villalona-Calero, M., **Eckhardt, S.G.**, Hammond, L., Campbell, L., Smith, L., Hidalgo, M., Britten, C., Beijnen, J., Guzman, C., Jimeno, J., Von Hoff, D., Rowinsky, E. Final Results of a Phase I and Pharmacokinetic (PK) Study of the Marine Minor Groove Binder ET-743 on a Daily x 5 Schedule. *Proc Am Soc Clin Oncol* 180a, 1999.
83. Cerna, C., Medina, L., Gomez, L., Troutt, A.B., Izbicka, E., **Eckhardt, S.G.**, Clark, G., Von Hoff, D., Weitman, S. Investigation of the Effects of HuCD40L on Human Tumor Specimens Taken Directly from Patients. *Proc Am Soc Clin Oncol* 181a, 1999.
84. Stephenson, J., Baker, S.D., Johnson, T., Simmons, C., Smith, L., Hunt, W., Deforges, C., Prouix, L., Jolivet, J., Hidalgo, M., **Eckhardt, S.G.**, Hammond, L., Diab, S., Smith, L., Von Hoff, D., Rowinsky, E. A Phase I and Pharmacokinetic (PK) Study of β -L Dioxolan-Cytidine (BCH-4556), an L-Nucleoside Antimetabolite on A Daily x 5 Every 3-Week. *Proc Am Soc Clin Oncol* 198a, 1999.
85. Siu, L.L., Hidalgo, M., Nemunatis, J., Rizzo, J., Moczygemba, J., **Eckhardt, S.G.**, Tolcher, A., Smith, L., Hammond, L., Blackburn, A., Tensfeldt, T., Silberman, S., Von Hoff, D.D., Rowinsky, E.K. Dose and Schedule-Duration Escalation of the Epidermal Growth Factor Receptor (EGFR) Tyrosine Kinase (TK) Inhibitor CP-358, 774: A Phase I and Pharmacokinetic (PK) Study. *Proc Am Soc Clin Oncol* 388a, 1999.
86. **Eckhardt, S.G.**, Siu, L., Clark, G., DeMoor, C., Von Hoff, D.D., Rowinsky, E.K. The Continual Reassessment Method (CRM) for Dose Escalation in Phase I Trials in San Antonio Does Not Result in More Rapid Study Completion. *Proc Am Soc Clin Oncol* 163a, 1999.
87. Lathia C., Seymour L., Grochow L., **Eckhardt, S.G.**, Erlichman C., Hirte H., Goel R., Elias I., Humphrey R. BAY 12-9566, a Selective, Non-peptidic Biphenyl Inhibitor of Matrix Metalloproteases (MMPs): Summary of Phase I Clinical and Pharmacokinetic (PK) Results. *AACR-NCI-EORTC Internatl Conf* 9a, 1999.
88. Patnaik A., Rowinsky E., Hammond L., Thurman, A., Hidalgo M., Siu, L., Williams, J. Holroyd K., Nelson, K., Von Hoff D.D., **Eckhardt, S.G.** A Phase I and Pharmacokinetic (PK) Study of the Unique Angiogenesis Inhibitor Squalamine Lactate (MSI-1256F). *AACR-NCI-EORTC Internatl Conf* 15a, 1999.
89. Rha, S.Y., Tolcher, A.W., Stephenson, J., Monroe, P., **Eckhardt, S.G.**, Hammond, L.A., Conlon, K.C., Korz, W., Von Hoff, D.D., Rowinsky, E.K. A Phase I Study of Brevarex, a Murine Monoclonal Antibody Directed at the MUC1 Antigen, In Patients with Advanced Solid Tumors. *Amer Soc Clin Onc* 1868a, 2000.
90. Patnaik, A., **Eckhardt S.G.**, Itzbicka, E., Hidalgo, M., McCreery, H., Mori, M., Terada, K., Tolcher, A., Smith, L., Britten, C., Bowden, C., Bol, K., Ochon, L., Davidson, K., Hammond, L., Schwartz, G., Horak, I., Gentner, L., Rowinsky, E. A Phase I and Pharmacokinetic (PK) Study of the Farnesyltransferase Inhibitor, R115777 In Combination with Gemcitabine. *Amer Soc Clin Onc* 5Aa, 2000.
91. Rowinsky, E.K., **Eckhardt, S.G.**, Rizzo, J., Hammond, L., Campbell, E., Felton, S., Denis, L., Rha, S., Schwartz, G., Tolcher, A., Izbecka, E., Hidalgo, M. Protracted Daily Treatment with Col-3, An Oral Tetracycline Analog, Matrix Metalloproteinase (MMP) Inhibitor, Is Feasible: A Phase I, Pharmacokinetic, and Biological Study. *Amer Soc Clin Onc* 700a, 2000.
92. Denis, L.J., Tolcher, A., Figueroa, J.A., Drengler, R., Geyer, C., **Eckhardt, S.G.**, Cutler, D.L., Reyderman, L., Von Hoff, D.D., Rowinsky, E.K., Protracted Daily Administration of Temozolomide Is Feasible: A Phase I and Pharmacokinetic – Pharmacodynamic Study. *Amer Soc Clin Onc* 786a, 2000.
93. Figueroa, J.A., Tolcher, A., Denis, L.J., Drengler, R., Geyer, C., **Eckhardt, S.G.**, Cutler, D.L., Reyderman, L., Von Hoff, D.D., Rowinsky, E.K. Protracted Cyclic Administration of Temozolomide Is Feasible: A Phase I, Pharmacokinetic and Pharmacodynamic Study. *Amer Soc Clin Onc* 868a, 2000.
94. Von Hoff, D.D., Cox, J.V., Tempero, M.A., Eder, Jr., J.P., **Eckhardt, S.G.**, Rowinsky, E.K., Smith, S.L., Smith, C.L., Stuart, K.E., Proper, J., MacDonald, J.R. Phase II Trial of Irofulven (MGI 114) in Patients with Advanced Pancreatic Cancer Who Have Progressed On Gemcitabine. *Amer Soc Clin Onc* 1219a, 2000.
95. Montserrat Munoz-Mateu, Linda A. deGraffenried, Letitia Fulcher, **S. Gail Eckhardt**, Jinee Rizzo, Eric K. Rowinsky, Manuel Hidalgo. Administration of Col-3, a Matrix Metalloproteinase (MMP) Inhibitor, Decreases

- the Expression of MMP9 in Patients' Peripheral Blood Mononuclear Cells (PBMCs) *Proc Am Assoc Cancer Res* 373a, 2001.
96. A. Patnaik, E. Izbicka, **S. G. Eckhardt**, K. Davidson, A. Goetz, H. McCreery, A. Tolcher, M. Mori, K. Terada, K. Bol, M. Rybak, A. Thibault, H. Richards, L. Gentner, E. Rowinsky. Inhibition of HDJ2 Protein Farnesylation in Peripheral Blood Mononuclear Cells as a Pharmacodynamic Endpoint in a Phase I Study of R115777 and Gemcitabine. *Proc Am Assoc Cancer Res* 2628a, 2001.
 97. Montserrat Munoz-Mateu, Linda deGraffenried, **S. Gail Eckhardt**, Shazly Malik, Jinee Rizzo, John Kuhn, Eric Rowinsky, Manuel Hidalgo. Pharmacodynamic Studies of Col-3, a Novel Matrix Metalloproteinase Inhibitor, in Patients with Advanced Cancer. *Proc Am Soc Clin Oncol* 302a, 2001.
 98. Scott N. Holden, **S. Gail Eckhardt**, Sandra Fisher, Martha Persky, Christine Mikule, Cindy L O'Bryant, Mark Morrow, Henry Richards, Steve Rodriguez, CJ Bol, Roger Cohen A Phase I Pharmacokinetic (PK) and Biological Study of the Farnesyl Transferase Inhibitor (FTI) R115777 and Capecitabine in Patients (PTS) with Advanced Solid Malignancies. *Proc Am Soc Clin Oncol*, 2001.
 99. Eric Keith Rowinsky, Lisa Hammond, Lillian Siu, Paul Jerabek, Jinee Rizzo, Louis Denis, John Nemunatis, Amita Patnaik, **S Gail Eckhardt**, Anthony Tolcher, Chris Takimoto, Karen Ferrante, Lee Lee Allen, Sandra Silberman, Manuel Hidalgo. Dose-Schedule-Finding, Pharmacokinetic (PK), Biologic, and Functional Imaging Studies of OSI-774, a Selective Epidermal Growth Factor Receptor (EGFR) Tyrosine Kinase (TK) Inhibitor. *Proc Am Soc Clin Oncol* 5a, 2001.
 100. Russell Bassar, Herb Hurwitz, Alan Barge, Ian Davis, Ric DeBoer, S Holden, Grant McArthur, Marti McKinley, Kevin Nairn, M Persky, Danny Rischin, Mark Rosenthal, Helen Swaisland, **Gail Eckhardt**. Phase 1 Pharmacokinetic and Biological Study of the Angiogenesis Inhibitor, ZD6474, in Patients with Solid Tumors. *Proc Am Soc Clin Oncol* 396a, 2001.
 101. Steven D. Weitman, Sheri Smith, JP Eder, MA Tempero, **SG Eckhardt**, E Reed, A Gordon, N Senzer, E Raymond, J Alexandre, M. Ould Kaci, John MacDonald. Irofulven Monotherapy: Impressive Phase I and II Clinical Antitumor Activity in Heavily Treated Patients. *Proc Am Soc Clin Oncol* 2081a, 2001.
 102. Scott N Holden, Mark Morrow, Cindy O'Bryant, James Pluda, **S. G Eckhardt**. Correlative biological assays used to guide dose escalation in a phase I study of the antiangiogenic aVb3 and aVb5 integrin antagonist EMD 121974 (EMD). *Proc Am Soc Clin Oncol* 110a, 2002.
 103. Patrick J Creaven, **S G Eckhardt**, John Hamm, Gary Schwartz, James W Sutton, Jumana Kaidbey, Chetan Lathia, Ralph Bernacki, Nithya Ramnath A phase I and pharmacokinetic study of a novel taxane BAY-59-8862. *Proc Am Soc Clin Oncol* 399a, 2002.
 104. Andrew S Pierson, Scott N Holden, Michele Basche, Cindy O'Bryant, Sara Zakneon, Paul Statkevich, Y Zhu, Christine Mikule, Stacy Grolnic, Christine Deem, Martha Persky, Dana Barrett, Mark Morrow, **S G Eckhardt**. A phase I pharmacokinetic (PK) and biological study of the farnesyl transferase inhibitor (FTI) sarasar (lonafarnib, SCH66336), cisplatin (C), and gemcitabine (G) in patients (pts) with advanced solid tumors. *Proc Am Soc Clin Oncol* 365a, 2002.
 105. T Mekhail, S Holden, S Pierson, F Lee, S Galbraith, M Cohen, M Messina, B Roedig, K Williams, P Weiss, M Persky, J Skillings, R M Bukowski, **S G Eckhardt**. A Phase I pharmacokinetic and biologic study of the novel epothilone BMS-310705 in patients with advanced cancer. *Proc Am Soc Clin Oncol* 408a, 2002.
 106. M Basche, A B Sandler, **S G Eckhardt**, P A Bunn, S N Holden, A S Pierson, W Jenner, V Paty, M Persky, R D Aitchison, G S Gordon, V P Parker, N Usman, M L Rothenberg. Angiozyme, an anti-VEGFR1 ribozyme, carboplatin, and paclitaxel: results of a phase I study. *Proc Am Soc Clin Oncol* 445a, 2002.
 107. H Hurwitz, S N Holden, **S G Eckhardt**, M Rosenthal, R de Boer, D Rischin, M Green, R Bassar Clinical evaluation of ZD6474, an orally active inhibitor of VEGF signaling, in patients with solid tumors. *Proc Am Soc Clin Oncol* 325a, 2002.
 108. Ghassan K Abou-Alfa, Eileen M O'Reilly, Eric K Rowinsky, Yehuda Patt, Gary K Schwartz, Sunil Sharma, Eve Siegel, **S. G Eckhardt**, C Becerra, Janet Jakubowitz, Anil Duggal, Stephan Lubicz, Robert De Jager. Final results of a phase II study of DX-8951f (DX, exatecan mesylate) in biliary tree cancers. *Proc Am Soc Clin Oncol* 561a, 2002.
 109. Yehuda Z Patt, E Rowinsky, E O'Reilly, **S G Eckhardt**, A Duggal, S Lubicz, P Dumas, T Brown, R De Jager Phase II trial of DX-8951f (exatecan mesylate) in hepatocellular carcinoma (HCC): a final analysis. *Proc Am Soc Clin Oncol* 555a, 2002.
 110. Andrew S. Pierson, Dan Gustafson, Mike Long, Dan C Chan, Karen Kelly, Paul Bunn, Christine Mikule, Scott N Holden, Martha Persky, **S. Gail Eckhardt**. A Phase I and Pharmacologic (PK) Study of Exisulind (E) Combined with Taxotere (T) in Patients with Advanced Cancer. *Proc Am Soc Clin Oncol* 475a, 2002.
 111. P. Sunpaweravong, S. Holden, V. Ratts, **S. G. Eckhardt**, D. Gustafson, P. A. Bunn, K. Kelly. A University of Colorado phase I trial of irinotecan (CPT-11) and carboplatin in advanced lung cancer. *Proc Am Soc Clin*

- Oncol* 2642a, 2003.
112. S. E. Witta, **S.G. Eckhardt**, M. Rothenberg, J. Sosman, D. L. Gustafson, C. L. O'Bryant, G. Weems, L. Herdrich, W. Cooper, J. Berlin A phase I combination trial of irifolven and gemcitabine in patients with advanced solid malignancies. *Proc Am Soc Clin Oncol* 552a, 2003.
 113. M. L. Basche, A. S. Pierson, S. N. Holden, L. Gore, C. O'Bryant, M. Persky, M. Morrow, D. Gustafson, J. Dancey, **S. G. Eckhardt**. A phase I trial of ZD1839 (Z) with capecitabine (Cp) and celecoxib (Cel) in patients (pts) with advanced solid tumors. *Proc Am Soc Clin Oncol* 836a, 2003.
 114. T. Mekhail, C. Chung, S. Holden, R. M. Bukowski, **S. G. Eckhardt**, M. Cunningham, M. Messina, M. Cohen, R. Peck, B. Sikic. Phase I trial of novel epothilone B analog BMS-310705 IV q 21 days. *Proc Am Soc Clin Oncol* 515a, 2003.
 115. Y. Z. Patt, E. Lin, J. Leibmann, W. Miller, F.-C. Lee, W. Keiser, J. Salvatore, D. Diamandidis, **S. G. Eckhardt**, M. Javle, G. R. Justice Capecitabine plus irinotecan for chemotherapy-naïve patients with metastatic colorectal cancer (MCRC): US multicenter phase II trial. *Proc Am Soc Clin Oncol* 1130a, 2003.
 116. Basche M, Pierson AS, Holden SN, Gore , O'Bryant C, Raj S, Morrow M, Gustafson D, Dancey J, **Eckhardt SG**. A phase I trial of ZD1839 (Z), capecitabine (Cp), and celecoxib (Cel): Preliminary results of an amended schedule. *Proc Am Soc Clin Oncol* 23:234 (Abst #3159), 2004.
 117. Falcon-Lizaraso S, Chong JL, Perazzo F, Goldwasser F, Cohn A, Kahatt C, Weems G, **Eckhardt SG** . Phase II trial of every 2 weeks dosing of irifolven (IROF) in patients (pts) with unresectable hepatocellular carcinoma (HCC): Preliminary results. *Proc Am Assoc Clin Oncol* 23:333 (Abst #4083), 2004.
 118. Gore L, Holden SN, Basche M, Raj SKS, Arnold I, O'Bryant C, Witta S, Rohde B, McCoy C, **Eckhardt SG**. Updated results from a phase I trial of the histone deacetylase (HDAC) inhibitor MS-275 in patients with refractory solid tumors. *Proc Am Soc Clin Oncol* 23:201 (Abst #3026), 2004.
 119. Gore L, Basche M, Holden SN, O'Bryant C, Schultz MK, Grolnic S, Morrow M, **Eckhardt SG**. A phase I pharmacological and biological study of Sarasar™ (lonafarnib, SCH66336), cisplatin and gemcitabine in patients with advanced solid tumors. 16th EORTC/NCI/AACR Symposium on Molecular Targets and Cancer Therapetucis, September, 2004, Geneva, Switzerland. *Eur J Cancer* (Abst # 92), 2004.
 120. S. Holden, C. Britten, D. Prager, R. Finn, M. Le, M. Basche, C. O'Bryant, A. Levin, D. Thornton, **S. Eckhardt**, A phase I dose escalation study with oral LY317615 (L) in combination with capectiabine (C) in advanced cancer patients. 16th EORTC/NCI/AACR Symposium on Molecular Targets and Cancer Therapetucis, September, 2004, Geneva, Switzerland. *Eur J Cancer* (Abst #156) 2004.
 121. J.D. Winkler, P.A. Lee, E. Wallace, G. Poch, K. Litwiler, T. Pheneger, J. Lyssikatos, M. Perrier, **S.G. Eckhardt**, T.C. Yeh, Anti-tumor activity, pharmacokinetic and pharmacodynamics effects of the MEK inhibitor ARRY-142886 (AZD6244) in a BxPC3 pancreatic tumor xenograft model. 16th EORTC/NCI/AACR Symposium on Molecular Targets and Cancer Therapetucis, September, 2004, Geneva, Switzerland. *Eur J Cancer* (Abst. 342) 2004.
 122. Miljus J, Trump S, Brown J, Leibfritz D, **Eckhardt SG**, Serkova N. MRS Assessment on metabolic response to a novel EGFR inhibitor ZD1839 in colon cancer cells. ISMRM Cancer Workshop, Manchester, UK. *Proceedings*, 2004.
 123. Miljus J, Melo JV, Boros L, Anderson N, Talpaz M, Leibfritz D, **Eckhardt SG**, Serkova N. Metabolic profile of imatinib resistance in CML cells. 46th American Society of Hematology Annual Meeting, December 4-7, 2004, San Diego, CA, 2004.
 124. Patt YS, Liebmann J, Diamandidis D, **Eckhardt SG**, Javle M, Justice GR, Keiser W, Lee FC, Miller LW, Lin E. Capecitabine (X) plus irinotecan (Xeliri) as first-line treatment for metastatic colorectal cancer (MCRC): Final safety findings from a phase II trial. *Proc Am Soc Clin Oncol* 23:271 (Abst #3602), 2004.
 125. Sujatha Hariharan, Lia Gore, **S. Gail Eckhardt**, Larua Chow, Sarah Eppers, Cindy O'Bryant, K. Padavic, Norma L. Fox, Larry Lo, Nancy Chesser, Rober B. Cohen, A Phase I and Pharmacological Study of HGS-ETR1, an Antibody Targeting TRAIL-R1, in Combination with Paclitaxel and Carboplatin in Patients with Advanced Solid Malignancies. *Proc AACR/NCI/ EORTC International Conference* (Abst. # B109) 2005
 126. Christopher H. Lieu, Stephen Leong, Michele Basche, Lia Gore, Kristin Leonardi, MaryKay Schultz, Sujatha Hariharan, Laura Chow, Sami Diab, Amy Gibbs, Ramesh Boipally, **S.G. Eckhardt**, Cindy L. O'Bryant, A Dose-Ranging Study of the Toxicities, Pharmacological, and Biological Effects of the Selective Apoptotic Antineoplastic Drug (SAAND), OSI-461, in Patients With Advanced Cancer, in the Fasting and Fed State. *Proc AACR/NCI/ EORTC International Conference* (Abst. # C18) 2005
 127. Cindy L. O'Bryant, Lia Gore, Michael Long, Daniel Gustafson, Sarah Eppers, Michele Basche, Mace Rothenberg, Gary Weems, Ajit Shah, Laura Herdrich, **S.G. Eckhardt**, Jordan Berlin, A Phase I Combination Study of Irofulven (IROF) and Gemcitabine (GEM) in Patients (pts) with Advanced Solid Malignancies. *Proc AACR/NCI/ EORTC International Conference* (Abst. # C83) 2005

128. M.P. Doyle, T. C. Yeh, B. Suzy, M. Morrow, P.A. Lee, A.M. Hughes, S. Cartlidge, E. Wallace, J. Lyssikatos, **S.G. Eckhardt**, J.D. Winkler, Validation and use a a biomarker for clinical development of the MEK1/2 inhibitor ARRY-142886 (AZD6244) *Proc Am Soc Clin Oncol* (Abst #3075), 2005
129. M.L. Basche, A.E. Barón, **S.G. Eckhardt**, L. Balducci, N. Jackson, P. Vranas, A. Levin, J. Steiner, A semi-quantitative survey of older adults to assess barriers to participation in early phase clinical trials (EPCTs). *Proc Am Soc Clin Oncol* (Abst #8086), 2005
130. LQM Chow, **SG Eckhardt**, J Reid, J Molina, L Hanson, J Piens, S Hariharan, M Basche, L Gore, S Diab, C O'Bryant, S. Grolnic, B Hippert, MP Doyle, L Maloney, G Gordon, S Brown, K Litwiler, G. Poch, A Adjei, A First in Human Dose-Ranging Study to Assess the Pharmacokinetics, Pharmacodynamics and Toxicities of the MEK Inhibitor. ARRY-142886 (AZD6244), in Patients with Advanced Solid Malignancies. *Proc AACR/NCI/ EORTC International Conference* (Abst. # C162) 2005
131. Mark Morrow, Owen Lockerbie, **S. Gail Eckhardt**, The combination of Bortezomib and SAHA induces a synergistic apoptotic response in colorectal cell lines *in vitro*. *Proc Amer Assoc Cancer Research Annual Meeting* (Abst 5331) 2006
132. S. Leong, R. Camidge, **G. Eckhardt**, M. Basche, L. Musib, C. Darstein, D. Thornton, C. Britten, A phase I dose-escalation and pharmacokinetic study of enzastaurin combined with capecitabine in patients with advanced cancer. *Proc Am Soc Clin Oncol* (Abst #2048), 2006
133. L.Q. Chow, **S.G. Eckhardt**, D.L. Gustafson, C. O'Bryant, S. Hariharan, S. Diab, N.L. Fox, A. Corey, K. Padavic, M. Brown, R. B. Cohen, HGS-ETR1, an antibody targeting TRAIL-R1, in combination with paclitaxel and carboplatin in patients with advanced solid malignancies: Results of a phase 1 and PK study. *Proc Am Soc Clin Oncol* (Abst #2515), 2006
134. R.S. Herbst, D.S. Mendolson, S. Ebbinghouse, M.S. Gordon, P. O'Dwyer, G. Lieberman, J. Ing, R. Kurzrock, W. Novotny, **G. Eckhardt**, A phase I safety and pharmacokinetic (PK) study of recombinant Apo2L/TRAIL, an apoptosis-inducing protein in patients with advanced cancer. *Proc Am Soc Clin Oncol* (Abst #3013), 2006
135. D.R. Camidge, **S.G. Eckhardt**, S. Diab, L. Chow, C. O'Bryant, E. Temmer, A. Ervin-Haynes, T. Katz, F. Fox, R.B. Cohen, A phase I dose-escalation study of weekly IMC-1121B, a fully human anti-vascular endothelial growth factor receptor 2 (VEGFR2) IgG1 monoclonal antibody (Mab), in patients (pts) with advanced cancer. *Proc Am Soc Clin Oncol* (Abst #3032), 2006
136. J. Ling, R.S. Herbst, D.S. Mendelson, **S.G. Eckhardt**, P. O'Dwyer, S. Ebbinghaus, R. Osborne, M. Cheu, G. Lieberman, B.L. Lum, Apo2L/TRAIL pharmacokinetics in a phase 1a trial in advanced cancer and lymphoma. *Proc Am Soc Clin Oncol* (Abst #3047), 2006
137. M.P. Morelli, T. Cascone, T. Troiani, C. Tuccillo, R. Bianco, M. Romano, **S.G. Eckhardt**, S. De Pacido, G. Tortora, F. Ciardiello, Antitumor activity of the combination of cetuximab, an anti-EGFR blocking monoclonal antibody and ZD6474, an inhibitor of VEGFR and EGFR tyrosine kinases. *Proc Am Soc Clin Oncol* (Abst #13170), 2006
138. T. Troiani, O. Lockerbie, M. Morrow, F. Ciardiello, **S.G. Eckhardt**, ZD6474, an inhibitor of VEGFR-C-induced activation of VEGFR-3 and cell proliferation in human colon cancer cell lines. *Proc Am Soc Clin Oncol* (Abst #13171), 2006
139. L. Gore, E. Rivera, K. Lavalley, S. Holden, S. Grolnic, D. Cleere, S.L. Moulder, Y.A. Elsayed, **S. Eckhardt**, Phase I combination study of travectedin (T) and capecitabine (C) in patients with advanced malignancies. *Proc Am Soc Clin Oncol* (Abst #2079), 2007
140. S. Leong, **S.G. Eckhardt**, E. Chan, L.Q. Chow, W. Vermeulen, D.R. Camidge, M.L. Rothenberg, E. Chow, Maneval, R. Chao, A.C. Lockhart, A phase I study of sunitinib in combination with modified FOLFOX 6 (mFOLFOX6) chemotherapy. *Proc ASCO/ASTRO/AGA/SSO Gastrointestinal Cancers Symposium*, (Abst. #285) 2007.
141. S. Diab, **S. Eckhardt**, A. Tan, G. Fernette, L. Gore, W. Depinto, J. Groppo, M. DeMario, S. Mikulski, S. Papadimitrakopoulou, A phase I study of R547, a novel, selective inhibitor of cell cycle and transcriptional cyclin dependent kinases (CDKs). *Proc Am Soc Clin Oncol* (Abst #3528), 2007.
142. M.S. Gordon, D.S. Mendelson, C. Sweeney, N. Erbeck, R. Patel, T. Kakkar, L. Yan, **S.G. Eckhardt**, L. Gore, Interim results from a first-in-human study with AMG102, a fully human monoclonal antibody that neutralizes hepatocyte growth factor (HGF), the ligand to c-Met receptor, in patients (pts) with advanced solid tumors. *Proc Am Soc Clin Oncol* (Abst #3551), 2007
143. D. Camidge, R. S. Herbst, M. Gordon, **S. Eckhardt**, R. Kurzroc, B. Durbin, J. Ing, J. Ling, J. Sager, D. Mendelson, A phase I safety and pharmacokinetic study of apomab, a human DR5 agonist antibody, in patients with advanced cancer. *Proc Am Soc Clin Oncol* (Abst #3582), 2007
144. J.H. Schellens, C.D. Britten, D.R. Camidge, D. Boss, S. Wong, S. Diab, F. Guo, R.P. Maguire, S. P. Letrent,

- S. G. Eckhardt**, First-in-human study of the safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) of PF-00299804, a small molecule irreversible panHER inhibitor in patients with advanced cancer. *Proc Am Soc Clin Oncol* (Abst #3599), 2007
145. K.T. Flaherty, L. Gore, A. Avadhani, S. Leong, K. Harlackner, Z. Zhong, R.G. Johnson, A.L. Hannah, P. O'Dwyer, **S.G. Eckhardt**, Phase I, pharmacokinetic (PK) and pharmacodynamics (PD) study of oral alvespimycin (A; KOS-1022; 17-DMAG): Two different schedules in patients with advanced malignancies. *Proc Am Soc Clin Oncol* (Abst #14059), 2007.
 146. Jennifer L. Spratlin, **S. Gail Eckhardt**, Lia Gore, D. Ross Camidge, Stephen Leong, Cindy O'Bryant, Sami Diab, Laura Q.M. Chow, Hagop Youssoufian, Floyd Fox, Roger B. Cohen. A phase I pharmacological and biological study of weekly IMC-1121B, a recombinant human IgG monoclonal antibody (MAb), in patients (pts) with advanced solid tumors. *Proc EORTC/NCI/AACR International Conference on Molecular Targets and Cancer Therapeutics*, (Abst. A33) 2007
 147. Stephen Leong, Lia Gore, Robert Benjamin, Terri L. Warren, **S. Gail Eckhardt**, D. Ross Camidge, Cinara Dias, Gerald Greig, Stanley R. Frankel, Razelle Kurzrock, A phase I study of R1507, a human monoclonal antibody IGF-1R (insulin-like growth factor receptor) antagonist given weekly in patients with advanced solid tumors. *Proc EORTC/NCI/AACR International Conference on Molecular Targets and Cancer Therapeutics*, (Abst. A78), 2007
 148. Cindy L. O'Bryant, Stephen Leong, D. Ross Camidge, Lia Gore, Sami Diab, Dan L. Gustafson, Justin Call, Jennifer Spratlin, James A. Zwiebel, **S. Gail Eckhardt**. A phase 1 study of belinostat (PXD101) in combination with bortezomib in patients with advanced solid tumors and lymphoma. *Proc EORTC/NCI/AACR International Conference on Molecular Targets and Cancer Therapeutics*, (Abst. A149), 2007,
 149. Colin D. Weekes, Dongweon Song, Belen Rubio-Viqueira, Antonio Jimeno, Wells A. Messersmith, **S. Gail Eckhardt**, Manuel Hidalgo, CXCR4 activation mediates resistance to mTOR-directed therapy via regulation of VHL. *Proc EORTC/NCI/AACR International Conference on Molecular Targets and Cancer Therapeutics*, (Abst. A197), 2007
 150. Sara A. Kaufman, Todd M. Pitts, Natalie J. Serkova, Andrew Stephens, **S. Gail Eckhardt**, Stephen Leong, *In vitro* assessment of the IGF-1R inhibitor, PQIP, alone and in combination with chemotherapy, against human colorectal cancer cell lines: Antiproliferative, molecular and metabolic effects. *Proc EORTC/NCI/AACR International Conference on Molecular Targets and Cancer Therapeutics*, (Abst. B44), 2007
 151. Ignacio Duran, Lillian L. Siu, Larry Gontovnick, Sonya Lovell, Stephen Leong, Lisa Wang, Curtis Braun, Thor Borgford, **S. Gail Eckhardt**, Lia Gore, Phase I study of the ribosome inactivating protein prodrug TST10088 (TST88) in patients with advanced solid tumors. *Proc EORTC/NCI/AACR International Conference on Molecular Targets and Cancer Therapeutics*, (Abst. B149), 2007
 152. D.R. Camidge, C.D. Britten, J.H.M. Schellens, F. Guo, R. Holham, **S.G. Eckhardt**, S.G. Wong, D.S. Boss, J. Lucca, P. A. Janne, First-in-human study of PF-00299804, a small molecule irreversible panHER inhibitor in patients with advanced cancer: Update on safety and pharmacokinetics and initial report on pharmacodynamics responses and clinical benefit. *Proc EORTC/NCI/AACR International Conference on Molecular Targets and Cancer Therapeutics*, (Abst. B229), 2007
 153. J.R. Infante, J. L. Spratlin, R. Kurzrock, **S.G. Eckhardt**, H.A. Burris, III, T.A. Puchalski, J. Li, K. Wu, J. Ochs, R.S. Herbst, Clinical Pharmacokinetic (PK), pharmacodynamics findings in a phase I trial of weekly (wkly) intravenous AZD4877 in patients with refractory solid tumors. *J Clin Oncol* (Abs # 2501) 2008
 154. K.T. Flaherty, L. Gore, A.N. Avadhani, J.L. Spratlin, K. Harlackner, Z. Zhong, R.G. Johnson, A.L. Hannah, P. J. O'Dwyer, **S.G. Eckhardt**. First use of an oral Hsp90 inhibitor in patients (Pts) with solid tumors: Alvespimycin (A) administered QOD or QD. *J Clin Oncol* (Abs # 2502) 2008
 155. Y. Xin, M. Tohny, R.S. Herbst, D.S. Mendelson, **S. G. Eckhardt**, P.J. O'Dwyer, W. Novotny, D.E. Allison, B.L. Lum, N. Jumbe. Population pharmacokinetic (PPK) analysis of recombinant human Apo2/Trail (rhApo2L/Trail) in a Phase 1a Study in advanced cancer and lymphoma. *J Clin Oncol* (Abs # 2525) 2008
 156. L.L. Siu, H.A. Burris III, L.R. Mileskin, D.R. Camidge, **S.G. Eckhardt**, A. Lamb, E.X. Chen, S.F. Jones, H. Xu, H. Fingert. A phase I clinical pharmacokinetic (PK) and pharmacodynamics (PD) evaluation of PF-00562271 targeting focal adhesion kinase (FAK) in patient (pts) with advanced solid tumors. *J Clin Oncol* (Abs # 3534) 2008
 157. R. Lal, D.R. Camidge, S. George, G.D. Demetri, **S.G. Eckhardt**, A. Stephens, J. Chick, R. Boinpally, S.B. Kaye, M. Scurr. A phase I, dose escalation (DE), pharmacokinetic (PK), and pharmacodynamics (PD) study of two schedules of OSI-930, an oral tyrosine kinase inhibitor (TKI) in patients (pts) with advanced solid tumors. *J Clin Oncol* (Abs # 3553) 2008

158. L.Q. Chow, D.J. Jonker, S.A. Laurie, J.A. Call, S.G. Diab, G. Goss, M. McWilliam, E. Wang, R. Chao, **S.G. Eckhardt**, D.R. Camidge. Sunitinib (SU) in combination with pemetrexed (P) in patients (Pts) with advanced solid malignancies: A phase I dose escalation study. *J Clin Oncol* (Abs # 3566) 2008
159. P.A. Janne, J.H. Schellens, J.A. Engelman, **S.G. Eckhardt**, R. Millham, L.J. Denis, C.D. Britten, S.G. Wong, D.S. Boss, D.R. Camidge. Preliminary activity and safety results from a phase I clinical trial of PF-00299804, an irreversible pan-HER inhibitor, in patients (pts) with NSCLC. *J Clin Oncol* (Abs # 8027) 2008
160. LQM Chow, DJ Jonker, SA Laurie, JA Call, SG Diab, G Goss, M McWilliam, E Wang, RC Chao, A Thall, **SG Eckhardt**, DR Camidge A Phase I Dose-escalation Study of Sunitinib in Combination with Pemetrexed in Patients with Advanced Solid Malignancies.
161. DCE-MRI endpoints reveal decreased tumor vascularity in patients with liver metastases: A Phase I dose escalating study with IMC-1121B. N.J. Serkova, J. Spratlin, **S.G. Eckhardt**, B. Milestone, E.G. Chiorean, H. Youssoufians, F. Fox, E. Rowinsky, R.B. Cohen. 20th EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics, Geneva, Switzerland, 21-24 October 2008, *Eur J Cancer*, (abst. 41), 2008
162. Development of predictive markers of responsiveness to the MEK 1/2 inhibitor AZD6244 in Colorectal Cancer (CRC). Nallanareddy, J.J. Tentler, C.D. Coldren, T.M. Pitts, SA Kaufman, **S.G. Eckhardt**. 20th EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics, Geneva, Switzerland, 21-24 October 2008, *Eur J Cancer*, (abst. 24), 2008
163. Development and characterization of predictive markers to the IGF-1R inhibitor, PQIP in colorectal cancer (CRC). T M. Pitts, S. A. Kaufman, J.J. Tentler, S. Leong, C.D. Coldren, F.R. Hirsch, M. Varella-Garcia, **S.G. Eckhardt**. 20th EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics, Geneva, Switzerland, 21-24 October, 2008, *Eur J Cancer*, (abst. 91), 2008
164. ENMD-2076 exerts anti-angiogenic and anti-proliferative activity against human colorectal cancer (CRC) xenograft models. J.J Tentler, E.L.B. Pierce, N.J. Serkova, T.M. Pitts, M.R. Bray, G.C. Fletcher, **S.G. Eckhardt**. 20th EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics, Geneva, Switzerland, 21-24 October 2008, *Eur J Cancer*, (abst. 284), 2008
165. Vorinostat sensitizes colorectal cancer cell (CRC) lines to AZD6244 and results in synergistic inhibitory effects on proliferation. M.R. Morelli, A.M. Meyer, J.J. Tentler, T.M. Pitts, S. Nallapareddy, P.D. Smith, **S.G. Eckhardt**. 20th EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics, Geneva, Switzerland, 21-24 October 2008, *Eur J Cancer*, (abst. 349), 2008
166. Phase I study of the ribosome inactivating protein prodrug TST10088 (TST88) in patients with advanced solid tumors. L. Duran, L.L. Siu, C. Kollmannsberger, L. Gontovnick, S. Leong, L. Wang, C. Braun, T. Borgford, **S.G. Eckhardt**, L. Gore. 20th EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics, Geneva, Switzerland, 21-24 October 2008, *Eur J Cancer*, (abst. 389), 2008
167. A phase I study of gemcitabine, capecitabine and vandetanib in patients with advanced solid tumors with an expanded cohort in biliary and pancreatic malignancies. S. Leong, C.L. OBryant, W.A. Messersmith, S. Diab, M. A. Kane, S. Nallapareddy, C. Weekes, J. Spratlin, J. Call, **S.G. Eckhardt**. 20th EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics, Geneva, Switzerland, 21-24 October 2008, *Eur J Cancer*, (abst. 402), 2008
168. First-in-human (FIH) study of PF-00299804 in advanced cancer patients: correlation between pharmacokinetics (PK) and pharmacodynamics (PD). J. Schellens, F. Guo, P.A. Janne, **S.G. Eckhardt**, D.R. Camidge, L. Taylor, J. Lucca, O.S. Boss, S.G. Wong, C.D. Britten. 20th EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics, Geneva, Switzerland, 21-24 October 2008, *Eur J Cancer*, (abst. 564), 2008
169. Population pharmacokinetic model of PI-88, a heparanase inhibitor. Susan F. Hudachek, Daniel L. Gustafson, S. Gail Eckhardt, Barbara Hicks. 100th Annual Meeting, Pro American Association for Cancer Research, Denver, Colorado, 18-22 April, 2009, (abst. 5437), 2009
170. Members of the noncanonical WNT pathway confer resistance to the MEK 1/2 inhibitor AZD6244 in colorectal cell lines. John J. Tentler, Sujatha Nallapareddy, Aik Choon Tan, Anna Spreafico, Sara A. Flanigan, Todd M. Pitts, **S. Gail Eckhardt**. *Molecular Targets and Cancer Therapeutics Program and Proceedings*. A38 (95) November, 2009. Boston, MA.
171. Development and validation of an integrated genomic classifier to predict sensitivity to the IGFR-1R/IR tyrosine kinase inhibitor, OSI-906, in colorectal cancer. Todd M. Pitts, Aik Choon Tan, Gillian N. Kulikowski, John J. Tentler, Sara A. Flanigan, Stephen Leong, Amy Brown, Chris D. Coldren, Marileila Varella-Garcia, Fred R. Hirsch, **S. Gail Eckhardt**. *Molecular Targets and Cancer Therapeutics Program and Proceedings*. A39 (95) November, 2009. Boston, MA.
172. MicroRNA expression patterns as potential biomarkers of responsiveness to the MEK 1/2 inhibitor, AZD 6244, in colorectal cancer cell lines. Anna Spreafico, Aik Choon Tan, John J. Tentler, Sujatha Nallapareddy,

- Todd M. Pitts, **S. Gail Eckhardt**. *Molecular Targets and Cancer Therapeutics Program and Proceedings*. A40 (96) November, 2009. Boston, MA.
173. Rational combination of the IGF-1R/IR tyrosine kinase inhibitor (TKI), OSI-906, with the MEK inhibitor, U0126 results in synergistic and apoptotic effects in human colorectal cancer (CRC) cell lines. Sara A. Flanigan, Todd M. Pitts, Gillian N. Kulikowski, Aik Choon Tan, Sujatha Nallapareddy, John J. Tentler, **S. Gail Eckhardt**, Stephen Leong. *Molecular Targets and Cancer Therapeutics Program and Proceedings*. A256 (162) November, 2009. Boston, MA.
 174. Characterization of *in vitro* activity and predictive biomarkers of the novel p21-activated kinase 4 (PAK4) inhibitor, PF-3758309, in colorectal cancer cell lines. Gillian N. Kulikowski, Todd M. Pitts, Aik Choon Tan, John J. Tentler, Blair C. Britt, Byron W. Britt, Brion W. Murray, William Carley, Tod Smeal, Chuangxing Guo, **S. Gail Eckhardt**. *Molecular Targets and Cancer Therapeutics Program and Proceedings*. B169 (219) November, 2009. Boston, MA.
 175. A phase 1 study of belinostat (PXD101) in combination with bortezomib in patients with advanced solid tumors or lymphoma. Sujatha Nallapareddy, Stephen Leong, Ross Camidge, Lia Gore, Sami, Diab, Wells Messersmith, Karl Lewis, Colin Weekes, Daniel Gustafson, Antonio Jimeno, James Zwiebel, Igor Espinoza-Delgado, **Gail Eckhardt**, Cindy O'Bryant. *Molecular Targets and Cancer Therapeutics Program and Proceedings*. B238 (241) November, 2009. Boston, MA.
 176. Identification of candidate microRNAs that correlate with sensitivity to the IGF-1R/IR inhibitor, OSI-906, in colorectal cancer (CRC) cell lines. Aik Choon Tan, John J. Tentler, Nadezdah Ryugazova, Maria I. Kachaeva, Todd M. Pitts, **S. Gail Eckhardt**. *Molecular Targets and Cancer Therapeutics Program and Proceedings*. C22 (259) November, 2009. Boston, MA.
 177. A novel multi-targeted Aurora A and VEGFR2 kinase inhibitor, ENMD-2076, demonstrates synergistic antiproliferative and proapoptotic effects in combination with chemotherapy and trastuzumab in breast cancer cell lines. Jennifer R. Diamond, **S. Gail Eckhardt**, Todd M. Pitts, Blair C. Britt, Maria I. Kachaeva, Marileila Varella-Garcia, Mark R. Bray, Graham C. Fletcher, John J. Tentler. *Molecular Targets and Cancer Therapeutics Program and Proceedings*. C75 (275) November, 2009. Boston, MA.
 178. A phase I study of gemcitabine, capecitabine and vandetanib in patient with advanced solid tumors with an expanded cohort in biliary and pancreatic malignancies. S. Nallapareddy, **S.G. Eckhardt**, C.L. O'Bryant, S. Eppers, S. Diab, M.A. Kane, C.D. Weekes, J.L. Spratlin, W.A. Messersmith, S. Leong. *J. Clin Oncol* (Abstract 2535), 2010
 179. Phase I study evaluating the safety, tolerability and pharmacokinetic (PK) of HGS1029, a small-molecule inhibitor of apoptosis protein (IAP), in patients (pts) with advanced solid tumors. **S.G. Eckhardt**, G. Gallant, B.I. Sikic, D.R. Camidge, Burris III, H.A. Wakelee, W.A. Messersmith, S.F. Jones, A.D. Colevas, J.R. Infante. *J. Clin Oncol* (Abstract 2580), 2010
 180. Phase I study of OSI-906, dual tyrosine kinase inhibitor of insulin-like growth factor-1 receptor (IGF-1R) and insulin receptor (IR) in combination with erlotinib (E) in patients with advanced solid tumors. B.M. Macaulay, M.R. Middleton, **S.G. Eckhardt**, R.A. Juergens, A.W. Stephens, S. Poondru, S.P. McCarthy, S.M. Gadgeel. *J. Clin Oncol* (Abstract 3016), 2010
 181. Final results from a phase I, dose-escalation study of PX-866, an irreversible, pan-isoform inhibitor of PI3 kinase. A. Jimeno, R.S. Herbst, G.S. Falchook, W.A. Messersmith, S. Hecker, S. Peterson, D.F. Hausman, R. Kurzrock, **S.G. Eckhardt**, D.S. Hong. *J. Clin Oncol* (Abstract 3089), 2010
 182. W. Fairbrother, H. Wong, N. Budha, B. Blackwood, S. Gould, R. Erickson, P. LoRusso, **S. G. Eckhardt**, A. Wagner, I. Chan. Pharmacokinetic-pharmacodynamic modeling of the effect of GDC-0152, a selective antagonist of the inhibitor of apoptosis (IAP) proteins, on monocyte chemotactic protein-1 (MCP-1) indicates species differences in MCP-1 response. EJC Supp. EORTC/NCI/AACR Symposium on Molecular Targets and Cancer Therapeutics, (Abst. 82), 2010.
 183. A. Jimeno, R. S. Herbst, G. S. Falchook, W. A. Messersmith, D. R. Camidge, S. R. Peterson, D. F. Hausman, R. Kurzrock, **S. G. Eckhardt**, D. S. Hong. A Phase 1 study of continuous dosing with PX-866, an irreversible pan-isoform inhibitor of P13 kinase. EJC Supp. EORTC/NCI/AACR Symposium on Molecular Targets and Cancer Therapeutics, (Abst. 366), 2010.
 184. W. Fairbrother, P. LoRusso, A. Wagner, N. Budha, W. Darbonne, Y. Shin, H. Wong, I. Chan, J. Ware, **S.G. Eckhardt**. Phase 1 pharmacokinetics and pharmacodynamics of GDC-0152, a novel IAP protein antagonist, administered to patients with locally advanced or metastatic malignancies. EJC Supp. EORTC/NCI/AACR Symposium on Molecular Targets and Cancer Therapeutics, (Abst. 393), 2010.
 185. Spreafico, J.J. Tentler, A. Tan, T. M. Pitts, M. I. Kachaeva, H. M. Selby, **S. G. Eckhardt**. Evaluation of antiproliferative and apoptotic effects of the rational combination of the MEK1/2 inhibitor selumetinib (AZD6244) and inhibitors of the hedgehog pathway in colorectal cancer (CRC) cell lines. Proc

AGA/ASCO/ASTRO/SSO Gastrointestinal Cancers Symposium, (Abst. 422), 2011.

186. E. Im, T. M. Pitts, G. Kulikowski, A. Tan, J. J. Tentler, B. Murray, W. Carley, T. Smeal, C. Guo, **S. G. Eckhardt**. Contribution of the epithelial-mesenchymal (EMT) phenotype to the sensitivity of colorectal cancer cell lines to the p21-activated kinase inhibitor. PF-375309. Proc AGA/ASCO/ASTRO/SSO Gastrointestinal Cancers Symposium, (Abst. 438), 2011.

SELECTED PRESENTATIONS

1. Characterization of a nuclear translocation signal in the core antigen of HBV. Cold Spring Harbor Symposium: The molecular biology of hepatitis B viruses; San Diego, CA. 1990.
2. Induction of differentiation in HL60 cells through the elimination of extrachromosomal DNA. Texas Triangle Meeting, 3/93, and the San Antonio Cancer Institute Symposium, 7/93.
3. Initial phase I assessment of the novel angiogenesis inhibitor DS4152. Eighth NCI-EORTC Symposium on New Drugs in Cancer Therapy. Amsterdam, The Netherlands, March 16, 1994.
4. From the Chromosome to the Clinic. The University of Texas Health Science Center at San Antonio Graduate Student Research Forum, September 1994.
5. Results of a phase I trial of the novel angiogenesis inhibitor, tecogalan sodium. American Association for Cancer Research 86th Annual Meeting. Toronto, Ontario, Canada, March 1995.
6. Angiogenesis Inhibitors in Clinical Trials. American Association for Clinical Research, Novel Strategies for Resistant Tumors. Fort Meyers, Florida, November 1995.
7. Clinical Trial Design Strategies. International Business Communications, Angiogenesis: Inhibitors and Stimulators. Philadelphia, PA. December 1995.
8. New Anticancer Agents with Novel Mechanisms of Action. Sixth International Congress on Anti-Cancer Treatment. Paris, France. February, 1996.
9. A Summary of Anti-angiogenesis Research. Albert Einstein Cancer Center, Thirteenth Annual Advances in Cancer Treatment. New York, NY, March, 1996.
10. AIDS-Related Malignancies. Grand Rounds, The University of Texas Health Science Center at San Antonio, Dept. of Medicine/Oncology. San Antonio, TX, May 15, 1996.
11. Panel Discussion on Trial Designs for Cytostatic Agents. National Cancer Institute, Cancer Therapy and Evaluation Program, Annual Fall Meeting. Bethesda, Maryland. September, 1996.
12. New Drug Development in the USA. National Congress of the Spanish Cancer Research Society. Oviedo, Spain, 1997.
13. A Phase I and pharmacokinetic (PK) study of the tyrosine kinase inhibitor SU101 in patients with advanced solid tumors. American Society of Clinical Oncology 23rd Annual Meeting. Denver, Colorado, 1997.
14. Angiogenesis Inhibitors Working Group. National Cancer Institute. Bethesda, Maryland. June 1997.
15. New Modalities for Metastatic Colon Cancer. Texas Society of Medical Oncology. San Antonio, TX. October 1997.
16. Update on the Use of CPT-11 in Metastatic Colon Cancer. Texas Oncology Fall Faculty Conference. Captiva Island, Florida. October 1997.
17. A Review of the Initial Phase I trials of Irinotecan. Irinotecan Clinical Status and Future Directions. The University of Texas MD Anderson Cancer Center, Houston, TX. January 1998.
18. Update on Angiogenesis Inhibitors in the Treatment of Cancer. American Medical Association: Fighting Cancer: Advances in Biotherapeutic Treatments. New York, NY. February 1998.
19. New Advances in the Treatment of Colorectal Cancer. The University of Texas Southwestern Medical School, Dallas, TX. February, 1998.
20. Update on the Use of CPT-11 in Metastatic Colon Cancer. The University of Texas Medical Branch. Galveston, TX. April, 1998.
21. Overview of the U.S. Trials of CPT-11 in Colorectal Cancer. Tokyo, Japan, May 1998.
22. New Formulations and Schedules of CPT-11. Second Annual Fall Oncology Conference: Advances in Solid Tumors. Hilton Head, SC. October 1998.
23. Squalamine, a Novel Angiogenesis Inhibitor. First International Symposium on Anti-angiogenic Agents. Dallas, TX. January 1999.
24. The Continual Reassessment Method (CRM) for Dose Escalation in Phase I Trials in San Antonio Does Not Result in More Rapid Study Completion. American Society of Clinical Oncology 25th Annual Meeting. Atlanta, Georgia, 1999.
25. Biological Surrogate Markers for Angiogenesis Inhibitors. NCI Phase I meeting. Bethesda, MD. March 2000.
26. Overview of Clinical Development of Angiogenesis Inhibitors. AACR. San Francisco, CA. April 2000.

27. Matrix Metalloproteinase Inhibitors as Anticancer Therapy. NCI/CAMO Symposium. Toronto, Canada. April 2000.
28. Progress in the Development of Farnesyltransferase Inhibitors. ASCO Industry-Supported Symposium. New Orleans, LA. May 2000.
29. Angiogenesis Inhibitors: Clinical and Developmental Progress. Twelfth Annual Cancer Progress Conference. New York, NY October, 2000.
30. Angiogenesis in Lung Cancer. University of Chicago Lung Cancer Symposium. Chicago, Ill. October, 2000.
31. ZD6474, a Novel Tyrosine Kinase Inhibitor. Third International Symposium on Anti-angiogenic Agents. Dallas, TX. January 2001.
32. Update on SU5416, SU6668, and ZD6474, novel tyrosine kinase inhibitors. Targeted Therapies in the Treatment of Lung Cancer. Aspen, CO. January 2001
33. Novel Agents and Strategies for the Treatment of GI Malignancies. Surgery Grand Rounds, UCHSC, February 2001.
34. Novel Agents and Strategies for the Treatment of Cancer. Medical Grand Rounds, UCHSC, May 2001.
35. Preclinical and Clinical Activity of Irofulven. Albert Einstein Cancer Center, 18th Annual Advances in Cancer Treatment. New York, NY, October, 2001.
36. Clinical Trials in Oncology and Drug Development. Sophomore Oncology Course, UCHSC, January 2002.
37. Farnesyl Transferase Inhibitors: Clinical and Pharmacodynamic Results. Targeted Therapy for Colorectal Cancer Symposium, Maui, February 2002.
38. Targeting VEGF in Lung Cancer: Overview. Targeted Therapy in Lung Cancer Symposium, Aspen, February 2002.
39. Novel Agents and Strategies for the Treatment of AIDS-related Kaposi's Sarcoma. NCI Symposium on AIDS-related Malignancies, Bethesda, MD, April 2002.
40. New Agents/ New Targets: Implications for Clinical Development. ASCO Integrated Symposium, Annual Meeting, San Francisco, CA, May 2002.
41. Integrating Biological Correlative Studies into Early Clinical Trials of Targeted Agents. ASCO Educational Session on Clinical Trials, Annual Meeting, San Francisco, CA, May 2002.
42. Update on Angiogenesis Inhibitors for the Treatment of Cancer. Mayo Clinic Oncology Symposium, Amelia Island, August, 2002.
43. Novel Agents for the Treatment of Cancer. Surgery Grand Rounds, UCHSC, August 2002.
44. Mechanism-Based Therapy for Cancer: New Agents, New Challenges. Internal Medicine Days, UCHSC, September 2002.
45. Poster Review. Signal Transduction Modulators in Cancer. Amsterdam, September, 2002.
46. Update on Signal Transduction Inhibitors: Are They Hitting the Target? ASCO/ESMO Joint Symposium, ESMO Annual Meeting, Nice, France, October 2002.
47. Designing Better Clinical Trials with Agents that Target Molecular Pathways. ASCO Molecular Therapeutics Symposium, San Diego, CA, November, 2002.
48. Angiogenesis Inhibitors. Cancer Pharmacology Lecture, UCHSC, January, 2003.
49. PI88 Heparanase Inhibitor: Old Class of Drug, New Target. Symposium on Angiogenesis Inhibitors in Cancer, San Diego, CA, January 2003.
50. Overview of Phase I Trial of ZD6474. Symposium on Targeted Therapy in Head and Neck Cancer, San Juan, PR, February, 2003.
51. Targeting the Extracellular Matrix in Colorectal Cancer. Symposium on Targeted Therapy in Colorectal Cancer. Beaver Creek, CO, February, 2003.
52. Developmental Therapeutics: Successes and Failures of Clinical Trial Designs of Targeted Compounds. ASCO Educational Session, Annual Meeting, Chicago, IL, May, 2003.
53. Signaling Pathways Revisited. AACR Annual Meeting, Orlando, FL April 2004.
54. Tyrosine kinase inhibitors that target more than the VEGF-R: SU11248 and ZD6474. NCI/EORTC/AACR Annual Meeting, Geneva, Switzerland, October, 2004.
55. New agents, New Targets for the Treatment of Colorectal Cancer. ASCO GI Symposium, Miami, FL, January 2005.
56. Phase I Trial Design. AACR Annual Meeting, Anaheim, CA, April 2005.
57. The combination of Bortezomib and SAHA induces a synergistic apoptotic response in colorectal cell lines *in vitro*. AACR Annual Meeting, Anaheim, CA, April 2005.
58. A semi-quantitative survey of older adults to assess barriers to participation in early phase clinical trials (EPCTs). ASCO Annual Meeting, Orlando, FL, May 2005.

59. Novel Agents/Targets for the Treatment of Colorectal Cancer. ASCO GI Symposium, Orlando, FL January 2005.
60. Phase I Clinical Trials. AACR Clinical Trials Workshop, Washington DC, April 2005.
61. Discussant, Developmental Therapeutics. ASCO National Meeting, Atlanta, GA, May 2005.
62. Developmental Therapeutics: Successes and Failures of Clinical Trial Designs of Targeted Compounds. ASCO Educational Session, Atlanta, GA May 2005.
63. Beyond VEGF and EGFR-targeted Agents: Novel Agents and Pathways on the Horizon for the Treatment of CRC. World Congress on GI Cancer Barcelona, Spain, June 2005.
64. Early Clinical Trial Design: What Have We Learned? FDA Visiting Professorship, Rockville, MD, July, 2005.
65. Phase I Trial of the VEGFR2 Antibody, IMC-1121B on a Weekly Schedule. Angiogenesis Symposium, San Diego, CA, January 2006.
66. Have Biological Markers of Targeted Therapy *Helped*? ASCO GI Symposium, Orlando, FL, January 2007.
67. A Phase I Study of Sunitinib in Combination with mFOLFOX6. Angiogenesis Meeting, San Diego, CA, January 2007.
68. Clinical Trials of Novel Cancer Therapeutics: Lessons Learned. Nature Meeting, Capri, Italy, October 2007.
69. New Agents and Targets for Cancer: Update. University of Colorado Denver, Medical Grand Rounds, Aurora, CO October 2007.
70. Clinical Trials of Novel Cancer Therapeutics: Lessons Learned. MD Anderson Grand Rounds, Houston, TX November 2007.
71. New Agents and Targets for Cancer. ECOG Fall Meeting, Fort Lauderdale, FL November 2007.
72. Clinical Trials of Novel Cancer Therapeutics: Lessons Learned? Grand Rounds, Roswell Park Cancer Institute, Buffalo, NY January 2008.
73. Clinical Trials of Novel Cancer Therapeutics: Lessons Learned? Grand Rounds, Ohio State University, Columbus, OH April 2008.
74. The Evolution of Predictive Markers for EGFR-directed Antibodies in CRC: Is it Time for Patient Selection (again)? Plenary Session, ASCO National Meeting, Chicago, IL June 2008.
75. Debate on the Use of Biomarkers in Clinical Trials of Anticancer Agents. 11th Annual Angiogenesis Symposium, San Diego, CA, February 2009.
76. Individualization of Novel Therapy for Colorectal Cancer. TAT/ESMO Symposium, Bethesda, MD. 2010
77. Development of Predictive Biomarkers for a PAK4 Inhibitor in CRC. CNIO Symposium, Madrid, Spain, 2010.
78. Novel Agents in Early Development for Colorectal Cancer: Approach to Individualized Therapy. AACR Colorectal Cancer Meeting, Philadelphia, PA October 30, 2010
79. Individualized and Rational Therapy for Colorectal Cancer. Johns Hopkins Visiting Professor: Baltimore, MD, November 4-5, 2010.
80. Development of Biomarkers for Colorectal Cancer. Biogen/IDEC Symposium: San Diego, CA, November 8th, 2010.
81. Individualized Therapy for Colorectal Cancer. Pfizer Proof-of-Concept Meeting: New York, NY, December 9th, 2010.
82. Individualized and Rational Therapy for Colorectal Cancer. UCCC Molecular Oncology Retreat: Boulder, CO, December 3rd, 2010.
83. The Intersection of Preclinical, Translational, and Clinical Research: How can we accelerate new drug development in GI Cancers? ASCO GI Symposium, San Francisco, CA, January 2011.
84. Clinical Applications of Metabolomics. AACR National Meeting, Orlando, FL, April 2011.
85. History of the Development of Novel Agents and Integration of Biomarkers in Colorectal Cancer. ASCO National Meeting, Chicago, IL, June 2011
86. US Academic/Industry Collaborations for Predictive Biomarkers in Early Clinical Development. Worldwide Innovative Networking (WIN) symposium on personalized cancer medicine. Paris, France, July 6-8 2011.
87. Individualized and Rational Therapy in Colorectal Cancer. Grand Rounds, Princess Margaret Hospital, Toronto, Ontario, September 2011.
88. KRAS Mutations in Colorectal Cancer: Lessons Learned and Future Progress. 5th EORTC-NCI-ASCO Annual Meeting on Molecular Markers in Cancer, Brussels, Belgium, October 2011.

SELECTED CLINICAL TRIALS (PRINCIPAL INVESTIGATOR, NON-COOPERATIVE GROUP TRIALS)

1. Phase I trial of the mushroom-derived cytotoxin, MGI 114, and CPT-11 in patients with advanced cancer. Phase II trial of MGI 114 in patients with advanced pancreatic cancer.

2. Phase I trial of the matrix metalloproteinase inhibitor, BAY 12-9566, in combination with paclitaxel and carboplatin.
3. Phase I trial of the angiogenesis inhibitor, squalamine, administered by a 5-day continuous infusion every three weeks.
4. Phase I study of the antitumor antibiotic, Rebeccamycin analog, given as a single bolus dose every three weeks.
5. Phase I study of the farnesyltransferase inhibitor, R115777, in combination with gemcitabine.
6. Phase I study of the oral matrix metalloproteinase inhibitor, Col-3, administered daily.
7. Phase I study of the recombinant p53-containing adenovirus, INGN 201, administered by intravenous infusion every three weeks.
8. Phase II trial of the topoisomerase inhibitor DX 8951 in patients with advanced pancreatic cancer.
9. Phase I study of the angiogenesis inhibitor Tecogalan Sodium in patients with advanced cancer.
10. Phase I study of the combination of temozolomide and cisplatin in patients with advanced cancer.
11. Phase I and pharmacologic study of the mitochondrial selective agent MKT 077 in patients with advanced cancer.
12. Phase I study of ISIS 3521, antisense to PKCa, in patients with refractory cancer.
13. Phase I study of the butyrate analog, AN-9, in patients with advanced cancer.
14. Phase I study of the polyamine biosynthesis inhibitor, CGP 48664, in patients with advanced cancer.
15. Phase I and pharmacologic study of the novel mushroom-derived cytotoxin, MGI 114, in patients with advanced malignancies.
16. Phase I study of the matrix metalloproteinase inhibitor, BAY 12-9566 in patients with advanced cancer.
17. Phase I and pharmacologic study of arginine butyrate, BL1001, in patients with advanced cancer.
18. Phase I study of the differentiating agent, vesnarinone, in combination with gemcitabine, in patients with advanced cancer.
19. Phase I study of recombinant CD40 ligand in patients with refractory solid tumors or lymphomas.
20. Phase I study of intratumoral injection of ONYX 015 into tumors of patients with refractory head and neck cancer.
21. Phase I study of the farnesyl transferase inhibitor, R115777, in combination with capecitabine in patients with advanced cancer.
22. Phase II study of the novel mushroom-derived cytotoxin, irofulven, on a daily-times-four schedule, in patients with advanced pancreatic cancer.
23. Phase I study of a tyrosine kinase inhibitor to VEGF, ZD6474, in patients with advanced cancer.
24. Phase I/II study of exisulind and taxotere in patients with advanced NSCLC.
25. Phase I study of lometrexol and gemcitabine in patients with advanced cancer.
26. Phase I study of the farnesyltransferase inhibitor, SCH66336 in combination with gemcitabine and cisplatin in patients with advanced pancreatic or NSCLC.
27. Phase I/II study of the heparanase inhibitor, PI88, in patients with advanced malignancies and melanoma.
28. Phase I and biological study of the integrin antagonist, EMD 121974 in patients with advanced cancer.
29. Phase I Study of the BMS epothilone in patients with advanced cancer.
30. Phase I/II study of ZD1839, capecitabine and celecoxib in patients with metastatic colorectal cancer.
31. Phase I study of irofulven and gemcitabine in patients with advanced cancer.
32. Phase II study of the topoisomerase I inhibitor, DX8951f, in patients with advanced hepatocellular or biliary cancer.
33. Randomized Phase II study of R115777 (farnesyltransferase inhibitor) versus placebo in combination with gemcitabine in patients with advanced pancreatic cancer (US Principal Investigator).
34. Phase I/II study of the proteasome inhibitor PS-341 + carboplatin and VP-16 in patients with advanced malignancies and small cell lung cancer.
35. Phase I study of the novel taxane, BAY59, in patients with advanced cancer.
36. Phase II study of CPT-11 + capecitabine in patients with colorectal cancer.
37. Phase I study of angiozyme (ribozyme against VEGF-1 receptor) + carboplatin + paclitaxel in patients with advanced cancer.
38. Phase I, Pharmacologic and Biologic Study of the Matrix Metalloprotease Inhibitor, SS3340 in patients with advanced Cancer.
39. Phase I Study of PG490-88Na, an inhibitor of NFκ-B, in patients with advanced malignancies.
40. Phase II Study of the liposomal topoisomerase inhibitor, NX211, in Patients with refractory colorectal cancer.
41. Phase I study of the histone deacetylase inhibitor, MS-275 in patients with lymphoma or advanced cancer.
42. Phase I study of CP-461, a cyclic GMP phosphodiesterase inhibitor, in patients with advanced cancer.
43. Phase I study of the MEK-1 inhibitor, AZD6244, in patients with advanced malignancies.

44. Phase I study of the humanized antibody against the human TRAIL receptor, TRM-1, with carboplatin and paclitaxel in patients with advanced cancer.
45. Phase I study of APO2L TRAIL ligand, in patients with advanced cancer.
46. Phase I study of a humanized antibody against the VEGFR2 receptor in patients with advanced cancer.
48. Phase I study of the cyclin dependent kinase inhibitor, RO4584820, in patients with advanced solid malignancies.
49. Phase I study of the IGF-1R antibody, BO19373, in patients with advanced solid malignancies.
50. Phase I study of the cytotoxic agent, AZD4877 in patients with advanced solid malignancies.
51. Phase I study of the pan-ERB inhibitor, PF- 00299804 in patients with advanced cancer.
52. Phase I study of FOLFOX and sunitinib in patients with advanced cancer.
53. Phase I combination study of the proteasome inhibitor, bortezomib, and the histone deactylase inhibitor, PXD-101, in patients with advanced solid malignancies.
54. Phase I study of the hsp90 inhibitor, KOS1022 in patients with advanced cancer.
55. Phase I study of the pro-apoptotic agent, AEG40826, in patients with advanced cancer.
56. Phase I study of the sheddase inhibitor, INCB7839-201, in patients with advanced malignancies.
47. Phase I combination study of erlotinib and the pan-VEGF inhibitor, pazopanib, in patients with advanced cancer.
48. Phase I study of the TWEAK antibody, PDL-192 in patients with advanced cancer.
49. Phase I study of the combination of the IGF-1R TKI, OSI906, and erlotinib in patients with advanced cancer.
50. Phase I study of an IAP inhibitor, AEG40826, in patients with advanced cancer.
51. Phase I study of the p21-activate kinase 4 inhibitor, PF-03758309, in patients with advanced cancer.
52. Phase I study of the jak2 inhibitor, AZD1480, in patients with advanced cancer.
53. Phase I study of the hedgehog inhibitor, TAK441, in patients with advanced cancer.

PREVIOUS AND CURRENT TRAINEES

Name	Year (s)	Current Position
Miguel Villalona, M.D.	1995-1997	Professor and Solid Tumor Division Head, Ohio State University
Lisa Hammond, M.D.	1995-1997	Private practice, San Antonio, TX
Sami Diab, M.D.	1997-1998	Private practice and Clinical Faculty, UCD
Sunil Sharma, M.D.	1997-1998	Associate Professor, University of Utah
Manuel Hidalgo, M.D., Ph.D.	1997-1999	Professor, CNIO, Madrid, Spain
Lillian Siu, M.D.	1998-1999	Professor, Princess Margaret Hospital, Toronto, CA
Carolyn Britten, M.D.	1997-1999	Associate Professor, Medical University of South Carolina
Amita Patnaik, M.D.	1997-1999	Member, START Oncology, San Antonio, TX
Sun-Young Rha, M.D.	1998-1999	University of Seoul, Korea
Desiree Hao, M.D.	1998-1999	Assistant Professor, University of Calgary, CA
Scott N. Holden, M.D. ¹	1999-2004	Medical Director, Genentech
Lia Gore, M.D. ¹	2001-2004	Associate Professor, UC Denver, CO
A. Scott Pierson, M.D.	2000-2002	Private Practice, New Jersey
Michele Basche, M.D. ^{1, 2}	2001-2004	Private Practice, CO
Samir N. Witta, M.D., Ph.D.	2002-2004	Private Practice, Phase I/II Research, Denver, CO
K.S. Raj, M.D.	2003-2004	Private Practice, FL
Bruno Medeiros, M.D.	2003-2005	Associate Professor, Stanford University
Heather Landau, M.D.	2003	Associate Professor, Memorial Sloan Kettering
Teresa Troiani, M.D.	2004-2006	Post-doctoral fellow, Naples, Italy
Sujatha Hariharan, M.D.	2004-2006	Private Practice, Atlanta, GA
Laura Chow, M.D.	2004-2005	Associate Professor, University of Washington, Seattle, WA
Thomas Flaig, M.D. ²	2006-present	Associate Professor, UC Denver, CO
Stephen Leong, M.D. ¹	2005-present	Associate Professor, UC Denver, CO
Colin Weekes, M.D., Ph.D. ^{1, 2}	2006-present	Assistant Professor, UC Denver, CO
Elaine Lam, M.D.	2004-present	Assistant Professor, UC Denver, CO
Chris Lieu, M.D. ^{1, 3, 5}	2005-present	Assistant Professor, UC Denver, CO
Justin Call, M.D.	2006-2008	Private Practice, Clinical Research Director, MI

Maria Pia Morelli, M.D. ⁴	2006-2009	Research Faculty, MDACC
D. Ross Camidge, M.D., Ph.D.	2005-present	Associate Professor, UC Denver, CO
Jennifer Spratlin, M.D.	2006-2008	Assistant Professor, University of Alberta, Canada
Sujatha Nallapareddy, M.D.	2007-2009	Private practice and Clinical Faculty, UCD
Erica Bradshaw-Pierce, Ph.D.	2007-present	Instructor, School of Pharmacy
Jennifer Diamond, M.D. ¹	2008-present	Assistant Professor, UC Denver, CO
Brian Harry	2008-2011	M.D./Ph.D. student, UC Denver, CO
Anna Spreafico, M.D.	2009- 2012	Phase I Fellow, Princess Margaret Hospital, Toronto, CA
Lindsey Micel, M.D.	2010-2012	Assistant Professor, UCD
Arvind Dasari, M.D.	2010-2011	Assistant Professor, MDACC
Ellie Im, M.D.	2010-2011	Pharmaceutical Industry, NY
Daniel Pollyea, M.D. ^{2, 5}	2011-present	Assistant Professor, UCD
Elizabeth Riley, M.D.	2011-present	Medical Oncology Fellow, UCD
Lindsey Davis, M.D.	2012-present	Medical Oncology Fellow, UCD

¹ NCI K12 recipient where Dr. Eckhardt was mentor

² NIH Loan Repayment Program where Dr. Eckhardt was mentor

³ JCO Young Investigator of the Year Award

⁴ AACR Lisa Dubow Fellowship in Colorectal Cancer

⁵ ASCO Career Development Award

ROBERT ALAN FIGLIN, M.D., F.A.C.P.

CURRICULUM VITÆ

PERSONAL DATA

Place of Birth: Philadelphia, Pennsylvania

Business Address: Samuel Oschin Comprehensive Cancer Institute
Cedars Sinai Medical Center
8700 Beverly Blvd.
Suite 1S28
Los Angeles, California 90048

Business Telephone: (310) 248-6728
(310) 248-6736 (Executive Assistant, Kim Morgan)

Business Fax: (310) 659-3928

E-Mail: Robert.Figlin@cshs.org

Personal Information: Spouse: Karen Lynn Reckamp M.D.
Children: Jonathan Blanchard Figlin
Zachary Hayden Figlin

EDUCATION

Pre-professional

High School: Central High School
Philadelphia, Pennsylvania 1966

College: Temple University
Philadelphia, Pennsylvania
B.A. Degree, Chemistry 1970

Graduate School: Temple University
Philadelphia, Pennsylvania
Inorganic Chemistry, 1972

Medical School: Medical College of Pennsylvania
Philadelphia, Pennsylvania, 1976

PROFESSIONAL

1976-79 Internal Medicine, Cedars-Sinai Medical Center, Los Angeles, CA
1979-80 Chief Medical Resident, Cedars-Sinai Medical Center, Los Angeles, CA
1980-82 Fellowship, Hematology-Oncology, David Geffen School of Medicine at
University of California, Los Angeles, CA.

ACADEMIC APPOINTMENT

2013- Deputy Director
Samuel Oschin Comprehensive Cancer Institute
Cedars-Sinai Medical Center
Los Angeles, California
2012- Steven Spielberg Family Chair in Hematology-Oncology
Samuel Oschin Comprehensive Cancer Institute
Cedars-Sinai Medical Center
Los Angeles, California
2011- Professor of Biomedical Sciences
Department of Biomedical Sciences
Division of Cancer Biology
Cedars-Sinai Medical Center
Los Angeles, California
2011- Professor of Medicine
Department of Medicine
Cedars-Sinai Medical Center,
Los Angeles, California
2010-12 Associate Director, Academic Programs
Samuel Oschin Comprehensive Cancer Institute
Cedars-Sinai Medical Center,
Los Angeles, CA.
2010- Chair, Division of Hematology Oncology
Department of Medicine,
Cedars-Sinai Medical Center,
David Geffen School of Medicine at UCLA,
Los Angeles, CA.
2007-9 Interim Director, City of Hope Comprehensive Cancer Center
City of Hope and Beckman Research Institute,
Duarte, CA.
2006-10 Chair, Department of Medical Oncology and Therapeutics Research
City of Hope and Beckman Research Institute,
Duarte, CA

- 2006-10 Arthur and Rosalie Kaplan Professor of Medical Oncology
City of Hope and Beckman Research Institute,
Duarte, CA.
- 2006-9 Associate Director for Clinical Research
City of Hope Comprehensive Cancer Center
City of Hope and Beckman Research Institute,
Duarte, CA
- 2006- Professor of Medicine and Urology, Emeritus
David Geffen School of Medicine, UCLA
- 2005-06 Co-Director, Lung Cancer Research Program,
Jonsson Comprehensive Cancer Center,
David Geffen School of Medicine, UCLA
- 2000-06 Professor of Clinical Urology,
David Geffen School of Medicine at UCLA
Division of Urologic Oncology, Department of Urology
- 2000-06 Henry Alvin and Carrie L. Meinhardt Chair in Urologic Oncology
David Geffen School of Medicine at UCLA,
Los Angeles, CA.
- 1998-01 Director - Solid Tumor Developmental Therapeutics Program,
Jonsson Comprehensive Cancer Center, UCLA
- 1997-98 Director - Solid Tumor Oncology Program,
Jonsson Comprehensive Cancer Center, UCLA
- 1996-97 Associate Director - Solid Tumor Oncology Program,
Jonsson Comprehensive Cancer Center, UCLA
- 1995-06 Medical Director - Genitourinary Oncology,
Departments of Medicine and Surgery,
Divisions of Hematology/Oncology and Urology,
UCLA School of Medicine
- 1994-06 Medical Director - Thoracic Oncology Program,
Departments of Medicine and Surgery,
Divisions of Hematology/Oncology and Thoracic Surgery,
UCLA School of Medicine
- 1994-06 Professor of Medicine,
Division of Hematology-Oncology,
Department of Medicine
David Geffen School of Medicine at UCLA
- 1994-95 Medical Director, University of California
Preferred Oncology Networks of California
- 1993-98 Director, Clinical Research Unit
Jonsson Comprehensive Cancer Center, UCLA
- 1993-95 Co-Director, Oncology Program Area
Division of Hematology-Oncology,
Department of Medicine, UCLA

- 1992 -03 Director, Hematology/Oncology Fellowship Program
Division of Hematology-Oncology,
Department of Medicine, UCLA
- 1990-92 Director, Bowyer Oncology Center
Director, Outpatient Clinical Research Unit
Jonsson Comprehensive Cancer Center, UCLA
- 1989-95 Executive Board, UCLA Medical/Surgical Oncology Center
- 1988-94 Associate Professor of Medicine,
Division of Hematology-Oncology, Department of Medicine
UCLA School of Medicine,
- 1985-90 Assistant Director, Bowyer Multidisciplinary Oncology Clinic,
Jonsson Comprehensive Cancer Center, UCLA
- 1982-88 Assistant Professor of Medicine,
Division of Hematology-Oncology, Department of Medicine
UCLA School of Medicine,

MEDICAL LICENSES

- 1983 Diplomate, American Board of Medical Oncology
- 1979 Diplomate, American Board of Internal Medicine
- 1977 Diplomate, National Board of Medical Examiners
- 1976 Medical Licensure, State of California - #G35300

MEMBERSHIP IN PROFESSIONAL SOCIETIES

- 2011- Association of Community Cancer Centers
- 2010- Association of American Cancer Institutes
- 2010- Samuel Oschin Comprehensive Cancer Institute
- 2006-10 City of Hope Comprehensive Cancer Center
- 2006-10 National Comprehensive Cancer Center Network
- 2000- American Urological Association
- 1995- International Association for the Study of Lung Cancer
- 1990- Association of Subspecialty Professors
- 1985- Fellow, International Society for Biologic Therapy
/Society for Immunotherapy of Cancer
- 1985- Fellow, American College of Physicians
- 1980- American Society of Clinical Oncology
- 1982- American Association for Cancer Research

MEMBERSHIP IN NATIONAL COOPERATIVE GROUPS

2010-	Southwest Oncology Group/Cedars-Sinai Medical Center Genito-Urinary Committee
2009-10	National Comprehensive Cancer Network – Oncology Best Practices Executive Planning Committee
2008-09	National Comprehensive Cancer Network – Board of Directors
2006-10	National Comprehensive Cancer Network/City of Hope Non-Small Cell Lung Cancer Panel, 2006-08. Kidney/Testicular Cancer Panel, 2006-10.
2006-10	Southwest Oncology Group/City of Hope Lung Committee, 2006-10 Genito-Urinary Committee, 2006-10
2000-06	American College of Surgeons Oncology Group/UCLA
1990-03	Southwest Oncology Group/UCLA Principal Investigator, 1990-2000 Member: Board of Governors, 1990-2000 Lung Committee, 1990-2003 Genito-Urinary Committee, 1990-2003 Molecular Therapeutics, 2000-2003
1988-93	Eastern Cooperative Oncology Group, Co-Principal Investigator/UCLA Member: Genito-Urinary Committee Kidney Cancer Subcommittee
1982-89	Lung Cancer Study Group, Co-Principal Investigator/UCLA Member: Executive Board

EDITORIAL SERVICES

2013	Guest Editor	New Drugs and Targets for Renal Cell Carcinoma, (ed: Figlin R.A.)The Cancer Journal: The Journal of Principles & Practice of Oncology, Lippincott Williams & Wilkins, Hagerstown, MD.
2014	Editor	Renal Cell Carcinoma: Molecular Targets and Clinical Applications, Third Edition (eds: R.Bukowski, R.A. Figlin , R.Motzer), Springer Science-Clinical Medicine, New York, NY.
2012	Editor	Renal Cell Carcinoma: Translational Biology, Personalized Medicine, and Novel Therapeutic Targets, (eds: Figlin, R.A. , Rathmell, W.K., Rini, B., Springer-Cancer Research, New York., NY.
2011	Guest Editor	EMonograph: Optimizing the Use of Novel Targeted Agents for the Treatment of Patients with Renal Cell Carcinoma, Center for Biomedical Continuing Education Irving, Texas.

2010-2009	Editor-In-Chief Editor	Oncology Business Review, Sausalito, CA. Renal Cell Carcinoma: Molecular Targets and Clinical Applications, 2 nd edition (eds: R.Bukowski, R.A. Figlin , R.Motzer), Humana Press, Inc., Totowa, NJ., USA.
2007	Guest Editor	Innovations and Challenges in Renal Cancer, Proceedings of The Second Cambridge Conference, <u>Clin Cancer Res</u> , 13(2): 667s-780s, 2007.
2007-10	Senior Editor	Kidney Cancer Journal International Genitourinary Publishing, Westhampton Beach, NY.
2007-	Editorial Board	Clinical Advances in Hematology & Oncology
	Section Editor	
2006	Editor	Seminars in Oncology, “Renal Cell Carcinoma” W.B. Saunders Company, Philadelphia, PA
2005	Editor	Controversies and Consensus in Kidney Cancer Genitourinary Publishing, Westhampton Beach, NY.
2005-6	Editor in Chief	Bladder Cancer Journal, Genitourinary Publishing Westhampton Beach, NY.
2004-8	Section Editor	Faculty of 1000 Medicine, Kidney Cancer
2003-	Editor	Kidney Cancer Journal, Genitourinary Publishing Westhampton Beach, NY.
2003	Editor	Cancer Treatment and Research Book Series: Kidney Cancer, Kluwer Academic Publishers
2003	Editor	Renal and Adrenal Tumors (eds A. Belldegrun, A. Ritchie, R. Figlin , T. Oliver, ED Vaughn) Oxford University Press, Oxford, England
1997-9	Editorial Board	Cancer Therapeutics
1997-	Editorial Board	Cancer Biotherapy and Radiopharmaceuticals
1996	Editor	Seminars in Oncology, “Evolving Clinical Applications of Hematopoietic Growth Factors” W.B. Saunders Company, Philadelphia, PA.
1995	Editor	Seminars in Oncology, “Renal Cell Carcinoma” W.B. Saunders Company, Philadelphia, PA.
1994-5	Editor	UCLA/JCCC Cancer Trials
1993-4	Editor	The Kidney Cancer Journal
1992-5	Affiliate Editor	Current Clinical Trials
1988-90	Editor	Interferons and Cytokines
1988-92	Associate Editor	Biotherapeutics and Cancer
1990-4	Editorial Board	UCLA Cancer Trials Newsletter

APPOINTMENTS

- 2014 NCI, Special Emphasis Panel/Scientific Review Group 2014/08
ZCA1 RPRB-M (A1): Provocative Questions B, D, and E (RO1 and R21)
Rockville, MD.
- 2014- Memorial Sloan-Kettering Cancer Center, Kidney Cancer SPORE,
External Advisory Board
- 2014 NCI IRG, Subcommittee A (parent committee), Cancer Centers,
Temporary Member, January, 2014, Bethesda, MD.
- 2013 NCI, Special Emphasis Panel/Scientific Review Group 2014/01
ZCA1 RTRB-Z (J1) Omnibus R03/R21: Tumor Immunology,
Rockville, MD.
- 2013 NCTN-Network Lead Academic Participating Sites Review
Member, July, 2013, Bethesda, MD.
- 2013 NCI IRG, Subcommittee A (parent committee), Cancer Centers,
Temporary Member, May, 2013, Bethesda, MD.,
- 2013 2nd Nanomedicine for Imaging and Treatment Conference, *Faculty/Session*
Chair, Cedars-Sinai Department of Neurosurgery and Samuel Oschin
Comprehensive Cancer Institute, Los Angeles, California.
- 2013 Oncology Exchange; Challenges in Treating Renal Cell Carcinoma
In the Community, *Chairperson*, Potomac Center for Medical
Education, Columbia, Maryland.
- 2013- AACR Cancer Biostatistics Workshop: *Organizing Committee*
- 2013 NCI, Special Emphasis Panel/Exploratory/Development Research Grant
ZCA1 RTRB-Z (O1), Tumor Immunology RO3/R21, Rockville, MD
- 2012 European Research Council, *Scientific Review Committee*, FP7 “Ideas”
Specific Programme
- 2012- American Association for Cancer Research - Kure It Grant for Kidney Cancer
Research, *Scientific Review Committee*.
- 2012- Galena Biopharma; *Scientific Advisory Board*, Lake Oswego, OR.
- 2012 Exploring the Implications of New Data on Established and Emerging
Therapies for Advanced Renal Cell Carcinoma: *Faculty*, Penn State
College of Medicine and Peer Review Institute for Medical Education,
May, 2012.
- 2012 California Healthcare Institute: Uniting Science and Policy to Advance Cancer
Care, *Featured Speaker*, “The State of Cancer Research in the Golden
State”, UCLA, Los Angeles, CA., July 12, 2012.
- 2012 NCI IRG, Subcommittee A (parent committee), Cancer Centers,
Temporary Member, May, 2012, Bethesda, MD.,
- 2012- InVentiv Medical Advisory Group, *Member*, Inventiv Medical & Scientific
Communications Group, Irving, Texas.
- 2012- Cedars-Sinai Virtual Tumor Board Series: Chronic Myelogenous
Leukemia, A Web-Based CME-Certified Curriculum, *Course Director*,
Los Angeles, California.

- 2012 New Therapeutics in Oncology – The Road to Personalized Medicine, Course Co-Director, *Organizing Committee, Faculty*, Samuel Oschin Comprehensive Cancer Institute, Cedars-Sinai Medical Center Los Angeles, CA, October 2012.
- 2012 NCI Scientific Review Group, P30, University of Hawaii Cancer Center/ University of Hawaii at Manoa, Honolulu, Hawaii, February 2012.
- 2012 The Center for Biomedical Continuing Education; The Individualized Treatment for Patients with Renal Cell Carcinoma: Bridging the Gap Between Evidence and Clinical Practice, *Chairman/Faculty*.
- 2012 American Urologic Association, Kidney Cancer: Advanced and Localized, Disease, *Abstract Review Team Member*, Atlanta, Georgia.
- 2011 California Healthcare Institute, “Shifting Sands: Forces Reshaping the Biomedical Innovation Business Model”, *Faculty*, San Francisco, CA.
- 2011 10th International Kidney Cancer Symposium, *Faculty/Moderator/Presenter*, Progressive Disease after Front-Line VEGF Therapy, Clinical Rationale for Sequential Treatment, Chicago, Ill. October, 2011.
- 2011 Clinical Applications of Targeted Therapy in Metastatic Renal Cell Carcinoma, a Grand Rounds, Morning Reports, and Expert Commentary Educational Series, *Faculty*, Quintiles, Hawthorne, NY.
- 2011 NCI IRG, Subcommittee A (parent committee), Cancer Centers, *Temporary Member*, August, 2011, Bethesda, MD.,
- 2011- NCI Genitourinary Steering Committee – *ad hoc member*
- 2011 NCI Scientific Review Group, P30, Dana-Farber/Harvard Cancer Center, Boston, MA. June, 2011.
- 2011- “Kure It” Cancer Research Foundation, *Board of Directors*
- 2011 American Society of Clinical Oncology, Genitourinary Cancer Symposium Identifying Risk Status, Selecting Therapy, and Limiting Side Effects in Renal Cell Carcinoma, Chair, Prova Education, Orlando, Florida., 2/18/11.
- 2011 American Society of Clinical Oncology, Genitourinary Cancer Symposium Multidisciplinary Assessments in Advanced Renal Cell Carcinoma: Translating Evidence into Practice, *Faculty*; Orlando, Florida., 2/17/11.
- 2011 American Urologic Association, Kidney Cancer: Advanced and Localized, Team 27A/30, *Abstract Review Team Member*, Washington, DC. 2011.
- 2010 NCI IRG, Subcommittee A (parent committee), Cancer Centers, *Temporary Member*, December, 2010, Bethesda, MD.,
- 2010 Ninth International Kidney Cancer Symposium, *Faculty Moderator*, Agents in the Renal Cell Carcinoma Pipeline, Chicago, Ill. October, 2010.
- 2010- *External Advisory Board Committee*, Roswell Park Cancer Institute. and Johns Hopkins University, Kidney SPORE, October, 2010, Lewiston, NY.
- 2010 NCI Scientific Review Group, P30, Penn State Hershey Cancer Institute, Penn State University, Hershey, Pennsylvania, September, 2010.
- 2010- *Program Planning Committee*, 2011 Clinical and Translational Research Workshop, Cedars-Sinai Medical Center, Samuel Oschin Comprehensive Cancer Institute, July 25-29, 2011, Los Angeles, CA.

- 2010 *Chairperson*, Molecular Pathways and Clinical Applications in Advanced Renal Cell Carcinoma, The Virtual Preceptorship, Quintiles Continuing Medical Education, Hawthorne, NY.
- 2010- Internet Oncology Congress, *Education Committee*, MedCases, Princeton, NJ.
- 2010 Clinical Immunotherapy Guidelines (CIG) Task Force, International Society For Biologic Therapy of Cancer
- 2010 NCI Program Project (PO1) Clinical Studies Special Emphasis Panel Review Committee, Washington, DC. June 2010.
- 2010 *Chairperson*, Improving Outcomes in Prostate and Renal Cell Carcinoma, AUA Annual Meeting, Satellite Symposium, San Francisco, CA. June, 2010.
- 2010 *Faculty*, Recent Advances in Diagnosis and Management of Kidney Cancer, AUA Annual Meeting, Course 691C, San Francisco, CA. June, 2010.
- 2009-10 *Chair*, Advances in Targeted Molecular Therapy for Renal Cell Carcinoma: Evolving Therapeutic Paradigms, The Center for Biomedical Continuing Education, National Program.
- 2009 *Co-Chair*, Renal Cell Cancer: Update, Conversations with Oncology Investigators, Bridging the Gap between Research and Patient Care, Research to Practice, Miami, Fl., September 2009.
- 2009-10 *Co-Chair*, Advanced Renal Cell Carcinoma: Molecular Pathways and Clinical Applications, National Program.
- 2009 *Chair*, Merging and Directing Traffic: Exploiting the Biology of Renal Cell Carcinoma, AUA, Chicago, IL., April, 2009.
- 2009 *Chair*, National Comprehensive Cancer Network Temsirolimus Scientific Review Committee, Pasadena, CA. February 2009.
- 2009 *Executive Planning Committee*, National Comprehensive Cancer Network Best Practices Conference (formerly the Ethics and Compliance in Oncology Research Conference), October 2009.
- 2009 *Co-Chair*, Critical Choices for Improving Outcomes in Renal Cell Carcinoma, ASCO, Orlando, Florida, May, 2009.
- 2009 *Chair*, Exploiting the Biology of Renal Cell Carcinoma: From the Laboratory to Practice, ASCO GU, Orlando, Florida. February 2009.
- 2009 *Chair*, Targeted Therapies for Advanced Renal Cell Carcinoma: New Standards of Care, ASCO GU, Orlando, Florida. February 2009.
- 2008-9 AACR Cancer Biostatistics Workshop: Developing Targeted Agents, Scientific Program Committee, Faculty, Sonoma, CA.
- 2008-10 STOP CANCER – *Research Awards Committee*
- 2008 NCI, Cancer Center Support Grant, P30, The University of Texas MD Anderson Cancer Center, Houston, Texas, February, 2008.
- 2008- Lung Cancer Foundation of America, *Board of Directors*
- 2007 *Chair*, Biomarkers and New Therapeutic Targets for Renal Cell Carcinoma, Sixth International Kidney Cancer Symposium, Chicago, Ill., October 2007.
- 2007-08 Dorothy P. Langdon – AACR Prize for Translational Cancer Research, *Selection Committee*, American Association for Cancer Research, Philadelphia, PA.

- 2007- Wayne D. Kuni & Joan E. Kuni Foundation, *Scientific Review Panel*,
Vancouver, Washington.
- 2007 *Chair*, Biology and Targeted Therapy for Advanced Renal Cell Carcinoma,
Amarican Society of Clinical Oncology, Annual Meeting, Chicago, Ill.,
June, 2007.
- 2007 *Chair*, Local Liason Committee, American Association for Cancer
Research, Annual Meeting, Los Angeles, CA.
- 2007 *Judge*, Undergraduate Student Caucus and Poster Competition, American
Association for Cancer Research, Annual Meeting, Los Angeles, CA.
- 2007 *Co-Chair*, City of Hope 1st Annual Conference on New Technologies and
Innovative Strategies for Genitourinary Malignancies, San Diego, CA.
- 2007 *Co-Chair*, Novel Targets, 7th Annual Targeted Therapies of the Treatment of
Lung Cancer, International Association for the Study of Lung Cancer, Santa
Monica, California, February, 2007.
- 2006 NIH, P30 Cancer Center Site Visit – H. Lee Moffitt Cancer Center and
Research Institute, Tampa, Florida, June 2006.
- 2006 *Chair*, Clinical Trial Design in Translational Research,
14th Annual SPORE Investigator’s Workshop, Baltimore, Maryland,
July, 2006.
- 2005- Phase One Foundation - *Chairman*, Scientific Advisory Board, Los Angeles.
2005 American Association of Cancer Research, Workshop in Cancer Biostatistics,
Planning Committee, July, 2008.
- 2005- *External Reviewer* – National Cancer Institute, Cancer Treatment Evaluation
Program, Phase 3 Clinical Trials.
- 2005 *Chairman*, Biomarkers in Renal Cell Carcinoma – The Fourth International
Kidney Cancer Symposium, Chicago, Illinois, October, 2005.
- 2005 *Chairman*, Advances in Targeted Molecular Therapies for Renal Cell
Carcinoma – The Fourth International Kidney Cancer Symposium, Chicago,
Illinois, October, 2005.
- 2005 *Chairman*, Immunotherapy and Emerging Therapies for Metastatic Renal
Cell Carcinoma and Metastatic Melanoma, Scottsdale, AZ.
- 2005 NIH, P30 Cancer Center Site Visit – University of Colorado Comprehensive
Cancer Center, Denver, Colorado, June, 2005.
- 2004 University of California, Irvine: *Ad Hoc Review Committee*
Committee on Academic Promotions
- 2004-07 National Kidney Cancer Association
Chairman, Corporate Relations Committee
- 2004-07 *Planning Committee*, International Congress on Kidney and Bladder
Cancer, Orlando, Florida.
- 2004 *Organizing Committee*, Genitourinary Malignancies: Translating Laboratory
Discoveries into Clinical Realities, University of Iowa, Iowa City, Iowa,
June 2004.
- 2003 Heinrich Warner Foundation Symposium: Renal Cell Carcinoma: Progress
in Basic Research, Diagnosis, Surgical and Medical Therapy, *Chairman*:
Therapeutic Approaches, Hamburg, Germany, October 2003.

- 2003 NIH, PO1 Program Grant, Site Visit - RNA Loaded Dendritic Cells for Urologic Malignancies, Duke University, Durham, NC, September 2003.
- 2003 University of California, Irvine: Office of Research & Graduate Studies, *Conflict of Interest Oversight Committee*, Irvine, CA, August 2003.
- 2003 NIH, PO1 Program Grant, Site Visit - RNA Loaded Dendritic Cells for Urologic Malignancies, Duke University, Durham, NC, January 2003.
- 2002 International Conference on Staging of Renal Cell Carcinoma, Lyon, France, October 2002
- 2001 Second International Kidney Cancer Symposia
Chair: Novel Approaches: Advanced Disease
Chicago, Illinois, October 2001
- 2001 NCI-Kidney and Bladder Cancer Review Group
Virginia, November 28-30, 2001
- 1998-00 *Faculty/Co-Director*, Joint ASCO/AACR Workshop: Methods in Clinical Cancer Research, Vail, CO.; '98, '99, '00.
- 1998 Cancer Initiative 2000; The Institute for Continuing Healthcare Education.
- 1997 *Scientific Committee*: Fourth International Symposium: EORTC; Biologic Therapy of Cancer - From Basic Research to Clinical Application
Munich, Germany, June 11-14, 1997.
- 1997 *Chairman*, Hematopoiesis and Cytokines/Growth Factors Session:Fourth International Symposium: EORTC; Biologic Therapy of Cancer From Basic Research to Clinical Application, Munich, Germany, June 11-14, 1997.
- 1997 *Chairman*, Society of Biologic Therapy's 12th Annual Scientific Meeting: Molecular Approaches To The Biotherapy of Cancer, Pasadena, California, October 22-25, 1997.
- 1997 *Chairman*, Site Visit - National Cancer Institute: Surgery Branch, Bethesda, Maryland.
- 1996 *Presidents Cancer Panel*-Managed Care's Role in the War on Cancer
Fred Hutchinson Cancer Center, Seattle, Washington, July 30, 1996.
- 1994-96 National Cancer Institute-*Planning Committee*
Renal Carcinoma: Recent Progress and Future Directions.
A National Cancer Institute Supported Symposium,
Washington, D.C., September 19-21, 1996.
- 1994- National Cancer Institute
PDQ *External Advisory Board*
- 1993-09 National Kidney Cancer Association
Medical Advisory Board
- 1991-94 University of California
Cancer Research Coordinating Committee
- 1991 National Cancer Institute
Special Emphasis Panel: "Autologous Marrow Transplantation"
Fred Hutchinson Cancer Center, Seattle, Washington
- 1990-92 Food and Drug Administration
Biologic Response Modifier Advisory Committee, *Consultant*

1989-97 Society for Biologic Therapy
 Program and Publications Committee

Cedars-Sinai Medical Center/Samuel Oschin Comprehensive Cancer Institute

2014- Beacon Steering Committee, Co-Chair
2014- Ambulatory Leadership Committee
2014- Investigator Initiated Trials, Mentoring Committee, Chair
2013- Senior Leadership Committee (SOCCI)
2013- Paul Rubenstein MD Prize for Excellence in Resident Research,
 Review Committee
2012- Cancer Grants Workshop, Faculty
2012- Cancer Quality Committee, Member
2012- Clinical Research Office Advisory Board, Member
2012-13 Personalized Medicine Task Force
2012- Faculty Based Clinical Programs Growth Initiative, Advisory Committee
2012- Protocol Prioritization Committee, Chair
2012-13 Urologic Oncology Center of Excellence, Member
2012- Developmental Funds Committee, Chair
2011- Clinical Research Pharmacy Strategic Planning Committee, Co-Chair
2011-13 Personalized Advanced Care Team – Organizing Committee
2011 Department of Medicine, Nominating Committee, Performance Improvement
 Committee
2011-12 Martz Translational Breast Cancer Research Fund Committee, Chair
2011- Clinical and Translational Research Workshop, Faculty/Mentor
2011- Clinical Scholars Grant Review Committee
2011 Continuing Medical Education, Strategic Planning Committee
2011- SOCCI, Program Development Committee, Chair
2011 Personalized Medicine Working Group
2011- SOCCI, Membership Committee
2011-13 Enhanced Services Working Group, SOCCI, Chair
2011 Cancer Survivor Day, Master of Ceremony and Featured Speaker
2010-11 Urology, Center of Excellence, Member
2010-11 Complementary, Alternative, and Integrative Medicine Task Force, Chair
2010- Clinical Scholars Advisory Committee
2010- Department of Medicine: Performance Improvement Committee
2010-11 Phase 1 Steering Committee,
2010- Cancer Institute Executive Committee (SOCCI)
2010-11 Director, Experimental Therapeutics, Search Committee, Co-Chair
2010- 12 Director GI Oncology, Search Committee

City of Hope National Medical Center and Beckman Research Institute

2009-10	Radiology Chair, Search Committee
2009-10	GMP Governance Board, Chair
2008-9	Research Conflict of Interest Committee, Chair
2008-9	Senior Leadership Council
2008- 9	Director, Department of Biomedical Informatics, Search Committee
2008-10	Sheri & Les Biller Family Resource Center, Advisory Board
2007-9	Executive Team
2007-10	Clinical Information System, Research Advisory Board
2007-10	Clinical Information System, Physician Advisory Board
2007-09	Charity Care Policy Committee
2007-10	Pediatrics Chair Search Committee
2007-09	Clinical Immunobiology Correlative Studies Laboratory, Advisory Committee
2006-08	Clinical Research Governance Board, Chair
2006-09	Medical Executive Committee
2006-09	Committee of Chairs
2006-07	Clinical and Scientific Executive Team
2006-08	Ad Hoc Hospitalist Committee
2006-08	Surgery Chair, Search Committee

City of Hope Medical Group/ California Cancer Specialists, Inc.

2010	Finance Committee
2007-8	Business Development Committee
2006-8, '09	Board of Directors

UCLA General Campus/UCLA School of Medicine*

2011-	System Based Health Care/Doctoring 3, Faculty
2006	Chair - Dean, School of Dentistry, Five Year Advisory Review Committee*
2006	Member, Campus Ad Hoc Review Committee*
2005-06	Enterprise Business Development and Outreach Group*
2005-06	Clinical Research – Private IRB Working Group
2005-06	Clinical Research Infrastructure Focus Group*
2005	Chair, Campus Ad Hoc Review Committee*

2004-06	Advisory Committee, Adverse Event Reporting, Office of Protection of Research Subjects*
2004-06	Clinical Research Steering Committee*
2004-05	Compensation for IRB Membership/Human Research Policy Board*
2004-07	Legislative Assembly Committee/Academic Senate
2004	Search Committee, Thoracic Surgery*
2004	Clinical Research Working Group*
2003	Campus Ad Hoc Review Committee, Review and Appraisals
2003-05	UCLA Healthcare Strategy Committee*
2003-04	Task Force: Community Based Clinical Research Networks II
2002-06	Prostate Cancer SPORE: Developmental Program Committee-Chair*
2002-06	K30 External Advisory Board*
2001-06	Medical Science College Foundations Week*
2001-08	Lung Cancer SPORE: Executive Committee*
2001-03	HIPAA Implementation Steering Committee-Research*
2001-02	Clinical Trials/Subject Injury Policy*
2001-02	Task Force: Community Based Clinical Research Networks I
2001-02	Task Force: Financial Conflicts of Interest and Clinical Research
1999-00	Non-Intellectual Property: Substance, Distribution, and Sale
1998- 06	Advisory Committee: VA Program in Gene Medicine*
1998	Campus Ad Hoc Review Committee
1998-00	Co-Chair, Eastside Master Planning Committee on Clinical Research*
1998-06	Human Research Policy Board
1998-06	Institutional Review Board - Chairman
1998-05	Board of Governors: Clinical Trials Office*
1998-99	Cancer Prevention Consensus Panel*
1997-02	Committee on Clinical Trials*
1997-98	Bridge Grant Review Committee
1997-98	Master Planning II: Clinical Effectiveness Task Force*
1997-98	Master Planning II: Clinical Research User Work Group*
1996-98	AFMR Representative*
1996-97	Clinical Trials Working Group*
1995-98	Institutional Review Board
1994-95	Clinical Effectiveness Committee*
1992-97	Clinical Research Center Advisory Committee – Chairman*
1991	Clinical Research Center Advisory Committee*
1988-90	Medical Records Task Force*
1987-96	Medical Records Committee – Chairman*
1986-96	Hospital Cancer Committee*

UCLA Jonsson Comprehensive Cancer Center

2005-6 Co-Director – Lung Cancer Research Program
2002-5 Tissue Array Core: Scientific Advisory Committee
2002-5 Bioinformatics Working Group
2002-5 Advisory Board, Ted Mann Family Resource Center
1998-01 Director, Solid Tumor Developmental Therapeutics Program
1997-98 Director, Solid Tumor Oncology Program
1995-5 Clinical Research Advisory Committee
1994-5 Medical Education Committee
1993-7 Leadership Advisory Committee
1993-5 Tumor Registry
1993-5 Scientific Peer Review Committee
1988-02 Clinical Programs
1985-92 Clinical Research Advisory Committee
1985-92 Clinical Studies Review Committee

UCLA Department of Medicine

1995-98 STAR Program-Candidate Study Section Committee
1995-96 Search Committee-Hematology/Oncology;
Director, Chemoprevention Program
1995-99 Appointments and Promotions
1995-96 Committee on Clinical Investigation - Chairman
1991-92 Physician Business Affairs Committee
1990-92 Physician Billing Task Force

HONORS AND AWARDS

2013 International Kidney Cancer Association Research Award
2010 Outstanding Alumni Clinician Award, Drexel University College of Medicine
2001 Stop Cancer Award, UCLA/Jonsson Comprehensive Cancer Center
1998- Who's Who in Science and Engineering
1997- Who's Who in the World
1997- Who's Who in Medicine and Healthcare
1996- Who's Who in America
1996-01 Who's Who in the West
1994- Best Doctors in America/Top Doctors for Cancer
1991 State of California Legislature Resolution
the UCLA/Kern Cancer Program
1991 Fellowship, American College of Physicians
1984-86 American Cancer Society Junior Faculty Fellowship, UCLA
1982 Richard F. Dwyer-Eleanor W. Dwyer Award, UCLA

1981-82 American Cancer Society Clinical Fellowship, UCLA
1973-74 AOA Research Award, Medical College of Pennsylvania

INVENTIONS AND PATENTS

“Methods for Enhancing Antigen-Presenting Cells and Anti-Tumor Responses in a Human Patient,” Inventors: Michael D. Roth, **Robert A. Figlin**, Sylvia M. Kiertscher, Barbara J. Gitlitz. United States Patent 6,838,081, January 4, 2005.

REVIEWED PAPERS

1. Weiss, B., Fertel, R., **Figlin, R.A.**, Uzunov, P. Selective alteration of the activation of the multiple forms of cyclic 3'5'-AMP phosphodiesterase of rat cerebrum, Molecular Pharmacology, 10:615-625, 1974.
2. Sarna, G., **Figlin, R.A.**, McCarthy, S., Phase I Study of Wellferon (Human Lymphoblastoid Alpha-interferon) as Cancer Therapy: Clinical Results. Journal of Biologic Response Modifiers, 2:187-195, 1983.
3. **Figlin, R.A.**, Callaghan, M., Sarna, G. Phase II Trial of Alpha Human Leukocyte Interferon Administered Daily in Adenocarcinoma of the Colon/ Rectum. Cancer Treatment Reports, 67:493-494, 1983.
4. Sarna, G., **Figlin, R.A.**, Callaghan, M. Alpha (Human Leukocyte) Interferon as Treatment for Non-small Cell Carcinoma of the lung: A Phase II Trial. Journal of Biologic Response Modifiers, 2:4, 1983.
5. **Figlin, R.A.**, Moriguchi, J., Coffey, R., Oi, S. Kaposi's Sarcoma and Immunoblastic Sarcoma in a Male Homosexual with the Acquired Immunodeficiency Syndrome. JAMA, 251:3, 1984.
6. Territo, M., Sarna, G., **Figlin, R.A.**, Effect of *in vivo* Administration of Interferon on Human Monocyte Function. Journal of Biologic Response Modifiers, 2:450-457, 1983.
7. deKernion, J.B., Sarna, G.P., **Figlin, R.A.**, Linder, A., Smith, R.B. The Treatment of Renal Cell Carcinoma with Human Leukocyte (alpha) Interferon. Journal of Urology, 130:1063-1066, 1983.
8. Sarna, G., Mitsuyasu, R., **Figlin, R.A.**, Ambersley, J., Groopman, J. Oral Vinzolidine as Therapy for Kaposi's Sarcoma, and Carcinomas of Lung, Breast, and Colon/Rectum. Cancer Chemotherapy and Pharmacology, 14:12-14, 1985.
9. Sarna, G., **Figlin, R.A.**, Bryson, Y. Garratty, E., Myers, L. LeFevre, C., Mauritzson, N., Cline, M., Human Alpha-lymphoblastoid Interferon: A Phase I Study including Pharmacokinetics and effects on Hematologic Stem Cells (CFU-GMs). American Journal of Clinical Oncology, 8:406-412, 1985.
10. **Figlin, R.A.**, deKernion, J.B., Maldazys, J., Sarna, G.P., The Treatment of Renal Cell Carcinoma with Alpha (Human Leukocyte) Interferon and Vinblastine in Combination: A Phase I-II Trial. Cancer Treatment Reports, 69:263-267, 1985.
11. Sarna, G.P., **Figlin, R.A.** Phase II Trial of Alpha-Lymphoblastoid Interferon (Wellferon) Given as Treatment of Advanced Breast Cancer. Cancer Treatment Reports, 69:547-549, 1985.

12. Sarna, G.P., Pertcheck, M., **Figlin, R.A.**, Ardalan, B. Phase I Study of Recombinant β ser 17 Interferon (Betaseron) in the Treatment of Cancer. Cancer Treatment Reports, 70:1365-1372, 1986.
13. Sarna, G.P., **Figlin, R.A.**, deKernion, J. Interferon in Renal Cell Carcinoma: The UCLA Experience. Cancer, 59:610-612, 1987.
14. Sarna, G.P., **Figlin, R.A.**, Pertcheck, M. Phase II Study of Betaseron^R (β ser 17 Interferon) as Treatment of Advanced Malignant Melanoma. Journal of Biologic Response Modifiers, 6:375-378, 1987.
15. Linderman, R.A., Jenkins, J.A., **Figlin, R.A.**, Golub, S.H. Application of a New Method for Detecting the Phenotype of Target Binding Cells. Cancer Immunology and Immunotherapy, 25:153-155, 1987.
16. **Figlin, R.A.** Biotherapy with Interferon in Solid Tumors. Oncology Nursing Forum, 14(6):23-26, 1987.
17. Ganz, P.A., Haskell, C.M., **Figlin, R.A.**, LaSota, N., Siau, J., for the UCLA Solid Tumor Study Group. Estimating the Quality of Life in a Clinical Trial of Patients with Metastatic Lung Cancer Using the Karnofsky Performance Status and the Functional Living Index-Cancer. Cancer, 61:849-856, 1988.
18. **Figlin, R.A.**, deKernion, J.B., Mukamel, E., Palleroni, A.V., Itri, L.M., Sarna, G.P. Recombinant Interferon Alfa-2a in Metastatic Renal Cell Carcinoma: Assessment of Antitumor Activity and Anti-Interferon Antibody Formation. Journal of Clinical Oncology, 6:1604-1610, 1988.
19. Martinez-Maza, O., **Figlin, R.A.**, Giorgi, J.V., Fahey, J.L. Selective Decrease in Leu 8-Negative T Cell Subpopulations Following Treatment with Recombinant Interferon Alfa-2a (rIFN-2a). Cellular Immunology, 117:89-98, 1988.
20. Moldawer, N.P., **Figlin, R.A.**, Tumor Necrosis Factor: Current Clinical Status and Implications for Nursing Management. Seminars in Oncology Nursing, 4(2):120-125, 1988.
21. **Figlin, R.A.**, Piantadosi, S., Feld, R. Intracranial Recurrence of Carcinoma after Complete Surgical Resection of Stage I, II and III Non-Small Cell Lung Cancer. New England Journal of Medicine, 318(20):1300-1305, 1988.
22. **Figlin, R.A.**, Itri, L.M. Anti-Interferon Antibodies: A Perspective. Seminars in Hematology, 25(3), suppl 3:9-15, 1988.
23. **Figlin, R.A.**, Biotherapy with Interferon. Seminars in Oncology 15(6), suppl 6:3-9, 1988.
24. Sarna, G.P., **Figlin, R.A.**, Pertcheck, M., Altrock, B., Kradjian, S.A. Systemic Administration of Recombinant Methionyl Human Interleukin-2 (ala 125) to Cancer Patients: Clinical Results. Journal of Biologic Response Modifiers, 8(1):16-24, 1989.
25. Ganz, P.A., **Figlin, R.A.**, Haskell, C.M., LaSota, N., Siau, J., for the UCLA Solid Tumor Study Group. Supportive Care Versus Supportive Care and Combination Chemotherapy in Metastatic Non-Small Cell Lung Cancer: Does Chemotherapy Make a Difference? Cancer, 63(7):1271-78, 1989.
26. Hait, W.N., Morris, S., Lazo, J.S., **Figlin, R.A.**, Durivage, H.J., White, K., Schwartz, P.E. Phase I-II Trial of Combined Therapy with Bleomycin and the Calmodulin Antagonist, Trifluoperazine. Cancer Chemotherapy and Pharmacology, 23: 358-362, 1989.

27. Kuei, J., Tashkin, D., **Figlin, R.A.**, Pulmonary Toxicity of Tumor Necrosis Factor. Chest, 96:334-338, 1989.
28. Robertson, P., Ross, H., **Figlin, R.A.**, Tumor Necrosis Factor Induces Hemorrhagic Necrosis of a Sarcoma. Annals of Internal Medicine, 111:682-684, 1989.
29. **Figlin, R.A.**, Biotherapy in Clinical Practice. Seminars in Hematology, 26:(3), suppl 3:15-24, 1989.
30. Sarna, G.P., Collins, J., **Figlin, R.A.**, Robertson, P., Altrock, B., Abels, R. A Pilot Study of Intralymphatic Interleukin-2: Clinical and Biological Results. Journal of Biologic Response Modifiers, 9:81-86, 1990.
31. Berenson, J., Koga, H., Yang, J., Pearl, J., Holmes, E.C., **Figlin, R.A.**, Frequent Amplification of the Bcl-1 Locus in Poorly Differentiated Squamous Cell Carcinoma of the Lung, Oncogene, 5:1343-1348, 1990.
32. Belldgrun, A., Koo, A.S., Bochner, B., **Figlin, R.A.**, deKernion, J.B. Immunotherapy for Advanced Renal Cell Cancer: The Role of Radical Nephrectomy. European Urology, 18: (suppl 2):42-45, 1990.
33. Rusch, V.W., **Figlin, R.A.**, Godwin, D., Piantadosi, S. Intrapleural Cisplatin and Cytosine Arabinoside in the Management of Malignant Pleural Effusions. Journal of Clinical Oncology, 9:313-319, 1991.
34. Ross, H.J., Moy, L.A., Kaplan, R., **Figlin, R.A.**: Bullous Pyoderma Gangrenosum Following Granulocyte-Colony Stimulating Factor Treatment. Cancer, 68:441-443, 1991.
35. Fishman, J., Aberle, D., Moldawer, N.P., Belldgrun, A., **Figlin, R.A.**, Atypical Contrast Reactions Associated with Systemic Interleukin-2 Therapy, American J. Roentgenology, 156:833-834, 1991.
36. Abi-Aad, S., **Figlin, R.A.**, Belldgrun, A., deKernion, J.B. Metastatic Renal Cell Cancer: Interleukin-2 Toxicity Induced by Contrast Agent Injection. Journal of Immunotherapy, 10:292-295, 1991.
37. Jacobs, E.L., Salzler, M., Chopra, I.J., **Figlin, R.A.**, Thyroid Function Abnormalities Associated with the Chronic Outpatient Administration of Recombinant Interleukin-2 and Recombinant Interferon-Alpha: Journal of Immunotherapy 10:448-455, 1991.
38. **Figlin, R.A.**, Abi-Aad, A.S., Belldgrun, A., deKernion, J.B., The Role of Interferon and Interleukin-2 in the Immunotherapeutic Approach to Renal Cell Carcinoma, Seminars in Oncology, 18:(5)102-107, suppl. 7, 1991.
39. Belldgrun, A., **Figlin, R.A.**, Haas, G., deKernion, J., Immunotherapy for Metastatic Renal Cell Carcinoma, World Journal of Urology, 9:157-159, 1991.
40. Belldgrun, A., Abi-Aad, A.S., **Figlin, R.A.**, and deKernion, J.B., Renal Cell Carcinoma: Basic Biology and Current Approaches to Therapy, Seminars in Oncology, 18:(5)96-107, suppl. 7, 1991.
41. **Figlin, R.A.**, Belldgrun, A., Moldawer, N., Zeffren, J., and deKernion, J., Concomitant Administration of Recombinant Human Interleukin-2 and Recombinant Interferon Alfa-2A: An Active Regimen in Metastatic Renal Cell Carcinoma, Journal of Clinical Oncology, 10:(3)414-421, 1992.
42. **Figlin, R.A.**, Belldgrun, A., Cancer Immunotherapy Using Tumor Infiltrating Lymphocytes, Seminars in Hematology, 29:(2)33-35, Suppl.1, 1992.

43. Belldegrun, A., **Figlin, R.A.**, Danella, J., deKernion J., Immunotherapy for Renal Cell Carcinoma, Seminars in Urology, 10:(1)23-27, 1992.
44. Hofmann, B., Bass, H., Nishanian, P., Faisal, M., **Figlin, R.A.**, Sarna, G.P., Fahey, J.L. Different Lymphoid Cell Populations Produce Varied Levels of Neopterin, Beta-2 Microglobulin, and Soluble IL-2 Receptor when Stimulated with IL-2, Interferon-Gamma or Tumor Necrosis Factor-Alpha. Clinical and Experimental Immunology, 88:548-554, 1992.
45. Duckett, M.D., **Figlin, R.A.**, Belldegrun, M.D., Biological Response Modifiers in Metastatic Renal Cell Carcinoma, Current Opinion in Urology, 2:339-343, 1992.
46. **Figlin, R.A.**, Belldegrun, A., deKernion, J., "Why Oncologists Burn Out", J Clin Oncol, 10; (9), 1503, 1992.
47. Pierce, W.C., **Figlin, R.A.**, Primary Tumors of the Lung Other Than Lung Cancer, Current Opinion in Oncology, 5:343-352, 1993.
48. Whitehead, R.P., **Figlin, R.A.**, Citron, M.C., Pfile, J., Moldawer, N., Patel, D., Jones, G., Levitt, D., Zeffren, J., A Phase II Trial of Concomittant Human Interleukin-2 and Interferon -2A in Patients with Disseminated Malignant Melanoma, J of Immunotherapy, 13:117-121, 1993.
49. Belldegrun, A., Pierce, W., Sayah, D., deKernion, J., Wallach, D., Aderka, D., **Figlin, R.A.**, Soluble Tumor Necrosis Factor Receptor Expression in Patients with Metastatic Renal Cell Carcinoma Treated With Interleukin-2 Based Immunotherapy, J of Immunotherapy, 13:175-180, 1993.
50. Reissmann, P.T., Koga, H., Takahashi, R., **Figlin, R.A.**, Holmes, C.E., Piantadosi, S., Cordon-Cardo, C., Slamon, D., and the Lung Cancer Study Group, Inactivation of the Retinoblastoma Susceptibility Gene in Non-Small Cell Lung Cancer, Oncogene, 8:1913-1919, 1993.
51. Belldegrun, A., Pierce, W., Kaboo, R., Tso, C.-L., Shau, H., Turcillo, P., Moldawer, N., Golub, S., deKernion, J., **Figlin, R.A.**, Interferon Alpha-Primed Tumor Infiltrating Lymphocytes Combined with Interleukin-2 and Interferon-Alpha as Therapy for Metastatic Renal Cell Carcinoma, Journal of Urology, 150, 1384-1390, 1993.
52. Vogelzang, N.J., Lipton, A., **Figlin, R.A.**, Subcutaneous Interleukin-2 Plus Interferon Alpha-2A in Metastatic Renal Cancer: An Outpatient Multicenter Trial, J of Clinical Oncology, 11:(9)1809-1816, 1993.
53. Janik, J.E., Sznol, M., Urba, W.J., **Figlin, R.A.**, Bukowski, R.M., Fyfe, G., Pierce, W.C., Belldegrun, A., Sharfman, W.H., Smith J.W., Longo, D.L., Erythropoietin Production, A Potential Marker for Interleukin-2/Interferon-Responsive Tumors, Cancer, 72:2656-2659, 1993.
54. **Figlin, R.A.**, Pierce, W., Belldegrun, A., Combination Biologic Therapy with Interleukin-2 and Interferon-Alpha in the Outpatient Treatment of Metastatic Renal Cell Carcinoma, Seminars in Oncology, 20:(6)11-15, Suppl 9, 1993.
55. Abi-Aad, A., Stenzl, A., Figlin, R., deKernion, J., **Figlin R.A.**, deKernion, J., Local Response and Long Term Results of Preoperative M-VAC Regimen in Regionally Advanced Transitional Cell Carcinoma of the Bladder, European Journal of Cancer, 29A:8:1223-1224, 1993.

56. Abi-Aad, A., Stenzl, A., **Figlin, R.A.**, deKernion, J., Pathologic Response and Long Term Results of Preoperative M-VAC Regimen in Regionally Advanced Transitional Cell Carcinoma of the Bladder, Acta Urologica Belgica, 61:(4)13-16, 1993.
57. Hathorn, R.W., Tso, C.L., Kaboo, R., Pang, S., **Figlin, R.A.**, Sawyers, C., deKernion, and Belldegrun, A., In Vitro Modulation of the Invasive and Metastatic Potentials of Human Renal Cell Cancer by IL-2 or/and IFN- Gene(s) Transfer, Cancer, 74:(7)1904-1911, 1994.
58. Steger, G.G., **Figlin, R.A.**, Czernin, J., Kaboo, R., Pierce, W.C., deKernion, J.B., Okarma, T., and Belldegrun, A., Patterns of Cytokine Release of Unselected and CD8+ Selected Renal Cell Carcinoma Tumor Infiltrating Lymphocytes; Evidence for Enhanced Specific Killing of TNF-secreting/IL-6-Non-secreting TIL *in vitro* and correlation with complete response *in vivo*, Clinical Immunology and Immunopathology, 72:(2)237-247, 1994.
59. **Figlin, R.A.**, Piantadosi, S. A Phase III Randomized Trial of Immediate Combination Chemotherapy Versus Delayed Combination Chemotherapy In Patients With Completely Resected Stage II And III Non-Small Cell Carcinoma Of The Lung., Chest, 106:(6)310S-312S, 1994.
60. **Figlin, R.A.**, Mendoza, E., Piantadosi, S., Rusch, V. Intrapleural Chemotherapy Without Pleurodesis for Malignant Pleural Effusions; The Lung Cancer Study Group Trial 861:, Chest, 106:(6)363S-366S, 1994.
61. Pierce, W.C., Belldegrun, A., **Figlin, R.A.**, Cellular Therapy: Scientific Rationale and Clinical Results in the Treatment of Metastatic Renal Cell Carcinoma, Seminars in Oncology, 22:(1) 74-80, 1995
62. Whitehead, R.P., Hauschild, A., Christophers, E., **Figlin, R.A.**, Diabetes Mellitus in Cancer Patients Treated with Combination Interleukin-2 and Interferon, J of Cancer Biotherapy, 10:(1) 45-51, 1995.
63. Taneja, S.S., Pierce, W., **Figlin, R.A.**, Belldegrun, A., Immunotherapy for Renal Cell Carcinoma: The Era of Interleukin-2 Based Treatment, Urology, 45:(6) 911-924, 1995.
64. **Figlin, R.A.**, Non-small Cell Lung Cancer Collaborative Group: Chemotherapy in Non-small Cell Lung Cancer: A Metaanalysis Using Updated Data on Individual Patients From 52 Randomized Clinical Trials, British Medical Journal, 311:899-909, 1995.
65. Belldegrun, A., Franklin, J., **Figlin, R.A.**, Prognostic Factors in Renal Cell Carcinoma, J Urol, 154:1274, 1995.
66. Lee, J., Perez, S., Wang, H.J., **Figlin, R.A.**, Holmes, E.C., Intrapleural Chemotherapy for Patients with Incompletely Resected Malignant Mesothelioma: The UCLA Experience, J Surgical Oncology, 60:262-267, 1995.
67. Steger, G.G., Kaboo, R., deKernion, J.B., **Figlin, R.A.**, Belldegrun, A.S., The Effects of Granulocyte-Macrophage-Colony Stimulating Factor on Tumor-Infiltrating Lymphocytes From Renal Cell Carcinoma, Brit J Can, 72(1):101-107, 1995.
68. **Figlin, R.A.**, Gitlitz, B.J., Belldegrun, A., "Immunologic Approaches to the Treatment of Cancer", Cancer Investigation, 13:3, 339-340, 1995.
69. **Figlin, R.A.**, Belldegrun, A., "Renal Cell Carcinoma", Seminars in Oncology, 22:1, 1-2, 1995.

70. Levin, W.J., Press, M.F., Gaynor, R.B., Sukhatme, V.P., Boone, T.C., Reissmann, P.T., **Figlin, R.A.**, Holmes, E.C., Souza, L.M., Slamon, D.J., Expression Patterns of Immediate Early Transcription Factors in Human Non-Small Cell Lung Cancer, Oncogene, 11:1261-1269, 1995.
71. Champlin, R.E., **Figlin, R.A.**, "Evolving Clinical Applications of Hematopoietic Growth Factors", Seminars in Oncology, 23:2(4) 1, 1996.
72. Fraser, J.K., Lill, M.C.C., **Figlin, R.A.**, The Biology of the Cytokine Sequence Cascade, Seminars in Oncology, 23:2(4), 2-8, 1996.
73. Aberle, D.R., Dionisio, J.D., McNitt-Gray, M.F., Taira, R.K., Cardenas, A.F., Goldin, J., Brown, K., **Figlin, R.A.**, Chu, W.W., Integrated Multimedia Timeline of Medical Images and Data for Thoracic Oncology Patients, Radiographics, 16:669-681, 1996.
74. **Figlin, R.A.**, Gilden, R., Taylor, C., University of California: Oncology Practice Guidelines - Methodology of Practice Guidelines, The Cancer Journal from Scientific American, 2(3A):4-6, 1996.
75. Love, S., Parker, B., Ames, M., Taylor, C., Gilden, R., **Figlin, R.A.**, Practice Guidelines or Breast Cancer, The Cancer Journal from Scientific American, 2(3A):7-22, 1996.
76. Cameron, R., Fringer, J., Taylor, C., Gilden, R., **Figlin, R.A.**, Practice Guidelines for Non-Small Cell Lung Cancer, The Cancer Journal from Scientific American, 2(3A):61-68, 1996.
77. Cameron, R., Smith, N.G., Taylor, C., Gilden, R., **Figlin, R.A.**, Practice Guidelines for Small Cell Lung Cancer, The Cancer Journal from Scientific American, 2(3A):69-76, 1996.
78. Ahlering, T., Parker, R., Kumar, S., Taylor, C., Gilden, R., **Figlin, R.A.**, Practice Guidelines for Prostate Cancer, The Cancer Journal from Scientific American, 2(3A):77-86, 1996.
79. Venook, A., Goodnight, J., Kumar, S., Taylor, C., Gilden, R., **Figlin, R.A.**, Practice Guidelines for Colorectal Cancer, The Cancer Journal from Scientific American, 2(3A):23-36, 1996.
80. Goodnight, J., Venook, A., Ames, M., Taylor, C., Gilden, R., **Figlin, R.A.**, Practice Guidelines for Esophageal Cancer, The Cancer Journal from Scientific American, 2(3A):37-44, 1996.
81. Venook, A., Goodnight, J., Smith, N.G., Taylor, C., Gilden, R., **Figlin, R.A.**, Practice Guidelines for Gastric Cancer, The Cancer Journal from Scientific American, 2(3A):45-52, 1996.
82. Goodnight, J., Venook, A., Fringer, J., Taylor, C., Gilden, R., **Figlin, R.A.**, Practice Guidelines for Pancreatic Cancer, The Cancer Journal from Scientific American, 2(3A):53-60, 1996.
83. Belldegrun, A., Tso, CL., Kaboo, R., Pang, S., deKernion, JB., Pierce, B., **Figlin, R.A.**, Natural Immune Reactivity-Associated Therapeutic Response in Patients with Metastatic Renal Cell Carcinoma (RCC) Receiving Tumor-Infiltrating Lymphocytes (TILs) and Interleukin-2 (IL-2) Based Therapy, J Immunotherapy, 19(2):149-161, 1996.

84. Economou, J., Belldegrun, A., Glaspy, J., Toloza, E., **Figlin, R.A.**, Hobbs, J., Meldon, N., Kaboo, R., Tso, CL., Miller, A., Lau, R., McBride, W., Moen, R., In Vivo Trafficking of Adoptively Transferred Tumor-Infiltrating Lymphocytes and Peripheral Blood Lymphocytes: Results of a Double Gene Marking Trial, Journal of Clinical Investigation, 97(2):1-7, 1996.
85. Gitlitz, B.J., Belldegrun, A., **Figlin, R.A.**, Renal Cell Carcinoma: Immunotherapy and Gene Therapy, Seminars in Urologic Oncology, 14(4):237-243, 1996.
86. **Figlin, R.A.**, Crowley, J.J., Jacobs, E., Muirhead, M., Goodwin, J., Rinehart, J.J., Livingston, R.B. Evaluation of Cisplatin, Carboplatin, and Etoposide in Metastatic Non-Small Cell Lung Cancer: A Phase II Study of the Southwest Oncology Group, Cancer, 78:998-1003, 1996.
87. Sokoloff, M., deKernion, J., **Figlin, R.A.**, Belldegrun, A., Current Management of Renal Cell Carcinoma, CA-Cancer Journal for Clinician's, 46:284-302, 1996.
88. Greco, F.A., **Figlin, R.A.**, York, M., Einhorn, L., Schilsky, R., Marshall, E.M., Buys, S.S., Froimchuk, M.J., Schuller, J., Schuchter, L., Buyse, M., Ritter, L., Man, A., Yap, A.K.L., A Phase III Randomized Study Comparing Interferon Alfa-2A in Combination with Fluorouracil Versus Fluorouracil Alone In Patients with Advanced Colorectal Cancer, J Clinical Oncology, 14(10):2674-2681, 1996.
89. Sokoloff, M.H., Tso, C.L., Kaboo, R., Nelson, S., Dorey, F., **Figlin, R.A.**, Pang, S., deKernion, J., Belldegrun, A.S., Quantitative Polymerase Chain Reaction Does Not Improve Pre-operative Prostate Cancer Staging: A Clinical Pathologic Molecular Analysis of 121 Patients, J. Urology, 156:1-7, 1996.
90. Franklin, J.R., **Figlin, R.A.**, Rauch, J., Gitlitz, B., Belldegrun, A.S., Cytoreductive Surgery in the Management of Metastatic Renal Cell Carcinoma: The UCLA Experience, Seminars in Urologic Oncology, 14(4):230-236, 1996.
91. Nishikubo, C.Y., Kunkel, L.A., **Figlin, R.A.**, Belldegrun, A., Rosen, P., Ellashoff, R., Wang, H., Territo, M.C., An Association Between Renal Cell Carcinoma and Lymphoid Malignancies: A Case Series of Ten Patients, Cancer, 78:2421-2426, 1996.
92. Franklin, J., **Figlin, R.A.**, Belldegrun, A., Renal Cell Carcinoma: Basic Biology and Clinical Behavior, Seminars in Urologic Oncology, 14(4):208-215, 1996.
93. Litwin, M.S., Fine, J., Dorey, F., **Figlin, R.A.**, Belldegrun, A.S., Health Related Quality of Life Outcomes in Patients Treated for Metastatic Kidney Cancer: A Pilot Study, J. Urology, 157:1608-1612, 1997.
94. Fanucchi, M., Glaspy, J., Crawford, J., Garst, J., **Figlin, R.A.**, Sheridan, W., Menchaca, D., Tomita, D., Ozer, H., Harker, L., Effects of Pegylated Recombinant Human Megakaryocyte Growth and Development Factor (PEG-rHuMGDF) on Platelet Counts After Chemotherapy for Lung Cancer: A Randomized, Double-Blind, Placebo-Controlled, Dose-Escalation Study, New England Journal of Medicine, 336:404-409, 1997.
95. Grote, T., Pineda, L., **Figlin, R.A.**, Pendergrass, K., Hesketh, P., Karlan, B., Reeves, J., Porter, L., Benedict, C., Hahne, W., Oral Dolasetron Mesylate in Patients Receiving Moderately Emetogenic Platinum-Containing Chemotherapy, The Cancer Journal from Scientific American, 3(1):45-51, 1997.
96. **Figlin, R.A.**, "Renal Cell Carcinoma and Interleukin-2: What Are The End Points?" The Cancer Journal from Scientific American, 3(1), S68-S69, 1997.

97. **Figlin, R.A.**, Pierce, W.C., Kaboo, R., Tso, C.L., Moldawer, N., Dolan, N., Gitlitz, B.J., deKernion, J., Belldegrun, A., Treatment of Metastatic Renal Cell Carcinoma With Nephrectomy, Interleukin-2 and Cytokine Primed or CD8(+) Selected Tumor Infiltrating Lymphocytes From Primary Tumor, J. Urology, 158:740-745, 1997.
98. Mulders, P., **Figlin, R.A.**, deKernion, J.B., Wiltout, R., Linehan, M., Parkinson, D., deWolf, W., Belldegrun, A., Renal Cell Carcinoma: Recent Progress and Future Directions, Cancer Research, 57, 5189-5195, 1997.
99. **Figlin, R.A.**, Gitlitz, B.J., Franklin J., Dorey, F., Moldawer, N., Rausch, J., deKernion J., Belldegrun, A., Interleukin-2 Based Immunotherapy for the Treatment of Metastatic Renal Cell Carcinoma: An Analysis of 203 Consecutively Treated Patients, The Cancer Journal From Scientific American, 3:(1), S92-S97, 1997.
100. Steger, G.G., Grant, M.F., Djavanmard, M.P., Mader, R.M., Jakesz, R., Pierce, W., deKernion, J.B., **Figlin, R.A.**, Belldegrun, A., The In-Vitro effects of Interleukin-12 Upon Tumor Infiltrating Lymphocytes Derived From Renal Cell Carcinoma, J Cancer Res Clin Oncol, 123:317-324, 1997.
101. Vokes, E.E., **Figlin, R.A.**, Hochster, H., Lotze, M., Rybak, M.E., A Phase II Study of Recombinant Human Interleukin 4 For Advanced or Recurrent Non-Small Cell Lung Cancer, The Cancer Journal from Scientific American, 4:46-51, 1998.
102. Mulders, P., Tso, C.L., Pang, S., Kaboo, R., McBride, W.H., Hinkell, A., Gitlitz, B.J., Dannull, J., Michel, K., deKernion, J., **Figlin, R.A.**, Belldegrun, A., Adenovirus Mediated Interleukin-2 Production by Tumors Induce Growth of Cytotoxic Tumor Infiltrating Lymphocytes Against Human Renal Cell Carcinoma, J Immunotherapy, 21(3):170-180, 1998.
103. Haskell, C.M., Mendoza, E., Pisters, K.M.W., Fossella, F.V., **Figlin, R.A.**, Phase II Study of Intravenous Adenosine 5'-Triphosphate in Patients with Previously Untreated Stage IIIB and Stage IV Non-Small Cell Lung Cancer, Investigational New Drugs, 16:81-85, 1998.
104. **Figlin, R.A.**, Renal Cell Carcinoma: Management of Advanced Disease, J Urology, 161:381-387, 1999.
105. Cangiano, T., Liao, J., Naitoh, J., Dorey, F., **Figlin, R.A.**, Belldegrun, A., Sarcomatoid Variant Renal Cell Carcinoma: Biologic Behavior, Prognosis and Response To Combined Surgical Resection and Immunotherapy, J Clinical Oncology, 17:523-528, 1999.
106. Mulders, P., Cho-Lea, T., Gitlitz, B., Kaboo, R., Hinkel, A., Frand, S., Kiertscher, S., Roth, M., deKernion, J., **Figlin, R.**, Belldegrun, A., Presentation of Renal Tumor Antigens By Human Dendritic Cells Activates Tumor Infiltrating Lymphocytes Against Autologous Tumor: Implications For Live Kidney Cancer Vaccines, Clinical Cancer Research, 5:445-454, 1999.
107. Naitoh, J., Kaplan, A., Dorey, F., **Figlin, R.A.**, Belldegrun, A., Metastatic Renal Cell Carcinoma (RCC) With Concurrent Inferior Vena Cava (IVC) Invasion: Long Term Survival Following Combination Therapy Using Radical Nephrectomy, Vena Cava Thrombectomy, and Postoperative Immunotherapy, J of Urology, 161:46-50, 1999.

108. **Figlin, R.A.**, Thompson, J.A., Bukowski, R.M., Vogelzang, N.J., Novick, A.C., Lange, P., Belldegrun, A., A Multicenter Randomized PhaseII/III Trial of CD8+ Tumor Infiltrating Lymphocytes in Combination with Recombinant Interleukin-2 in Metastatic Renal Cell Carcinoma, J Clinical Oncology, 17:2521-2529, 1999.
109. **Figlin, R.A.**, Parker, S.E., Horton, H.M., Interleukin-2 Gene Therapy For The Treatment of Renal Cell Carcinoma, Current Opinion in Molecular Therapeutics, 1(2):271-278, 1999.
110. **Figlin, R.A.**, Parker, S.E., Horton, H.M., Leuvectin, Current Opinion in Oncologic, Endocrine & Metabolic Investigational Drugs, 1(3):323-331, 1999.
111. Reissman, P.T., Koga, H., **Figlin, R.A.**, Holmes, E.C., Slamon, D.J., Amplification and Overexpression of the Cyclin D1 and EGFR Receptor Genes In Non-Small Cell Lung Cancer, J Cancer Res Clin Oncol, 125(2):61-70, 1999.
112. Yang, H., Rosove, M.H., **Figlin, R.A.**, Tumor Lysis Syndrome Occurring After The Administration of Rituximab in Lymphoproliferative Disorders: High-Grade Non-Hodgkin's Lymphoma and Chronic Lymphocytic Leukemia, Am J. Hematology, 62:247-250, 1999.
113. Hoffman, DMJ., Gitlitz, B., Belldegrun, A., **Figlin, R.A.**, Adoptive Cellular Therapy, Seminars in Oncology, 27(2):221-233, 2000.
114. Belldegrun, A., Shvarts, O., **Figlin, R.A.**, Expanding the Indications for Surgery and Adjuvant Interleukin-2 Based Immunotherapy in Patients with Advanced Renal Cell Carcinoma, Cancer J Sci Am, 6:(suppl 1) S88-S92, 2000.
115. Tsui, K.H., Shvarts, O., Smith, R.B., **Figlin, R.A.**, deKernion, J.B., and Belldegrun, A., Renal Cell Carcinoma: Prognostic Significance of Incidentally Detected Tumors, J of Urology, 163:426-430, 2000.
116. Hoffman, D., **Figlin, R.A.**, Intratumoral IL-2 For Renal Cell Carcinoma By Direct Gene Transfer Of A Plasmid DNA/DMRIE/DOPE Lipid Complex, World J of Urol, 18:152-156, 2000.
117. Roth, M.D., Gitlitz, B.J., Kiertscher, S.M., Park, A.N., Mendenhall, M., Moldawer, N., **Figlin, R.A.**, Granulocyte/Macrophage-Colony Stimulating Factor and Interleukin-4 Enhance the Number and Antigen-Presenting Activity of Circulating CD14+ and CD83+ Cells in Cancer Patients, Cancer Research, 60, 1934-1941, 2000.
118. Tsui, K.H., Shvarts, O., Smith, R.B., **Figlin, R.A.**, deKernion, J.B., and Belldegrun, A., Prognostic Indicators in Renal Cell Carcinoma: A Multivariate Analysis of 643 Patients Implementing The Revised 1997 TNM StagingCriteria. J of Urology, 163:1090-1095, 2000.
119. Small, E.J., **Figlin, R.A.**, Petrylak, D., Vaughn, D.J., Sartor, O., Horak, I., Pincus, R., Kremer, A., Bowden, C., A Phase I/II Pilot Study of KW-2189 in Patients with Advanced Renal Cell Carcinoma, Investigational New Drugs, 18:193-197, 2000.
120. Tsui, K.H., Shvarts, O., Barbaric, Z., **Figlin, R.A.**, deKernion, J.B., and Belldegrun, A., Is Adrenalectomy A Necessary Component of a Radical Nephrectomy?: UCLA Experience in 511 Radical Nephrectomies. Journal of Urology 163, 437-441, 2000.

121. Hinkel, A., Tso, C.L., Gitlitz, B.J., Neagos, N., Schmid, I., Paik, S.H., deKernion, J., **Figlin, R.A.**, Belldgrun, A., Immunomodulatory Dendritic Cells Generated From Nonfractionated Bulk Peripheral Blood Mononuclear Cell Cultures Induce Growth of Cytotoxic T Cells Against Renal Cell Carcinoma, J of Immuotherapy, 23(1):83-93, 2000.
122. Elias, L., Lew, D., **Figlin, R.A.**, Flanigan, R.C., Thompson, M.E., Triozzi, P.L., Belt, R.J., Wood, D.P., Rivkin, S.E., Crawford, E.D., Infusional Interleukin-2 and 5-Fluorouracil with Subcutaneous Interferon- α for Advanced Renal Cell Carcinoma: A Southwest Oncology Group Phase II Study, Cancer, 89:597-603, 2000.
123. Goldman, D.P., Schoenbaum, M., Potosky, A., Weeks, J., Berry, S.H., Escarce, J.J. Weidmer, B., Kilgore, M.L., Wagle, N., Adams, J., **Figlin, R.A.**, Lewis, J.H., Rosen, M., Cohen, J., Kaplan, R., McCabe, M., Measuring the Incremental Cost of Clinical Cancer Research, J Clin Oncol., 19:105-110, 2001
124. Gitlitz, B.J., **Figlin, R.A.**, Pantuck A.J., Belldgrun, A.S., Dendritic Cell Based Immunotherapy of Renal Cell Carcinoma, Current Urology Reports, 2:46-52, 2001.
125. Belldgrun, A., Tso, C.L., Zisman, A., Naitoh, J., Said, J., Pantuck, A.J., Hinkel, A., deKernion, J.B., **Figlin, R.A.**, Interleukin-2 (IL- 2) Gene Therapy For Prostate Cancer: Phase I Clinical Trial and Basic Biology, Human Gene Therapy, 12(7):883-892, 2001.
126. Zisman, A., Pantuck, A.J., Dorey, F., Said, J.W., Shvarts, O., Quintana, D., Gitlitz, J., deKernion, J.B., **Figlin, R.A.**, Belldgrun, A.S., Improved Prognostication of RCC Using An Integrated Staging System (UISS), J Clinical Oncology, 19:1649-1657, 2001.
127. Gitlitz, B.J., Belldgrun, A.S., **Figlin, R.A.**, Gene and Vaccine Therapy; Renal Cell Carcinoma, Seminars In Urologic Oncology, 19(2):141-147, 2001.
128. Khuri, F.R., Rigas, J.R., **Figlin, R.A.**, Gralla, R.J., Shin, D.M., Munden, R., Fox, N., Crisp, M.R., Kean, Y., Reich, S.D., Hong, W.K., Multi-Institutional Phase I/II Trial of Oral Bexarotene in Combination with Chemotherapy for Previously Untreated Patients With Advanced Non-Small Cell Lung Cancer, J Clinical Oncology, 19:2626-2637, 2001.
129. Gitlitz, B.J., Hoffman, D.M., Moldawer, N., Belldgrun, A., **Figlin, R.A.**, Treatment of Metastatic Renal Cell Carcinoma with High-Dose Bolus Interleukin-2 in a Non Intensive Care Unit: An Analysis of 124 Consecutively Treated Patients, Cancer J Sci Amer, 7(2):112-120, 2001.
130. Zisman, A., Pantuck, A.J., Chao, D., Dorey, F., Said, J.W., Gitlitz, B.J., deKernion, J.B., **Figlin, R.A.**, Belldgrun, A.S. Reevaluation of the 1997 TNM Classification for RCC: T1 and T2 Cut-Off Point at 4.5 cm Rather Than 7cm Better Correlates with Clinical Outcome, Journal of Urology, 166:54-58, 2001.
131. Tso, C.L., Zisman, A., Pantuck, A., Hernandez, J., Calilli, R., Nguyen D., Shintaku, P.I., deKernion J., **Figlin, R.A.**, Belldgrun, A.S., Induction of G250 Targeted And T-Cell Mediated Anti-Tumor Activity Against Renal Cell Carcinoma Using A Chimeric Fusion Protein Consisting of G250 and Granulocyte-Monocyte Colony Stimulating Factor, Cancer Research, 61:7925-7933, 2001.
132. Zisman, A., Pantuck, A.J., **Figlin, R.A.**, Belldgrun, A.S., Validation of the UCLA Integrated Staging System for Patients with Renal Cell Carcinoma, J Clin Oncol, 19(17),3792-3793, 2001.

133. Pantuck, A.J., Belldegrun, A.S., **Figlin, R.A.**, Nephrectomy and Interleukin-2 for Metastatic Renal-Cell Carcinoma, N Engl J Med, 345(23),1711-1712, 2001.
134. Zisman, A., Pantuck, A.J., Dorey, F., Chao, D., Gitlitz, B.J., Moldawer, N., Lazarovici, D., deKernion, J.B., **Figlin, R.A.**, Belldegrun, A.S., A Mathematical Model To Predict Individual Survival for Patients with Renal Cell Carcinoma, J Clinical Oncology, 20:1368-1374, 2002.
135. Safaei, A., **Figlin, R.A.**, Hoh, C., Silverman, D., Phelps, M.E., Czernin, J., The Usefulness of F-18 Deoxy-Glucose Whole Body Positron Emission Tomography (PET) for Staging of Advanced Renal Cell Cancer, Clinical Nephrology, 57(1):56-62, 2002.
136. Chao, D., Zisman, A., Pantuck, A.J., Gitlitz, B.J., Freedland, S.J., Said, J.W., **Figlin, R.A.**, Belldegrun, A.S., Collecting Duct Renal Cell Carcinoma: Clinical Study of a Rare Tumor, J Urol, 167:71-74, 2002.
137. Zisman, A., Chao, D.H., Pantuck, A.J., Kim, H.J., Wieder, J.A., **Figlin, R.A.**, Said, J.W., Belldegrun, A.S., Unclassified Renal Cell Carcinoma: Clinical Features and Prognostic Impact of a New Histologic Subtype, J Urol, 168:950-955, 2002.
138. Zisman, A., Pantuck, A., Chao, D., **Figlin, R.A.**, Wieder, J., Dorey, F., Said, J., deKernion, J., Belldegrun, A., Renal Cell Carcinoma with Tumor Thrombus: Is Cytoreductive Nephrectomy for Advanced Disease Associated with an Increased Complication Rate? J Urol, 168:962-967, 2002.
139. Zisman, A., Pantuck, A., Wieder, J., Chao, D., Dorey, F., Said, J., deKernion, J., **Figlin, R.A.**, Belldegrun, A., Risk Group Assessment and Clinical Outcome Algorithm to Predict the Natural History of Patients with Surgically Resected Renal Cell Carcinoma, J Clinical Oncology, 20:4559-4566, 2002.
140. Motzer, R.J., Rakhit, A., Thompson, J., Gurney, H., Selby, P., **Figlin, R.A.**, Negrier, S., Ernst, S., Hofstetter, A., Rittweger, K., Hooftman, L., Phase II Trial of Branched PEG Interferon Alfa-2a for Patients with Advanced Renal Cell Carcinoma, Ann Oncol, 13:1799-1805, 2002.
141. Bui, M., Seigson, D., Han, K., Pantuck, A., Dorey, F., Huang, Y., Horvath, S., Leibovich, B., Chopra, S., Liao, S., Stanbridge, E., Lerman, M., Palotie, A., **Figlin, R.**, Belldegrun, A., Carbonic Anhydrase IX is an Independent Predictor of Survival in Advanced Renal Cell Carcinoma: Implications for Prognosis and Therapy, Clinical Cancer Research, 9:802-811, 2003.
142. Han, K., Bui, M., Pantuck, A., Freitas, D., Leibovich, B., Dorey, F., Zisman, A., Janzen, K., Mukoyama, H., **Figlin, R.**, Belldegrun, A., TNM T3a Renal Cell Carcinoma: Adrenal Gland Involvement is not the Same as Renal Fat Invasion, J Urol, 169(3):899-904, 2003.
143. Han, K., Pantuck, A., Shvartz, O., Bui, M., Freitas, D., Zisman, A., Leibovich, B., Dorey, F., Gitlitz, B., **Figlin, R.**, Belldegrun, A., Number of Metastatic Sites Rather Than Location Dictates Overall Survival of Patients with Node Negative Metastatic Renal Cell Carcinoma, Urology, 61:314-319, 2003.
144. Zisman, A., Wieder, J.A., Pantuck, A.J., Chao, D.H., Dorey, F., Said, J.W., Gitlitz, B.J., deKernion, J.B., **Figlin, R.A.**, Belldegrun, A.S., Renal Cell Carcinoma with Tumor Thrombus Extension: Biology, Role of Nephrectomy and Response to Immunotherapy, J Urology, 169(3):909-16, 2003.

145. Pantuck, A.J., Zisman, A., Dorey, F., Chao, D.H., Han, K.R., Said, J., Gitlitz, B.J., **Figlin, R.A.**, Belldegrun, A.S., Renal Cell Carcinoma with Retroperitoneal Lymph Nodes: Role of Lymph Node Dissection, J Urology, 169:2076-2083, 2003.
146. Hernandez, J.M., Bui, M., Han, K., Mukouyama, H., Freitas, D.G., Nguyen, D., Caliliw, R., Shintaku, P.I., Paik, S.H., Tso, C.L., **Figlin, R.A.**, Belldegrun, A.S., Novel Kidney Cancer Immunotherapy Based On The Granulocyte-Macrophage Colony-Stimulating Factor and Carbonic Anhydrase IX Fusion Gene, Clinical Cancer Research, 9:1906-1916, 2003.
147. Hyung, L.K., Belldegrun, A.S., **Figlin, R.A.**, Immune Gene Therapy for Kidney Cancer: the search for a magic trigger. Molecular Therapy, 7(2): 153-154, 2003.
148. Rochlitz, C., **Figlin, R.A.**, Squiban, P., Salzberg, M., Pless, M., Herrmann, M.B., Tartour, E., Yongxiang, Y., Bizouarne, N., Baudin, M., Acres, B., Phase I Immunotherapy with a Modified Vaccinia Virus (MVA) Expressing Human MUC1 as Antigen-Specific Immunotherapy in Patients with MUC-1 Positive Advanced Cancer, The Journal of Gene Medicine, 5:690-699, 2003.
149. Palapattu, G., Pantuck, A., Dorey, F., Said, J., **Figlin, R.A.**, Belldegrun, A., Collecting System Invasion in Renal Cell Carcinoma: Impact on Prognosis and Future Staging Strategies, Journal of Urology, 170:768-772, 2003.
150. Gitlitz, B.J., Belldegrun, A.S., Zisman, A., Chao, D.H., Pantuck, A.J., Hinkel, A., Mulders, P., Moldawer, N., Tso, C.L., **Figlin, R.A.**, A Pilot Trial of Tumor Lysate-Loaded Dendritic Cells for the Treatment of Metastatic Renal Cell Carcinoma, J Immunotherapy, 26:412-419, 2003.
151. Clark, J.I., Atkins, M.B., Urba, W.J., Creech, S., **Figlin, R.A.**, Dutcher, J.P., Flaherty, L., Sosman, J.A., Logan, T.F., White, R., Weiss, G.R., Redman, B.G., Ernstoff, M.S., McDermott, D., Smith, J.W., Gordon, M.S., Margolin, K.A., Adjuvant High-Dose Bolus Interleukin-2 for Patients with High-Risk Renal Cell Carcinoma – A Cytokine Working Group Randomized Trial, J Clin Oncol, 21(16):3133-3140, 2003.
152. Kim, H.L., Belldegrun, A.S., Freitas, D.G., Bui, M., Han, K.R., Dorey, F.J., **Figlin, R.A.**, Paraneoplastic Signs and Symptoms of Renal Cell Carcinoma: Implications for Prognosis, Journal of Urology, 170(5):1742-1746, 2003.
153. Thompson, J.A., **Figlin, R.A.**, Sifri-Steele, C., Berenson, R.J., Frohlich, M.W., A Phase I Trial of CD3/CD28 Activated T Cells (Xcellerated T Cells) and IL-2 In Patients with Metastatic Renal Cell Carcinoma, Clinical Cancer Research, 9:3562—3570, 2003.
154. Gitlitz, B.J., **Figlin, R.A.**, Kiertscher, S.M., Moldawer, N., Rosen, F., Roth, M., A Phase I Trial of Granulocyte Macrophage-Colony Stimulating Factor and Interleukin-4 as a Combined Immunotherapy for Cancer, J Immunotherapy, 26(6):171-178, 2003.
155. Pantuck A, Zisman A, Dorey F, Chao D, Han K, Said J, Gitlitz B, Belldegrun A, **Figlin R.A.**, Renal Cell Carcinoma with Retroperitoneal Lymph Nodes: Impact on Survival and Benefits of Immunotherapy. Cancer, 97(12):2995-3002, 2003.
156. Kiertscher, S.M., Gitlitz, B.J., **Figlin, R.A.**, Roth, M.D., GM-CSF and IL-4 Expand and Activate Type-1 Dendritic Cells (DC1) When Administered In Vivo to Cancer Patients, International Journal of Cancer, 107(2):256-261, 2003.

157. Visapaa, H., Bui, M., Huang, Y., Seligson, D., Tsai, H., Pantuck, A., **Figlin, R.A.**, Rao, J.Y., Belldegrun, A.S., Horvath, S., Palotie, A., Correlation of Ki67 and Gelsolin Expression to Clinical Outcome in Renal Clear-Cell Carcinoma, Urology, 61(4):845-850, 2003.
158. Pantuck, A.J., Zeng, G., Belldegrun, A.S., **Figlin, R.A.**, Pathobiology, Prognosis and Targeted Therapy for Renal Cell Carcinoma: Exploiting the Hypoxia-Induced Pathway, Clinical Cancer Research, 9(13):4641-4652, 2003.
159. Han, K., Bleumer, I., Pantuck, A.J., Kim, H.L., Dorey, F.J., Janzen, N.K., Zisman, A., Dinney, C.P., Wood, C.G., Swanson, D.A., Said, J.W., **Figlin, R.A.**, Mulders, P., Belldegrun, A.S., Validation of an Integrated Staging System Towards Improved Prognostication of Patients with Localized Renal Cell Carcinoma In An International Population, J Urology, 170:2221-2224, 2003.
160. Gitlitz, B.J., Baker, C., Chapman, Y., Yoder, L., Allen, H.J., Bosserman, L.D., Patel, R., Sanchez, J.D., Shapiro, R.M., **Figlin, R.A.**, A Phase II Study of Gemcitabine and Docetaxel Therapy in Patients with Advanced Urothelial Cancer, Cancer, 1;98(9):1863-9, 2003.
161. Leibovich, B.C., Han, K.R., Bui, M.H.T., Pantuck, A.J., Dorey, F.J., **Figlin, R.A.**, Belldegrun, A.S., Scoring Algorithm to Predict Survival After Nephrectomy and Immunotherapy (SANI Score) for Metastatic RCC: A Stratification Tool for Prospective Clinical Trials, Cancer, 98:2566-2575, 2003.
162. Riedl, K., Baratelli, F., Batra, R., Yang, S.C., Luo, J., Escudro, B., **Figlin, R.A.**, Strieter, R., Sharma, S., Dubinett, S., Overexpression of CCL-21/Secondary Lymphoid Tissue Chemokine in Human Monocyte-Derived Dendritic Cells Augments Paracrine Chemotactic Activities for Lymphocytes and Antigen Presenting Cells, Molecular Cancer, 2:35, Nov 2, 2003.
163. Foon, K.A., Yang, X.D., Weiner, L., Belldegrun, A., **Figlin, R.A.**, Crawford, J., Rowinsky, E.K., Dutcher, J.P., Vogelzang, N.J., Gollub, J., Thompson, J., Schwartz, G., Bukowski, R.M., Roskos, L., Schwab, G., Preclinical and Clinical Evaluations of ABX-EGF, a Fully Human Anti-Epidermal Growth Factor Receptor Antibody, Intl J Radiation Oncology Biol. Phys., 58(3):984-90, 2004.
164. Shvarts, O., Lam, J., **Figlin, R.A.**, Belldegrun, A.S., Heat Shock-Peptide Complex Vaccine As Adjuvant Therapy for High-risk Patients with Resected Renal Cell Carcinoma, Curr Urol Rep, 5(1):11-2, 2004.
165. Kim, H.L., Zisman, A., Han, K.R., **Figlin, R.A.**, Belldegrun, A.S., Prognostic Significance of Venous Thrombus in Renal Cell Carcinoma: Are Renal Vein and Inferior Vena Cava Involvement Different? J Urol, 171:588-91, 2004.
166. Suh, R.D., Goldin, J.G., Wallace, A.B., Sheehan, R.E., Heinze, S.B., Gitlitz, B.J., **Figlin, R.A.**, CT-Guided Immunotherapy: A Safe and Effective Technique for the Delivery of Gene Therapy in the Treatment of Metastatic Renal Cell Carcinoma, Radiology, 231(2): 359-364, 2004.
167. Han, Ken-ryu, Hyung, K., Pantuck, A., Dorey, F., **Figlin, R.A.**, Belldegrun, A.S. The Use of the American Society of Anesthesiologists Physical Status Classification to Assess Perioperative Risk in Patients Undergoing Radical Nephrectomy for Renal Cell Carcinoma, Urology 63: 841-847, 2004.

168. Pantuck, A.J., Ophoven, A.V., Gitlitz, B.J., Tso, C.L., Acres, B., Squiban, P., Belldegrun, A.S., **Figlin, R.A.**, Phase I Trial of Antigen-Specific Gene Therapy Using a Recombinant Vaccinia Virus Encoding MUC-1 and IL-2 Positive Patients with Advanced Prostate Cancer, J Immunotherapy, 27(3): 240-253, 2004..
169. Seligson, D.B., Pantuck, A.J., Liu, X., Huang, Y., Horvath, S., Bui, M., Han, K.R., Correa, A., Eeva, M., Tze, S., Belldegrun, A.S., **Figlin, R.A.**, EpCAM (KSA) Expression: Pathobiology and Its Role as an Independent Predictor of Survival in Renal Cell Carcinoma, Clinical Cancer Research, 10(8): 2659-2669, 2004.
170. Patard, J.J., Shvarts, O., Lam, J.S., Pantuck, A.J., Kim, H.L., Ficarra, V., Cindolo, L., Han, K., De La Taille, A., Tostaine, J., Artibani, W., Abbou, C.C., Lobel, B., Chopin, D.K., **Figlin, R.A.**, Mulders, PFA, Belldegrun, A.S., Safety and Efficacy of Partial Nephrectomy for all T1 Tumors Based on an International Multicenter Experience, J Urology, 171(6): 2181-2185, 2004.
171. Kim, H.L., Han, K., Zisman, A., **Figlin, R.A.**, Belldegrun, A.: Cachexia-Like Symptoms Predict a Worse Prognosis in Localized, T1 Renal Cell Carcinoma, J Urol, 171(5): 1810-1813, 2004.
172. Bui, M., Visapaa, H., Seligson, D., Kim, H., Han, K., Huang, Y., Horvath, S., Stanbridge, E.J., Patotie, A., **Figlin, R.A.**, Belldegrun, A.S., Prognostic Value of Carbonic Anhydrase IX and Ki67 as Predictors of Survival for Renal Clear Cell Carcinoma, J Urology, 171(6): 2461-2466, 2004.
173. Mukouyama, H., Janzen, N.K., Hernandez, J.M., Shvarts, O., Lam, J.S., Calilw, R., Wang, A.Y., Aldridge, M.E., **Figlin, R.A.**, Belldegrun, A.S., Zeng, G., Generation of Kidney Cancer Specific Anti-Tumor Immune Responses Using Peripheral Blood Monocytes Transduced with a Recombinant Adenovirus Encoding Carbonic Anhydrase 9, Clin Cancer Res, 10(4): 1421-1429, 2004.
174. Rowinsky, E.K., Schwartz, G.H., Gollob, J.A., Thompson, J.A., Vogelzang, N.J., **Figlin, R.A.**, Bukowski, R., Haas, N., Lockbaum, P., Li, Y.P., Arends, R., Foon, K.A., Schwab, G., Dutcher, J., Safety Pharmacokinetics, and Activity of ABX-EGF, A Fully Human Anti-Epidermal Growth Factor Receptor Monoclonal Antibody in Patients With Metastatic Renal Cell Cancer, J Clin Oncol, 22(15): 3003-15, 2004.
175. Riedl, K., Krysan, K., Pold, M., Dalwadi, H., Heuze-Vourc'h, N., Dohadwala, M., Liu, M., Cui, X., **Figlin, R.A.**, Mao, J.T., Strieter, R., Sharma, S., Dubinett, S., Multifaceted Roles of Cyclooxygenase-2 in Lung Cancer, Drug Resist Update, 7:169-184, 2004.
176. Patard, J.J., Kim, H.L., Dorey, F., Pantuck, A.J., Zisman, A., Cindolo, L., Han, K., Ficarra, V., De La Taille, A., Tostain, J., Artibani, W., Dinney, C.P., Wood, C.G., Swanson, D.A., Abbou, C.C., Lobel, B., Mulders, P., Chopin D.K., **Figlin, R.A.**, Belldegrun, A.S., The Use of UISS (UCLA Untegrated Staging System) to Predict Survival in Renal Cell Carcinoma: An International Multicenter Study in 4202 Patients, J Clin Oncol, 22(16): 3316-22, 2004.
177. Shvarts, O., Lam, J.S., Kim, H.L., Han, K.R., **Figlin, R.A.**, Belldegrun, A.S., Eastern Cooperative Oncology Group Performance Status Predicts Bone Metastasis in Patients Presenting with Renal Cell Carcinoma: Implication for Preoperative Bone Scans, J Urol, 172 (3) 867-70, 2004.

178. Lam, J.S., Belldegrun, A.S., **Figlin, R.A.**, Tissue Array-Based Predictions of Pathobiology, Prognosis, and Response to Treatment for Renal Cell Carcinoma Therapy, Clin Cancer Res, 15;10(18):6304s-6309s, 2004.
179. Kim, H.L., Seligson, D., Liu, X., Janzen, N., Bui, M.H.T., Yu, H., Shi, T., **Figlin, R.A.**, Horvath, S., Belldegrun, A.S., Using Protein Expressions to Predict Survival in Clear Cell Renal Carcinoma, Clin Cancer Res, 15; 10(16):5464-71, 2004.
180. Schiller, G.F., Malone, R., **Figlin, R.A.**, Allogeneic Transplantation After Nonmyelosuppressive Conditioning - The Effect of Single-Agent Pentostatin, Biology of Blood and Marrow Transplantation, 10(8): 576-577, 2004.
181. **Figlin, R.A.**, Target-Specific Therapy Requires Target-Specific Populations in the Treatment of Renal Cell Carcinoma, Der Urologe, Suppl 2, 43:S144-S145, 2004.
182. Atkins, M.B., Avigan, D.E., Bukowski, R.M., Childs, R.W., Dutcher, J.P., Eisen, T.G., **Figlin, R.A.**, Finke, J.H., Flanigan, R.C., George, D.J., Goldberg, S.N., Gordon, M.S., Iliopoulos, O., Kaelin, W.G. Jr., Linehan, W.M., Lipton, A., Motzer, R.J., Novick, A.C., Stadler, W.M., Teh, B.T., Yang, J.C., King, L., Innovations and Challenges in Renal Cancer: Consensus Statement from the First International Conference, Clin Cancer Res, 15;10(18):6277S-6281S, 2004.
183. Patard, J.J., Dorey, F.J., Cindolo, L., Ficarra, V., De La Taille, A., Tostain, J., Artibani, W., Abbou, C.C., Lobel, B., Chopin, D.K., **Figlin, R.A.**, Belldegrun, A.S., Pantuck, A.J., Symptoms as Well as Tumor Size Should be Included in the TNM Classification for Localized Renal Tumors, J Urol, 172:2167-2171, 2004.
184. Lam, J.S., Belldegrun, A.S., **Figlin, R.A.**, Advances in Immune-based Therapies of Renal Cell Carcinoma, Expert Review of Anticancer Therapy, 4(6): 1081-1096, 2004.
185. Lam, J.S., Pantuck, A.J., Belldegrun, A.S., **Figlin, R.A.**, G250: A Carbonic Anhydrase IX Monoclonal Antibody, Current Oncology Reports, 7(2): 109-115, 2005.
186. Shvarts, O., Seligson, D., Lam, J., Shi, T., Horvath, S., **Figlin, R.A.**, Belldegrun, A., Pantuck, A., P53 Is An Independent Predictor of Tumor Recurrence and Progression After Nephrectomy For Patients with Localized Renal Cell Carcinoma, J Urol, 173(3):725-728, 2005.
187. Lam, J.S., Leppart, J.T., **Figlin, R.A.**, Belldegrun, A.S., Surveillance Following Radical or Partial Nephrectomy for Renal Cell Carcinoma, Curr Urol Rep, Feb; 6(1):7-18, 2005.
188. Lu, QY, Jin, Y.S., Pantuck, A., Zhang, Z.F., Heber, D., Belldegrun, A., Brooks, M., **Figlin, R.A.**, Rao, J., Green Tea Extract Modulates Actin Remodeling Via Rho Activity in an In Vitro Multistep Carcinogenic Model, Clin Cancer Res, 15; 11(4):1675-83, 2005.
189. Kim, H.L., Seligson, D., Liu, X.L., Janzen, N., Bui, M., Yu, H., Shi, T., Belldegrun, A.S., Horvath, S., **Figlin, R.A.**, Using Tumor Markers to Predict Survival of Metastatic Renal Cell Carcinoma Patients, J Urol, 173(5):1496-1501, 2005.
190. Patard, J.J., Rioux-Leclercq, N., Cindolo, L., Ficarra, V., Han, K.R., De La Taille, A., Tostain, J., Artibani, W., Abbou, C.C., Lobel, B., Guille, F., Chopin, D.K., Mulders, P.F., Wood, C.G., Swanson, D.A., **Figlin, R.A.**, Belldegrun, A.S., Pantuck, A.J., Prognostic Value of Histologic Subtypes in Renal Cell Carcinoma (RCC). A Multicenter Experience in 4063 Patients, J Clin Oncol, 23(12): 2763-2771, 2005.
191. Lam, J.S., Shvarts, O., Leppert, J.T., **Figlin, R.A.**, Belldegrun, A.S., Renal Cell Carcinoma 2005: New Frontiers in Staging, Prognostication and Targeted Molecular Therapy, J Urol, 173:1853-1862, 2005.

192. Lam, J.S., Shvarts, O., Said, J.W., Pantuck, A.J., Seligson, D.B., Aldridge, M.E., Bui, M.H., Liu, X., Horvath, S., **Figlin, R.A.**, Belldegrun, A.S., Clinicopathologic and molecular correlations of necrosis in the primary tumor of patients with renal cell carcinoma, Cancer, 103(12):2517-2525, 2005.
193. Yang, X.J., Tan, M.H., Kim, H.L., Ditlev, J.A., Betten, M.W., Png, C.E., Kort, E.J., Futami, K., Dykema, K.J., Furge, K.A., Takahashi, M., Kanayama, H.O., Tan, P.H., Teh, B.S., Luan, C., Wang, K., Pins, M.R., Tretiakova, M., Anema, J., Kahnoski, R., Nicol, T., Stadler, W., Vogelzang, N.G., Amato, R., Seligson, D., **Figlin, R.A.**, Belldegrun, A.S., Rogers, C.G., Teh, B.T., A Molecular Classification of Papillary Renal Cell Carcinoma, Cancer Res, Jul 1; 65 (13): 5628-37, 2005.
194. Garland, L., Gitlitz, B., Ebbinghaus, S., Pan, H., De Haan, H., Puri, R.K., Von Hoff, D., **Figlin, R.A.**, Phase I Trial of Intravenous IL-4 Pseudomonas Exotoxin Protein (NBI-3001) In Patients With Advanced Solid Tumors That Express The IL-4 Receptor, J Immunotherapy, July/August; 28 (4): 376-381, 2005.
195. Lam, J.S., Shvarts, O., Pantuck, A.J., **Figlin, R.A.**, Belldegrun, A.S., Postoperative Surveillance Protocol for Patients with Localized and Locally Advanced Renal Cell Carcinoma Based on a Validated Prognostic Nomogram and Risk Group Stratification System, J Urol, 174, 466-472, 2005.
196. Lam, J.S., Leppert, J.T., Belldegrun, A.S., **Figlin, R.A.**, Novel Approaches in the Therapy of Metastatic Renal Cell Carcinoma, World J Urol, 23; (3): 202-212, 2005
197. **Figlin, R.A.**, Establishing A Multidisciplinary Approach To Treating RCC In Both the Adjuvant and Metastatic Setting, Clinical Advances in Hematology & Oncology, 3(5):7 (suppl 5), 2005.
198. Leppert, J.T., Lam, J.S., Pantuck, A.J., **Figlin, R.A.**, Belldegrun, A.S., Carbonic Anhydrase IX and the Future of Molecular Markers in Renal Cell Carcinoma, British J Urology, 96; (3): 281-285, 2005.
199. Truell, J.S., Fishbein, M.C., **Figlin, R.**, Myocarditis Temporally Related to the Use of Gefitinib (Iressa), Arch Pathol Lab Med, 129; (8): 1044-1046, 2005.
200. Lam, J.S., Leppert, J.T., Belldegrun, A.S., **Figlin, R.A.**, Adjuvant Therapy of Renal Cell Carcinoma: Patient Selection and Therapeutic Options, British J Urol, 96;483-488, 2005
201. Lam, J.S., Leppert, J.T., **Figlin, R.A.**, Belldegrun, A.S., Role of Molecular Markers in the Diagnosis and Therapy of Renal Cell Carcinoma, Urology, Nov; 66 (Suppl):1-9, 2005.
202. Mestas, J., Burdick, M.D., Reckamp, K., Pantuck, A., **Figlin, R.A.**, Strieter, R.M., The Role of CXCR2/CXCR2 Ligand Biological Axis in Renal Cell Carcinoma, J Immunol 175: 5351-5357, 2005.
203. Cao, W., Cai, L., Rao, JY., Pantuck, A., Lu, ML., Dalbagni, G., Reuter, V., Scher, H., Cordon-Cardo, C., **Figlin, R.A.**, Belldegrun, A., Zhang, ZF., Tobacco Smoking, GSTP1 Polymorphism, and Bladder Cancer, Cancer, 104 (11): 2400-2408, 2005.
204. **Figlin, R.**, Wood, C.G., Belldegrun, A.S., Clinical Roundtable Monograph: Advances In Adjuvant Therapies for Renal Cell Carcinoma, Clinical Advances in Hematology & Oncology. 3(5) 3-7,(suppl 5), 2005.

205. Motzer, R.J., Michaelson, M.D., Redman, B.G., Hudes, G.R., Wilding, G., **Figlin, R.A.**, Ginsberg, M., Kim, S.T., Baum, C., DePrimo, S., Li, J.Z., Bello, C.L., Theuer, C.P., George, D.J., Rini, B.I., Activity of SU11248, a Multitargeted Inhibitor of Vascular Endothelial Growth Factor Receptor and Platelet-Derived Growth Factor Receptor, Demonstrates Antitumor Activity in Patients with Metastatic Renal Cell Carcinoma, J Clin Oncol, 24 (1), 16-24, 2006.
206. Chin, A.I., Lam, J.S., **Figlin, R.A.**, Belldegrun, A.S., Surveillance Strategies for Renal Cell Carcinoma Patients Following Nephrectomy, Rev Urol, 8 (1), 1-7, 2006.
207. Lam, J.S., Belldegrun, A.S., **Figlin, R.A.**, Adjuvant Treatment for Renal Cell Carcinoma, Expert Opin Pharmacother, 7 (6), 705-720, 2006.
208. Reckamp, K.L., Krysan, K., Morrow, J.D., Newman, R.A., Tucker, C., Dubinett, S.M., **Figlin, R.A.**, A Phase 1 Trial to Determine the Optimal Biologic Dose of Celecoxib When Combined with Erlotinib in Advanced Non-Small Cell Lung Cancer, Clin Cancer Res, 12 (11), 3381-8, 2006.
209. Jin, Y., Iwata, K.K., Belldegrun, A., **Figlin, R.A.**, Pantuck, A., Lieberman, R., Zhang, Z., Rao, J., Effect of Erlotinib on Actin Remodeling in a Multistep Bladder Cancer Carcinogenesis Model, Mol Cancer Ther, Jul; 5 (7): 1754-63, 2006.
210. Ross, H.J., Hart, L.L., Swanson, P.M., Rarick, M.U., **Figlin, R.A.**, Jacobs, A.D., McCune, D.E., Rosenberg, A.H., Baron, A.D., Grove, L.E., Thorn, M.D., Miller, D.M., Sing, A.P., Drachman, J.G., Rudin, C.M., A Randomized, Multicenter Study to Determine the Safety and Efficacy of the Immunoconjugate SGN-15 plus Docetaxel for the Treatment of Non-Small Cell Lung Carcinoma, Lung Cancer, 54 (1): 69-77, 2006.
211. Shuch, S.M., Lam, J.S., Belldegrun, A.S., **Figlin, R.A.**, Prognostic Factors in Renal Cell Carcinoma – Implications for Individualized Prognosis, and Selection for Therapeutic Treatment, Semin Oncol, 33 (5): 563-575, 2006.
212. Pantuck, A.J., Thomas, G., Belldegrun, A.S., **Figlin, R.A.**, Mammalian Target of Rapamycin Inhibitors in Renal Cell Carcinoma: Current Status and Future Applications, Semin Oncol, 33 (5): 607-613, 2006.
213. **Figlin, R.**, Renal Cell Carcinoma – The Translation of Biology to Clinical Application, Semin Oncol, 33 (5): 525-526, 2006.
214. Xiao, G.G., Jin, Y.S., Lu, Q.Y., Zhang, Z.F., Belldegrun, A., **Figlin, R.A.**, Pantuck, A., Yen, Y., Rao, J.Y., Annexin-I as a Target Protein for Green Tea Extract (GTE) Induced Actin Remodeling, Int J Cancer, 120 (1):111-120, 2006.
215. Halbert, R.J., **Figlin, R.A.**, Atkins, M.B., Bernal, M., Hutson, T.E., Uzzo, R.G., Bukowski, R.M., Khan, K.D., Motzer, R.J., Wood, C.G., Gearhart, B.L., Dubois, R., Treatment of Patients with Metastatic Renal Cell Cancer: A RAND Appropriateness Panel, Cancer, 107 (10): 2375-2383, 2006.
216. Hung, J.C., Lu, Q.Y., Rao, J.Y., Pantuck, A., Reuter, V.E., Cordon-Cardo, C., Scher, H.I., **Figlin, R.A.**, Belldegrun, A.S., Heber, D., Zhang, Z.F., Protective Effects of Plasma Carotenoids on the Risk of Bladder Cancer, J Urol, 176(3):1192-7, 2006.
217. Shvarts, O., Janzen, N., Lam, J.S., Leppert, J.T., **Figlin, R.A.**, Belldegrun, A.S., Zeng, G., RENCA/CA IX: A Murine Model of a CA IX Expressing Renal Cell Carcinoma, Urology, 68 (5): 1132-1138, 2006.

218. Lam, J.S., Breda, A., Belldegrun, A.S., **Figlin, R.A.**, Evolving Principles of Surgical Management and Prognostic Factors for Outcome in Renal Cell Carcinoma, J. Clin Oncol. 24 (35): 5565-75, 2006.
219. Yang, Y.C., Lu, M.L., Rao, J.Y., Wallerand, H., Cai, L., Cao, W., Pantuck, A., Dalbagni, G., Reuter, V., Scher, H., **Figlin, R.A.**, Belldegrun, A., Cordon-Cardo, C., Zhang, Z.F., Joint Association of Polymorphism of the FGFR4 Gene and Mutation TP53 Gene with Bladder Cancer Prognosis, Br J Cancer, Dec 4;95(11):1455-8,2006.
220. Weiss, R.H., Borowsky, A.D., Seligson, D., Lin, P.Y., Dillard-Telm, L., Belldegrun, A.S., **Figlin, R.A.**, Pantuck, A.D., p21 is a Prognostic Marker in Renal Cell Carcinoma: Implications for Novel Therapeutic Approaches, J Urol, 77 (1):63-69, 2007.
221. Weber, W.A., **Figlin, R.A.**, Monitoring Cancer Cells with PET/CT. Does it make a difference? J Nuclear Med, 48 (Suppl 1):36S-44S, 2007.
222. Paiva, M.B., Sercarz, J.A., Pantuck, A.J., Polyakov, M., **Figlin, R.A.**, Canalis, R.F., Castro, D.J., Combined cytoreductive laser therapy and immunotherapy for palliation of metastatic renal cell carcinoma to the head and neck. Lasers Med Sci, 22(1):60-3, 2007.
223. Motzer, R.J., Hutson, T.E., Tomczak, P., Michaelson, M.D., Bukowski, R.M., Rixe, O., Oudard, S., Negrier, S., Szczyluk, C., Kim, S.T., Chen, I., Baum, C.M., **Figlin, R.A.**, Phase III Randomized Trial of Sunitinib Malate Versus Interferon-alfa as First Line Systemic Therapy for Patients with Metastatic Renal Cell Carcinoma., N Engl J Med.356(2):115-124,2007.
224. Lam, J.S., Pantuck, A.J., Belldegrun, A.S., **Figlin, R.A.**, Protein Expression Profiles in Renal Cell Carcinoma: Staging, Prognosis, and Patient Selection for Clinical Trials, Clin Cancer Res. 13(2):703s-708s, 2007.
225. Pantuck, A.J., Belldegrun, A.S., **Figlin, R.A.**, Cytoreductive Nephrectomy for Metastatic Renal Cell Carcinoma: Is It Still Imperative in the Era of Targeted Therapy? Clin Cancer Res. 13(2):693s-696s, 2007.
226. Atkins, M.B., Ernstoff, M.S., **Figlin, R.A.**, Flaherty, K.T., George, D.J., Kaelin, W.G., Kwon, T.A., Libermann, T.A., Linehan, W.M., McDermott, D.F., Ochoa, A.C., Pantuck, A.J., Rini, B.I., Rosen, M.A., Sosman, J.A., Sukhatme, V.P., Vieweg, J.W., Wood, C.G., King, L., Innovations and Challenges in Renal Cell Carcinoma: Summary Statement from the Second Cambridge Conference, Clin Cancer Res. 13(2):667s-670s, 2007.
227. **Figlin, R.A.**, Newly Approved Therapies for RCC and Their Effect on the Standard of Care, Clin Adv in Hematol Oncol, 5 (1); 35-6, 2007.
228. Klatte, T., Chung, J., Leppert, J.T., Lam, J.S., Pantuck, A.P., **Figlin, R.A.**, Belldegrun, A.S., Prognostic Relevance of Capsular Involvement and Collecting System Invasion in Stage I and II Renal Cell Carcinoma, BJU Int, 99 (4): 821-824, 2007.
229. Leppert, J.T., Pantuck, A.J., **Figlin, R.A.**, Belldegrun, A.S., The Role of Molecular Markers in the Staging of Renal Cell Carcinoma, BJU Int, 99 (6):1208-11, 2007.
230. Reckamp, K.L., **Figlin, R.A.**, Moldawer, N., Pantuck, A.J., Belldegrun, A.S., Burdick, M.D., Strieter, R.M., Expression of CXCR3 on Mononuclear Cells and CXCR3 Ligands in Patients with Metastatic Renal Cell Carcinoma in Response to Systemic IL-2 Therapy, J Immunother, 30 (4): 417-424, 2007.

231. Pantuck, A.J., Seligson, D., Klatte, T., Wu, H., Leppert, J., Lam, J., O'Toole, T., Dukart, G., Gibbons, J., Belldegrun, A.S., **Figlin, R.A.**, Prognostic Relevance of the mTOR Pathway in Renal Cell Carcinoma – Implications for Molecular Patient Selection for Targeted Therapy, Cancer.109(11):2257-2267, 2007.
232. Lam, J.S., Klatte, T., Patard, J.J., Goel, R.H., Guille, F., Lobel, B., Abbou, C.C., De La Taille, A., Tostain, J., Cindolo, L., Altieri, V., Ficarra, V., Artibani, W., Prayer-Galetti, T., Schipps, L., Zigeuner, R., Pantuck, A.J., **Figlin, R.A.**, Belldegrun, A.S., Prognostic Relevance of Tumor Size in T3a Renal Cell Carcinoma: A Multicentre Experience, Eur Urol. ;52 (1):155-62, 2007.
233. Klatte, T., Pattard, J.J., Goel, R.H., Kleid, M.D., Guille, F., Lobel, B., Abbou, C.C., De La Taille, A., Tostain, J., Cindolo, L., Altieri, V., Ficarra, V., Artibani, W., Prayer-Galetti, T., Allhoff, E.P., Schips, L., Zigeuner, R., **Figlin, R.A.**, Kabbinar, F.F., Pantuck, A.J., Belldegrun, A.S., Lam, J.S., Prognostic Impact of Tumor Size on pT2 Renal Cell Carcinoma: An International Multicenter Experience, J Urol. 21;178 (1)35-40, 2007.
234. Hudes, G., Carducci, M., Tomczak, P., Dutcher, J., **Figlin, R.A.**, Kapoor, A., Staroxlawska, E., Sosman, J., Atkins, M., Bodrogi, I., Kovacevic, Z., Lesovoy, V., Schmidt-Wolf, I., Barbarash, O., Gokmen, E., Galand, L., Thiele, A., O'Toole, T., Kong, S., Park, Y., Moore, L., Motzer, R.;Global ARCC Trial, Temsirolimus, Interferon Alfa, or Both for Advanced Renal-Cell Carcinoma, N Engl J Med. 356:2271-81, 2007.
235. Twardowski, P., **Figlin, R.A.**, What are the Indications for Sorafenib Treatment in Patients with Renal Cell Carcinoma, Nat Clin Pract Oncol. 4(8):456-7, 2007.
236. Bukowski, R.M., Kabbinar, F.F., **Figlin, R.A.**, Flaherty, K., Srinivas, S., Vaishampayan, U., Drabkin, H., Dutcher, J., Ryba, S., Scappaticci, F.A., McDermott, D., Randomized Phase II Study of Erlotinib Combined with Bevacizumab Compared with Bevacizumab Alone in Metastatic Renal Cell Cancer, J Clin Oncol. 10;25(29):4536-41, 2007.
237. Hutson, T.E., **Figlin, R.A.**, Practice of Oncology: Recent Advances; Renal Cell Cancer, The Cancer Journal. 13: (5); 282-286, 2007.
238. **Figlin, R.A.**, Temsirolimus for Advanced Renal Cell Carcinoma, “New Drug Review – Perspectives on Recent FDA Drug Approvals in Hematology and Oncology”, Clin Adv in Hematol Oncol. 5: (11); 893, 2007.
239. Avigan, D.E., Vasir, D., George, D.J., Atkins, M., McDermott, D., Oh, W., Kantoff, P.W., **Figlin, R.A.**, Vasconcelles, M.J., Xu, Y., Kufe, D., Bukowski, R.M., Phase I/II Study of Vaccination with Electrofused Allogeneic Dendritic Cells/Autologous Tumor-derived Cells in Patients with Stage IV Renal Cell Carcinoma, J Immunother. 30 (7);749-761, 2007.
240. Hutson, T.E., **Figlin, R.A.**, Evolving Role of Novel Targeted Agents in Renal Cell Carcinoma, Oncology. 21 (10); 1175-1180, 2007.
241. Pal, S.K., **Figlin, R.A.**, D'Apuzzo, M., Mixed Epithelial Stromal Tumor (MEST) of the Kidney: A Case Report and Review of the Literature, Kidney Cancer J. 5; (2), 85-86, 2007.

242. Ebbinghaus, S., Hussain, M., Tannir, N., Gordon, M., Desai, A.A., Knight, R.A., Humerickhouse, R.A., Qian, J., Gordon, G.B., **Figlin, R.A.**, Phase 2 Study of the Thrombospondin-1-Mimetic Angiogenesis Inhibitor, ABT-510, in Patients with Previously Untreated, Advanced Renal Cell Carcinoma, Clin Cancer Res, 15;13(22):6689-6695, 2007.
243. **Figlin, R.**, Temsirolimus for Advanced Renal Cell Carcinoma, Clin Adv Hematol Oncol, Nov; 5 (11):893, 2007.
244. Klatte T, Patard JJ, Goel RH, Kleid MD, Guille F, Lobel B, Abbou CC, De La Taille A, Tostain J, Cindolo L, Altieri V, Ficarra V, Artibani W, Prayer-Galetti T, Allhoff EP, Schips L, Zigeuner R, **Figlin RA**, Kabbinarav FF, Pantuck AJ, Belldegrin AS, Lam JS, Prognostic Impact of Tumor Size on pT2 Renal Cell Carcinoma: An International Multicenter Experience, Urol Oncol, Jan-Feb; 26(1):100-1, 2008.
245. Weiner, L.M., Belldegrin, A., Crawford, J., Tolcher, T.W., Lockbaum, P., Arends, R., Navale, L., Amado, R., Schwab, G., **Figlin, R.A.**, Dose and Schedule Study of Panitumumab Monotherapy in Patients with Advanced Solid Malignancies, Clin Cancer Res., Jan 15;14(2):502-8, 2008.
246. Reckamp, K.L., Gardner, B.K., **Figlin, R.A.**, Elashoff, D. Krysan, K., Dohadwala, M., Mao, J., Sharma, S., Inge L., Rajasekaran, A., Dubinett, S.M., Tumor Response to Combination Celecoxib and Erlotinib Therapy in Non-Small Cell Lung Cancer is Associated with a Low Baseline Matrix Metalloproteinase (MMP)-9 and a Decline in Serum Soluble E-cadherin (sEC), J Thor Oncol, 3;(2):117-124, 2008.
247. Lam, J.S., Klatte, T., Kim, H.L., Patard, J.J., Breda, A., Zisman, A., Pantuck, A., **Figlin, R.A.**, Prognostic Factors and Selection for Clinical Studies of Patients with Kidney Cancer, Crit Rev in Oncol/Hematol, 65:235-262, 2008.
248. Ettinger, D.S., Akerley, W., Bepler, G., Chang, A., Cheney, R.T., Chirieac, L.R., D'Amico, T.A., Demmy, T.L., Feigenberg, S.J., **Figlin, R.A.**, Govindan, R., Grannis, F.W., Jr., Jahanzeb, M., Kessinger, A., Komaki, R., Kris, M.G., Langer, C.J., Le, Q.T., Martins, R., Otterson, G.A., Patel, J.D., Robert, F., Sugarbaker, D.J., Wood, D.E., Non-Small Cell Lung Cancer, J Natl Compr Canc Netw, 6(3):228-69, 2008.
249. Jonasch, E., Stadler, W., Bukowski, R., Hayes, T., Varadhachary, A., Malik, R., **Figlin, R.A.**, and Srinivas, S., Phase Two Trial of Talactoferrin in Previously Treated Patients with Metastatic Renal Cell Carcinoma, Cancer, 16;113(1):72-77, 2008,
250. Reckamp, KL., Streiter, RM., **Figlin, RA.**, Chemokines as Therapeutic Targets in Renal Cell Carcinoma, Expert Rev Anticancer Ther, 8(6); 887-93, 2008.
251. Twardowski, P., **Figlin, R.A.**, Bevacizumab Plus Interferon Alpha-2a in Patients with Metastatic Renal Cell Carcinoma, Nat Clin Prac Oncol., Aug; 5 (8): 436-437, 2008.
252. Moldawer, N.P., **Figlin, R.A.**, Renal Cell Carcinoma: The Translation of Molecular Biology into New Treatments, New Patient Outcomes, and Nursing Implications, Oncol Nurs Forum.Jul; 35 (4); 699-708, 2008.
253. **Figlin, R.A.**, Mechanisms of Disease: Survival Benefit of Temsirolimus Validates a Role for mTOR in the Biology of Advanced Renal Cell Carcinoma, Nat Clin Pract Oncol., 5 (10):601-9, 2008.
254. Hurria, A., Balducci, L., Naeim, A., Gross, C., Gupta, S., Klepin, H., **Figlin, R.A.**, Mentoring Junior Faculty in Geriatric Oncology: Report from the Cancer and Aging Research Group, J Clin Oncol. Jul 1; 26 (19); 3125-7, 2008.

255. Wood, C., Srivastava, P., Bukowski, R., Lacombe, L., Gorelov, A.I., Gorelov, S., Mulders, P., Zielinski, H., Hoos, A., Teofilovici, F., Isakov, L., Flanigan, R., **Figlin, R.A.**, Gupta, R., Escudier, B., for the C-100-12 RCC Study Group, An adjuvant autologous therapeutic vaccine (HSPPC-96; vitesin) versus observation alone for patients at high risk of recurrence after nephrectomy for renal cell carcinoma; a multicentre, open-label, randomized phase III trial. Lancet. Jul 12; 372(9633):145-54, 2008.
256. Motzer, R.J., Escudier, B., Oudard, S., Hutson, T.E., Porta, C., Bracarda, S., Grunwald, V., Thompson, J.A., **Figlin, R.A.**, Hollaender, N., Urbanowitz, G., Berg, W.J., Kay, A., Lebwohl, D., Ravaud, A., Efficacy of everolimus in advanced renal-cell carcinoma: a double-blind randomized, placebo controlled phase III trial. Lancet. 9; 372 (9637):449-56, 2008.
257. Motzer, R.J., Bukowski, R.M., **Figlin, R.A.**, Hutson, T.E., Michaelson, M.D., Kim, S.T., Baum, C.M., Kattan, M.W., Prognostic Nomogram for Sunitinib in Patients with Metastatic Renal Cell Carcinoma, Cancer, Aug 20;113 (7):1552-1558, 2008.
258. Hutson, T.E., **Figlin, R.A.**, Kuhn, J.G., Motzer, R.J., Targeted Therapies for Metastatic Renal Cell Carcinoma: An Overview of Toxicity and Dosing Strategies, The Oncologist, Oct; 13(10):1084-1096, 2008.
259. Hutson, T.E., **Figlin, R.A.**, Experimental Therapy for Advanced Renal Cell Carcinoma, Expert Opin Investig Drugs, Nov; 17(11):1693-1702, 2008.
260. **Figlin, R.A.**, Brown, E., Armstrong, A.J., Akerley, W., Benson, A.B., Burstein, H.J., Ettinger, D.S., Febbo, P.G., Fury, M.G., Hudes, G.R., Kies, M.S., Kwak, E.L., Morgan, R.J., Mortimer, J., Reckamp, K., Venook, A.P., Worden, F., Yen, Y., NCCN Task Force Report: mTOR Inhibition in Solid Tumors, J Natl Compr Canc Netw (Supplement), 6(5):S1-S22, 2008.
261. Pal, S.K., **Figlin, R.A.**, Reckamp, K.L., The Role of Targeting Mammalian Target of Rapamycin in Lung Cancer, Clin Lung Cancer, Nov;9(6):340-5, 2008.
262. Xin, H., Zhang, C., Herrmann, A., Du, Y., **Figlin, R.A.**, Yu, H., Sunitinib Inhibition of Signal Transducer and Activator of Transcription 3 Induces Renal Cell Carcinoma Tumor Cell Apoptosis and Reduces Immunosuppressive Cells, Cancer Res, Mar 15;69 (6):2506-13, 2009.
263. Motzer, R.J., Hudes, G., Wilding, G., Schwartz, L.H., Hariharan, S., Kempin, S., Favvad, R., **Figlin, R.**, Phase I Trial of Sunitinib Malate plus Interferon-alfa for Patients with Metastatic Renal Cell Carcinoma, Clin Genitourin Cancer, Jan;7 (1):28-33, 2009.
264. Dutcher, J.P., de Souza, P., McDermott, D., **Figlin, R.A.**, Berkenblit, A., Thiele, A., Krygowski, M., Strahs, A., Feingold, J., Hudes, G., Effect of Temsirolimus versus Interferon- α on Outcome of Patients with Advanced Renal Cell Carcinoma of Different Tumor Histologies, Med Oncol, 26(2):202-9, 2009.
265. Pal, S.K., Gupta, R.K., Dosik, G., **Figlin, R.A.**, Concomitant Renal Cell Carcinoma and Chronic Myelogenous Leukemia: Use of a Targeted Approach, Current Oncology, 16(2): 44-7, 2009.
266. Hutson, T.E., **Figlin, R.A.**, Novel Therapeutics for Metastatic Renal Cell Carcinoma. Cancer, 115(S10):2361-2367, 2009.

267. Atkins, M.B., Bukowski, R.M., Escudier, B.J., **Figlin, R.A.**, Hudes, G.H., Kaelin, W.G., Linehan, W.M., McDermott, D.F. Mier, J.W., Pedrosa, I., Rini, B.I., Signoretti, S., Sosman, J.A., The, B.T., Wood, C.G., Zurita, A.J., King, L., Innovations and Challenges in Renal Cancer: Summary Statement From the Third Cambridge Conference, Cancer, 115(S10):2247-2251, 2009.
268. Kapoor, A., **Figlin, R.A.**, Targeted Inhibition of Mammalian Target of Rapamycin (mTOR) for the Treatment of Advanced Renal Cell Carcinoma, Cancer, May 28;115(16):3618-3630, 2009.
269. Motzer, R.J., Hutson, T.E., Tomczak, P., Michaelson, M.D., Bukowski, R.M., Oudard, S., Negrier, S., Szczylik, C., Pili, R., Bjarnason, G.A., Garcia del Muro, X., Sosman, J.A., Solska, E., Wilding, G., Thompson, J.A., Kim, S.T., Chen, I., Huang, X., **Figlin, R.A.**, Overall Survival and Updated Results for Sunitinib Versus Interferon Alfa in Patients with Metastatic Renal Cell Carcinoma, J Clin Oncol, Aug 1;27(22):3484-90, 2009.
270. **Figlin, R.A.**, de Souza, P., McDermott, D., Dutcher, J.P., Berkenbilt, A., Thiele, A., Krygowski, M., Strahs, A., Feingold, J., Boni, J., Hudes, G., Analysis of PTEN and HIF-1 and Correlation with Efficacy in Patients with Advanced Renal Cell Carcinoma Treated with Temsirolimus versus Interferon alone, Cancer, Jun 12;115(16):3651-3660, 2009.
271. Motzer RJ, Agarwal N, Beard C, Bolger GB, Boston B, Carducci MA, Choueiri TK, **Figlin RA**, Fishman M, Hancock SL, Hudes GR, Jonasch E, Kessinger A, Kuzel TM, Lange PH, Levine EG, Margolin KA, Michaelson MD, Olencki T, Pili R, Redman BG, Robertson CN, Schwartz LH, Sheinfeld J, Wang J. NCCN Clinical Practice Guidelines in Oncology: Kidney Cancer, J Natl Compr Canc Netw, Jun;7 (6):618-630, 2009.
272. Motzer RJ, Agarwal N, Beard C, Bolger GB, Boston B, Carducci MA, Choueiri TK, **Figlin RA**, Fishman M, Hancock SL, Hudes GR, Jonasch E, Kessinger A, Kuzel TM, Lange PH, Levine EG, Margolin KA, Michaelson MD, Olencki T, Pili R, Redman BG, Robertson CN, Schwartz LH, Sheinfeld J, Wang J., NCCNm Clinical Practice Guidelines in Oncology: Testicular Cancer, J Natl Compr Canc Netw, May;7 (5):672-693, 2009.
273. Reckamp, KL, **Figlin, RA**, Burdick, MD, Dubinett, SM, Elashoff, RM, Strieter, RM, CXCR4 Expression on Circulating Pan-Cytokeratin Positive Non-Small Cell Lung Cancer (NSCLC) Cells Is Associated with Survival In Patients with Advanced Non Small Cell Lung Cancer, BMC Cancer, Jun 29;9 (1):213, 2009.
274. Porta, C., **Figlin, R.A.**, Phosphatidylinositol-3-Kinase/Akt Signaling Pathway and Kidney Cancer, and the Therapeutic Potential of Phosphatidylinositol-3-Kinase/Akt Inhibitors, J Urol, Dec; 182 (6):2569-77, 2009.
275. **Figlin, R.**, Anti-angiogenic Therapy in Renal Cell Carcinoma: Alone, in Combination, or Sequentially, Clin Adv in Hematol Oncol, 7; (10): 662-5, 2009.
276. Hutson, T.E., Davis, I.D., Machiels, J.P., deSouza, P.L., Rottey, S., Hong, B.F., Epstein, R., Baker, K.L., McCann, L., Crofts, T., Liu, Y., Pandite, L., **Figlin, R.A.**, Efficacy and Safety of Pazopanib in Patients with Metastatic Renal Cell Carcinoma, J Clin Oncol. Jan 20; 28(3):475-80, 2010.

277. Stadler, W.M., **Figlin, R.A.**, McDermott, D.F., Dutcher, J.P., Knox, J.J., Miller, W.H., Hainsworth, J.D., Henderson, C.A., George, J.R., Hajdenberg, J., Kindwall-Keller, T.L., Ernstoff, M.S., Drabkin, H.A., Curti, B.D., Chu, L., Ryan, C.W., Hotte, S.J., Xia, C., Cupit, L., Bukowski, R.M., Safety and Efficacy Results of the Advanced Renal Cell Carcinoma Sorafenib (ARCCS) Expanded Access Program in North America, Cancer. Jan 15;116(5):1272-1280, 2010.
278. Pal, S.K., **Figlin, R.A.**, Renal Cell Carcinoma Therapy in 2010: Many Options with Little Comparative Data, Clin Adv in Hematol Oncol, 8; (3), 191-200, 2010.
279. Pal, S.K., **Figlin, R.A.**, Pazopanib: Carving a Niche in a Crowded Therapeutic Landscape, Nat Rev Clin Oncol, Jul;7 (7):362-3, 2010.
280. Pal, S.K., **Figlin, R.A.**, Treatment Options in Metastatic Renal Cell Carcinoma: Focus on mTOR Inhibitors, Clin Med Insights Oncol, 4; 43-53, 2010.
281. Motzer, R.J., Escudier, B., Oudard, S., Hutson, T.E., Porta, C., Bracarda, S., Grunwald, V., Thompson, J.A., **Figlin, R.A.**, Hollaender, N., Kay, A., Ravaud, A., for the RECORD-1 Study Group, Phase 3 Trial of Everolimus for Metastatic Renal Cell Carcinoma: Final Results and Analysis of Prognostic Factors, Cancer. Sept 15; 116 (18):4256-4265, 2010.
282. Pal, S.K., **Figlin, R.A.**, Reckamp, K., Targeted Therapies for Non-Small Cell Lung Cancer: An Evolving Landscape, Mol Cancer Ther, July;9 (7):1931-44, 2010.
283. Pal, S.K., **Figlin, R.A.**, Targeted Therapies for Renal Cell Carcinoma (RCC): Understanding Their Impact on Survival, Target Oncol, Jun; 5(2):131-8, 2010.
284. Pal, S.K., **Figlin, R.A.**, Yu, H., Deciphering the Anticancer Mechanisms of Sunitinib, Cancer Biol and Ther, 10:7, 1-3, 2010.
285. Bukowski, R.M., Stadler, W.M., McDermott, D.F., Dutcher, J.P., Knox, J.J., Miller, W.H., Hainsworth, J.D., Henderson, C.A., George, J.R., Hajdenberg, J., Kindwall-Keller, T.L., Ernstoff, M.S., Drabkin, H.A., Curti, B.D., Chu, L., Ryan, C.W., Hotte, S.J., Xia, C., Cupit, L., **Figlin, R.A.**, Safety and Efficacy of Sorafenib in Elderly Patients Treated in the North American Advanced Renal Cell Carcinoma Sorafenib (ARCCS) Expanded Access Program, Oncology, 78(5-6):340-347, 2010.
286. Hermann, A., Kortylewski, M., Kujawski, M., Zhang, C., Reckamp, K.L., Armstrong, B., Wang, L., Kowolik, C.M., Deng, J., **Figlin, R.**, Yu, H., Targeting Stat3 in the Myeloid Compartment Drastically Improves Adoptively Transferred T Cell Antitumor Functions in vivo. Cancer Res, 70 (19); 7455-64, 2010.
287. Pal, S.K., Reckamp, K.L., Yu, H., **Figlin, R.A.**, Akt inhibitors in Clinical Development for the Treatment of Cancer, Expert Opin Investig Drugs, 19 (11); 1-12. 2010.
288. Pal, S.K., **Figlin, R.A.**, Bevacizumab for Metastatic Renal Cell Carcinoma: a Monoclonal Antibody in a Sea of Small Molecules, Expert Opin Biol Ther, 10 (11): 1517-1520, 2010.
289. Wiesner, C., Hannum, C., Reckamp, K., **Figlin, R.**, Dubridge, R., Roy, S.M., Lin, S., Becker, C.H., Jones, T., Hiller, J., Cheville, J.C., Wilson, K., Consistency of a two clinical site sample collection: a proteomics Study, Proteomics-Clin Appl, Sep;4(8-9):726-738, 2010..
290. Pal, S.K., Kortylewski, M., Yu, H., **Figlin, R.A.**, Breaking through a Plateau in Renal Cell Carcinoma Therapeutics: Development and Incorporation of Biomarkers, Mol Cancer Ther, Dec 9(12):3115-25, 2010.

291. Kujawski, M., Zhang, C., Hermann, A., Reckamp, K., Scuto, A., Jensen, M., Deng, J., Forman, S., **Figlin, R.**, Yu, H., Targeting STAT3 in Adoptively Transferred T Cells Promotes Their In Vivo Expansion and Antitumor Effects, Cancer Res, Dec 1; 70(23):9599-610, 2010.
292. Hutson, T.E., Bukowski, R.M., Cowey C.L., **Figlin, R.A.**, Escudier, B., Sternberg, C.N., Sequential Use of Targeted Agents in the Treatment of Renal Cell Carcinoma, Crit Rev Oncol Hematol Jan;77(1):48-62, 2011. Epub 2010 Aug 11.
293. Benedict, A., **Figlin, R.A.**, Sandstrom, P., Harmenberg, U., Ullen, A., Charbonneau, C., Sandin, R., Remak, E., Hariharan, S., Negrier, S., Economic Evaluation of New Targeted Therapies for the First-line Treatment of Patients with Metastatic Renal Cell Carcinoma, BJU Int, Jan 25, 2011, [Epub ahead of print].
294. Patil, S., **Figlin, R.A.**, Hutson, T.E., Michaelson, M.D., Negrier, S., Kim, S.T., Huang, X., Motzer, R.J., Prognostic factors for progression-free and overall survival with sunitinib targeted therapy and with cytokine as first-line therapy in patients with metastatic renal cell carcinoma, Ann Oncol. Feb; 22(2):295-300, 2011.
295. Cowey, C.L., Hutson, T.E., **Figlin, R.**, Pazopanib in the Treatment of Renal Cell Carcinoma, Clin Invest, 1 : (1), 75-85, 2011.
296. Pal, S.K., **Figlin, R.A.**, Future Directions of Mammalian Target of Rapamycin (mTOR) Inhibitor Therapy in Renal Cell Carcinoma, Target Oncol, 6 (1): 5-16, 2011.
297. Rini, B.I., Cohen, D.P., Lu, D.R., Chen, I., Hariharan, S., Gore, M.E., **Figlin, R.A.**, Baum, M.S., Motzer, R.J., Hypertension as a Biomarker of Efficacy in Patients with Metastatic Renal Cell Carcinoma Treated with Sunitinib, J Natl Cancer Inst. 103 (9):763-73, 2011.
298. Lee, H., Pal, S.K., Reckamp, K., **Figlin, R.A.**, Yu, H., STAT3: A Target to Enhance Antitumor Immune Response, Curr Top Microbiol Immunol, 344:41-59, 2011.
299. Pal, S.K., Vanderwalde, A., Hurria, A., **Figlin, R.A.**, Systemic Therapies for Metastatic Renal Cell Carcinoma in Older Adults, Drugs Aging, 28 :(8); 635-649, 2011.
300. Pal, S., **Figlin R.A.**, Unraveling the Role of Hypoxia Inducible Factor (HIF) in Renal Cell Carcinoma: A Biologic and Therapeutic Perspective, Cancer Discovery, 1(3); 198-9, 2011.
301. Xin, H., Hermann, A., Reckamp, K., Zhang, W., Pal, S., Hedvat, M., Zhang, C., Liang, W., Scuto, A., Weng, S., Morosini, D., Cao, Z.A., Zinda, M., **Figlin, R.**, Huszar, D., Jove, R., Yu, H., Anti-angiogenic and Anti-metastatic Activity of JAK Inhibitor AZD 1480, Cancer Res , Nov 1;71 (21);6601-10, 2011 Epub 2011 Sept 15.
302. Benz, M.R., Hermann, K., Walter, F., Garon, E.B., Reckamp, K.L., **Figlin, R.**, Phelps, M.E., Weber, W.A., Czernin, J., Allen-Auerbach, M.S., 18F-FDG-PET/CT for Monitoring Treatment Responses to the Epidermal Growth Factor Receptor Inhibitor Erlotinib, J Nucl Med. Nov; 52 (11):1684-9, 2011.
303. Calvo, E., Escudier, B., Motzer, R.J., Oudard, S., Hutson, T.E., Porta, C., Bracarda, S., Grunwald, V., Thompson, J.A., Ravaud, A., Kim, D., Panneerselvam, A., Anak, O., **Figlin, R.A.**, Everolimus in Metastatic Renal Cell Carcinoma (mRCC): Subgroup Analysis of Patients with 1 or 2 Previous Vascular Endothelial Growth Factor Receptor-Tyrosine Kinase Inhibitor (VEGFR-TKI) Therapies Enrolled in the Phase 3 RECORD-1 Study, Eur J Cancer, Feb; 48(3):333-339, 2012.

304. Deng, J., Liu, Y., Lee, H., Hermann, A., Zhang, W., Zhang, C., Shen, S., Priceman, S., Kujawski, M., Pal, S., Raubitschek, A., Hoon, D.S., Forman, S., **Figlin, R.**, Jove, R., Yu, H., S1PR1-STAT3 Signaling is Crucial for Myeloid Cell Colonization at Future Metastatic Sites. Cancer Cell May 25;25(5), 642-54, 2012. PMID:22624714.
305. Wu, X., Weng, L., Li, X., Guo, C., Pal, S.K., Jin, J.M., Nelson, R.A., Mu, B., Onami, S.H., Wu, J.J., Ruel, N.H., Gao, H., Covarrubias, M., **Figlin, R.A.**, Weiss, L.M., Wu, H., Identification of a 4-microRNA Signature for Clear Cell Renal Cell Carcinoma Metastasis and Prognosis, PLoS ONE 7(5):e35661, Epub 2012, May 18. PMID:22623952.
306. Motzer, R.J., Hutson, T.E., Olsen, M.R., Hudes, G.R., Burke, J.M., Edenfield, W.J., Wilding, G., Agarwal, N., Thompson, J.A., Cella, D., Bello, A., Korytowsky, B., Yuan, J., Valota, O., Martell, B., Hariharan, S., **Figlin, R.A.**, Randomized Phase II Trial of Sunitinib on an Intermittent versus Continuous Dosing Schedule as First-Line Therapy of Advanced Renal Cell Carcinoma, J Clin Oncol. Apr 20; 30(12):1371-7, 2012.
307. **Figlin, R.A.**, Sternberg, C., Wood, C., Novel Agents and Approaches for Advanced Renal Cell Carcinoma, J Urol Sept; 188 (3):707-15, 2012. PMID: 22818130.
308. Patil, S., **Figlin, R.A.**, Hutson, T.E., Michaelson, M.D., Negrier, S., Kim, S.T., Huang, X., Motzer, R.J., Q-Twist Analysis to Estimate Overall Benefit for Patients with Metastatic Renal Cell Carcinoma Treated in a Phase III Trial of Sunitinib versus Interferon-alfa., British J Cancer 106, 1587-1590, 2012.
309. Posadas, E.M., **Figlin, R.A.**, Systemic Therapy in Renal Cell Carcinoma: Advancing Paradigms, Oncology, March; 26 (3): 290-301, 2012.
310. Bracarda, S., Hutson, T.E., Porta, C., **Figlin, R.A.**, Calvo, E., Grunwald, V., Ravaud, A., Motzer, R., Kim, D., Anak, O., Panneerselvam, A., Escudier, B., Everolimus in Metastatic Renal Cell Carcinoma Patients Intolerant of Previous VEGFr-TKI Therapy: A RECORD-1 Subgroup Analysis, Br J Cancer Apr 24;106(9):1475-80, 2012.
311. Pal, S.K., Jones, J.O., Carmichael, C., Saikia, J., Hsu, J., **Figlin, R.A.**, Twardowski, P., Lau, C., Clinical Outcome in Patients Receiving Systemic Therapy for Metastatic Sarcomatoid Renal Cell Carcinoma: A Retrospective Analysis, Urol Oncol, 2102 May 17, [Epub ahead of print]. PMID: 22608544.
312. **Figlin, R.A.**, Personalized Immunotherapy: Optimizing Immunopotency in Dendritic Cell-Based Therapy, Kidney Cancer J, 10; 1, 10-19, 2012.
313. Tran, H.T., Liu, Y., Zurita, A.J., Lin, Y., Baker-Neblett, L., Martin, A.M., **Figlin, R.A.**, Hutson, T., Sternberg, C., Amado, R., Pandite, L.N., Heymach, J.V., Prognostic or Predictive Plasma Cytokine and Angiogenic Factors for Patients Treated with Pazopanib for Metastatic Renal Cell Cancer: A Retrospective Analysis of Phase 2 and Phase 3 Trials. Lancet Oncol, Aug; 13(8):827-37, 2012. PMID: 22759480.
314. Mita, A.C., **Figlin, R.A.**, Mita, M., Drug Updates: Cabazitaxel: More Than a New Taxane for Metastatic Castrate-resistant Prostate Cancer, Clin Cancer Res. Dec 15; 18(24):6574-9, 2012. PMID 23091116.
315. Pal, S.K., Bergerot, P.G., **Figlin, R.A.**, Tivozanib: Current Status and Future Directions in the Treatment of Solid Tumors, Expert Opin Investig Drugs Dec; 21(12):1851-9, 2012. PMID: 23013465.

316. Cho, D.C, Hutson, T.E., Samlowski, W., Sportelli, P., Somer, B., Richards, P., Sosman, J.A., Puzanov, I., Michaelson, M.D., Flaherty, K.T., **Figlin, R.A.**, Vogelzang, N.J., Two Phase II Trials of the Novel Akt Inhibitor Perifosine in Patients with Advanced Renal Cell Carcinoma after Progression on Vascular Endothelial Growth Factor-Targeted Therapy, Cancer 118 (24):6055-62, Dec 15, 2012..PMID: 22674198
317. Posadas, E.M., **Figlin, R.A.**, Understanding the Role of MET Kinase in Cancer Therapy, J Clin Oncol. Jan 10; 31 (2): 169-170, 2013, PMID: 23213104.
318. **Figlin, R.A.**, Kaufmann, I., Brechbiel, J., Targeting PI3K and mTORC2 in Metastatic Renal Cell Carcinoma: New Strategies for Overcoming Resistance to VEGFR and mTORC2 Inhibitors: Int J Cancer 2013 Aug 15;133(4):788-96. PMID: 23319457.
319. Zhang, H., Berel, D., Wang, Y., Li, P., Bhowmick, N.A., **Figlin, R.**, Kim, H.L., A Comparison of Ku0063794, a dual mTORC1 and mTORC2 inhibitor, and Temsirolimus in Preclinical Renal Cell Carcinoma Models, PLoS ONE 2013;8(1):e54918, Epub 2013 Jan 22, PMID:23349989.
320. **Figlin, R.A.**, Tivozanib in Renal Cell Carcinoma, Clin Adv Hematol Oncol, 11(1):43-5, 2013, PMID:23416862.
321. Pal, S.K., Hsu, J., Hsu, S., Hu, J., Bergerot, P., Carmichael, C., Saikia, J., Liu, X., Twardowski, P., **Figlin, R.A.**, Yuh, B.E., Impact of Age on Treatment Trends and Clinical Outcome in Patients with Metastatic Renal Cell Carcinoma, J Geriatr Oncol, Apr 1;4(2): 128-133, 2013.
322. Zhang, W., Pal, S.K., Liu, X., Yang, C., Allahabadi, S., Bhanji, S., **Figlin, R.A.**, Yu, H., Reckamp, K.L., Anthroctic Myeloid Clusters are Associated with a Pro-Metastatic Environment and Poor Prognosis in Smoking-Related Early Stage Non-Small Cell Lung cancer: PLoS One 2013 May24;8(5):e65121. PMID: 2371769.
323. Pal, S.K., Hu, A., **Figlin, R.A.**, A New Age for Vaccine Therapy in Renal Cell Carcinoma: Cancer J, Jul-Aug; 19 (4): 365-70, 2013. PMID: 23867519.
324. **Figlin, R.A.**, Renal Cell Carcinoma: The Next Decade of Development, Cancer J, Jul-Aug; 19 (4):297-8, 2013. PMID: 23867509.
325. Posadas, E.M., Limvorasak, S., Sharma, S., **Figlin, R.A.**, Targeting Angiogenesis in Renal Cell Carcinoma, Expert Opin Pharmacother, Nov;14 (16):2221-2236, 2013 PMID: 23984807.
326. Harmon, C.S., DePrimo, S.E., **Figlin, R.A.**, Hudes, G.R., Hutson, T.E., Michaelson, D., Negrier, S., Kim, S.T., Huang, X., Williams, J.A., Eisen, T., Motzer, R.J., Circulating Proteins as Potential Biomarkers of Sunitinib and Interferon – Alfa Efficacy in Treatment-naïve Patients with Metastatic Renal Cell Carcinoma, Cancer Chemother Pharmacol, Jan;73 (1):151-61, 2014 PMID: 24220935.
327. Forscher, C., Mita, M., **Figlin, R.**, Targeted Therapy for Sarcomas, Biologics, 8, 91-105, 2014. PMID: 24669185.
328. Cella, D., Davis, M.P., Negrier, S., **Figlin, R.A.**, Michaelson, M.D., Bushmakina, A.G., Cappelleri, J.C., Sandin, R., Korytowsky, B., Charbonneau, C., Matczak, E., Motzer, R.J., Characterizing Fatigue Associated with Sunitinib and its Impact on Health-Related Quality of Life in Patients with Metastatic Renal Cell Carcinoma, Cancer 2014 Mar 13. [Epub ahead of print] PMID: 24634003.

329. Rosenberg, J.E., Bambury, R.M., Van Allen, E.M., Drabkin, H.A., Lara, P.N., Harzstark, A.L., Wagle, N., **Figlin, R.A.**, Smith G.W., Garraway, L.A., Choueiri, T., Erlandsson, F., Laber, D.A., A Phase II Trial of AS1411 (a novel nucleolin-targeted DNA aptamer) in Metastatic Renal Cell Carcinoma, Invest New Drugs. Feb; 32(1):178-87, 2014, PMID 24242861.
330. Wang, Y., Sparwasser T., **Figlin, R.**, Kim, H., Foxp3+ T Cells Inhibit Antitumor Immune Memory Modulated by mTOR Inhibition, Cancer Res Apr 15; 74(8):2217-28, 2014. PMID: 24574514.
331. Pal, S.K., Hu, A., Chang, M., **Figlin, R.A.**, Programmed Death-1 (PD-1) Inhibition in Renal Cell Carcinoma: Clinical Insights and Future Directions, Clin Adv Hematol Oncol, 12 ;(2): 90-99, 2014.
332. Hutson, T.E., Bukowski, R.M., Rini, B.I., Gore, M.E., Larkin, J.M., **Figlin, R.A.**, Barrios, C.H., Escudier, B., Lin, X., Fly, K., Martell, B., Matczak, E., Motzer, R.J., Efficacy and Safety of Sunitinib in Elderly Patients with Metastatic Renal Cell Carcinoma, Br J Cancer, Mar 4;110 (5):1125-32, 2014. PMID: 24434434.
333. Posadas, E.M., **Figlin, R.A.**, Kidney Cancer: Progress and Controversies in Neoadjuvant Therapy, Nat Rev Urol, 2014 Apr 22. PMID: 24752207.
334. Negrier, S., Bushmakin, A.G., Cappelleri, J.C., Korytowsky, B., Sandin, R., Charbonneau, C., Michaelson, M.D., **Figlin, R.A.**, Motzer, R.J., Assessment of Progression-Free Survival as a Surrogate Endpoint for Overall Survival in Patients with Metastatic Renal Cell Carcinoma, Eur J Cancer 2014 Apr 23. [Epub ahead of print] PMID:24768571.
335. **Figlin, R.A.**, A Novel Personalized Vaccine Approach in Combination with Targeted Therapy in Advanced Renal Cell Carcinoma, Immunotherapy, Mar 6 (3): 261-8, 2014. PMID: 24354908.
336. Pal, S.K., **Figlin, R.A.**, Ramucirumab in Metastatic Renal Cell Carcinoma (mRCC): The Beginning or the End? Cancer, Jun 1; 120(11):1604-7, 2014. PMID: 24577887.

REVIEWED PAPERS (Submitted)

337. Motzer, R.J., Hutson, T.E., Hudes, G.R., **Figlin, R.A.**, Martini. JF., English, P.A., Wood, L., Huang, X., Valota, O., Williams, J.A., Novel Circulating Proteins, Single Nucleotide Polymorphisms, and Molecular Tumor Markers as Potential Efficacy Biomarkers of First-Line Sunitinib Therapy for Advanced Renal Cell Carcinoma, Cancer Chemotherapy and Pharmacology (submitted).
338. Pal, S.K., Tong, T., He, M., Wu, H., Liu, X., Lau, C., **Figlin, R.A.**, Jones, J.O., mTOR Pathway Activation in Patients with Sarcomatoid Metastatic Renal Cell Carcinoma, J Cancer Biology and Therapy (submitted).
339. DeBenedette, M., Jurisica, I., Gamble, A., Amin, A., **Figlin, R.A.**, Tcherepanova, I., Nicolette, C., Multi-functional Cytotoxic T Cells Correlate with Overall Survival after

- Administration of Autologous Dendritic Cell Immunotherapy in Renal Cell Cancer Patients, *PLOS ONE* (submitted).
340. Amin, A., Dudek, A.Z., Logan, T.F., Lance, R.S., Holzbeierlein, J.M., Knox, J.J., Master, V.A., Pal, S.K., Miller, W., Karsh, L., Williams, W.L., Plessinger, D., Nicolette, C.A., **Figlin, R.A.**, and the AGS-003 Study Group, Safety and Activity of AGS-003, an Autologous Dendritic Cell-based Immunotherapy, in Combination with Sunitinib in Patients with Advanced Renal Cell carcinoma (RCC), Phase 2 Study Data, *Cancer*, (submitted).
 341. Pal, S.K., Hossain, D.S., Zhang, Q., Gao, C., Henry, Frankel, P.H., Jones, J.O., Carmichael, C., Ruel, C., Lau, C., **Figlin, R.A.**, Kortylewski, M., Pazopanib as Third-line Therapy for Metastatic Renal Cell Carcinoma: Clinical Efficacy and Temporal Analysis of Cytokine Profile, *Cancer*, (submitted).
 342. McDermott, D.F., Cheng, S., Signoretti, S., Margolin, K.A., Clark, J., Sosman, J., Dutcher, J., Logan, T., Curti, B., Ernstoff, M., Appleman, L., Wong, M., Kushalani, N., Oleksowicz, L., Vaishampayan, U., Mier, J., Panka, D., Bhatt, R., Bailey, A., Liebovich, B., Kwon, E., **Figlin, R.**, Pantuck, A., Atkins, M.B., The High-Dose Aldesleukin (HD IL-2) "Select" Trial: A Trial Designed to Prospectively Validate Predictive Models of Response to HD IL-2 Treatment in Patients with Metastatic Renal Cell Carcinoma (mRCC), *J Clin Oncol*, (submitted).
 343. Bono, P., Oudard, S., Bodrogi, I., Hutson, T.E., Escudier, B., Machiels, J.P., Thompson, J.A., **Figlin, R.A.**, Ravaud, A., Basaran, M., Lee, S.H., Bracarda, S., Panneerselvam, A., Anak, O., Grunwald, V., Motzer, J., Outcomes in Patients with Metastatic Renal Cell Carcinoma who Develop Everolimus-related Hyperglycemia and Hypercholesterolemia: Subgroup Analysis of RECORD-1 and REACT Trials, *Ann Oncol*, (submitted).

NON-PEER REVIEWED PUBLICATIONS

1. **Figlin, R.A.**, deKernion, J.B. Is Antibody to Recombinant Interferon-Alfa-2a Clinically Significant? *The Interferon Letter*, Vol. 3:2, July 1986.
2. Belldegrun, A., **Figlin, R.A.**, Immunotherapy for Advanced Renal Cell Carcinoma, *AUA Today*, 7(12): 18-19, 1994.
3. **Figlin, R.A.**, "Renal Carcinoma: Biologic Therapy", *AUA. Today*, 9(2)19, 1996.
4. **Figlin, R.A.**, Renal Cell Carcinoma: Current Status and Future Plans, *The Cancer Journal From Scientific American*, 6(Suppl 1): 552-554, 2000.
5. **Figlin, R.A.**, Kidney Cancer, ONE, *Oncology Economics*, 1 (12):21;2000.
6. **Figlin, R.A.**, Commentary: Fluorouracil Does Not Enhance The Limited Effectiveness of Subcutaneous Recombinant Interleukin-2 And Recombinant Interferon Alfa-2a For Metastatic Renal Cancer, *Evidence-based Oncology*, 2:94-95, 2001.
7. **Figlin, R.A.**, Clinical Trial Enrollment Serves as Helpful Marker of Progress, *Kidney Cancer Journal*, 1; (2): 2, 2004.
8. Shvarts, O., Lam, J., **Figlin, R.A.**, Belldegrun, A.S., Pantuck, A., Improving Postnephrectomy Follow-up in RCC Patients: Looking at Stage and Beyond, *Contemporary Urology*, 16(9): 18-27, 2004.

9. **Figlin, R.A.**, Reflections on AUA and ASCO: Benchmarks of RCC Research, Kidney Cancer Journal, 2; (1): 2, 2004.
10. **Figlin, R.A.**, Genetic Research in Renal Cell Carcinoma: It's a Marathon, Not a Sprint, Kidney Cancer Journal, 2; (3): 2, 2004.
11. **Figlin, R.A.**, Wish List for 2005: Integrating Adjuvant Therapy and Prognostic Classification, Kidney Cancer Journal, 2; (4): 2, 2004.
12. Bukowski, R.M., **Figlin, R.A.**, Motzer, R.J., Novel Targeted Approaches to Management of Advanced Renal Cell Carcinoma, ASCO Educational Book, 41st Annual Meeting, 385-90, 2005.
13. **Figlin, R.**, The Hidden Message From ASCO 2005: Caveats and Conundrums, Kidney Cancer Journal, 3 (2): 2, 2005.
14. Vogelzang, N., **Figlin, R.A.**, Debating the Relative Merits and Validity of Progression-Free Survival as an Endpoint in Renal Cell Carcinoma Clinical Trials, Controversies and Consensus in Kidney Cancer, pgs 17-19, 2005.
15. Lam, J., **Figlin, R.A.**, Molecular Prognostic Factors in Renal Cell Carcinoma, in Monographs in Renal Cell Carcinoma, 1, (1), 9-13, 2005.
16. **Figlin, R.**, Finding a Stronger Voice for Patient Advocacy and Promoting the Oncology Nurse with a Special Emphasis in Renal Cancer Management, Kidney Cancer Journal, 3 (3): 2, 2005.
17. **Figlin, R.**, Nexavar, Sutent, Drive Home the Message: Bench to Bedside Research in Kidney Cancer is the Only Path to Finding a Cure, Kidney Cancer Journal, 3 (4): 2, 2006.
18. Bukowski, R.M., **Figlin, R.A.**, Multitargeted Therapy in Kidney Cancer, Oncology Consultations, 3 (4): 2006.
19. **Figlin, R.**, Behind the Data Explosion at ASCO 2006: How Do You Apply New Clinical Trials Information? Kidney Cancer Journal, 4 (1): 2, 2006.
20. **Figlin, R.**, ASCO 2006 – Banner Day for Kidney Cancer, but New Paradigm Poses Challenging Clinical and Research Questions. Kidney Cancer Journal, 4 (2): 2, 2006.
21. Twardowski, P.W., **Figlin, R.A.**, Emerging Targeted Therapies for Renal Cell Carcinoma, Monographs in Renal Cell Carcinoma, 1 (2); 10-13, 2006.
22. **Figlin, R.**, Let's Keep Randomization as Clinical Trial Design Gold Standard, Kidney Cancer Journal, 4 (3); 2, 2006.
23. **Figlin, R.**, A Hard Act to Follow in Kidney Cancer, But Expectations for 2007 and Beyond Remain High, Advances in Kidney Cancer, pg 2, Winter 2006-2007.
24. **Figlin, R.**, Once Elusive, Additional Pathways in Renal Cell Carcinoma Begin to Emerge, Kidney Cancer Journal, 5:(1); 2007.
25. Hutson, T.E., **Figlin, R.A.**, Mechanisms of Action for Targeted Agents in Renal Cell Carcinoma, Monographs in Renal Cell Carcinoma, 2:(1),3-6, 2007.
26. **Figlin, R.**, A Retrospective on ASCO 2007 and a Prospective Look at its Challenges, Kidney Cancer Journal, 5: (2); 2007.
27. **Figlin, R.A.**, Revisiting RECIST – Imperfections and Implications of the Criteria, Kidney Cancer Journal, 5: (4); 2008.
28. **Figlin, R. A.**, Book Review, Clinical Management of Renal Tumors, Edited by Bukowski, R.M., and Novick, A.C. Totowa, NJ, Humana Press, 2008, N. Engl J Med., 359; 15:1635, 2008.
29. **Figlin, R.A.**, VEGF Resistance: Maybe the Most Vexing Problem Facing Oncologists,

Kidney Cancer Journal, 6:(2); 2008.

30. Carroll, P., **Figlin, R.A.**, Identifying Racial, Ethnic and Sex Disparities in Kidney Cancer: Who is Most at Risk and Why, Kidney Cancer Journal, 7: (1); 267-71, 2009.
31. **Figlin, R.A.**, Cytoablative Nephrectomy for Metastatic Renal Cell Carcinoma; Issues in Managing Urogenital Cancer, Audio-Digest Urology, 32; 12, December 2009.
32. **Figlin, R.A.**, Optimizing Our Strategies – Removal of the Primary Tumor and Planning Treatment with Targeted Therapies, Kidney Cancer Journal, 7: (3); 318, 2009.
33. **Figlin, R.A.**, Revisiting the Role of Immunotherapy in RCC and a New Alert on Potential Pulmonary Toxicity with Targeted Therapy, Kidney Cancer Journal, 8: (1); 6, 2010.
34. **Figlin, R.A.**, Looking Back at ASCO 2010 and its Messages, Kidney Cancer Journal, 8: (2); 34, 2010.
35. **Figlin, R.A.**, New ASCO Recommendations Stress Greater Focus on Palliative Care Issues, Need for Earlier Intervention, Kidney Cancer Journal, 8: (4); 102, 2011.
36. **Figlin, R.A.**, ASCO 2011 Serves as a Time Capsule to View the Future, Kidney Cancer Journal, 9: (2); 50, 2011.
37. **Figlin, R.A.**, Will a Renaissance in Immunotherapy Become Part of the Paradigm of Cancer Care? Kidney Cancer Journal, 9: (4); 102, 2012.
38. **Figlin R.A.**, An Alarming Trend and Changing Dynamic That Threaten the Quality of Cancer Care, Kidney Cancer Journal, 10: (2); 38, 2012.
39. **Figlin, R.A.**, the Renaissance in Immunotherapy: Boosting the Immune Response by Targeting the “Checkpoints” of RCC, Kidney Cancer Journal, 11: (1); 8, 2013.
40. **Figlin, R.A.**, Turn on your GPS: Here’s a Road Map to the Next Decade, Kidney Cancer Journal, 11: (2); 40, 2013.
41. **Figlin, R.A.**, Finding the Needle in a Haystack: Navigating Oncology Websites for News You Can Use, Kidney Cancer Journal, 12: (1); 6, 2014.

BOOK CHAPTERS

1. Sarna, G.P., Holmes, E.C., Petrovich, Z., **Figlin, R.A.** Lung Cancer in Cancer Treatment, 2nd Edition (C.E. Haskell, ed.) W.B. Saunders, Philadelphia, PA, 1985.
2. deKernion, J.B., Mukamel, E., **Figlin, R.A.** Renal Cell Carcinoma in Interferons in Cancer Treatment, (H.K.B. Silver, ed.) Medical Education Services, Mississauga, Ontario 1986.
3. **Figlin, R.A.**, Holmes, E.C., Petrovich, Z., Sarna, G.P. Lung Cancer in Cancer Treatment, 3rd Edition (C.E. Haskell, ed.), W.B. Saunders, Philadelphia, PA 1990.
4. **Figlin, R.A.**, Mesothelioma in Cancer Treatment, 3rd Edition (C.E. Haskell, ed.), W.B. Saunders, Philadelphia, PA 1990.
5. Neuwirth, H., **Figlin, R.A.**, deKernion, J.B. Renal Cell Carcinoma in Cancer Treatment, 3rd Edition (C.E. Haskell, ed.), W.B. Saunders, Philadelphia, PA 1990.
6. **Figlin, R.A.**, Sarna, G., deKernion, J.B. Biologic Response Modifier Therapy of Metastatic Renal Cell Carcinoma: The UCLA Experience in Immunotherapy of Urologic

- Tumors, (J.B. deKernion, ed.), Monograph of International Society of Urology, Churchill Livingstone, London, England 1990.
7. **Figlin, R.A.**, Abi-Aad, A.S., Belldegrun, A., deKernion, J.B., The Role of Combination Biologic Therapy in the Immunotherapeutic Approach to the Treatment of Renal Cell Carcinoma; in Combination Therapies, (A.L. Goldstein and E. Garaci, ed.), Plenum Press, New York, pp 57-65, 1992.
 8. MacFarlane, M.T., **Figlin, R.A.**, deKernion, J.B., Neoplasms of the Genitourinary Tract: Neoplasm of the Bladder; in Cancer Medicine, Third Edition, (J. Holland ed.), Lea & Febiger, Philadelphia/London, pp 1546-1559, 1993.
 9. MacFarlane, M.T., **Figlin, R.A.**, deKernion, J.B., Neoplasms of the Genitourinary Tract: Neoplasms of the Urethra; in Cancer Medicine, Third Edition, (J. Holland ed.), Lea & Febiger, Philadelphia/London, pp 1559-1561, 1993.
 10. **Figlin, R.A.**, Pierce W.C., Moldawer, N., deKernion, J., Belldegrun, A., Immunotherapy of Patients with Metastatic Renal Cell Carcinoma Using an Outpatient Regimen of Interleukin-2 and Interferon-Alpha: The UCLA Experience, Renal Cell Carcinoma: Immunotherapy and Cellular Biology, (Ronald Bukowski, ed.) Marcel Dekker, Inc., New York, N.Y., 24:261-271, 1993.
 11. Belldegrun, A., Steger G., Tso, C., Kaboo, R., Duckett, T., **Figlin, R.A.**, deKernion J., Adoptive Immunotherapy for Renal Cell Carcinoma Using Cytokine Modulated-Tumor Infiltrating Lymphocytes: The UCLA Experience, Renal Cell Carcinoma: Immunotherapy and Cellular Biology (ed. Ronald Bukowski, M.D.) Marcel Dekker, Inc., New York, N.Y., 15:151-159, 1993.
 12. Jacobs, E.L., **Figlin, R.A.**, Current Concepts in the Biology and Clinical Management of Lung Cancer, Current Pulmonology, (Donald F. Tierney, ed.) Mosby-Year Book, Inc., Chicago, Ill, Vol 14, 95-141. 1993
 13. Moldawer, N.P., **Figlin, R.A.**, The Interferons in Biotherapy: A Comprehensive Overview, (P.T. Rieger, ed.) Jones and Bartlett, Boston, MA., 4:69-92, 1994.
 14. Taneja, S.S., Pierce, W., **Figlin, R.A.**, Belldegrun, A., Management of Disseminated Kidney Cancer, Urologic Clinics of North America, Evaluation and Management of Recurrent Malignant Disease, (M. Resnick, ed.) W.B. Saunders, Philadelphia, PA, Vol. 21, 4:625-637, November 1994.
 15. Pierce, W.C., **Figlin, R.A.**, Belldegrun, A., Immunotherapy of Renal Cell Carcinoma with Sensitized T-lymphocytes: The UCLA Experience in Immunotherapy of Cancer with Sensitized T-lymphocytes. (A.E. Chang, S. Shu, eds.) R.G. Landes, Austin, Texas, 11:155-164, 1994.
 16. Rusch, V.W., **Figlin, R.A.**, Pleural Mesothelioma in Cancer Treatment, 4th Edition (C.E. Haskell, ed) W.B. Sanders, Philadelphia, PA, pp. 421-425, 1995.
 17. Gitlitz, B.J., **Figlin, R.A.**, Cell, Gene and Vaccine Based Strategies in Kidney Cancer, Kidney Cancer, Kluwer Academic Publishers, (S.T. Rosen ed.) 11:183-198, 2003.
 18. **Figlin, R.A.**, deKernion, J.B., Urinary Tract Cancers in Manual of Clinical Oncology, 3rd Edition (D.A. Casciato and B.B. Lowitz, ed.) Little, Brown, and Company, Boston, MA, 13:237-257, 1995.
 19. **Figlin, R.A.**, Gitlitz, B.J., Belldegrun, A., Renal Cell Carcinoma in Cancer Treatment, 4th Edition (C.E. Haskell, ed) W.B. Sanunders, Philadelphia, PA., pp. 598-613, 1995.

20. **Figlin, R.A.**, Holmes, E.C., Turrissi, A., Non-Small Cell Lung Cancer in Cancer Treatment, 4th Edition, (C.E. Haskell, ed) W.B. Saunders, Philadelphia, PA., pp. 385-413, 1995.
21. Belldgrun, A., Dardashti, K., Tso, C.L., Kaboo, R., Taneja, S., deKernion, J.B., **Figlin, R.A.**, The Use of Cytokines, Tumor Infiltrating Lymphocytes, and Gene Therapy in the Treatment of Advanced Renal Cell Carcinoma: The UCLA Experience, Biology of Renal Cell Carcinoma, (R.M. Bukowski, J.H. Finke, E.A. Klein eds.) Springer-Verlag, New York, NY, 18:204-209, 1995.
22. **Figlin, R.A.**, Gitlitz, B.J., Belldgrun, A., Kidney Cancer: Management of Metastatic Disease, Cellular and Gene Therapy in Comprehensive Textbook of Genito-Urinary Oncology. (N.J. Vogelzang, P.T. Scardino, W.U. Shipley, D.S. Coffey, eds.) Williams & Wilkins, Baltimore, MD, 15D: 261-275, 1996.
23. Sokoloff, M.H., **Figlin, R.A.**, Belldgrun, A.S., Management of Advanced Renal Cell Carcinoma in America Urological Association Update Series (T.P. Ball Jr., eds) AUA Office of Education, Bellaire, Texas, XV (30)238-243, 1996.
24. Dardashti, K., **Figlin, R.A.**, Taneja, S., deKernion, J, Belldgrun, A., Immunotherapy in Renal Cell Carcinoma; Cellular Immunotherapy, Basic Research in Urological Oncology, Luciani (eds) S. Karger, Basel, pp146-160, 1996.
25. Sokoloff, M.H., **Figlin, R.A.**, deKernion, J., Belldgrun, A.S., Systemic Immunotherapy of Genitourinary Neoplasms, in Principles and Practice of Genitourinary Oncology. (D. Raghavan, H.I. Scher, S.A. Leibel, P. Lange, eds.) J.B. Lippincott, Philadelphia, PA, 84:869-883, 1997.
26. Sokoloff, M.H., **Figlin, R.A.**, Belldgrun, A.S., Treatment of Metastatic Renal Cell Carcinoma in Current Genitourinary Cancer Surgery (D. Crawford and S. Das, Eds), Williams & Wilkins, Baltimore, MD, 48:619-630, 1997.
27. **Figlin, R.A.**, and Gitlitz, B.J., Interferon in Urological Tumours-Renal Cell Carcinoma in The Clinical Application of the Interferons, (R. Stuart-Harris, R. Penny, eds.) Chapman and Hall, London, England, 16:211-224, 1997.
28. Sokoloff, M.H., **Figlin, R.A.**, Belldgrun, A.S., Papel de la inmunoterapia en la recidiva de los tumores genitourinarios, Diagnosis and Treatment of Recurrences of Urologic Tumors, (C.D. Vera-Donosa, J.F. Jiminez Cruz, eds) Valencia, Spain, 2;23-45, 1996.
29. Abi-Aad, A., **Figlin, R.A.**, Metastatic Renal Cell Carcinoma: Systemic Treatment, Adjuvant Treatment In Urological Cancer, Abi-Aad (ed), Parthenon Publishing; England, in press.
30. **Figlin, R.A.**, Managed Care's Role in the War on Cancer, The California Experience in, President's Cancer Panel National Cancer Program, Fighting The War on Cancer in an Evolving Health Care System (Freeman, H.P., Visco, F.M., Calabresi, P. eds), National Cancer Institute, USA, A-24 - A-26, 1997.
31. Tucker, S.J., Belldgrun, A., **Figlin, R.A.**, Immunotherapy and Chemotherapy for Metastatic Renal Cell Carcinoma, Carcinoma of the Kidney, Testis and Uncommon Tumors of the Genitourinary Tract, Innovations in Management, (Petrovich, Z., Baert, L., Brady, L.W., eds) Springer-Verlag, New York, 117-130, 1999.

32. Naitoh J., **Figlin, R.A.**, Belldegrun, A., Controversies in the Surgical Management of Renal Cell Carcinoma: 1998 Recent Advances in the Diagnosis and Management of Kidney Cancer, American Urology Association Post Graduate Course.
33. Rusch, V.W., **Figlin, R.A.**, Pleural Mesothelioma in Cancer Treatment, 5th Edition (C.E. Haskell, ed) W.B. Sanders, Philadelphia, PA, 39:639-646, 2000.
34. Gitlitz, B.J., Belldegrun, A., **Figlin, R.A.**, Kidney Cancer: Management of Metastatic Disease, Cellular and Gene Therapy in Comprehensive Textbook of Genito-Urinary Oncology, 2nd Edition (N.J. Vogelzang, P.T. Scardino, W.U. Shipley, D.S. Coffey, eds.) Williams & Wilkins, Baltimore, MD, 234-247, 2000.
35. **Figlin, R.A.**, Cameron, R., Turrisi, A. III, Neoplasms of the Lung, Pleura, and Mediastinum, Non-Small Cell Lung Cancer, Cancer Treatment, 5th Edition (C.M. Haskell, M.D.) W.B. Saunders, 36:598-628, 2000.
36. Prager, D., Cameron, R., Ford, J., **Figlin, R.A.**, Bronchogenic Carcinoma, Textbook of Respiratory Medicine, 3rd Edition (J.F. Murray, M.D., J.A. Nadel, M.D., J. Mason, M.D., H.A. Boushey, Jr., M.D.), W.B. Saunders, 1415-1451, 2000.
37. Gitlitz, B.J., Belldegrun, A.S., **Figlin, R.A.**, Adoptive Immunotherapy in Renal Cell Carcinoma in Current Clinical Urology: Renal Cell Carcinoma: Molecular Biology, Immunology, and Clinical Management, (R.M. Bukowski, A. Novick, eds) Humana Press Inc., Totowa, N.J., 23:1-21, 2000.
38. Zisman, A., Belldegrun, A., **Figlin, R.A.**, Urinary Tract Cancers in Manual of Clinical Oncology, 4th Edition (D.A. Casciato and B.B. Lowitz, ed.) Little Brown and Company, Boston, MA, 13:278-302, 2000.
39. Belldegrun, A.S., **Figlin, R.A.**, Patel, B., Cell Transfer Therapy: Clinical Applications, Renal Cell Carcinoma, Principles and Practice of the Biologic Therapy of Cancer 3rd Edition, S.A. Rosenberg (ed), Lippincott Williams and Wilkins, NY, NY, 13:2;333-345, 2000.
40. Gitlitz, B.J., Hoffman, DMJ, Belldegrun, A.S., **Figlin, R.A.**, Genitourinary Neoplasms, Kidney, Cancer Treatment, 5th Edition (C.M. Haskell, ed) WB Saunders, 53:863-880, 2000.
41. **Figlin, R.A.**, Moldawer, N.P., Aldesleukin-2, Outline of Oncology Therapeutics: (Ratain, M.J., Tempero, M., Skosey, C., eds) WB Saunders, Orlando, Florida, 83-84, 2001.
42. Gitlitz, B.J., Belldegrun, A.B., **Figlin, R.A.**, Cell Based Therapy of Renal Cell Carcinoma, Renal and Adrenal Tumors (eds. Belldegrun, A.B., Ritchie, A., **Figlin, R.A.**, Oliver, T., Vaughn, E.D.) Oxford University Press, Oxford, England, 411-423, 2003.
43. Hoffman, D.M.J., **Figlin, R.A.**, Natural History and Prognostic Factors Associated with Metastatic Renal Cell Carcinoma, Renal and Adrenal Tumors (eds. Belldegrun, A.B., Ritchie, A., **Figlin, R.A.**, Oliver, T., Vaughn, E.D.) Oxford University Press, Oxford, England, 351-358, 2003.
44. Ucar, K., **Figlin, R.A.**, Principles of Immunotherapy of Cancer in Current Cancer Diagnosis and Treatment, (C. Henderson, C. Wilson, T. Phillips, H. Debas, D. Northfelt, eds.) Appleton and Lange, Norwalk, CT, in press.
45. Leibovich, B.C., Pantuck, A.J., Bui, M.H.T., Han, K., Zisman, A., **Figlin, R.A.**, Belldegrun, A.S., Current Staging of Renal Cell Carcinoma, Urologic Clinics of North America, 30:481-497, 2003.

46. Gitlitz, B.J., **Figlin, R.A.**, Cytokine-Based Therapy for Metastatic Renal Cell Carcinoma, Urologic Clinics of North America, 30:589-600, 2003.
47. Gitlitz, B.J., **Figlin, R.A.**, Cell, Gene and Vaccine Based Strategies in Kidney Cancer, Cancer Treat Res., 116:183-98, 2003.
48. Janzen, N.K., Kim, H.L., **Figlin, R.A.**, Belldegrun, A.S., Surveillance After Radical or Partial Nephrectomy for Localized Renal Cell Carcinoma and Management of Recurrent Disease, Urol Clin N Am, 30:843-852, 2003.
49. Kim, H.L., Gitlitz, B.J., **Figlin, R.A.**, Kidney Cancer Vaccines, Cancer Drug and Discovery: Handbook of Cancer Vaccines, (M. Morse, H.K. Lyster, T.M. Clay eds) Humana Press, Totowa, N.J., 415-423, 2004.
50. Krupski, T., Kim, H., **Figlin, R.A.**, Belldegrun, A., Treatment of Advanced Renal Cell Carcinoma, (Richie J, D'Amico, A, eds) Urologic Oncology, Elsevier, Philadelphia, PA, 258-268, 2004.
51. Zisman, A., Belldegrun, A.S., **Figlin, R.A.**, Urinary Tract Cancers in Manual of Clinical Oncology, 5th Edition (D.A. Casciato, ed.) Lippincott Williams & Wilkins, 295-320, 2004.
52. Hutson, T.E., **Figlin, R.A.**, Tyrosine Kinase Inhibitors in Renal Cell Carcinoma, in Principles and Practice of Oncology Updates (DeVita, VT., Lawrence, TS., Rosenberg, SA., eds) Wolters Kluwer Health-Lippincott Williams and Wilkins, NY., NY., 21 (1); 1-8, 2007.
53. Pal, S.K., **Figlin R.A.**, Prognostic Factors in Renal Cell Carcinoma Patients: Localized and Metastatic Disease, in New Treatment Paradigms in Renal Cell Cancer, The Beam Institute, The Oncology Group, CMP Medica, Inc.pps 35-60, 2007.
54. Reckamp K.L., Strieter R.M., **Figlin R.A.**, Anti-angiogenesis Therapies in Renal Cell Carcinoma, in Renal Cell Cancer: Diagnosis and Therapy (de la Rosette, J., Sternberg, C.N., van Poppel, H., eds) Springer-Verlag (London) Ltd., UK. 449-456, 2008.
55. Zisman, A., Twardowski, P., Leibovici, D., **Figlin, R.A.**, Urinary Tract Cancers in Manual of Clinical Oncology, 6th Edition (D.A. Casciato, ed.) Lippincott Williams & Wilkins, 307-331, 2009.
56. Bukowski, R.M., **Figlin, R.A.**, Motzer, R.J., Targeted Therapy for Metastatic Renal Cell Carcinoma: Overview, in Renal Cell Carcinoma: Molecular Targets and Clinical Applications, 2nd Edition (Bukowski, R.M., **Figlin, R.A.**, Motzer, R.J., eds) The Humana Press Inc. Totowa, NJ USA. 2009.
57. Reckamp K.L., **Figlin R.A.**, Strieter R.M., Chemokines in renal cell carcinoma-Implications for tumor angiogenesis and metastasis, in Renal Cell Carcinoma: Molecular Targets and Clinical Applications, 2nd Edition (Bukowski, R.M., **Figlin, R.A.**, Motzer, R.J., eds) The Humana Press Inc. Totowa, NJ USA. 2009.
58. Shuch, B., Belldegrun, A.S., **Figlin, R.A.**, Carbonic Anhydrase IX: Biology and Clinical Approaches, in Renal Cell Carcinoma: Molecular Targets and Clinical Applications, 2nd Edition (Bukowski, R.M., **Figlin, R.A.**, Motzer, R.J., eds) The Humana Press Inc. Totowa, NJ USA. 2009.
59. Lam, J.S., **Figlin, R.A.**, Belldegrun, A.S., VEGF and PRGF Receptors: Biologic Relevance and Clinical Approaches to Inhibition, in Renal Cell Carcinoma: Molecular Targets and Clinical Applications, 2nd Edition (Bukowski, R.M., **Figlin, R.A.**, Motzer, R.J., eds) The Humana Press Inc. Totowa, NJ USA. 2009.

60. Sonpavde, G., Hutson T.E., **Figlin, R.A.**, Sternberg, C.N., Pazopanib, in Renal Cell Carcinoma: Molecular Targets and Clinical Applications, 2nd Edition (Bukowski, R.M., **Figlin, R.A.**, Motzer, R.J., eds) The Humana Press Inc. Totowa, NJ USA. 2009.
61. Pal, S.K., and **Figlin, R.A.**, Trends in Molecularly Targeted Therapies of Renal Cancer, Encyclopedia of Cancer, (Schwab, Manfred, Ed) Springer, NY. NY. 2009.
62. Twardowski, P.W., **Figlin, R.A.**, Treatment of Metastatic Kidney Cancer, in Evidence-Based Urology, (Dahm, P., Dmochowski, R, eds) Wiley-Blackwell, BMJI Books, West Sussex, UK, Chapter 35, 343-50, 2010.
63. Twardowski, P., **Figlin, R.A.**, Adjuvant and Neoadjuvant Treatment for Genitourinary Cancers – Commentary, in Principles and Practice of Surgical Oncology. Multidisciplinary Approach to Difficult Problems, (Silberman, H., Silberman, A.W., eds) Lippincott, Williams and Wilkins, Baltimore, MD. 55:992-995, 2010.
64. Pal, S.K., Reckamp, K., Yu, H., **Figlin, R.A.**, Immunotherapy in the Management of Renal Cell Carcinoma, in Comprehensive Textbook of Genitourinary Oncology, 6th Edition (Vogelzang, N., Scardino, P.T., Zelefsky, M.J., Linehan, W.M., eds) Lippincott, Williams & Wilkins, Philadelphia, PA., in press.
65. Pal, S., **Figlin, R.A.**, Other Renal Parenchymal Disorders: Renal Neoplasias, in Nephrology Secrets, (Lerma, E.V., and Nissenson, A., eds), Elsevier/Mosby, Philadelphia, PA., Chapter 48, 346-350.
66. Pal, S., Kim, H., **Figlin, R.A.**, Urinary Tract Cancers in Manual of Clinical Oncology, 7th Edition (D.A. Casciato, M.C. Territo, eds.) 13; 365-394, 2012, Lippincott Williams & Wilkins, Philadelphia, PA.
67. Kim, H.L., Posadas, E.M., **Figlin, R.A.**, Presurgical Therapy for Renal Cell Carcinoma and Implications for Window of Opportunity Trials, Renal Cell Carcinoma: Biology, Prognostic Factors, and Therapeutic Targets, (**Figlin, R.A.**, Rathmell, K., Rini, B., eds) Chapter 13, 271-282, Springer, NY, NY.
68. Pal, S.K., Reckamp, K., Yu, H., **Figlin, R.A.**, Characterizing and Modulating the Tumor Micro-Environment in Renal Cell Carcinoma: Potential Therapeutic Strategies, Renal Cell Carcinoma: Biology, Prognostic Factors, and Therapeutic Targets, (**Figlin, R.A.**, Rathmell, K., Rini, B., eds) Chapter 11, 239-252, Springer, NY, NY.
69. Pal, S.K., **Figlin, R.A.**, Development and Incorporation of Biomarkers in Renal Cell Carcinoma Therapeutics, in Renal Cell Carcinoma, Molecular Targets and Clinical Applications, 3rd Edition, (Bukowski, R.M., **Figlin, R.A.**, Motzer, R.J., eds) The Humana Press, New York, New York, (in press).
70. Koopman, S., Afshar, A., **Figlin, R.**, Kim, H.L., Molecularly Targeted Staging Strategies in Renal Cell Carcinoma, in Renal Cell Carcinoma, Molecular Targets and Clinical Applications, 3rd Edition, (Bukowski, R.M., **Figlin, R.A.**, Motzer, R.J., eds) The Humana Press, New York, New York, (in press).
71. Tan, C.C., **Figlin, R.A.**, Hendifar, A.E., The Evolving Role of Mammalian Target of Rapamycin (mTOR) Inhibitors in Renal Cell Carcinoma, in mTOR Inhibitors for Cancer Therapy – Past, Present, and Future, (Mita, M., Mita. A., Rowinsky, E., eds) Springer-Verlag GmbH, Berlin, Germany, (in press).

Name: Mark M. Moasser

Date of Birth: 10/07/62

Nationality: U.S.A.

Office Address: UCSF Box 1387
University of California, San Francisco
San Francisco, CA 94143
Tel: (415) 476-0158
Fax: (415) 353-9592
Email: mark.moasser@ucsf.edu

Medical Licensure:
1989, New York,
2004, California

Board Certification:
Internal Medicine, 1991
Medical Oncology, 1996,2005

Education:

University of Pennsylvania
May 1984, B.A., Philadelphia, PA

Tufts University School of Medicine
June 1988, M.D., Boston, MA

Postdoctoral training:
1988 – 1989 Internship, The New York Hospital - Cornell Medical Center, Internal Medicine, New York, NY
1989 – 1991 Residency, The New York Hospital - Cornell Medical Center, Internal Medicine, New York, NY
1991 – 1995 Fellowship, Memorial Sloan-Kettering Cancer Center, Medical Oncology, New York, NY
1995 – 1996 Special Fellowship, Memorial Sloan-Kettering Cancer Center, Breast Cancer Medicine Service, New York, NY

Positions and Appointments:
1996-1999 Instructor, Dept. of Medicine, Breast Cancer Medicine Service, Memorial Sloan-Kettering Cancer Center, New York, NY
1996-2004 Instructor, Dept. of Medicine, Cornell University Medical College, New York, NY
1999-2004 Clinical Assistant, Dept of Medicine, Breast Cancer Medicine Service, Memorial Sloan-Kettering Cancer Center, New York, NY

2004-2007	Associate Clinical Professor, Dept. of Medicine, Division of Hematology/Oncology, University of California, San Francisco
2008-2010	Associate Professor in Residence, Dept. of Medicine, Division of Hematology/Oncology, University of California, San Francisco
2010-present	Professor in Residence, Dept. of Medicine, Division of Hematology/Oncology, University of California, San Francisco
2008-present	Member, Biomedical Sciences Program, University of California, San Francisco

Scientific and Medical Societies:

American Society of Clinical Oncology
American Association for Cancer Research
American Society for Clinical Investigation

Honors and Awards:

Phi Beta Kappa (1984)
Clinical and Molecular Cancer Research Training Fellowship Award (1992-1993)
American Society for Clinical Oncology Young Investigator Award (1994) (declined)
Charles A. Dana Fellowship Award (1993-1995)
Clinical Scholars Award, Biomedical Research Training Program, Sloan-Kettering Institute (1993-1995)
Ethel Abbott Fellowship Award (1995-1996)
Byrne Fund Award (1997-1999)
American Society for Clinical Oncology Career Development Award (1997-2000)
American Cancer Society Research Scholar (2002-2006)
Susan Komen Breast Cancer Research Foundation Award (2005-2007)
California Breast Cancer Research Program Award (2005-2006)
Elected to the American Society for Clinical Investigation, 2008

Patents

Feb 15, 2005 Co-inventor, "Method of treating cancer". US #20050137207.

INVITED PRESENTATIONS**NATIONAL**

Jan 2004, "A molecular basis for the anti-tumor activity of ZD1839". Thoracic Oncology Seminar. MD Anderson Cancer Center, Houston TX.

Jan 14-16, 2005, "New directions in novel therapies for breast cancer". 4th Annual UCSF Clinical Cancer Update, North Lake Tahoe, CA

May 31, 2007, "Understanding resistance to tyrosine kinase inhibitors in breast cancer", Cancer Center Seminar, UC Davis, Davis, CA

June 2, 2007, co-Chair, Clinical Science Symposium, “Targeting breast cancer with monoclonal antibodies and small molecules: beyond HER2”. 43rd Annual Meeting of the American Society of Clinical Oncology, Chicago, IL

November 2, 2007, “Towards the eradication of HER2-driven breast cancer”. Genentech, Inc., South San Francisco, CA

November 12, 2007, “The role of HER3 in HER2-driven tumors”, Genentech-Pertuzumab Advisory Board Meeting, San Antonio, TX

June 6, 2008, “Towards highly effective treatment of HER2-driven breast cancer”. Duke Univ Cancer Center Seminar, Durham, NC

June 18, 2008, “The Molecular Basis of Cancer: Fundamental and Evolving Concepts”. Hematology/Oncology Pharmacist Association Annual Conference, Anaheim, CA

August 4, 2008, “The HER family in human cancer”. AVEO Pharmaceuticals Scientific Advisory Board Meeting, Cambridge, MA

October 30, 2009, “Towards highly effective treatment of HER2-driven cancer”, Guest Speaker, Ambit Biosciences, San Diego, CA

November 13, 2009, “Treatment of HER2-driven Cancer through the Inactivation of HER2 Closing in on an elusive treatment hypothesis”, Elkin Lecture, Emory Winship Cancer Institute, Emory University, Atlanta, GA

July 30, 2010, “Treatment of HER2-driven Cancer through the Inactivation of HER2 Closing in on an elusive treatment hypothesis”, Guest Speaker, Merrimack Pharmaceuticals, Cambridge, MA

August 21, 2010, "Phosphotyrosine signaling in epithelial cells has two functional modes, linked with cell anchorage", Meeting on Protein Phosphorylation and Cell Signaling, The Salk Institute, La Jolla, CA

November 15, 2010, "Two modes of phosphotyrosine signaling in epithelial cells; Resiliency in the HER2-HER3 tumor driver". Cold Spring Harbor Laboratory Cancer Center Seminar, Cold Spring Harbor, NY

January 14, 2011, “Treatment of HER2-driven cancer through the inactivation of HER2; Closing in on an elusive treatment hypothesis”. Guest speaker, Sealane Biotechnologies. Mountain View, CA

May 18, 2012, “The treatment of HER2-driven cancer through the inactivation of HER2; The third decade”. Visiting Professor Lecture, Fox Chase Cancer Center, Philadelphia, PA

April 18, 2013, “The treatment of HER2-driven cancer through the inactivation of HER2; The

third decade”, Department of Human Oncology Seminar Series, University of Wisconsin, Madison, Madison, WI

May 1, 2013, “Mapping the network topology underlying HER3 resiliency in HER2-amplified cancers”, NCI Integrated Cancer Biology Program (ICBP) Retreat, Oregon Health Sciences University, Portland, OR

June 2013, “HER3 Action in Therapy-Resistant Breast Cancer “, The Endocrine Society 95th Annual Meeting, San Francisco, CA

December 2014; “HER2 Positive Breast Cancer: Insights from the Lab and Clinic”, San Antonio Breast Cancer Symposium. San Antonio, TX

REGIONAL

July 2004, “A novel mitotic substrate of src kinases”. UCSF Dept of Anatomy, Host; Zena Werb

October 2004, “Inhibition of HER family signaling by TK inhibitors”. UCSF Dept of Cellular and Molecular Pharmacology, Host: Kevan Shokat

Jan 31, 2005, “HER3 signaling evades HER family TK inhibitors”. 2005 UCSF Breast Oncology Program Scientific Retreat. San Francisco, CA.

March 7, 2005, “Novel agents in the treatment of breast cancer”. 2005 UCSF Breast Oncology Program curriculum course. UCSF Cancer Center, San Francisco, CA

June 29, 2005. “A novel mitotic substrate of src kinases”. Division of Biochemistry & Molecular Biology, University of California, Berkeley. Host: Steve Martin

September 16, 2005, “A novel mitotic substrate of src kinases”. Dept of Molecular & Cellular Biology, University of California, Berkeley. Host: John Kuriyan

January 5, 2006, “Tyrosine kinase inhibitors in the treatment of breast cancer”, Medical Grand Rounds, UCSF Department of Medicine

January 31, 2008, “Towards highly effective treatment of HER2-driven breast cancer”. UCSF Breast Oncology Program retreat, San Francisco, CA

February 29, 2008, “Towards highly effective treatment of HER2-driven breast cancer”. Division of Hematology/Oncology scientific retreat. San Francisco, CA

May 2, 2008, “A src-driven pathway in the origins of pancreatic cancer”. UCSF Pancreatic Cancer SPORE Program EAB meeting. San Francisco, CA

January 26, 2009, “Targeted therapy for patients with BRCA - associated cancer”. UCSF Department of Physiology, San Francisco, CA

January 23, 2009, “A src-driven pathway in the origins of pancreatic cancer”. UCSF Pancreatic Cancer SPORE program meeting. San Francisco, CA

January 29, 2009, “Treating HER2-Driven Breast Cancer Through the Inactivation of HER2”. UCSF Breast Oncology Program retreat, San Francisco, CA

January 26, 2009, “BRCA 1 & 2; From genetics to therapeutics”. UCSF Biomedical Sciences Program, Lecture in Demystifying Medicine series. San Francisco, CA

September 2009, "Molecular Targets in Breast Cancer", Stanford University, Comprehensive Cancer Research Training Program, Menlo Park, CA

August 5, 2009, “Towards effective inactivation of tumor HER2; closing in on an elusive treatment hypothesis”, Integrative Cancer Biology Program Seminar, Lawrence Berkeley National Laboratory, Berkeley, CA

August 27, 2009, “The src phosphorylation of Trask prevents integrin activation and defines the anchorage-independent state of epithelial cells”. UCSF Helen Diller Family Cancer Center Symposium, San Francisco, CA

December 4, 2009, “Treatment of HER2-driven Cancer through the Inactivation of HER2 Closing in on an elusive treatment hypothesis”, Radiation Oncology Grand Rounds, UCSF Cancer Center, San Francisco, CA

September 2010, "Molecular Targets in Breast Cancer", Stanford University, Comprehensive Cancer Research Training Program, Menlo Park, CA

January 29, 2010, “Systems Biology; Tackling the complex network fueling HER2 addiction”. UCSF Breast Oncology Program Retreat, San Francisco, CA

December 3, “Molecular Targets & Cancer Therapeutics”, UCSF Comprehensive Cancer Center. Clinical Research Seminar Series

March 16, 2011, “A tumor suppressing function in Src kinases”. Breast Oncology Program Seminar. UCSF Comprehensive Cancer Center, San Francisco, CA

March 18, 2011, “Resolving the complex network fueling HER2-HER3 addiction”, Physical and Computational Approaches to Cancer Biology. A UCSF/QB3 workshop in cancer & physics. San Francisco, CA

October 28-29, 2011, “Understanding HER2 structure and signaling pathway”, Expert Forum on HER2 inhibition, University of Miami Sylvester Cancer Center, Miami, FL

December 8, 2011, “Treating HER2-Driven Breast Cancer Through the Inactivation of HER2”, Ambit Biosciences, San Diego, CA

January 25, 2013, “Mechanistic Complexity and Redundancy in Tumor Adaptation”, UCSF Breast Oncology Program Retreat, San Francisco, CA

February 8, 2013, “Understanding and targeting the oncogenic function of HER2; The fourth decade”, UCSF Helen Diller Family Comprehensive Cancer Center Seminar Series, San Francisco, CA

April 8, 2013, Minisymposium Chair, “Novel Approaches to Targeting Critical Signaling Pathways”. AACR Annual Meeting, Washington, DC

June 2, 2013; Session Chair, Tumor Biology Oral Abstract Session, ASCO Annual Meeting, Chicago, IL

May 31, 2014; Session Chair, Tumor Biology Clinical Science Symposium, ASCO Annual Meeting, Chicago, IL

Committees

2005-present, Steering Committee, UCSF Cancer Center Preclinical Core facility

2005-2012, Member, UCSF Comprehensive Cancer Center Protocol Review Committee

2005-2010, Member, Biotechnology Executive Committee, University of California Industry-University Cooperative Research Program (IUCRP, now UC Discovery)

2009, Chair, Biotechnology Executive Committee, University of California Industry-University Cooperative Research Program (IUCRP, now UC Discovery)

2006-pres., Member, UCSF Division of Hematology/Oncology Fellowship Program Task Force
2006-pres., Member, UCSF Division of Hematology/Oncology Fellowship Selection Committee

2007-2011., Member, external advisory board, UCSF Prostate Cancer SPORE program

2008-pres, Member, Breast Oncology Program Tissue Utilization Committee

2004-present, Member, UCSF Breast Oncology Program Site Committee

2008- present, Member and co-Chair, UCSF Phase I Program Site Committee

2009-present, Member, UCSF Investigational Therapeutics Initiative Steering Committee

2011, Chair, Tumor Biology IV section, San Antonio Breast Cancer Symposium Program Committee,

2012 Member, AACR Outstanding Investigator Award in Breast Cancer Research Selection Committee

2012-pres, Member, 2012-2014 AACR Laboratory Research Awards Committee

2012-pres, Member, ASCO Scientific Program Committee

2013-pres, Chair, ASCO Scientific Program Committee, Tumor Biology Track Leader

2013-pres, Member, ASCO Cancer Education Committee, Tumor Biology Track

2012-pres, Member, UCSF Limited Submission Program standing Cancer Review Committee.

2013-pres, Member, UCSF Resource Allocation Program (RAP) Cancer Review Committee

2013-pres, Member, UCSF-Onyx Alliance Oncology Innovation Alliance Joint Steering Committee

2014 – Member, Gynecologic Oncology Program Director search committee

Thesis committee service:

2010: Lisa Singer, UCSF/UCB Joint Graduate Group in Bioengineering

2010: Guang Lin, Stony Brook University, Cold Spring Harbor Laboratories

2011: Samantha Liang, UCSF Tetrad, Dept of Biochem & Biophys

2011: Kliment Verba, UCSF Tetrad Program, Dept of Biochem & Biophys

2013: Bianca Lee, UCSF BMS Program,

2013: Gorjan Hrustanovic, UCSF BMS Program, Qualifying exam committee chair

Review panels

2003-2004; Grants review committee member, Susan Komen Breast Cancer Foundation

2007- pres; Susan G. Komen for the Cure, Review panel

2005, Member of Clinical Investigator Research Program Review Committee, UCSF Comprehensive Cancer Center

2005-present, Member, University of California Industry-University Cooperative Research Program (IUCRP, now UC Discovery) Biotechnology sector review panel

2008, 2011-present. Chair, University of California Industry-University Cooperative Research Program (IUCRP, now UC Discovery) Biotechnology sector review panel

2005-2007, Member, Centers of Excellence Review Panel, Department of Defense Breast Cancer Research Program

2006, Chair, Consortium Review Panel, Department of Defense Neurofibromatosis Research Program,

2007-pres, Member, Review Panel, Department of Defense Breast Cancer Research Program

2006-pres, Member, UCSF Cancer Center Stewart Trust Fund review panel

2007, Reviewer for Cancer Research UK

2009, Ad Hoc Review panel, University of Miami Sylvester Cancer Center

2010, Review panel, Mary Kay Ash Charitable Foundation

2010, Review panel, National Institutes of Health, Developmental Therapeutics Study Section

2010, Ad Hoc reviewer, Washington University St Louis

2010, Review panel, UCSF Graduate Education in Medical Sciences fellowship

2010, Review panel, UCSF internal panel to select V-foundation applicant

2011, Chair, UCSF pre-application review panel for the Mark Kay Ash Charitable Foundation grant applications

2010, 2011 Ad Hoc reviewer, NIH Developmental Therapeutics Study Section

2012, Science Committee Expert review panel, Cancer Research UK

2014, Review panel, NIH Special Emphasis Panel

Reviewer for following Journals

Cancer Cell

PNAS

Nature

Nature Communications

Science Translational Medicine

Science Signaling

PLoS Medicine

PLoS One,

Journal of Clinical Oncology,

New England Journal of Medicine

Journal of Clinical Investigation,
Cancer Research,
Clinical Cancer Research,
Molecular Cancer Therapeutics,
Molecular Cancer Research,
Cancer Epidemiology, Biomarkers & Prevention,
Journal of the American Medical Association,
Journal of Cellular Physiology,
Oncogene,
Cancer Investigation,
British Journal of Cancer

Editorial Boards

Journal of Clinical Oncology (2009- 2011)

Book Chapters

Moasser, MM. Neoplasia. Pathophysiology of Disease, McPhee SJ, Vishwanath R, Ganong W. 5th Edition 2005. McGraw Hill/Appleton & Lange.

Moasser, MM. Neoplasia. Pathophysiology of Disease, McPhee SJ, Hammer GD. 6th Edition 2010. McGraw Hill/Appleton & Lange.

Moasser, MM. Neoplasia. Pathophysiology of Disease, McPhee SJ, Hammer GD. 7th Edition 2013. McGraw Hill/Appleton & Lange.

Publications

1. Moasser MM., DeBlasio A, and Dmitrovsky E. Response and resistance to retinoic acid are mediated through the retinoic acid nuclear receptor in human teratocarcinomas. *Oncogene* 1994; 9: 833-840.
2. Moasser, MM, Reuter V, Dmitrovsky E. Over-expression of the retinoic acid receptor directly induces terminal differentiation of human embryonal carcinoma cells. *Oncogene* 1995; 10: 1537-1543.
3. Ahn MJ, Nason-Burchenal K, Moasser MM, Dmitrovsky E. Growth suppression of acute promyelocytic leukemia cells having increased expression of the non-rearranged alleles: RAR α or PML. *Oncogene* 1995; 10: 2307-2314.
4. Moasser,MM, Motzer RJ, Khoo KS, Lyn P, Murphy B, Bosl GJ, Dmitrovsky E. All-Trans Retinoic Acid for Germ Cell Tumors: In Vitro Activity and Results of a Phase II Study, *Cancer* 1995; 76: 680-686.
5. Ahn MJ, Langenfeld J, Moasser MM, Rusch V, and Dmitrovsky E. Growth suppression of transformed human bronchial epithelial cells by all-trans retinoic acid occurs through specific retinoid receptors, *Oncogene* 1995; 11: 2357-2364.
6. Baldassarre G, Bianco C, Tortora G, Ruggiero A, Moasser M, Dmitrovsky E, Bianco AR, and Ciardiello F. Transfection with a crypto anti-sense plasmid suppresses endogenous crypto expression and inhibits transformation in a human embryonal carcinoma cell line. *Int. J.*

- Cancer* 1996; 66: 538-543.
7. Moasser MM, Khoo KS, Maerz W, Zelenetz A, Dmitrovsky E. Derivation and characterization of retinoid resistant human embryonal carcinoma cells. *Differentiation* 1996; 60: 251-257.
 8. Moasser MM, Sepp-Lorenzino L, Kohl NE, Oliff A, Baalog A, Su D, Danishefsky SJ, and Rosen N. Farnesyl Transferase Inhibitors cause enhanced mitotic sensitivity to taxol and epothilones. *Proc Natl. Acad. Sci. USA* 1999; 95: 1369-1374.
 9. Moasser MM, Srethapakdi M, Sachar KS, Kraker AJ, and Rosen N. Inhibition of src kinases by a selective tyrosine kinase inhibitor causes mitotic arrest. *Cancer Research* 1999; 54: 6145-6152.
 10. Sepp-Lorenzino L, Tjaden G, Moasser MM, Timaul N, Ma Z, Kohl NE, Gibbs JB, Oliff A, Rosen N, Scher HI. Farnesyl:protein transferase inhibitors as potential agents for the management of prostate cancer. *Prostate Cancer and Prostatic Diseases* 2001; 4: 33-43.
 11. Van Poznak C, Seidman AD, Reidenberg MM, Moasser MM, Sklarin N, Van Zee K, Borgen P, Gollub M, Bacotti D, Yao TJ, Bloch R, Ligueros M, Sonenberg M, Norton L, and Hudis C. Oral Gossypol in the treatment of patients with refractory metastatic breast cancer: A phase I/II clinical trial. *Breast Cancer Research and Treatment* 2001; 66: 239-248.
 12. Seidman AD, Fornier MN, Esteva FJ, Tan L, Kaptain S, Bach A, Panageas KS, Arroyo C, Valero V, Currie V, Gilewski T, Moynahan ME, Moasser M, Sklarin N, Dickler M, D'Andrea G, Cristofanilli M, Rivera E, Hortabagyi GN, Norton L, and Hudis C. Weekly Trastuzumab and paclitaxel therapy for metastatic breast cancer with analysis of efficacy by HER2 immunophenotype and gene amplification. *J Clin Oncology* 2001; 19:2587-95.
 13. Moasser MM, Basso A, Averbuch SD, Rosen N. The tyrosine kinase inhibitor ZD1839 ('Iressa') inhibits HER2-driven signaling and suppresses the growth of HER2-overexpressing tumors. *Cancer Research* 2001; 61: 7184-7188.
 14. Munster PN, Srethapakdi M, Moasser MM, Rosen N. Inhibition of heat shock protein 90 function by ansamycins causes the morphological and functional differentiation of breast cancer cells *Cancer Research* 2001; 61:2945-52.
 15. MN Fornier, AD Seidman, M Theodoulou, ME Moynahan, V Currie, M Moasser, N Sklarin, T Gilewski, G D'Andrea, R Salvaggio, KS Panageas, L Norton, C Hudis. Doxorubicin Followed by Sequential Paclitaxel and Cyclophosphamide vs Concurrent Paclitaxel and Cyclophosphamide: 5-Year Results of a Phase II Randomized Trial of Adjuvant Dose-Dense Chemotherapy for Women with Node-positive Breast Carcinoma. *Clin. Cancer Res.* 2001 7: 3934-3941.
 16. Moasser MM & Rosen N. Molecular markers in the farnesyltransferase inhibitor (FTI) therapy of breast cancers. *Breast Cancer Research & Treatment* 2002; 73:135-144.
 17. Huron DR, Gorre ME, Kraker AJ, Sawyers CL, Rosen N, Moasser MM. A novel pyridopyrimidine inhibitor of Abl kinase is a picomolar inhibitor of Bcr-abl driven K562 cells and is effective against STI571-resistant Bcr-abl mutants. *Clinical Cancer Research* 2003; 9: 1267-1273.
 18. She QB, Solit D, Basso A, Moasser MM. Resistance to gefitinib (ZD1839, Iressa) in PTEN null HER overexpressing tumor cells can be overcome through restoration of PTEN function or pharmacologic modulation of constitutive PI3K/Akt pathway signaling. *Clinical Cancer Research* 2003; 9: 4340-4346.
 19. Mizenina OA & Moasser MM. S-phase Inhibition of Cell Cycle Progression by a Novel

- Class of Pyridopyrimidine Tyrosine Kinase Inhibitors. *Cell Cycle* 3; p796-803 (2004).
20. Dang CT, Dannenberg AJ, Subbaramaiah K, Dickler MN, Moasser MM, Seidman AD, D'Andrea GM, Theodoulou M, Panageas KS, Norton L, Hudis CA. Phase II study of celecoxib and trastuzumab in metastatic breast cancer patients who have progressed after prior trastuzumab-based treatments. *Clinical Cancer Research* 10; p4062-7 (2004).
 21. Modi S, Seidman A, Dickler M, Moasser M, D'Andrea G, Moynahan M, Menell J, Panageas K, Tan L, Norton L, Hudis C. A phase II trial of imatinib mesylate monotherapy in patients with metastatic breast cancer. *Breast Cancer Res Treat.* 2005, 90;p157-63.
 22. Modi S, Currie VE, Seidman AD, Bach AM, Panageas KS, Theodoulou M, Moasser MM, D'Andrea GM, Lake DE, Choi J, Norton L, Hudis CA. A Phase II Trial of Gemcitabine in Patients with Metastatic Breast Cancer Previously Treated with an Anthracycline and Taxane. *Clin Breast Cancer.* 6; p55-60 (2005)
 23. Bhatt AS, Erdjument-Bromage H, Tempst P, Craik CS, Moasser MM. Adhesion Signaling by a novel mitotic substrate of src kinases. *Oncogene* 24; p5333-5343 (2005).
 24. Hurria A, Zuckerman E, Panageas KS, Fornier M, D'Andrea G, Dang C, Moasser M, Robson M, Seidman A, Currie V, VanPoznak C, Theodoulou M, Lachs MS, Hudis C. A prospective, longitudinal study of the functional status and quality of life of older patients with breast cancer receiving adjuvant chemotherapy. *J Am Geriatr Soc* 54, p1119-1124 (2006).
 25. Hurria A, Rosen C, Hudis C, Zuckerman E, Panageas KS, Lachs MS, Witmer M, van Gorp WG, Fornier M, D'Andrea G, Moasser M, Dang C, VanPoznak C, Holland J. Cognitive function of older patients receiving adjuvant chemotherapy for breast cancer: a pilot prospective longitudinal study. *J Am Geriatr Soc* 54; p925-931 (2006).
 26. Hurria, A., Goldfarb, S., Rosen, C., Holland, J., Zuckerman, E., Lachs, M. S., Witmer, M., van Gorp, W. G., Fornier, M., D'Andrea, G., Moasser, M., Dang, C., Van, Poznak C., Robson, M., Currie, V. E., Theodoulou, M., Norton, L., and Hudis, C. Effect of adjuvant breast cancer chemotherapy on cognitive function from the older patient's perspective. *Breast Cancer Res Treat* 98; 343-348 (2006)
 27. Sergina NV, Rausch M, Wang D, Blair J, Hann B, Shokat KM, Moasser MM. Escape from HER family tyrosine kinase inhibitor therapy by the kinase inactive HER3. *Nature* 445; p437-441 (2007). PMID: 17206155; PMCID: PMC3025857.
 28. Moasser MM, Wilmes LJ, Wong CH, Li K, Wang D, Hom YK, Hann B, Hylton NM. Improved tumor vascular function following high dose epidermal growth factor receptor tyrosine kinase inhibitor therapy. *J Mag Res Imag* 2007 26:1618-25. PMID: 17968965; PMCID: PMC3024590.
 29. Moasser MM. The oncogene HER2; Its signaling and transforming functions and its role in human cancer pathogenesis. *Oncogene* 26; p6469-6487 (2007). PMID: 17471238; PMCID: PMC3021475.
 30. Moasser MM. Targeting the function of the HER2 oncogene in human cancer therapeutics. *Oncogene* 26; p6577-6592 (2007). PMID: 17486079; PMCID: PMC3071580.
 31. Hsieh AC & Moasser MM. Targeting HER proteins in cancer therapy and the role of the non-target HER3. *Br J Cancer* 97; p453-457 (2007). PMID: 17667926; PMCID: PMC2360352.
 32. Sergina NV & Moasser MM. The HER family: emerging molecular mechanisms and therapeutic targets. *Trends Mol Med* 13; p527-534 (2007). PMID: 17981505; PMCID: PMC3035105.

33. Traina TA, Poggesi I, Robson M, Asnis A, Duncan BA, Heerdt A, Dang C, Lake D, Moasser M, Panageas K, Borgen P, Norton L, Hudis C, Dickler MN. Pharmacokinetics and safety of exemestane plus raloxifene in breast cancer. *Breast Can Res Treat* 2008; 111: 377-88. PMID: 17952589.
34. Wieduwilt WJ & Moasser MM. The epidermal growth factor receptor family: biology driving targeted therapeutics. *Cell & Mol Life Sci* 2008; 65: 1566-84. PMID: 18259690; PMCID: PMC3060045.
35. Chien AJ & Moasser MM. Cellular Mechanisms of Resistance to Anthracyclines and Taxanes in Cancer: Intrinsic and Acquired. *Semin Oncol* 35(Suppl 2); S1-S14 (2008). PMID: 18410794.
36. Torbett NE, Luna A, Knight ZA, Houk A, Moasser MM, Weiss W, Shokat KA and David Stokoe. A chemical screen in diverse breast cancer cell lines reveals genetic enhancers and suppressors of sensitivity to PI3K isotype-selective inhibition. *Biochemical J* 2008; 415: 97-110. PMID: 18498248; PMCID: PMC3079392.
37. Aliu SO, Wilmes LJ, Moasser MM, Hann BC, Li KL, Wang D, Hylton NM. MRI methods for evaluating the effects of tyrosine kinase inhibitor administration used to enhance chemotherapy efficiency in a breast tumor xenograft model. *J Magn Reson Imaging*. 2009; 29:1071-9. PMID: 19388114.
38. Wong CH, Baehner FL, Spassov DS, Ahuja D, Wang D, Hann B, Blair J, Shokat K, Welm AL, Moasser MM The src phosphorylation of its epithelial substrate Trask is tightly regulated in normal epithelia but widespread in many human epithelial cancers. *Clin Cancer Res* 2009; 15: 2311-2322. PMID: 19318475; PMCID: PMC3023342.
39. Dickler MN, Rugo HS, Eberle CA, Brogi E, Caravelli JF, Panageas KS, Boyd J, Yeh B, Lake DE, Dang CT, Gilewski TA, Bromberg JF, Seidman AD, D'Andrea GM, Moasser MM, Melisko M, Park JW, Dancey J, Norton L, Hudis CA. A phase II trial of erlotinib in combination with bevacizumab in patients with metastatic breast cancer. *Clin Cancer Res* 2008; 14: 7878-83. PMID: 19047117; PMCID: PMC2748748.
40. Arkin M & Moasser MM. HER2 directed small molecule antagonists. *Curr Opin Investigat Drugs* 2008; 9: 1264-76. PMID: 19037833; PMCID: PMC3031872.
41. Spassov DS, Baehner FL, Wong CH, McDonough S, Moasser MM. The Transmembrane src Substrate Trask Is an Epithelial Protein that Signals during Anchorage Deprivation. *Am J Pathol* 2009 174: 1756-1765. PMID: 19349359; PMCID: PMC2671264.
42. Chien AJ, Illi JA, Ko AH, Korn WM, Fong L, Chen L, Kashani-Sabet M, Ryan CJ, Rosenberg JE, Dubey S, Small EJ, Jahan TM, Hylton NM, Yeh BM, Huang Y, Koch KM, Moasser MM. A phase I study of a 2-day lapatinib chemosensitization pulse preceding nanoparticle albumin-bound paclitaxel for advanced solid tumor malignancies. *Clin Cancer Res* 2009; 15: 5569-75. PMID: 19706807; PMCID: PMC3029022.
43. Amin DA, Sergina N, Ahuja D, McMahon M, Blair JA, Wang D, Hann B, Koch KM, Shokat KM, Moasser MM. Resiliency and vulnerability in the HER2-HER3 tumorigenic driver. *Science* 2010; 328(5978): 1666-1670. PMID: 20371474; PMCID: PMC3033659.
44. Campbell MR, Amin D, Moasser MM. HER3 comes of age: new insights into its functions and role in signaling, tumor biology, and cancer therapy. *Clin Cancer Res* 2010; 16:1373-83. PMID: 20179223; PMCID: PMC2831167.
45. Amin DN, Campbell MR, Moasser MM. The role of HER3, the unpretentious member of the HER family, in cancer biology and cancer therapeutics. *Semin Cell Dev Biol*. 2010; 21: 944-50. PMID: 20816829; PMCID: PMC2991618.

46. Spassov DS, Wong CH, Sergina N, Ahuja D, Fried M, Sheppard D, Moasser MM. Phosphorylation of Trask by Src kinases inhibits integrin clustering and functions in exclusion with focal adhesion signaling. *Mol Cell Biol.* 2011; 31:766-82. PMID: 21189288; PMCID: PMC3028653.
47. Spassov DS, Wong CH, Ahuja D, Moasser MM. The structural features of Trask that mediate its anti-adhesive function. *PLoS One* 2011; 6: e19154. PMID: 21559459.
48. Spassov DS, Wong CH, Moasser MM. Trask phosphorylation defines the reverse mode of a phosphotyrosine signaling switch that underlies cell anchorage state. *Cell Cycle* 2011; 10: 1225-32. PMID: 21490433.
49. McArthur HL, Rugo H, Nulsen B, Hawks L, Grothusen J, Melisko M, Moasser M, Paulson M, Traina T, Patil S, Zhou Q, Steingart R, Dang C, Morrow M, Cordeiro P, Fornier M, Park J, Seidman A, Lake D, Gilewski T, Theodoulou M, Modi S, D'Andrea G, Sklarin N, Robson M, Moynahan ME, Sugarman S, Sealey JE, Laragh JH, Merali C, Norton L, Hudis CA, Dickler MN. A Feasibility Study of Bevacizumab plus Dose-Dense Doxorubicin-Cyclophosphamide (AC) Followed by Nanoparticle Albumin-Bound Paclitaxel in Early-Stage Breast Cancer. *Clin Cancer Res* 2011; 17: 3398-407. PMID: 21350003
50. Munster PN, Thurn KT, Thomas S, Raha P, Lacevic M, Miller A, Melisko M, Ismail-Khan R, Rugo H, Moasser M, Minton SE. A phase II study of the histone deacetylase inhibitor vorinostat combined with tamoxifen for the treatment of patients with hormone therapy-resistant breast cancer. *Br J Cancer.* 2011; 104: 1828-35. PMID: 21559012. PMCID: PMC3111195.
51. Spassov DS, Wong CH, Harris G, McDonough S, Phojanakong P, Wang D, Hann B, Bazarov AV, Yaswen P, Khanafshar E, Moasser MM. A tumor suppressing function in the epithelial adhesion protein Trask. *Oncogene* 2012; 31:419-31. PMID: 21706059, PMCID: PMC3184310
52. Amin DN, Sergina N, Lim L, Goga A, Moasser MM. HER3 signalling is regulated through a multitude of redundant mechanisms in HER2-driven tumour cells. *Biochem J* 2012; 447: 417-25. PMID: 22853430
53. Spassov DS, Wong CH, Wong SY, Reiter JF, Moasser MM. Trask loss enhances tumorigenic growth by liberating integrin signaling and growth factor receptor cross-talk in unanchored cells, *Cancer Res* 2013; 73: 1168-79. PMID: 23243018, PMCID: PMC3563920.
54. Chien AJ, Munster PN, Melisko ME, Rugo HS, Park JW, Goga A, Auerback G, Khanafshar E, Ordovas K, Koch KM, Moasser MM. Phase I Dose-Escalation Study of 5-Day Intermittent Oral Lapatinib Therapy in Patients With Human Epidermal Growth Factor Receptor 2-Overexpressing Breast Cancer. *J Clin Oncol.* 2014 Apr 14. [Epub ahead of print]
55. Littlefield P, Moasser MM, Jura N. An ATP-Competitive Inhibitor Modulates the Allosteric Function of the HER3 Pseudokinase. *Chem Biol.* 2014; 21:453-8
56. Moasser MM. Two Dimensions in Targeting HER2. *J Clin Oncol* 2014 (*in press*)
57. Amin DA, Ahuja D, Yaswen P, Moasser MM. mTORC2-Akt coupling in HER2-amplified cancers coopts HER3 into the signaling network driving cellular homeostasis (submitted manuscript)
58. Chang YH, Korkola J, Amin DA, Moasser MM, Carmena JM, Gray JW, Tomlin CJ. Disentangling Multidimensional Spatio-Temporal Data into their Common and Aberrant Responses. (submitted manuscript)



Business Experience

Nora worked in publishing for more than thirty years on both electronic and print publications. She worked through the transaction from galleys, pasteup, and burning negatives to plates for printing to electronic files, conversion to pdf and html, and digital printing. As a Senior Production Coordinator, she managed production for scientific research journals for a non-profit scientific association in Washington, D.C. (American Geophysical Union). She coordinated file formatting with overseas vendors, as well as directed text and art file in-house revisions from authors' files for web posting. She also sent out special projects for bid, evaluated, awarded, scheduled and supervised projects with in-house graphics staff and external vendors.

Nora was a Client Services Manager for a commercial publishing small business (Mercury Publishing) in Maryland. She handled projects from clients, scheduling in-house desktop publishing, worked with art directors, page makeup, proofreading, layout, ad managers and sales staff, printers, and mail houses.

Advocate History

Nora attended Project LEAD (National Breast Cancer Coalition science training for breast cancer advocates) in 1995, completed Clinical Trials LEAD training in 2003, and served as an advocate reviewer for the California Breast Cancer Research Program (2000, 01 & 02), an NCI advocate reviewer in 2011, and a Department of Defense Breast Cancer Research Program reviewer in 2014. As an advocate representative for the Georgetown Lombardi Cancer Center breast SPORE from 2002 to 2006, Georgetown TBCRC (Translational Breast Cancer Research Consortium) from 2008 to present, and the Georgetown breast cancer advocates' group (GLBCPAC), she has worked with bench scientists and clinicians evaluating research and clinical trial proposals. She is co-author of a Cochrane Collaboration Systematic Review on the efficacy of prophylactic mastectomy published in 2004 and is currently rewriting its second major revision. She has also edited both the informational web site and a training program for CISN (Cancer Information & Support Network).

She earned a BA in English and Anthropology from the University of Wisconsin, Madison, Wisconsin

**Meryl Weinreb**

Meryl Weinreb is a retired pharmaceutical marketing executive with extensive experience in oncology – both from an industry and personal perspective. As a 3 time breast cancer survivor, she was uniquely equipped to successfully lead consumer marketing strategy and execution for AstraZeneca’s US oncology portfolio. She was responsible for a number of awarding-winning patient education and support programs for breast, prostate and lung cancer therapies. She led innovative adherence programs, and worked with company researchers to create patient-friendly PI's and clinical protocols.

As President of Somerset Lake Consulting, Ms. Weinreb has worked with a number of clients to provide strategic help with a variety of business challenges. Clients have included Abbott Labs, Genentech, Onyx, Cardinal Health and GlaxoSmithKline. These projects have covered a variety of tumor types including breast, non-small cell lung, hepacellular carcinoma, and leukemia.

Additionally, for the past 7 years, Ms. Weinreb served on the Executive Board of the Philadelphia affiliate of the Susan G. Komen Foundation, a non-profit organization that educates the community about breast cancer, and funds research, screening and support programs. She continues to serve as the affiliate’s Education Chair, and leads public policy initiatives for Komen’s Advocacy Alliance in Pennsylvania and Delaware. In 2013, she was invited to join Komen’s Advocates in Science Program and has served as a consumer reviewer for the Department of Defense’s Breast Cancer Research Program.



Valerie Guild started AIM at Melanoma after the death of her daughter Charlie from melanoma at the age of 26.

In the area of patient advocacy, among its accomplishments, AIM has lead the fight in the US to ban minors from indoor tanning. The AIM website (www.AIMatMelanoma.org) is considered the most comprehensive information site for patients and caregivers, and has launched in France, Italy, Spain, Germany, U.K. and Australia.

In the area of research she has founded, in conjunction with Dr. John Kirkwood, the International Melanoma Working Group (IMWG) an international think tank that brings together world-renowned translational researchers and industry in an effort to move research forward.

The Foundation is currently involved in launching a melanoma brain metastases bank and a first of its kind fully annotated primary melanoma tissue bank at four sites throughout the US and a fifth site in Europe.

She serves as the patient representative on the FDA, NCCN, SWOG, and ECOG, as well as the patient advisor to the Skin Cancer Spore and the CDMRP.

Valerie holds a BA, MA, and MBA.

BRENDA D. GAVIN, D.V.M., M.B.A.

516 Pine Street
Philadelphia, PA 19106
215-988-6812 (office)
267-239-2023 (home)
bgavin@quakerpartners.com

PROFILE: Senior executive with broad and deep experience in management, fundraising, proposal evaluation, allocation of financial resources, and results monitoring. Active board member and advisor to multiple for-profit, non-profit, and economic development organizations.

EXPERIENCE:

2002 – present **QUAKER PARTNERS**, Philadelphia, PA – A life sciences venture capital firm

Founding Partner

As a founding Managing Partner at Quaker Partners, integral in raising this \$700 million venture fund, focused on healthcare and biotechnology investment opportunities. Responsible for sourcing, evaluating, and selecting opportunities for funding. Works actively with portfolio company management to achieve value creation and returns to investors. Nurtures relationships with universities, economic development agencies, incubators, and other venture funds to assure access to high quality opportunities for asset allocation. Serves on the boards of multiple portfolio companies in order to mentor and assist management in achievement of goals. Manages internal operations of the fund, including hiring, employee development, and budgeting.

2000 -02 **EUCLIDSR PARTNERS CORPORATION**, New York and W. Conshohocken, PA – A life sciences and information technology venture capital firm

General Partner

Raised capital for this \$250 million investment fund. Selected and managed private equity investments in healthcare and information technology companies. Formed investment syndicates and served on company boards of directors. This fund was managed concurrent with GSK's corporate fund, S.R. One, Limited (see below).

1989 - 02 **S.R. ONE, LIMITED**, West Conshohocken, PA - A bioscience venture investment company (a wholly owned subsidiary of GlaxoSmithKline),

President (1999-2002)

Selected and managed investments in biotechnology, healthcare, and information technology companies. Served on boards of new companies, and led syndicates of investors. Managed 4 senior professionals and 2 support staff. Interfaced extensively with upper management of parent company, GlaxoSmithKline. Investments were selected to achieve both financial and corporate goals consistent with the strategy established by the parent company.

Vice-President (1989-99)

Assessed investment opportunities, recommended investments, reviewed legal documents. Participated in board meetings of entrepreneurial companies. Developed relationships in the venture capital and entrepreneurial communities.

1986 - 89 **SMITHKLINE BEECHAM ANIMAL HEALTH PRODUCTS**, Philadelphia, PA

Director, Business Development

Managed market development of diagnostic and vaccine products. Coordinated the search for and licensing of products for worldwide operating divisions in the field of animal health.

1981 - 86

INTERNATIONAL MINERALS AND CHEMICAL CORP., Northbrook, IL

Manager, New Business Development (1985-86)

Managed IMC's investments in venture capital funds. Identified potential corporate acquisitions and coordinated due diligence efforts. Acted as liaison between R&D and business groups.

Manager, New Products Development (1981-85)

Identified technologies, products, companies of interest for acquisition. Evaluated technological and market soundness of new products and businesses. Negotiated license contracts.

1980

CAMINO REAL HEALTH SYSTEMS AGENCY, San Antonio, TX
(Part-time during MBA program)

Health Planning Specialist

Assessed market needs for health services in 21-county area. Designed and conducted market surveys to determine consumer satisfaction with services.

1977 - 79

CENTERS FOR DISEASE CONTROL, Atlanta, GA

Epidemic Intelligence Service – Commissioned Officer in the US Public Health Service
Investigated epidemics of Legionnaire's disease, salmonellosis, hepatitis B, leprosy, DDT toxicity, and leptospirosis. Traveled to study sites and set up all field investigations, managed medical teams, analyzed data, and interacted with news media. Wrote and published reports of studies.

1971 - 72

PHILADELPHIA DEPARTMENT OF PUBLIC HEALTH, Philadelphia, PA

Sanitarian, Environmental Health Division

Inspected food establishments: dairies, restaurants, food processing plants. Conducted investigations of cases of lead poisoning and other environmentally-acquired disease. Managed 12 environmental technicians.

1970 - 71

UNIVERSITY OF PENNSYLVANIA SCHOOL OF MEDICINE, Philadelphia, PA

Research Assistant, Department of Anesthesia

Conducted experiments in hemorrhagic shock.

EDUCATION:

Bachelor of Science - Baylor University, 1970. Major-Biology, Minor-Chemistry
Doctor of Veterinary Medicine, *magna cum laude* - University of Missouri, 1977
Master of Business Administration - University of Texas (Austin, San Antonio), 1981.

COMMUNITY & PROFESSIONAL ORGANIZATIONS:

National Venture Capital Association Board, 1999-2004
Greater Philadelphia Venture Group - President, 1994-95; Chairman, 1995-96
Ben Franklin Technology Partners of Southeastern Pennsylvania Board, 1994-2009
Ben Franklin Technology Development Authority Board, 1999-2009
Penn State Research Foundation Board, 2002-present
International Advisory Board of the Monell Institute, 2001-present
WHYY Health & Science Advisory Board, 2010-present
The Crossroads School Board, 1996-2004

HONORS:

2002 Recipient of the Greater Philadelphia Venture Group Blair Thompson Lifetime Venture Award
2005 Recipient of Alliance of Women Entrepreneurs Iris Newman Award
2009 Recipient of Early Stage East Sal Buccieri Venture Impact Award
2010 Recipient of Pennsylvania Biotechnology Association Hubert Schoemaker Leadership Award



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

Oversight Committee Nominations Subcommittee

Peer Review Panel Nominations

Peer Review Panel Members for Approval

Clinical and Translational Cancer Research

Margaret Tempero, M.D., Chair

1. Donna Niedzwiecki, Ph.D.

Imaging Technology and Informatics

Sanjiv “Sam” Gambhir, M.D., Ph.D., Chair

1. Ross Berbico, Ph.D.
2. John Gore, Ph.D.
3. Hossein Jadran, M.D./Ph.D./M.P.H./M.B.A.

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Donna Niedzwiecki	POSITION TITLE		
eRA COMMONS USER NAME niedz001	Associate Professor		
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
Boston University	A.B.	May 1973	Mathematics
Brown University	M.S.	June 1975	Applied Mathematics
Yale University	Ph.D.	May 1984	Biostatistics

A. PERSONAL STATEMENT

Donna Niedzwiecki, PhD., is an Associate Professor in the Department of Biostatistics and Bioinformatics at Duke University Medical Center and in the Duke Cancer Institute (DCI) Biostatistics Shared Resource (GI). She is also the Associate group statistician at Duke and faculty statistician on the GI committee for the Alliance for Clinical Trials in Oncology (Alliance) Statistics and Data Center. Through her role as faculty statistician on the Alliance GI Committee, statistician for the DCI Biostatistics Shared Resource, and experience as principal investigator of the biostatistics cores on two P01s, she has collaborated with many academic and industry researchers studying GI cancers. Dr. Niedzwiecki has experience collaborating with laboratory and clinical investigators on single-institution and multi-institution clinical trials in a broad variety of cancer-related areas and in administration within the cooperative group and national clinical trials network structures.

B. POSITIONS AND HONORS

2013 to present	Associate Professor, Department of Biostatistics and Bioinformatics, Duke University Medical Center, Durham, NC
2008 to present	Senior Director, CALGB Statistical Center and Associate group statistician, Alliance Statistics and Data Center, Duke University, Durham, NC
1997 to 2013	Assistant Professor, Department of Biostatistics and Bioinformatics, Duke University Medical Center, Durham, NC
1996	Acting Director of Biostatistics, MetaWorks, Inc., Boston, MA
1992 to present	Independent consultant
1990 to 1992	Assistant Attending Biostatistician, Memorial Hospital, Division of Biostatistics/Dept. of Epidemiology and Biostatistics, New York, New York.
1985 to 1990	Assistant Biostatistician, Memorial Hospital, Division of Biostatistics/Dept. of Epidemiology and Biostatistics, New York, New York.
1985 to 1986	Adjunct Assistant Professor, Baruch College, CUNY, Dept. of Statistics and CIS
1984	Research Associate, Biostatistics, Sloan-Kettering Institute, New York, New York

OTHER EXPERIENCE AND PROFESSIONAL MEMBERSHIP

2000 to 2010	Mentor, Duke Clinical Research Training Program: Michael Morse, MD, May 2000 (committee chair), Jason Stout, MD, August 2001, Philipp Dahm, MD, May 2006, John Castor, MD, August 2010.
2001	Faculty member, American Society of Clinical Oncology Workshop, Vail, Colo.
2002 to 2006	Co-Investigator, HL67314-01, Cord Blood Transplantation
2003	Faculty member, The Southeastern Fellows Research Skills Retreat, Sunset Beach, NC
2005 to 2006	Faculty member, Accelerating Anticancer Agent Development and Validation Workshop (AACR-Duke Workshop), North Bethesda, MD

2005 to 2010 Co-Investigator, CA078673-05, Immunotherapy with High Frequency, CEA Specific T Cells
2011 ASCO Annual Meeting Chicago, IL: Educational Session Faculty, "Moving the Bar in Upper Gastrointestinal Malignancies: A Review of Recent Upper Gastrointestinal Phase III Studies—Clinically Meaningful or Just Statistically Positive?"
2013 to present Statistical Reviewer, NCI GI Steering Committee
2014 to present Member, American Society of Clinical Oncology

HONORS:

1979 to 1984 National Research Service Award, Yale University

C. SELECTED PEER-REVIEWED PUBLICATIONS

JOURNAL ARTICLES (Selected partial listing from 144 papers):

Morse MA Hobeika AC Osada T Berglund P Hubby B Negri S **Niedzwiecki D** Devi GR Burnett BK Clay TM Smith J Lysterly HK. An alphavirus vector overcomes the presence of neutralizing antibodies and elevated numbers of Tregs to induce immune responses in humans with advanced cancer. *J Clin Invest.* 2010 Sep;120(9):3234-41. doi: 10.1172/JCI42672. Epub 2010 Aug 2. PubMed PMID: 20679728; PubMed Central PMCID: PMC2929723.

Kanda J Rizzieri DA Gasparetto C Long GD Chute JP Sullivan KM Morris A Smith CA Hogge DE Nitta J Song K **Niedzwiecki D** Chao NJ Horwitz ME. Adult dual umbilical cord blood transplantation using myeloablative total body irradiation (1350 cGy) and fludarabine conditioning. *Biol Blood Marrow Transplant.* 2011 Jun;17(6):867-74. Epub 2010 Sep 22. PubMed PMID: 20868761.

Niedzwiecki D, Bertagnolli MM, Warren RS, et. al.: Documenting the natural history of patients with resected stage II adenocarcinoma of the colon after randomization to adjuvant treatment with edrecolomab or observation (CALGB 9581), *J. Clin. Oncol.* 29(23): 3146-52, 2011, PMID: 21747085.

Bertagnolli MM, Redston M, Compton CC, **Niedzwiecki D**, Mayer RJ, Goldberg RM, Colacchio TA, Saltz LB, Warren RS: Microsatellite instability and loss of heterozygosity at chromosomal location 18q: prospective evaluation of biomarkers for stages II and III colon cancer--a study of CALGB 9581 and 89803. *J Clin Oncol* 29(23):3153-62, 2011, PubMed PMID: 21747089.

Osada T, Berglund P, Morse MA, Hubby B, Lewis W, **Niedzwiecki D**, Yang XY, Hobeika A, Burnett B, Devi GR, Clay TM, Smith J, Kim Lysterly H: Co-delivery of antigen and IL-12 by Venezuelan equine encephalitis virus replicon particles enhances antigen-specific immune responses and antitumor effects. *Cancer Immunol Immunother.* 2012 Nov;61(11):1941-51. doi: 10.1007/s00262-012-1248-y. Epub 2012 Apr 10. PubMed PMID: 22488274.

Kanda J Chiou LW Szabolcs P Sempowski GD Rizzieri DA Long GD Sullivan KM Gasparetto C Chute JP Morris A McPherson J Hale J Livingston JA Broadwater G **Niedzwiecki D** Chao NJ Horwitz ME. Immune recovery in adult patients after myeloablative dual umbilical cord blood, matched sibling, and matched unrelated donor hematopoietic cell transplantation. *Biol Blood Marrow Transplant.* 2012 Nov;18(11):1664-1676. Epub 2012 Jun 12. PubMed PMID: 22698485; PubMed Central PMCID: PMC3472115.

Venook AP, **Niedzwiecki D**, Lopatin M, Ye X, Lee M, Friedman PN, Frankel W, Clark-Langone K, Millward C, Shak S, Goldberg RM, Mahmoud NN, Warren RS, Schilsky RL, Bertagnolli MM: Biologic determinants of tumor recurrence in stage II colon cancer: validation study of the 12-gene recurrence score in cancer and leukemia group B (CALGB) 9581. *J Clin Oncol.* 2013 May 10;31(14):1775-81. Epub 2013 Mar 25. PubMed PMID: 23530100; PubMed Central PMCID: PMC3641698.

Morse MA, **Niedzwiecki D**, Marshall JL, Garrett C, Chang DZ, Aklilu M, Crocenzi TS, Cole DJ, Dessureault S, Hobeika AC, Osada T, Onaitis M, Clary BM, Hsu D, Devi GR, Bulusu A, Annechiarico RP, Chadaram V, Clay TM, Lysterly HK: A Randomized Phase II Study of Immunization With Dendritic Cells Modified With Poxvectors Encoding CEA and MUC1 Compared With the Same Poxvectors Plus GM-CSF for Resected Metastatic Colorectal Cancer. *Ann Surg.* 2013 Dec; 258(6):879-86. PubMed PMID: 23657083.

Warren RS*, Atreya CE*, **Niedzwiecki D***, Weinberg V, Donner DB, Mayer RJ, Goldberg RM, Compton C, Zuraek MB, Ye X, Saltz LB, Bertagnolli MM: Association of TP53 Mutational Status and

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Berbeco, Ross I., PhD	POSITION TITLE Associate Professor of Radiation Oncology		
eRA COMMONS USER NAME (credential, e.g., agency login) RBERBECO36764			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	MM/YY	FIELD OF STUDY
University of California, Berkeley	B.A.	12/96	Physics, Astrophysics
University of Michigan, Ann Arbor	Ph.D.	04/02	Physics
Harvard Medical School, Boston, MA	Postdoctoral	03/05	Medical Physics

B. Positions and Honors

Positions and Employment

2002-2005	Postdoctoral Fellow in Radiation Oncology, Massachusetts General Hospital and Harvard Medical School, Boston, MA
2005	Adjunct Lecturer in Biophysics, Suffolk University, Boston, MA
2005-2008	Instructor of Radiation Oncology, Brigham and Women's Hospital, Dana-Farber Cancer Institute and Harvard Medical School, Boston, MA
2008-2014	Assistant Professor of Radiation Oncology, Brigham and Women's Hospital, Dana-Farber Cancer Institute and Harvard Medical School, Boston, MA
2010-present	Director of Preclinical Physics, micro-irradiator facility, Department of Radiation Oncology, Dana-Farber Cancer Institute, Boston, MA
2014-present	Associate Professor of Radiation Oncology, Brigham and Women's Hospital, Dana-Farber Cancer Institute and Harvard Medical School, Boston, MA

Professional Associations

American Association of Physicists in Medicine (AAPM), member
AAPM, Small Animal Irradiator Working Group, member
AAPM, Therapy Imaging Subcommittee, member
New England Chapter of the American Association of Physicists in Medicine (NEAAPM), member
NEAAPM, President-Elect (2013-2014)
American Physical Society (APS), member
APS, Division of Biological Physics, member
American Society for Therapeutic Radiology and Oncology (ASTRO), associate member
ASTRO, CME/MOC Committee of the Education Council, member
Dana-Farber/Harvard Cancer Center, Lung Cancer Program, Cancer Imaging Program, member

Invited Lectures

Massachusetts General Hospital (2005, 2011), Johns Hopkins University, Mannheim Summer Workshop, GSI (Darmstadt, Germany), Washington University in St. Louis, University of California at San Diego, Varian Imaging Laboratory, Varian Research Partners Symposium (2008, 2013), Scientific Conference on SBRT (University of Rochester), ESTRO (Goteborg, Sweden), AAPM Annual Meeting (2009, 2010, 2012, 2014), Princess Margaret Hospital, RSNA (2009-2011), Stanford University, New

England AAPM (2011, 2012, 2014), ASTRO (Miami, FL), HMS Joint Program in Nuclear Medicine, EPI2K12 (Sydney, Australia), Northeastern University, Yale University, IWPFI 2013 (Madison), CDHA Oncology Rounds (Halifax, Canada), Harvard Catalyst - Imaging for Clinical/Translational Cancer Research, 13th IWRDD (Cambridge, MA), 8th ECMP (Athens, Greece)

Editorial Boards

Medical Physics (Board of Associate Editors), Physics in Medicine and Biology, Radiotherapy and Oncology, International Journal of Radiation Oncology*Biology*Physics, Radiation Oncology, International Journal of Computer Assisted Radiology and Surgery, PLoS ONE, Technology in Cancer Research and Treatment, Practical Radiation Oncology, Physica Medica, Journal of Biomedical Nanotechnology

Congressionally Directed Medical Research Programs, Prostate, *ad hoc* reviewer
CDMRP, Breast Cancer Research Program, scientific review panel (2007-2010)
Veteran's Administration, *ad hoc* reviewer
NIH/NSF Special Emphasis Panel, scientific review panel (2012)
CPRIT, Informatics and Imaging Technology (2014-present)

Certification

2010 American Board of Radiology, Therapeutic Radiologic Physics

Honors

2003 Kent M. Terwilliger Memorial Thesis Prize (University of Michigan)
2008, '09, '12 Kaye Scholar Award (DFCI)
2011 *Best in Physics*, AAPM Annual Meeting (Senior Author)
2012 Leadership Strategies for the Researcher (Harvard Catalyst)
2014 *Best in Physics*, AAPM Annual Meeting (Senior Author)
2014 *Best in Physics*, ASTRO Annual Meeting (Senior Author)

C. Selected Peer-reviewed Publications (15 of 62)

1. Li J, **Berbeco R**, Distel R, Janne P, Makrigiorgos M. s-RT-MELT for rapid mutation scanning using enzymatic selection and real time DNA-melting: new potential for multiplex genetic analysis. *Nucleic Acids Research* 2007; 35(12): e84.
2. Li J, Wang L, Mamon H, Kulke MH, **Berbeco R**, Makrigiorgos GM. Replacing PCR with COLD-PCR enriches variant DNA sequences and redefines the sensitivity of genetic testing. *Nature Medicine* 2008; 14(5): 579-84. PMID: 18408729
3. Ngwa W, Makrigiorgos GM, **Berbeco RI**. Applying gold nanoparticles as tumor-vasculature disrupting agents during brachytherapy: Estimation of endothelial dose enhancement. *Physics in Medicine and Biology*. 2010; 55(21): 6533-6548. PMID: 20959684
4. **Berbeco RI**, Ngwa W, Makrigiorgos GM. Localized dose enhancement to tumor blood vessel endothelial cells via megavoltage x-rays and targeted gold nanoparticles: new potential for external beam radiotherapy. *International Journal of Radiation Oncology Biology Physics* 2011; 81(1) 270-276. Published online 15 Dec. 2010. *Selected as an issue highlight*. PMID: 21163591
5. Ngwa W, Korideck H, Chin LM, Makrigiorgos GM and **Berbeco RI**. MOSFET assessment of radiation dose delivered to mice using the small animal radiation research platform (SARRP). *Radiation Research*. 2011; 176 (6): 816-820. Published online 30 September 2011. PMID: 21962005

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME John C. Gore, Ph.D.	POSITION TITLE Hertha University Professor		
eRA COMMONS USER NAME (credential, e.g., agency login) JOHNGORE			
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)			
INSTITUTION AND LOCATION	DEGREE (if applicable)	MM/YY	FIELD OF STUDY
University of Manchester, U.K.	B.Sc.	1972	Physics
University of London, U.K.	Ph.D.	1976	Physics
Ealing College, London, U.K.	B.A.	1982	Law

A. Personal Statement

Dr. Gore has been an active leader in imaging research and applications for over 30 years. He has broad experience in multiple modalities (including ultrasound and X-ray imaging), but is best known for his contributions to the development and applications of MRI. He has contributed to our fundamental understanding of the information provided by MRI including basic studies of relaxation, diffusion, flow, contrast agents and BOLD effects. He has also contributed to translational applications of MRI in radiology and the neurosciences in particular. His current research emphasizes basic animal studies of the biophysical basis of BOLD and functional connectivity. He currently directs several trainees engaged in the development of advanced MRI methods at very high fields (7T and above). He has supervised numerous PhD students and has previously directed successful T32 programs, and the proposed training program will be a major priority for his efforts.

B. Positions and Honors

Positions and Employment

1975-1981	Physicist, Royal Postgraduate Medical School & Hammersmith Hospital, London
1981-1982	Technical Director, TEM Instruments, Ltd., Crawley, U.K.
1982-1990	Associate Professor, Diagnostic Radiology, Yale University School of Medicine
1982-2002	Director of NMR Research and Physics, Yale University School of Medicine
1990-2002	Professor of Radiology, Yale University School of Medicine
1991-2002	Professor of Applied Physics, Yale University
1997-2001	Chairman, Program in Biomedical Engineering, Yale University
2001-2002	Professor of Psychology, Yale University
2002-Present	Hertha Ramsey Cress University Professor, Vanderbilt University Director, Vanderbilt University Institute of Imaging Science
2002-Present	Professor of Radiology and Radiological Sciences, Biomedical Engineering, Physics and Astronomy, and Molecular Physiology and Biophysics, Vanderbilt University

Honors

1985	Fellow of Institute of Physics, U.K.
1989	Fellow, International Society for Magnetic Resonance in Medicine
1998	Fellow, American Institute of Medical and Biological Engineers
2004	Gold Medal, International Society for Magnetic Resonance in Medicine
2011	Fellow, American Association for the Advancement of Science
2011	Member, National Academy of Engineering
2013	Fellow, American Physical Society

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Hossein Jadvar, MD, PhD, MPH, MBA		POSITION TITLE Associate Professor of Radiology Associate Professor of Biomedical Engineering	
eRA COMMONS USER NAME (credential, e.g., agency login) jadvar			
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)			
INSTITUTION AND LOCATION	DEGREE (if applicable)	MM/YY	FIELD OF STUDY
Iowa State University, Ames, IA	B.S.	1982	Chemical Engineering
University of Wisconsin, Madison, WI	M.S.	1984	Biomedical Engineering
University of Michigan, Ann Arbor, MI	M.S.E.	1986	Computer Engineering
University of Michigan, Ann Arbor, MI	Ph.D.	1988	Bioengineering
University of Chicago (Pritzker), Chicago, IL	M.D.	1993	Medicine
University of California, San Francisco, CA	Internship	1994-1995	Internal Medicine
Stanford University, Stanford, CA	Residency	1995-1998	Radiology & Nucl Med
Harvard Medical School, Boston, MA	Fellowship	1998-1999	PET
Harvard University, Cambridge, MA	M.P.H.	2005	Public Health
University of Southern California, Los Angeles, CA	M.B.A.	2007	Bus. Admin. (Executive)
Univ. of Pennsylvania (Wharton), Philadelphia, PA	Certificate	2009	Leadership (Executive)

A. Personal Statement

I have been a member of the USC Norris Comprehensive Cancer Center since 2005. In particular I am a member of the Developmental Therapeutics Program and the new Translational Oncology Program with expertise and interest in translational and clinical molecular imaging. My research over the past several years have focused on translational and clinical molecular imaging of prostate cancer with particular interest in the impact of imaging on patient outcome and clinical decision-making and management.

B. Positions and Honors**Positions and Employment**

1999-2005 Assistant Professor of Radiology (tenure-track), University of Southern California, Los Angeles, CA
 2000-2005 Assistant Professor of Biomedical Engineering, USC, Los Angeles, CA (joint appointment)
 2001-2006 Visiting Associate in Bioengineering, California Institute of Technology, Pasadena, CA
 2005- Associate Professor of Radiology (with tenure), University of Southern California, Los Angeles, CA
 2005- Associate Professor of Biomedical Engineering, USC, Los Angeles, CA (joint appointment)
 2005- USC Norris Comprehensive Cancer Center member (Translational Oncology)
 2006-13 Vice Chair of Research, Department of Radiology, University of Southern California, Los Angeles

Selected Honors and Awards

1994 NIH Resident Research Award, Office of Education, National Institutes of Health, Bethesda, MD
 1997 Roentgen Resident/Fellow Research Award, Radiological Society of North America (RSNA)
 1998 Resident Research Award, American College of Nuclear Physicians (ACNP)
 2000 Marc Tetalman Young Investigator Award, Society of Nuclear Medicine (SNM)
 2003 Fellow, American College of Nuclear Medicine (ACNM)
 2006 Senior Member, IEEE-Engineering in Medicine and Biology Society
 2007-10 Inaugural Faculty Fellow, USC Center for Excellence in Research (CER)
 2009 Invited Guest editor, *PET Clinics* and *Theranostics* (Prostate Cancer)
 2010 Distinguished Scientist Award, 35th Annual Western Regional Society of Nuclear Medicine
 2010-14 San Gabriel Valley Top Doctors, Pasadena Magazine
 2011-14 Best Doctors in America

2014 Distinguished Investigator Award, Academy of Radiology Research

Selected Major Other Experience and Professional Activities

2003-08 Board of Directors, American College of Nuclear Medicine (ACNM)
2004- Editorial Board Member, Molecular Imaging and Biology
2006- Editorial Board Member, Journal of Nuclear Medicine (JNM)
2007- Deputy Editor, Clinical Nuclear Medicine
2007-11 NIH-NCI Medical Imaging (MEDI) Study Section Charter Member (2005-07 Ad Hoc)
2007-10 NIH-NCI In Vivo Cellular and Molecular Imaging Centers (ICMICS) Study Section
2008- Assistant Editor, Molecular Imaging Section, American Journal of Roentgenology (AJR)
2008 NIH-NCI Subcommittee H – Cancer and Leukemia Group B (CALGB) Study Section
2009 NCI-ARRA Grand Opportunity (GO) Study Section
2009-11 President, Pacific Southwest Chapter of Society of Nuclear Medicine
2009-13 Board of Directors, Society of Nuclear Medicine and Molecular Imaging (SNMMI)
2010 Scientific Program Chair, Annual Meeting of Western Regional SNMMI, Garden Grove, CA
2010-13 NIH Loan Repayment Program Study Section
2011-12 NIH-NCI Division of Translational and Clinical Sciences (DTCS) Study Section
2011 Associate Editor, Radiology (Nuclear Medicine Section)
2012-14 Chair, SNMMI Publications Committee
2011-15 President, SNMMI PET Center of Excellence
2013-14 President, American College of Nuclear Medicine (ACNM)
2013-14 Vice President-Elect, SNMMI
2014-15 President-Elect, SNMMI
2015-16 President, SNMMI

C. Selected Peer-reviewed Publications (please refer to <http://www-hsc.usc.edu/~jadvar>)

1. **Jadvar H**, Li X, Shahinian A, Park R, Tohme M, Pinski J, Conti PS. Glucose metabolism of human prostate cancer mouse xenografts, *Mol Imaging* 4(2):91-7; 2005.
2. **Jadvar H**, Ye W, Groshen S, Conti PS. [F-18]-Fluorodeoxyglucose PET-CT of normal prostate gland, *Ann Nucl Med* 22(9):787-93; 2008.
3. **Jadvar H**, Gurbuz A, Li X, Shahinian A, Conti PS. Choline autoradiography of human prostate cancer xenograft: effect of castration, *Mol Imaging* 7(3):147-152; 2008.
4. **Jadvar H**. Molecular imaging of prostate cancer with [F-18]-fluorodeoxyglucose PET, *Nat Rev Urol* 6(6):317-323; 2009.
5. **Jadvar H**. Molecular imaging of prostate cancer: a concise synopsis, *Mol Imaging* 8(2):56-64; 2009.
6. **Jadvar H**, Alavi A, Gambhir SS: [F18]-fluorodeoxyglucose uptake in lung, breast and colon cancers: molecular biology correlates and disease characterization, *J Nucl Med* 50:1820-1827; 2009.
7. **Jadvar H**. Prostate cancer: PET with 18F-FDG, 18F- or 11C-acetate, and 18F- or 11C-choline, *J Nucl Med* 52(1):81-9; 2011. (**Top 25 Most Read Article in JNM as of June 2011**)
8. **Jadvar H**, Yap L-P, Park R, et al. [18F]-2'-fluoro-5-methyl-1-beta-D-arabinofuranosyluracil (¹⁸F-FMAU) in prostate cancer: initial preclinical observations. *Mol Imaging* 11:426-32; 2012.
9. **Jadvar H**, Desai B, Ji L, Conti P, Dorff T, Groshen S, Gross M, Pinski J, Quinn D: Prospective evaluation of ¹⁸F-NaF and ¹⁸F-FDG PET/CT in detection of occult metastatic disease in biochemical recurrence of prostate cancer, *Clin Nucl Med* 37(7):637-643; 2012.
10. **Jadvar H**. Molecular imaging of prostate cancer – PET radiotracers, *Am J Roentgenol* 199:278-9; 2012.
11. **Jadvar H**. Imaging evaluation of prostate cancer with ¹⁸F-fluorodeoxyglucose PET/CT: utility and limitations, *Eur J Nucl Med Mol Imaging* 40 Suppl 1:5-10; 2013.
12. **Jadvar H**, Desai B, Ji L, Groshen S, Conti P, Dorff T, Pinski J, Quinn D: ¹⁸F-fluorodeoxyglucose PET/CT parameters as imaging biomarkers of overall survival in castrate-resistant metastatic prostate cancer, *J Nucl Med* 54(8):1195-1201; 2013.
13. **Jadvar H**. Molecular imaging of prostate cancer with PET. *J Nucl Med* 54:1685-8; 2013.
14. **Jadvar H**, Quinn DI. Targeted alpha particle therapy of bone metastases of prostate cancer. *Clin Nucl Med* 38(12):966-71; 2013.
15. **Jadvar H**, Colletti PM. Competitive advantage of PET/MRI, *Eur J Radiol* 83(1):84-94; 2014.

Research Advocate Reviewer

Basic Cancer Research-1

David Houchens, Ph.D.
Us TOO International, Inc.
Columbus, OH

Roxana Bellia, Ph.D.
USC Norris Comprehensive Cancer Center
Long Beach, CA

Basic Cancer Research-2

Margerie Manning, D.D.S.
San Luis Obispo Young Survivors
San Luis Obispo, CA

Sarah Wise Miller, M.B.A.
Kidney Cancer Association
Rye, NY

Cancer Biology

Ann Tonachel
Boston Medical Center
Boston, MA

Carol Vallett, Ed.D.
Cancer Patient Support Program
Fairfax, VT

Cancer Prevention Research

Michal-Judith Gillman
San Luis Obispo Young Survivors
Central Coast Survive Oars
Atascadero, CA

Brian Booher
Ann's Place, Inc.
Brookfield, CT

Clinical and Translational Cancer Research

Laura Porter, M.D.
Colon Cancer Alliance
Cheverly, MD

Robert Mesloh
Lymphoma Research Foundation
NJ

Imaging Technology and Informatics

Stephanie Dunn Haney
American Lung Association, National Headquarters
Bloomsburg, PA

Jilda Nettleton, M.D., Ph.D.
Young Survival Coalition
Seattle, WA

February 2014

CURRICULUM VITAE

NAME: David P. Houchens, Ph.D.

1501 Langston Drive
Columbus, Ohio 43220

Tel. (614) 451-3891
Cellular: (614) 214-7952
e-mail: houchens.david@gmail.com

Career Profile

Senior scientist/administrator with extensive experience in pharmaceutical R&D with industry, university medical centers, contract laboratories and government funding agencies. Proven ability to develop, plan and manage both laboratory and clinical research programs within time and budget. Knowledge and experience with GLP, GCP, GMP regulations and preparation and submission of documentation to US and European Regulatory Agencies. Experience with technology review and licensing.

Selected Accomplishments

- Implemented strategic planning for programs, budgets and contracts.
- Oversight responsibility for development of R&D efforts for evaluation of new biopharmaceutical products in cancer diagnosis and therapy.
- Directed collaborative research efforts with physicians and scientists at institutions in both the US and Europe.
- Planned, organized and chaired scientific meetings.
- Developed animal tumor models for use in evaluation of diagnostic procedures and new therapeutic modalities in cancer, including chemotherapy, immunotherapy, radiotherapy and hyperthermia.
- Member of various committees including: Clinical Trials; Animal Care and Use; Radiation Safety; Research.
- Prepared and reviewed scientific manuscripts, grants and contracts.

PROFESSIONAL EXPERIENCE

BATTELLE MEMORIAL INSTITUTE-Columbus, Ohio **1998-2013**

Program Manager 2000-2013

Management of Endocrine Disruptor Screening Program under contract to the US Environmental Protection Agency (EPA). Oversees the Data Coordinating Center, Quality Assurance Office, Chemical Repository, Mammalian Toxicology Area and Ecotoxicology Area for establishing and validating in vitro and in vivo protocols that will be used by the EPA for assessment of chemicals used in manufacturing and agricultural products.

Visiting Scientist 1998-2000

Review of preclinical data and preparation of documentation for filing IND applications to the FDA for pulmonary therapy of lung cancer.

CONSULTANT-PHARMACEUTICAL DEVELOPMENT **1998-2000**

NEOPROBE CORPORATION, Dublin, Ohio **1990-1998**

Vice President, Preclinical Studies 1996-1998

Located and developed new agents for the company pipeline. Responsible for ensuring that in vitro and in vivo preclinical assessments were completed for regulatory filing in both the US and Europe. Managed the development of clinical material for five potential candidate agents. Coordinated a company committee for the evaluation of a new formulation for the first commercial product. Worked with other senior management in strategic planning and budget setting for the company. Coordinated outside contracts for biological assessments of new agents. Managed the internal company review of scientific abstracts and manuscripts for presentation at national and international meetings and publication in peer reviewed publications.

Vice President , Corporate Development 1994-1996

Recommended new technologies and products for the company to investigate related to RIGS7 surgery. Worked closely with the President in arranging licensing agreements and technology transfer. Coordinated contracts with clinical centers and laboratories.

Vice President, Clinical Development 1993-1994

Developed protocols for assessing the evaluation of occult metastases in patients with colon cancer in Radioimmunoguided Surgery Studies. Coordination with Clinical and Regulatory Departments. Developed, planned and conducted European Collaborative Research Meeting for the Company. Coordinated the establishment of the Scientific Advisory Board.

**Director, Research and Development and
Director, Laboratory and Clinical Sciences**

1990-1993

Organized and directed the preclinical assessment of radiolabeled monoclonal antibodies for use in Radioimmunoguided Surgery. Developed and established GLP procedures for the company's laboratory studies. Coordinated collaborative research efforts with scientists and physicians in both the US and Europe.

BATTELLE MEMORIAL INSTITUTE, Columbus, Ohio

1976-1990

**Projects Manager, Pharmacology/Molecular Biology and
Projects Manager, Chemical Safety and Drug Development Section**

1984-1990

Coordinated efforts for developmental cancer therapy and immunotoxicology research (\$1.5 million per year). Organized, marketed and managed personnel and resources in those areas.

Associate Section Manager, Medical and Molecular Biology Section

1979-1984

Developed and implemented scientific goals and personnel needs for a 65 person section. Directed contracts for the pharmaceutical industry and for the National Cancer Institute.

Principal Research Immunologist, Biomedical Sciences Section

1976-1979

Directed 35 staff members in two contracts for The National Cancer Institute for the evaluation of potential anti-cancer compounds in a panel of murine and human tumor models. Conducted detailed studies on route, dose and schedule of drug administration and on combined modality therapy studies. Co-directed the operation of a major facility for the clean environment handling of up to 12,000 athymic (nude) mice for human tumor model studies.

NATIONAL CANCER INSTITUTE, Bethesda, Maryland

1971-1976

**Senior Staff Fellow, Immunochemotherapy Section,
Division of Cancer Treatment**

Conducted studies on the treatment of murine and human tumors with chemoimmunotherapy. Commenced work with athymic (nude) mice and human tumor xenografts as one of the pioneer researchers in the world in this area. Co-organized and chaired an international meeting on the use of Levamisole in cancer treatment. Directed a number of technicians in the laboratory and co-directed several international visiting scientists in their studies. Served as the project officer for four immunotherapy projects.

BIONETICS RESEARCH LABORATORIES, Kensington, Maryland
Junior Professional

1968-1971

Conducted tissue culture studies for evaluation of anti-cancer therapeutic agents.

Education

B.S. - 1959- Stetson University, DeLand, Florida (Biology)
M.S. -1964- George Washington University, Washington, D.C. (Biology)
Ph.D. -1971- George Washington University, Washington, D.C.
(Microbiology/Immunology)

Research Interests

- Diagnosis and Therapy of Cancer with Radiolabeled Monoclonal Antibodies
- Immunologic Effects of Chemicals and Drugs
- Chemotherapy
- Immunotherapy and Combined Modality Therapy of Animal and Human Tumors

Management Experience

- Personnel Management and Administration
- Research Program Management
- Contract and Grant Proposal Preparation
- Contract and Grant Reviews
- Marketing
- Financial Planning
- Strategic Planning

Academic Appointments

- Adjunct Associate Professor, Pathology Department, The Ohio State University, Columbus, Ohio, 1985-Present
- Instructor, Biology Department, Montgomery College, Takoma Park, Maryland, 1971-1973
- Fellow in Microbiology, Department of Microbiology, The George Washington University, Washington, D.C., 1968-1971

Appointments

- Co-chairman, Symposium on the Use of Athymic (Nude) Mice in Cancer Research, 1977.
- Co-editor, Heterotransplantation Section in Experimental Cell Biology
- Member U.S. Organizing Committee, Third International Workshop on Nude Mice, 1979.
- Member IACUC Committee, Battelle Columbus Lab, 1985-1990
- Member, Developmental Therapeutics Contracts Review Committee, National Cancer Institute, 1987-1991.
- Member, National Institutes of Health Reviewers Reserve, 1991 to 1995
- Member, American Association for Cancer Research State Legislative Committee of Ohio 1993-2000
- Member Board of Directors, Us TOO International 2008-2013

- Consumer Reviewer for Department of Defense prostate cancer scientific peer review panels. 2009, 2010, 2011, 2012, 2013

Honors

- Listed in American Men and Women in Science
- Distinguished Alumni Award - Stetson University, 1981

Professional Memberships

- American Association for Cancer Research


Continuing Education and Training (Partial Listing)

- Project Management in the Research-based Pharmaceutical Industry.
- Radiation Safety in the Laboratory.
- Animal Care and Use Regulations
- Preclinical Requirements for Biologics
- Good Laboratory and Good Clinical Practices Requirements
- Tumor Model Workshops

Military

US Army Chemical Corps., Lieutenant, Bacteriologist- 1959-62

ROXANA E. BELLIA, P.H.D.

📍 | 2121 E. 1st Street #301, Long Beach, Ca 90803
📞 | (562) 673 – 7174
✉ | bellia_r@hotmail.com  | <http://www.linkedin.com/in/bellia>

TALENT MANAGEMENT PROFESSIONAL & CERTIFIED COACH



Executive Summary

Seasoned talent management and performance development professional, facilitator and ICF Certified Coach with a demonstrated track record in the development and delivery of end-to-end talent management solutions, including development of employee and manager and above leadership and professional development programs, performance management, business client lead, delivery of organizational change initiatives, resulting in individual, team and organizational effectiveness. Strong commitment to client satisfaction. Multilingual.



Core Skill Set

- Facilitation & Meeting Design
- Strategic Planning
- Data Gathering & Analysis
- Performance Management
- Executive Coaching & Development
- Conflict Resolution & Mediation
- Training Design & Delivery
- Leadership Development
- Learning & Development



Employment Experience

University of Southern California - Los Angeles, CA

Feb 2013 - Present

Sr. Manager, Leadership & Organizational Effectiveness

- Lead the design and implementation of an enterprise-wide performance management system for 12,000+ staff.
- Design and develop learning and development solutions for all staff, including contribution to learning strategy, competency development, content mapping, learning path creation and marketing.
- Conceptualize and deliver management and leadership programs intended to augment foundational and strategic skills.
- Consult with schools and administrative units on strategic planning, team building, learning and performance needs.

University of Southern California - Los Angeles, CA

Jan 2012 – Jan 2013

Talent Management Business Partner

- Designed, developed and delivered client services to include facilitation, strategic planning, data gathering and analysis, team building, resulting in increases in effectiveness, team cohesion and alignment to strategic goals.
- Contributed to the development of internal talent management protocols and templates and capacity building in fast-paced start-up team organization targeting scalability, impact, relevance and innovation across USC.
- Assessed leadership competencies and plans development for individuals and teams; designed and delivered leadership training series for leadership teams at USC Keck School of Medicine and other executive teams.

Independent Consultant - Los Angeles, CA

Aug 2009 – Dec 2011

Trainer and Coach

- Designed and delivered customized training on customer service, conflict resolution, career coaching, communication, motivation, language skill development and others, increasing retention rates, improving morale and skill development.
- Delivered coaching and co-design developmental action plans with executives, enhancing individual and team efficacy.

- Designed communications plan and strategy, go-live communications, team effectiveness activities, change readiness surveys, feedback resulting in increases in buy-in and staying on track with project budget and schedule.

IBM - Glendale, CA

Jan 2006 - May 2009

Strategy & Change Management Senior Consultant

- Generated awareness and commitment to large-scale technical implementations by working closely with client and impacted stakeholders to develop change strategy documents (stakeholder analysis, communications, change impact).
- Conducted extensive interviews and facilitated group brainstorming, resulting in executive-supported recommendations.
- Created a long distance learning forum for JIT (just in time training) and cross-skill knowledge transfer that led to significant improvements in applied knowledge and skills and an increase in billable hours for the business unit.
- Conducted organizational assessments and health checks by completing interviews, key performance indicators review, time allocation study, and identifying key themes.
- Summarized areas of opportunity in a fast turn-around work environment through the collection, analysis, interpretation of culture, performance survey and interview data.
- Interviewed, evaluated and recruited MBA candidates at on-campus events leading to successful placement of graduates.

City of Long Beach Dept of Health & Human Services - Long Beach, CA

April 1998 – Nov 2005

Program Manager, Organization Development Project Lead

- Led the development and implementation of a two-year planning process to create programs and processes resulting in significant improvements in building line and management trainings, on-boarding, and employee engagement.
- Designed leadership development training series for supervisors and managers that enabled communication, performance improvements and increases in skill development.
- Conducted needs assessments and delivered training for public health field and medical professionals that improved skills in Spanish, time management, conflict resolution and customer service.
- Managed a HUD community-grant research housing program designed to reduce asthma, lead and injuries.
- Served the Health Department Director, neighborhood development committees and large-scale community projects.



Education and Certifications

Alliant International University , Los Angeles, CA Doctorate, Industrial – Organizational Psychology	2001 - 2007
California State University Los Angeles , Los Angeles, CA MS, Public Administration – Minor, Public Personnel Administration	1989 - 1994
California State University Northridge , Northridge, CA BA, Psychology – Magna Cum Laude	1985 - 1989
Certifications & Assessments , Los Angeles, CA Lominger's Leadership Architect, VOICES 360, Team Architect; HCI Human Capital Strategist; MBTI, Firo-B; Strengths Finder; Crucial Conversations	2007 - 2012
Fielding Graduate University , Santa Barbara, CA International Coaching Federation (ICF) Certified Coach, ACC – Evidenced-based coaching program	2009 - 2010
Loyola Law School and LA City Attorney , Los Angeles, CA Conflict resolution/mediation certificate and A.B.A. Legal-Ease	2009 - 2010



Volunteer Contributions

- **USC Women in Management, Public Relations**, Board Member, Los Angeles, CA

2013 - Present

▪ USC Cancer Survivorship Advisory Council , Chair, Los Angeles, CA	2013 - Present
▪ USC Norris Comprehensive Cancer Center Executive Committee , Member, Los Angeles, CA	2013 - Present
▪ USC Staff Assembly, Rights & Responsibilities , Member, Los Angeles, CA	2013 - Present
▪ SIOP, Veterans Pilot Project , Volunteer Coach, Career Transition	2012 - 2013
▪ Leadership Long Beach – Former Board Member and Volunteer, Long Beach, CA	2010 - 2012
▪ LA City Attorney’s Office Dispute Resolution Program - Mediator, Los Angeles, CA	2009 - 2012
▪ International Coach Federation – Former Board Member, Los Angeles, CA	2010

MARGERIE MCNEILL MANNING

889 Isabella Way, San Luis Obispo, CA 93405 | 805.712.2290 | margeriemanning@yahoo.com

EDUCATION

Northwestern University, Chicago, IL

D.D.S.

1993

Research Tract, Pathology Department

Honor Society, Dean's List

University of California, Davis, CA

B.S. in Biological Sciences

1989

RELATED EXPERIENCE

Congressionally Directed Medical Review Panel Consumer Reviewer

2009- present

[Participated in 5 panel sessions]

Author/Illustrator *There Is Life After Breast Cancer*

2012

[Book and resource website for breast cancer survivors and their loved ones]

Co-Founder Breast Cancer Reconstruction Choices

2009- present

[Advocacy and information website for women undergoing breast reconstruction due to cancer]

Co- Founder/Facilitator San Luis Young Survivor Group

2006- present

[Young survivors support group]

Hearst Cancer Resource Center, San Luis Obispo, CA]

General Dentist

1993-2003

Partner, Peach Tree Dental

San Luis Obispo, CA

SARAH WISE MILLER
6 MORRIS CT.
RYE, NY 10580
914.899.3178
swise611@gmail.com

QUALIFICATIONS AND SKILL SETS:

- Strategic planning and implementation
- Managing various constituencies and driving results
- Achieving results in a not-for-profit environment
- Conducting market analyses and designing, developing and deploying new products and services
- Planning and implementing marketing, sales, and business development programs to increase business and drive revenue and profit
- Developing, coordinating and executing national advertising, analyst relations, public relations and promotional programs that result in revenue growth
- Managing marketing and support staff
- Coordinating community events, press conferences and public relations
- Writing, editing and producing proposals, reports, articles, annual reports and newsletters

EDUCATION

MBA, Columbia University Graduate School of Business, New York, NY 1981

Marketing and Management of Organizations

BA, University of Illinois, Champaign, Illinois 1974

Liberal Arts and Sciences independent study program in architecture history

Graduated with honors

EXPERIENCE

BOARD OF TRUSTEES, Rye Free Reading Room

Rye, NY 1013 to present; Vice President 2014 to present

BOARD OF DIRECTORS, Kidney Cancer Association

Evanston, Illinois 2006 to present

Served in various capacities, including terms as Chairman of the Board, Vice Chair, Vice President, and head of government affairs and strategic planning committees. Participate in lobby efforts at state and federal levels. Frequent speaker at patient and medical symposia on the role of advocacy. Represent the Association at government, medical, pharmacology and cancer meetings and conferences. The Kidney Cancer Association is an international organization of patients, researchers and physicians dedicated to reducing suffering from kidney cancer.

REVIEWER, Department of Defense, Office of Congressionally Directed Medical Research Programs (CDMRP) Peer Reviewed Cancer Research Program (PRCRP)

Washington DC 2009-present

Serve as a consumer reviewer of research proposals for solid tumor cancers, particularly kidney cancer, in the Army's Peer Reviewed Cancer Research Program. The CDMRP is a unique partnership among the U.S. Congress, the public, and the military supporting untapped research opportunities to encourage innovation and ingenuity in biomedical science. The vision of the CDMRP is to find and fund the best research to eradicate diseases.

SARAH WISE MILLER
6 MORRIS CT.
RYE, NY 10580
914.899.3178
swise611@gmail.com

MARKETING DIRECTOR, KPMG, Risk Advisory Services Practice

New York, NY and Montvale, New Jersey 1997 to 2006

Responsible for business development and increasing revenue through strategic targeting, pursuit planning and customer relationship management for a multi-million dollar technology practice. Provided oversight and coordinated and implemented business development, advertising, public relations, analyst relations, conferences and collateral production.

BUSINESS AND MARKETING CONSULTANT 1992-97

Clients included largest automobile emission control company in state of Georgia and local school district. Conducted market analyses, developed business plans and created and helped implement public awareness campaigns.

PUBLIC RELATIONS DIRECTOR, March of Dimes Birth Defects Foundation

Atlanta, Georgia, 1985 and Indianapolis, Indiana 1983-85

Led donor development and major contribution efforts. Produced and directed March of Dimes Telethon in the Indianapolis and Atlanta markets. Developed and organized volunteer committees, pretelethon promotions and fund raising events. Successfully increased visibility of foundation, contributing to increased revenues of 35 percent.

DIRECTOR OF MARKETING, Holywell Corporation

Miami, Florida 1982-83 (real estate)

SALES MANAGER, Elizabeth Arden, Inc.

Fort Lauderdale, Florida 1981-82 (cosmetics)

MANAGER OF CORPORATE COMMUNICATIONS, Electronic Data Systems

Dallas, Texas 1978-79 (computer services)

DIRECTOR OF CORPORATE INFORMATION, Anacomp, Inc.

Indianapolis, Indiana 1975-78 (computer services)

VOLUNTEER ACTIVITIES

Served in various capacities for many not-for-profit organizations including participation on numerous PTA committees and as treasurer of Murray Avenue PTA, Mamaroneck, NY. Also served as a Community Advisory Board member of Larchmont Mamaroneck RADAR (Responsible Action: A Drug and Alcohol Resource), a community coalition striving to create a safe, healthy, drug and alcohol free environment for youth.

Anne Tonachel Bio Sketch

Anne Ramey Tonachel

Undergraduate Education: University of Maryland at Frankfurt, Germany

Middlesex Community College

Employment: Early childhood educator 1972 -2002

Program manager Hospitality Homes, 2002-2005

Cancer History

Ovarian cancer 3C. August 2005,

Clinical trial at Dana-Farber Cancer Institute, Boston

Founded Boston Medical Center Mind and Body Ovarian Cancer Support Group, 2006

Speaker at GYN conference, DFCI, 2007

Speaker at Ovations for the Cure conference, Boston, 2011

Peer reviewer DOD CDMRP 3 times

One hour TV program about ovarian cancer 2012

Co-Founded Turning the Tide Retreat for Women with Ovarian Cancer 2012

Active member of Survivors Teaching Students (ovarian cancer awareness program at medical schools)

Member of Patient and Family Advisory Council at Dana-Farber

Volunteer at Dana Farber

Co-Founded Ambassador Program at Dana-Farber 2011

Carol M. Vallett, Ed.D.

287 Buck Hollow Rd.

Fairfax, VT 05454

802-578-1196

carolvallett@arcsvt.com

EDUCATION

- Ed.D. Leadership and Policy Studies, 2008
University of Vermont
*Dissertation: Exploring Relationships Between Organizational
Virtuousness and Organizational Culture in Higher Education*
- M.B.A. University of Phoenix, 1996
*Thesis: Effects of Unemployment Statistics on Community College
Enrollment*
- B.S. Chemical Engineering, 1978
University at Buffalo
State University of New York
Magna cum laude
- Certificate Management and Leadership in Higher Education, 2006
Harvard Graduate School of Education

PROFESSIONAL EXPERIENCE

- Research Associate Professor, University of Vermont, 2009-present
Instructor, EDFS 200 Research in the Digital Age
EDCI 324 Assessment and Technology
- Principal, Academic Research and Consulting Services LLC, 2009-present
- Dean / Director, Continuing Education, University of Vermont, 2002-2009
- Academic Programs Manager, Continuing Education, University of Vermont, 1999-2002
- Coordinator of Academic Services, Community College of Vermont, 1991-1999
- Adjunct Faculty, Community College of Vermont, 1996-1999
Algebra (MATH 0221)
- Part-time Teacher, Science and Math, Bellows Free Academy, Fairfax, VT, 1987-1991
- Staff Engineer, Union Carbide Corporation, Tonawanda, NY, 1980-1982
- Assistant Staff Engineer, Union Carbide Corporation, Tonawanda, NY, 1978-1980

INSTITUTIONAL SERVICE

University of Vermont

Search Committee Memberships

Dean, School of Business Administration, 2008-2009
Director, Center for Teaching and Learning, 2006
Chief Information Officer, 2005
Dean, College of Education and Social Services, 2004-2005
Dean, College of Engineering and Mathematical Sciences, 2004

Committee and Taskforce Memberships

President's Commission on Racial Diversity 2007-2009
Leading by Design proposal committee-2008
Summer Strategy Taskforce, co-chair, 2007-2008
Academic Program Committee for Reaccreditation Self-Study, 2007-2008
Academic Continuity for Pandemic Planning, 2007-2009
ERP Steering Committee, 2004-2006
Information Technology Planning Council, 2004-2005
Part-time faculty bargaining team, 2004-2006
Council of Deans, 2002-2009

Community College of Vermont

Academic Review Board, 1993-1999
Emerging Technologies Committee, 1996-1999
Science, Math and Technical Committee, Chair, 1993-1995, 1996-1999
Vermont State Colleges 2000 Taskforce, 1995-1996
Chancellor's Committee on K-12 Alignment, 1997-1998

CERTIFICATIONS AND MEMBERSHIPS

Certified by the Vermont State Board of Education in Science, secondary level
Member of Tau Beta Pi, National Engineering Honor Society
Vermont Leadership Institute of the Snelling Center for Government, class of 2000
Member of the American Educational Research Association
Member of the American Evaluation Association

PRESENTATIONS, GRANTS AND AWARDS

“Women in Non-Traditional Work”, presented at the Community College of Vermont conference, Careers for the Future, October 24, 1995

Resume for Michal-Judith (Miki) Gillman, L.M.F.T

9100 San Gregorio Road
Atascadero CA 93422-1242
mikigillman@sbcglobal.net
Home Phone: 805-460-6945
Cell Phone: 805-550-7196

BREAST CANCER SURVIVOR SINCE 2002

Licensed Marriage and Family Therapist (MFC 24751) since December 1988

FORMAL EDUCATION

Cal Poly University: Spring 1988, Ethics & the Law; Winter, 1988, Advanced Marriage & Family Counseling.

California State University, Fresno: Fall 1978: 18 units toward Pupil Personnel Services and School Psychologist Credentials.

California State University, Fresno: **Master of Arts Degree, Psychology**, May 1978.
[Thesis: *Personality Correlates and Sex Differences in Self-Attribution to Success and Failure*, published in *Sex Roles*, 1982.]

Tufts University, Medford, Massachusetts: **Bachelor of Science Degree, Clinical Psychology**, June, 1967.

Brighton High School, Rochester, New York: **Regents Diploma with Honor in Latin and French**, June 1963.

SALIENT CANCER-RELATED EDUCATION

Attended Era of Hope Conference, August 2011.

Reading: Research articles and discussions presented on www.breastcancer.org and other web sites, *Cure*, *Mamm*, and similar magazines and several books, including *Passages in Caregiving* by Gail Sheehy, *The Wandering Gene and the Indian Princess* by Jeff Wheelwright (2012), & *The Immortal Life of Henriette Lacks* by Rebecca Skloot.

Salient Classes & Other Presentations I Have Attended:

- Various presentations sponsored by HCRC on Integrative Cancer Care, Clinical Trials, and similar topics.
- Gail Sheehy Keynote at 10/2011 Bioneers' conference, San Luis Obispo.
- Several presentations on wellness & complementary methods.
- 02/24/09: Frankly Speaking about New Discoveries in Cancer Treatment
- Fall 2008: Cancer Series (Cuesta College & Hearst Cancer Resource Center)
- October 2007: Series on Breast Cancer

PARTICIPATION IN CANCER-RELATED ORGANIZATIONS

- **Consumer Advocate and Consumer Reviewer for Congressionally Directed Medical Research Program-Breast Cancer Research Program (CDMRP~BCRP) since April 2009.** Mentored a novice in each 2010, 2011 & 2013. Gave the Consumer Reviewer presentation at the Consumer Orientation & gave the Moment of Silence Presentation at the Plenary Dinner for the 01/2011 session. Have recruited 3 other reviewers.
- **Consumer Reviewer for Peter T. Rowley Breast Cancer Scientific Research Projects 02/2012** (NY State Dept. of Health Wadsworth Center and Health Research Science Board)
- **President of Central Coast Survivors Dragon Boating Team, since January 2014** (elected for a 2-year term); **Recording Secretary** of CCSO Spring 2013 through December 2013; **Dragon Boater** since 2009. (CCSO is part of the San Luis Obispo Chapter of Team Survivor.)
- **Volunteer at Hearst Cancer Resource Center** since Spring 2008. Facilitated the Caregivers' Support Group March 2009 till May 2012. Organized a panel of Caregivers for our 2011 Caregiver Celebration and recognition event. Have written 2 articles on Caregiving for the HCRC Newsletter.
- **Co-founded the SLO Chapter of Team Survivor, 11/2007.** Co-led semi-monthly "Walk & Talk", 12/08 through 2009. Served on Advisory Board 11/07 through 2008.
- **San Luis Young Survivors** (support group). Participant since April 2008. Co-Facilitator since August 2013.
- **American Cancer Society Breast Cancer Support Group:** Active participant November 2002 through 2012; have arranged for 3 guest speakers; as needed, substitute as facilitator.
- **Enhancement, Inc., breast cancer workshops/support.** Participated regularly January 2009 through 2010. Participated in their Healing Retreat, April 2010.
- **Informally have mentored** cancer patients and family members, as requested, since 2002.

PROFESSIONAL EXPERIENCE

Contract Mediator for The Consortium for Children of San Rafael, CA, October 2013 to present. Received training in General Mediation and in Permanency Planning Mediation, October 2013.

San Luis Obispo County Department of Social Services, Family and Children's Services (Child Welfare Services and Adoptions): 02/01/79 to 11/17/08 (retired):

Social Worker Supervisor II, 05/03/93 to 11/17/09 [Provisional Division Manager, 05/24/04 – 10/04/04: leave replacement]: Supervised all programs: Adoptions, Foster Home Licensing, Family Preservation, North County SAFE Collaborative, Emergency Response, Dependency Investigations, WRAP, Family Maintenance, Family

Reunification, wrote policies and procedures. Served on numerous committees for CWS Redesign, multi-agency collaborations, etc. Presented data to management to support programs and staffing levels.

Social Worker IV: 02/01/79 – 05/03/93:

Adoptions, 08/01/86 – 05/03/93: Expert witness; court reports; therapeutic interventions; found adoptive families for children; home studies; assessments; co-developed & taught PACE (Parenting Abused Children Effectively); co-created Adoption Fund for Birth Mothers; media presentations.

Foster Home Evaluator, 05/01/85 – 08/01/86.

Permanency Planning, 12/06/82 – 05/01/85: Guardianships, Long-Term Foster Care.

Child Protective Services Intake, 02/01/79: Prevention, crisis intervention, treatment; Emergency Response Investigations; Sexual Assault Response Team.

California State University, Fresno, Student Counseling Center, Spring 1978:

Student Affairs Officer III: Counseled students: personal, marriage, academic, career.

PROFESSIONAL AFFILIATIONS

Life Member, California Association of Marriage & Family Therapists (CAMFT)

Member, Central Coast Chapter (CCC-CAMFT); President 1991-1992.

Member, San Luis Obispo County Child Abuse Prevention Council

Member, Beginnings (Task force for preventing perinatal substance abuse)

Member, North American Council on Adoptable Children (NACAC) 08/1989 through 2009 & since 2013.

Brian W. Booher

45 South Lake Shore Drive
Brookfield, CT 06804
Cell: (203) 470-6017
Work: (203) 229-6097
Fax: (212) 948-1921
e-mail: brian.w.booher@mercer.com

Date of Birth:
January 4, 1951

Education:
Bachelor of Arts, Georgetown University, 1972, *magna cum laude*, *Phi Beta Kappa*
Master of Arts, Rutgers University, 1976

Employment:
Mercer Health & Benefits
Title: Principal

I have worked as an Employee Benefits Consultant for Mercer H&B LLC since 1997 and for A. Foster Higgins & Company, Inc. from 1985 to 1997 (when Mercer acquired Foster Higgins). I don't have a current resume in a Word document. My company "bio" is attached.

I served as a Consumer Reviewer for the CDMRP Prostate Cancer Research Program (PCRP):

- Participating in on-site review panels in 2008, 2010, 2011, and 2012; and
- Participating in a web and teleconference review panel in 2013.

I have participated in the Us TOO support group for prostate cancer survivors in Danbury, CT since my diagnosis and treatment in 2006.

The following updates my “bio” at the company where I work

Brian W. Booher

Brian Booher is a senior consultant in Mercer’s Norwalk, Connecticut office and is responsible for servicing clients and managing technical projects concerning healthcare and group benefits, cost containment, and compliance. With 29 years of health and group benefits consulting experience, Brian assists his clients with the integration of their employee benefit programs with their business objectives in the areas of finance, vendor management, plan administration and compliance. His finance-oriented responsibilities include analyses of renewals and financial settlements, rate calculation and flex plan pricing. Vendor management skills include vendor selection, transfer and servicing. Plan administration responsibilities consist of contract, plan document, and summary plan description reviews, and consulting on compliance with ERISA, HIPAA and emerging legislation.

Brian also serves in the Risk & Compliance department for Mercer Health & Benefits.

Brian has the Certified Employee Benefits Specialist (CEBS) designation and has served on the Publications Committee of the ISCEBS and as past President of the Southern New England Chapter of the ISCEBS.

Brian holds a BA from Georgetown University, *magna cum laude*, where he was elected to *Phi Beta Kappa*. He also holds an MA from Rutgers University.

Robert Henry Mesloh

Biographical and Professional Background

Born in Brooklyn, New York, October 2, 1948

Employment History

Employed at New York Telephone Co. 1966-1968

Middle/executive management positions global telecommunications industry 1971-2001

Consultant to the Submarine Cable Industry 2001-2003

Substitute teacher since 2003 in Parsippany & Montville New Jersey

Assistant baseball coach Central Middle School, Parsippany New Jersey 2008-current

Lymphoma Research Foundation (LRF) inaugural Ambassador

Military Service

Drafted April 16, 1968 into the US Army

- Army Basic Training 12 weeks Fort Gordon, Georgia as platoon leader
- Army Advanced Infantry Training Signal Corps 8 weeks Fort Huachuca, Arizona
- Army Infantry Battalion Headquarters, Fort Gordon, Georgia and promoted to Spec 4
- Recommended for Non-Commissioned Officer School, Fort Gordon, Georgia
- Assigned to 8th Army South Korea June 1969
 - Section Chief to A Battery 1/25th Artillery, Camp St Barbara, South Korea 1969
- Army reassigned Sept 1970 to 4th Infantry Battalion Hdqtrs, Fort Carson, Colorado
- Honorably Discharged US Army June 1971

Education

Bachelor of Arts Marketing Degree Saint Mary's College, Moraga, California

Masters Certificate Project Management George Washington University, Washington DC

Masters Certificate General Management Wharton University, Pennsylvania

Other Volunteer Service

- Baseball manager in Little League/Junior League/Senior League/American Legion
- Proud member of the American Legion

Laura D. Porter, MD
5720 Euclid Street
Cheverly, MD 20785
(301) 386-3806
lporter@ccalliance.org

PROFESSIONAL EXPERIENCE:

2007-Present	Colon Cancer Alliance Patient Advocate Medical Consultant
2002-2003	Howard University Hospital, combined 2003 with Children's National Medical Center, Washington, DC Pediatric Resident
1996-1997	RAND Corporation, Santa Monica, CA. Consultant. Administered mental health surveys and enrolled eligible participants in a two-year study of depression.
1991-1996	University of Maryland at Baltimore, Baltimore, MD. Research Assistant, Senior. Conducted research in pediatric oncology, pediatric HIV and AIDS, and managed three labs.
1988-1991	Molecular Oncology, Inc., Gaithersburg, MD Research Associate. Conducted research in breast cancer, and managed two labs.
1987-1988	Rorer Pharmaceuticals, Gaithersburg, MD. Lab Technician. Conducted breast cancer research and managed a lab

EDUCATION:

M.D.	Howard University College of Medicine, Washington, D.C. May 2002.
B.S.	St. Mary's College of Maryland, St. Mary's City, MD. May 1987, Major-Biology.
A.A.	Montgomery College, Rockville, MD. December 1983, Major-Criminal Justice Corrections.

HONORS AND RECOGNITION:

2003	Best Pediatric Intern in Ambulatory/Emergency Pediatrics, Howard University Hospital
1996	Whitman Walker Clinic Honor Roll, recognition for outstanding contribution in the fight against HIV and AIDS.

1983	Graduated with Honors, Montgomery College.
1979,80,83,84	Dean's List, Montgomery College.
1980	Certificate of Appreciation, Maryland Juvenile Services Administration.

PUBLICATIONS:

Porter, Laura D. Knocking Out the Side Effects of Colorectal Cancer Treatment. Coping with Cancer. March/April 2010.

Tal, Michael, C. Richter King, Matthias H. Kraus, Axel Ullrich, Joseph Schlessinger, and David Givol. Human HER2 (neu) Promoter: Evidence for multiple Mechanisms for Transcriptional Initiation. Molecular and Cellular Biology, 1987:7, 2597-2601.

King, C. Richter, Sandra M. Swain, **Laura Porter**, Seth Steinberg, Marc E. Lippman and Edward Gelmann. Heterogeneous Expression of erbB-2 Messenger RNA in Human Breast Cancer. Cancer Research, 1989:49, 4185-4191.

King, C. Richter, Ivan Borrello, **Laura Porter**, Paolo Comoglio and Joseph Schlessinger. Ligand-independent tyrosine phosphorylation of EGF receptor and the *erbB-2/neu* proto-oncogene product is induced by hyperosmotic shock. Oncogene, 1989:4, 13-18.

Rosengard, Ariella M., Henry C. Krutzsch, Allen Shearn, Joseph R. Biggs, Edward Barker, Inger M. K. Margulies, C. Richter King, Lance A. Liotta and Patricia S. Steeg. Reduced Nm23/Awd protein in tumour metastasis and aberrant Drosophila development. Nature, 1989:342, 177-180.

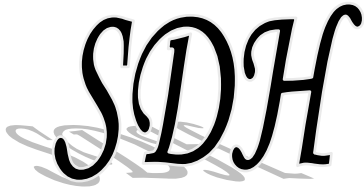
Stahl, John A., Alvaro Leone, Ariella M. Rosengard, **Laura Porter**, C. Richter King and Patricia S. Steeg. Identification of a Second Human *nm23 Gene*, *nm23- H2*. Cancer Research, 1991:51, 445-449.

ORGANIZATION MEMBERSHIPS:

2013- present	American Society of Clinical Oncology
2002-2004	American Academy of Pediatrics
1997-2005	American Medical Association
1997-2004	American Medical Women's Association
1997-2004	American Medical Student Association.

ACTIVITIES:

2013-present	Member of Phase II Trial of Therapeutic Interventions Directed to Genomically-Defined Sub-populations of Colorectal -ASSIGN , Therapeutic sub-committee
2013-present	Member of PCORI-funded project Improving Informed Consent for Palliative Chemotherapy
2013	Member of ASCO working group Clinical Meaningful Outcomes in colorectal cancer
2013	Member of AHRQ committee Oral Mechanical Bowel Preparation for Colorectal Surgery
2011, 2012	Consumer reviewer for the Peer Reviewed Cancer Research Program (PRCRP) sponsored by the Department of Defense on colorectal cancer research proposals.
2010	Participated in informational videos for the Colon Cancer Alliance through Health Charities.
2006-2010	Moderator of CCA's on-line Community chat room
2004-2010	Buddy with the Colon Cancer Alliance's (CCA) Buddy Program
2002-2003	Graduate Medical Education Class Representative
2002-2003	Graduate Medical Education Resident member for The Department of Pediatrics at Howard University Hospital
2002	Speaker "Life as a Resident" seminar, National Youth Leadership Forum on Medicine.
2001	Served on the Resources Facilities Committee Roster, for the Liaison Committee on Medical Education Self-Study for accreditation for Howard University College of Medicine.
2001	Howard University Hospital Booth at NBC News 4 Your Health Expo.
2000	Planned and Organized, "The Face of Addiction: A Forum for Medical Students and Faculty.
1995	Marshall, AIDS Walk 95, Washington, D.C.
1995	AIDS Walk, Baltimore, MD.
1995	Chase Brexton Booth at First Annual Maryland's Women's Expo



Stephanie Dunn Haney

49 Prince George Street, Bloomsburg, PA 17815
570-380-9070 (cell) shaney49@gmail.com

Advocacy Statement

Since being diagnosed with Stage IV lung cancer in the fall of 2007, I have found a new-found purpose in sharing my experience and helping others, with me, to fight the disease. Lung cancer is shamefully underfunded and neglected, only so because the public chooses to prioritize blame over compassion and reality. I have been blessed with time that few lung cancer patients receive, and I am grateful...I feel a responsibility to do with that time something that honors those who have passed before me. I have been fortunate to have responded to new medications that have been under study and emerging as successful new drugs on the market and benefitted significantly from these research advances. I therefore want to "give back" and contribute to the research process for the benefit of others living with cancer.

Advocacy Experience

U.S. Department of Defense Congressionally Directed Medical Research Programs (Lung Cancer Research Program) – September, 2009-present

On five occasions thus far (three on-site meetings and two online review processes), I have participated as a Consumer Reviewer during the process for selection of grants to be awarded funding from the Lung Cancer Research Program. I also served as a guest speaker at the opening dinner in 2010.

National Lung Cancer Partnership Volunteer Advocate – November, 2008 to present

I currently work with an active local committee, which I founded, to raise over \$60,000 in five years as part of the Free to Breathe National Walk program benefitting the National Lung Cancer Partnership. I am proud that others I've encouraged to participate are becoming strong advocates themselves. I wrote an online blog over nearly a year for the Partnership, have participated in NLCP planning calls, and was a member (2009 and 2010) and presenter/facilitator (2010, 2013) for the Partnership's annual Advocacy Summit.

Lung Cancer Alliance Volunteer Advocate – July, 2008 to present

I have visited and written federal legislators, educating them about lung cancer and emphasizing the need to support and sponsor the Lung Cancer Mortality Reduction Act bill, which transitioned into the recently passed Recalcitrant Cancer Act.

Profiles

I have been profiled on the Congressionally Directed Medical Research Program site at http://cdmrp.army.mil/cwg/stories/2012/haney_profile.shtml in 2012, three-times in the Press-Enterprise newspaper (Bloomsburg, PA) in 2009, 2011, and 2012, and on the Fox Chase Cancer Center's patient profiles at <http://www.fccc.edu/whyChoose/testimonials/lung/metastatic/haney/>. I have also been interviewed for a television story for a local PBS affiliate and for a drug marketing kick-off in Boston, MA (2011).

Writing

- *just breathe...life (with lung cancer)*—Regular blog
- *Stand Up To Cancer Patient Story*—November, 2010
- *life and breath: living with lung cancer, blog by Linnea Duff*—Guest blogger, August, 2010

Training

National Lung Cancer Partnership Advocacy Summit—April, 2009 and April, 2010

Attended four day, intensive programs with other survivors, caregivers and individuals committed to changing the face of lung cancer. Training included factual and scientific information about lung cancer, communications, social media, legislative issues, fundraising, and research advocacy.

Lung Cancer Alliance Capitol Forum--May, 2009 and November, 2009

Attended one and two day programs that included training on the governmental funding process and the passage of legislation. Had one-on-one appointments with house and senate staff members from our states to educate and encourage support and sponsorship for the Lung Cancer Mortality Reduction Act bill.

E d u c a t i o n

- **University of Maryland, College Park, Maryland**
24 Post-Master's credits earned (Higher Education Administration); August, 1996—December, 1998
- **The Ohio State University, Columbus, Ohio**
Master of Arts (Student Personnel/Counseling Emphasis); September, 1993
- **Bucknell University, Lewisburg, Pennsylvania**
Bachelor of Arts (Major—Psychology; Minors—Education and Music); June, 1990

W o r k E x p e r i e n c e

- ***Township Manager and Treasurer***—*January, 2003 to present*
Hemlock Township, Bloomsburg, Pennsylvania
- ***Director/Assistant Director of Student Activities***—*February, 2001 to January, 2003*
Pennsylvania College of Technology, Williamsport, Pennsylvania
- ***Director of Residence Life and Judicial Affairs***—*July, 1995 to January, 2001*
Goucher College, Baltimore, Maryland
- ***Residence Hall Director***—*July, 1993 to July, 1995*
Bowling Green State University, Bowling Green, Ohio
- ***Residence Hall Director/Assistant Residence Hall Director***—*August, 1991 to July, 1993*
The Ohio State University, Columbus, Ohio

JILDA S. NETTLETON

206-406-8383 (cell) • jilda2bean@yahoo.com

PROFILE

Breast cancer survivor and advocate with extensive science, teaching, research, and grant experience

EDUCATION

Ph.D. Physiology and Biophysics, University of Washington (1998) *Thesis dissertation*: “Summation of AMPA-mediated EPSPs in Rat Neocortical Pyramidal Neurons.”

B.S. Physics, University of Rochester, with honors and *cum laude* (1987)

RELATED EXPERIENCE

Sacajawea PTA Seattle, WA (2012-Present)

VP Fundraising (2013-Present)

- Analyze data from fundraisers in previous years to determine effectiveness of fundraisers and present to executive board in order to develop fundraising strategy with goal of approximately \$100k/year
- Create fundraising webpage to inform school parents about current upcoming fundraisers in addition to other forms of written and verbal communication.

Auction Committee - Data Entry & Finances (2012-2013)

- Entered procurement data and managed fiscal aspects of auction

Department of Defense – Breast Cancer Research Program, Washington DC (Aug 2011 & Nov 2013)

Consumer Reviewer on Peer Review Panel

- Evaluated research proposals from scientists primarily in terms of their impact on the breast cancer community. Orally presented summary to other panel members.
- Scored all grant proposals on their scientific merit and impact through written summaries and discussion.

Young Survival Coalition, Seattle Chapter, Seattle, WA (2008 – present)

- Supported group members by listening to survivors stories and conveying empathy and sharing personal experience. Was told by other survivor that “you always seem to know what to say.”
- Worked on leadership board during transition from local support group for young breast cancer survivors to chapter of national support group.
- Participated in first major fundraising venue where group raised \$6000 for starting new chapter.

North Seattle Community College Co-operative Preschools Seattle, WA (2006-2012) Multiple leadership positions

Victory Heights Parent Coordinator (2010-2012)

- Maintained a full co-op of 20 members through familiarizing incoming parents to co-op expectations and structure; creating promotional material for co-op and keeping co-op web site up to date.

Meadowbrook 3-5's, Chair (2009-10)

- Managed co-op of 12 families. Complimented for holding together co-op during a difficult year when the co-op had low enrollment and financial issues.

North Seattle Toddler Co-op – PAC (Parent Advisory Council) Representative (2006-07, 2008-09)

- Represented co-op at monthly council meetings where guidelines for all co-op are discussed and adjusted.
- Researched and wrote grants to fund scholarship program that needed additional funding during recession.

Oxnard College, Ventura County Community College District, Oxnard, CA (2002-2004)

Instructor - General Human Anatomy Lecture and Laboratory courses (4 semesters) & General Biology Laboratory course (2 semesters)

- Dedicated to giving students every opportunity to learn. Provided individual and group study sessions outside of regularly scheduled class times. Students that took full advantage of class time and study sessions earned A's and B's in my class.

- Created laboratory projects, study guides, and review sheets to help students learn and remember material. My laboratory exercises were described as “challenging one to really think about course material.”

Survival Systems, Ventura, CA (2000-2002)

Sr. Account Manager, Technical Recruiter

- Effectively evaluated and instructed job search candidates on resume writing and interviewing skills. Successfully placed candidates created \$100,000 in individual billing and over \$350,000 in billing for recruiting company.

Kelly Scientific Resources, Woodland Hills, CA (2000)

Recruiter/Admin

- Evaluated resumes and interviewed applicants from lab technicians to senior scientists for temporary and permanent positions in chemical and biological laboratories.

University of Washington, Seattle, WA– Multiple positions

Research Associate, Physiology and Biophysics Department (1992-1998)

- Designed, planned, and completed research projects in cellular (neuronal) functionality using electrophysiology, small animal surgery, immunocytochemistry, and fluorescent microscopy.
- Experienced in setting up and troubleshooting equipment used in biological experiments. Completed research projects in the areas of neurobiology, physiology, cell and molecular biology.

Computer Services Consultant Psychology Department (1998)

- Designed computer program for and advised in the setup of computer-driven biological experiments.

Teaching Assistant - Physiology and Biophysics Department (1993) & ***Physics Department*** (1990-1)

- Assisted teaching introductory physics and human physiology courses by conducting weekly laboratory and review sessions as well as tutoring individual students.

OTHER ORGANIZATIONS AND ACTIVITIES

Sacajawea Elementary (2010-Present) - Assist with reading and math in K-3 classrooms

Youth Tutoring Program, Seattle, WA (2009-2010) - Tutored at risk students in reading, math, literature and general study skills as well as assisting with understanding and completion of homework assignments.

International Toastmasters, Competent Toastmaster, (1996 -2004) - Offices held: President (2003), VP Education (2002-2003), Secretary (2001), VP Membership (1997).

Oregon Public Networking/Eugene Free Net, Eugene, OR (1999) Technical Assistant Volunteer, Public Relations Committee member

SAMANTHA R. GUILD, ESQ.

AIM at Melanoma
3040 Cutting Blvd.
Richmond, CA 94804
Telephone No. (916) 706-0599
E-Mail: sguild@AIMatMelanoma.org

PROFESSIONAL EXPERIENCE

6/08 – present AIM at Melanoma – Patient Advocate

Responsible for finding and assisting state legislators in introducing and passing indoor tanning bed legislation, acting as the liaison between various advocacy groups and legislators and providing testimony and materials discussing need for such legislation. Organizing Patient and Caregiver Symposiums at major cancer centers throughout the country. Responsible for reviewing new developments in melanoma and skin cancer research and treatment and making that information available to melanoma patients and their caregivers, as well as the general public.

8/04 – present Binding Systems of Cal. – Vice President

Responsible for all aspects of marketing BSI's services to the major law firms throughout the United States and abroad as well as all client contact.

4/01 – 8/04 Angelo, Kilday & Kilduff - Associate

Responsible for all phases of case management in defending public entities and private employers in general defense litigation, employment matters, personal injury and civil rights cases in state and federal court. This included legal decision-making, attending court appearances, preparing and responding to discovery requests, taking and defending depositions, preparing and responding to motions, meeting with potential witnesses and preparing for trial.

2/00 - 2/01 Lanahan & Reilley LLP - Associate

Responsible for all phases of case management in defending insurance carriers in personal injury cases in state court and represented plaintiffs in employment matters in state and federal court. This included legal decision-making, attending court appearances, preparing and responding to discovery requests, taking and defending depositions and preparing and responding to motions.

EDUCATIONAL BACKGROUND

1999 J.D. - University of the Pacific, McGeorge School of Law - Sacramento, CA

1995 B.A. - Clark University - Worcester, MA – American Government/Women's Issues

COURT ADMISSIONS

December 1999 Admitted to practice before all California courts

May 2001 Admitted to practice before the U.S. Court of Appeals for the Ninth Circuit

July 2000 Admitted to practice before the U.S. District Court for the Eastern District of CA

PROFESSIONAL MEMBERSHIPS

State Bar of California

Sacramento Breakfast Rotary Club

VOLUNTEER POSITIONS

Crisis counselor for Community Violence Solutions

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

Donna Nichols Threlkeld		POSITION TITLE Breast Cancer Research Advocate	
eRA COMMONS USER NAME (credential, e.g., agency login)			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	MM/YY	FIELD OF STUDY
Indiana University, Bloomington, Indiana	B.A.	1969	Government
Indiana University Law School, Indianapolis, Indiana	J.D.	1981	Law

Please refer to the application instructions in order to complete sections A, B, C, and D of the Biographical Sketch.

A. Personal Statement

Ten-year two time breast cancer survivor and active cancer research advocate. Following training by the Research Advocacy Network, have had ongoing involvement in national peer review process for Susan G. Komen and the Department of Defense Congressionally Directed Medical Research Program. For the last six years have served as a community member on Indiana University's Institutional Review Board and the last four years have reviewed proposals for the Susan G. Komen for the Cure Tissue Bank at the IU Simon Cancer Center. Active member of the Komen Advocates in Science and scholarship recipient for the 2013 ASCO Breast Cancer Symposium. Have been involved in community and state-wide breast cancer advocacy as chair of a breast cancer support organization, member of the Susan G. Komen, Central Indiana Affiliate, Public Policy Committee, member of the Steering Committee for the Weekend to End Breast Cancer, and Secretary of the Indiana Breast Cancer Awareness Trust Board. Most recently have served as an advocate advisor for Komen and Department of Defense Postdoctoral Fellowship Proposals. These roles and experiences have given me the understanding and opportunity to represent and appreciate the perspective of the patient. Serving in State Government as an attorney and administrator of the Attorney General's Office, the State Treasurer's Office, and the Indiana Bond Bank further reflect my desire to serve, to make a difference, and to advocate.

B. Positions and HonorsEmployment

1969-1977 Indiana and Southwestern Bell Telephone Companies, Data Systems Assistant and Unit Manager

1981-1993 Office of the Indiana Attorney General, Deputy Attorney General and Director of Personnel
2000-1003

1993-1997 Office of the Indiana State Treasurer, Chief Deputy Treasurer, Deputy Treasurer/Special Counsel

1997-1999 Indiana Bond Bank, Executive Director

Advocacy Positions/Affiliations

2007-Present Indiana University Institutional Review Board, Community Member

2007-Present Komen for the Cure Advocates in Science Grant Peer Review, Advocate Reviewer

2008-09 Susan G. Komen, Central Indiana Affiliate, Public Policy Committee, Member

2009 Weekend to End Breast Cancer Steering Committee, Member

2008-Present Indiana Breast Cancer Awareness Trust Board, Secretary

2009-Present Komen Tissue Bank at the IU Simon Cancer Center, Consenter and Reviewer

2009-10 Pink Ribbon Connection, Breast Cancer Support Organization, Chair

2011-Present Department of Defense Congressionally Directed Medical Research Program, Consumer Reviewer

2013-Present Advocate Advisor, Dr. Antonella Chiechi, Susan G. Komen Postdoctoral Fellowship Proposal, Treatment of Breast Cancer Bone Metastases

2014 Advocate Advisor, Dr. Laura Wright, Department of Defense Postdoctoral Fellowship Proposal, Musculoskeletal Complications and Bone Metastases in Breast Cancer Patients

Advocacy Training

2007 Graduate, Research Advocacy Network Training

2007 ASCO Annual Meeting

2008 National Breast Cancer Coalition Fund Advocacy Training Conference

2008 Hoosier Oncology Group, Inc Research Celebration Conference

2008-Present Komen Advocates in Science Training

2008,10,11 Amelia Project

2010 Collaborative Institutional Training Initiative (CITI) Program, for Human Subjects Research

2010 International Symposium on Breast Cancer Prevention

2013 ASCO Breast Cancer Symposium

C. Selected Peer-reviewed Publications

N/A

D. Research Support

N/A



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT: FY 2015 HONORARIA POLICY
DATE: AUGUST 13, 2014

Summary and Recommendation:

The CPRIT's enabling legislation requires CPRIT's Chief Executive Officer, in consultation with the Oversight Committee, to adopt a policy regarding honoraria paid by CPRIT for peer review services. The Oversight Committee approved the FY 2014 honoraria policy at the November 1, 2013 meeting. The FY2015 honoraria policy is the same as previously approved with one change to reflect the new position of Deputy Chair for the Product Development Review Council. I recommend approval of the FY 2015 honoraria policy.

Discussion:

CPRIT's Scientific Research and Prevention Programs committee members (also referred to as "peer reviewers") are responsible for reviewing grant applications and recommending grant awards for meritorious projects addressing cancer prevention and research (including product development) in Texas. State law authorizes CPRIT to pay honoraria to individuals appointed to CPRIT's Scientific Research and Prevention Programs committees (Health and Safety Code § 102.151(d)). The ability to pay honoraria is essential to retaining individuals with the expertise and experience to carry out the complex review process required by statute and CPRIT's administrative rules.

The State Auditor recommended that CPRIT implement a process to support the amount of honorarium it pays, to justify any changes, and to ensure that the honoraria are reasonable and competitive for the value CPRIT receives. Adopting documentation and process requirements for honoraria payments was also recommended. This guidance was codified in Section 102.151(e) of the Health and Safety Code.

CPRIT's program staff relied upon historical information as well as anticipated workload projections to perform a detailed analysis of the activities, hours, and units for peer reviewer workload. The FY 2015 policy incorporates the different roles and responsibilities assigned to Review Council chairs, Peer Review panel chairs, and peer review panel members and justifies the FY 2015 honorarium amount paid for each role. In the event that honoraria rates are not standard across the prevention, scientific research, and product development programs, the policy justifies the reasons for paying

different amounts. The approved policy fully implements the statutory mandate and the State Audit recommendations.

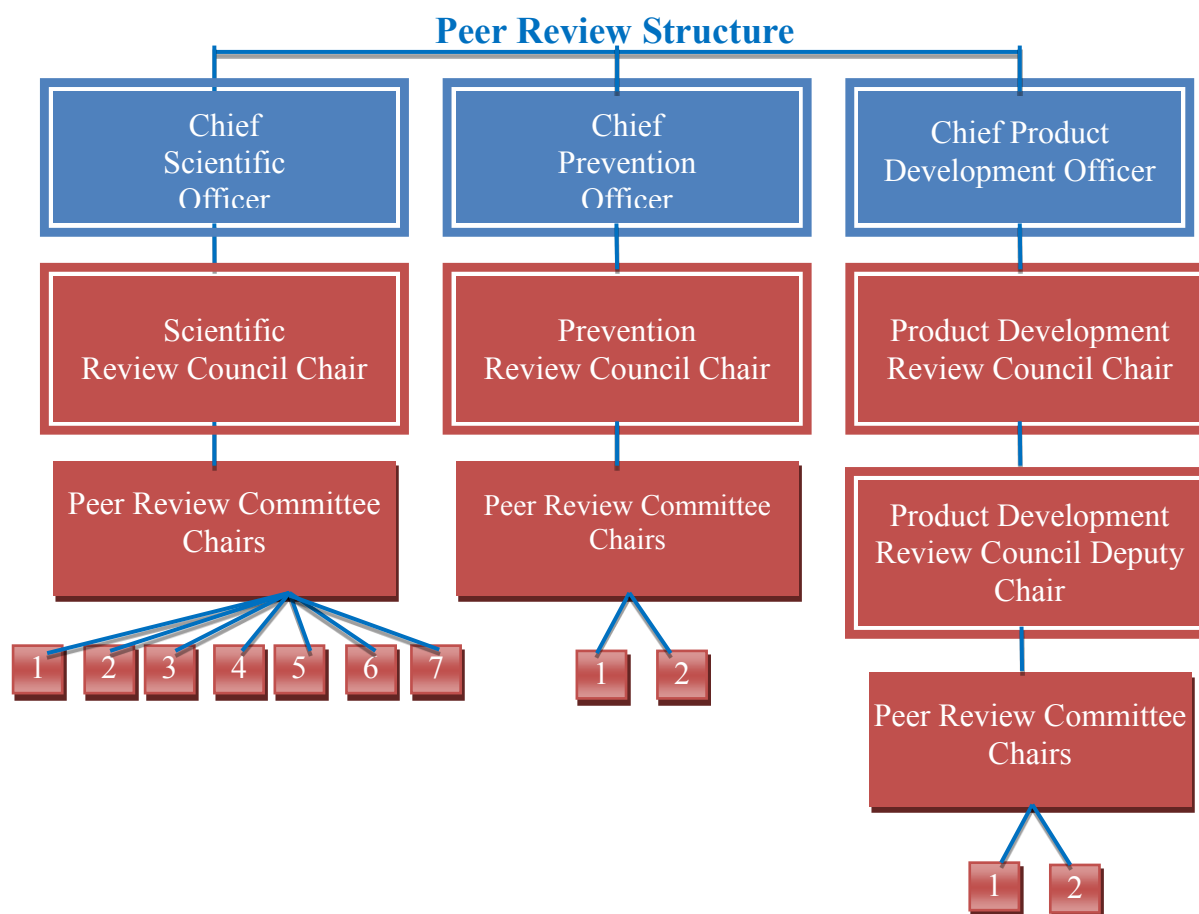
I have made one change to the FY 2015 honoraria policy to reflect the new position of Deputy Chair for the Product Development Review Council (PDRC). Creating the position of PDRC Deputy Chair is necessary because the number of applications submitted to the Product Development program have increased, necessitating two review panels to meet several times during the cycle. The Deputy Chair heads up one of the two review panels. The FY 2015 policy breaks down the Deputy Chair's role into components to justify the honoraria amount associated with the time commitment.

CPRIT PEER REVIEW HONORARIA POLICY¹

Adopted September 1, 2013

Revised, August 20, 2014

Peer review of prevention and research applications is the evaluation process conducted by qualified experts for feasibility, significance, and potential for impact. Like many funding agencies, CPRIT has implemented a tiered peer review process designed to identify the best projects based on excellence, program-specific objectives, and organizational priorities.² Maximizing the success of CPRIT's scientific research, product development, and prevention programs is dependent upon the quality of the peer reviewers CPRIT recruits. Therefore the peer reviewers must be exceptionally qualified, highly respected, well-established members of the cancer research, product development, and prevention communities.



¹ Adopted pursuant to TEX. HEALTH & SAFETY CODE Section 102.151(e).

² A tiered approach to peer review has been recommended by the National Academies of Sciences.

CPRIT relies upon a pool of approximately 170 expert peer reviewers to evaluate, score and rank grant applications based upon significance and merit. As reflected above, the general peer review structure is the same for CPRIT's three grant programs. Reviewers are assigned to peer review committees based upon their expertise and background. The evaluations conducted by the peer review committees are used to develop the list of grant applications recommended for CPRIT grant awards.³

All of CPRIT's expert peer reviewers live and work outside Texas, which is an uncommon requirement among grant-making organizations. CPRIT implemented this peer reviewer qualification to ensure an impartial review, minimize conflicts of interest and provide the opportunity to select the best projects without regard for self-interest.

Honoraria

In recognition of the work undertaken by CPRIT peer reviewers, state law authorizes CPRIT to pay honoraria to its peer reviewers.⁴ CPRIT's ability to pay honoraria is essential to retaining individuals with the expertise and experience to carry out the complex review process required by statute and CPRIT's administrative rules.

CPRIT recruits world-renowned experts who live and work outside of the state to be peer reviewers. CPRIT's residency policy is important to maintaining a review process that minimizes the potential for political and other outside influences, but it means that the CPRIT review process, by design, lacks non-monetary incentives common to other grant review processes that may otherwise justify the time commitment required of CPRIT peer reviewers in addition to their full-time jobs.

Specifically, CPRIT reviewers are not eligible to compete for CPRIT grants. This is different than other cancer grant-making organizations such as National Institutes of Health (NIH), Centers for Disease Control and Prevention, Department of Defense, American Cancer Society, and Susan G. Komen for the Cure. For example, NIH reviewers may review grant applications as well as compete for NIH grants. Familiarity with the NIH review process gained by serving as an NIH peer reviewer provides the individual a significant nonmonetary benefit since that understanding better positions the reviewer to compete for and secure NIH grant funds as an applicant. This benefit is not available to CPRIT's reviewers.

A second nonmonetary benefit from serving on a review panel is that such service is an indication of external recognition in one's field, which is essential for academic promotion. Using peer reviewers who are already well-established in their careers means that this is not an incentive for CPRIT peer reviewers to participate.

The Chairs of CPRIT review panels are all highly distinguished in their respective fields and bring enormous stature to the peer review process. Unlike chairs of other review processes, CPRIT's chairs are responsible for recruiting peer reviewers for their panel. In addition, they

³ For more information about the grant review process undertaken by the peer review committees, please see CPRIT's administrative rules, 25 T.A.C. Part 11, Sections 703.6 and 703.7.

⁴ TEX. HEALTH & SAFETY CODE Section 102.151(d)

serve as strategic advisors for CPRIT's grant programs. These responsibilities are unique to CPRIT review panel chairs and require considerably more effort and expertise than simply chairing a committee. Having panel chairs of this caliber distinguishes CPRIT's peer review process from all others.

Honoraria Payment Process and Documentation

Review Council and Committee Chairs receive quarterly honoraria payments directly from CPRIT. The honoraria payment process for Review Council chairs and Committee chairs is as follows:

1. At the end of the fiscal quarter, the Review Council chairs and Committee chairs submit to CPRIT a written confirmation of the work performed and an estimate of hours* spent related to CPRIT's peer review activities for the quarter.
2. The CPRIT Program Officer reviews the confirmations and approves payment of quarterly honoraria to the Review Council chair and Committee chairs.
3. CPRIT's financial staff authorizes payment of the honoraria and retains the documentation supporting the honoraria payment.
4. The Chief Compliance Officer and Internal Auditor may also review the confirmations submitted.

* NOTE: Honorarium is paid for the annual service of the Review Council chair or Committee chair. Payment is not based on an hourly wage structure; the estimated number of hours devoted to CPRIT activities by a Review Council or Committee chair may vary by quarter depending upon the timing of review cycle activities. The hourly estimate is used at the end of the year to set honoraria payment structures for the next fiscal year.

Peer reviewers are paid by CPRIT's third party grant administrator for each review cycle in which they participate. To document the work performed by a peer review committee member for the review cycle, CPRIT's third party grant administrator confirms that the reviewer attended the peer review meeting and submitted written comments and scores for the grants assigned to the reviewer for evaluation.

CPRIT also reimburses travel expenses and pays the Texas state per diem when peer reviewers and Review Council chairs and Committee chairs travel to attend peer review meetings. CPRIT relies upon standard travel documentation for travel reimbursements.

Peer Review Responsibilities

Review Council Chairs

The Council Chair works directly with the CPRIT Program Officer to coordinate the peer review activities for each CPRIT program. The CPRIT model for peer review is unique. Other grant-

making programs typically use committee chairs only to preside at committee meetings; however, CPRIT engages preeminent experts in their field for the Council Chair and Committee Chair positions to advise CPRIT on program aspects, including the short-term and long-term direction of the program, the review process itself, and the award portfolio composition. This work is done in addition to the administrative tasks associated with chairing Review Council meetings. Many of the Council Chair responsibilities are similar across the three CPRIT programs, including:

- advising on the selection of committee chairs
- assisting with peer reviewer selection
- reviewing all abstracts of projects that are to be discussed at Prevention, Scientific, and Product Development Review Council meetings
- chairing Review Council meetings
- chairing a peer review panel meeting if a chair has an unexpected conflict
- finalizing grant award recommendations to the Chief Executive Officer
- providing ongoing advice to CPRIT staff on programs, review processes, and future funding opportunities

Estimated Annual Time Commitment: Council Chairs are expected to commit approximately 240 hours to CPRIT-related activities in FY2015. This equates to 11.5% of a standard 2080 hour work year. **Table 1** provides a detailed analysis of the activities, hours, and units used to project the Council Chair workload. The information in Table 1 is based upon 2009 – 2012 review cycle information and the projected workload for FY 2015.

NOTE: In addition to the regular Council Chair duties in FY 2015, CPRIT anticipates that the Product Development Review Council Chair will perform services totaling approximately 60 additional hours. Examples of the additional activities include coordinating the review of annual progress reports and milestone funding decisions and providing expert advice and assistance related to CPRIT's product development portfolio and substantive grant contract amendment requests. In FY 2015 there is a need for a Product Development Review Council Deputy Chair position as there are now two review panels. This position is substantially equivalent to the Council Chair position except that the Deputy Chair will not prepare slate recommendation for the Chief Executive Officer, review draft RFA's, propose new RFA's, or analyze data for the Product Development program.

Hourly Rate Proxy: Honorarium is paid for the annual service of the Review Council chair and is not based on an hourly wage structure. However for comparison, the honoraria paid to Review Council chairs equate to a \$250/hour rate. This is in line with hourly rates paid for skilled professional services in other industries and less than the \$500/hour rate paid for medical experts in malpractice cases.⁵ The hourly rate used by CPRIT is also likely to be less than rates used to calculate consultant fees for physicians and scientists who advise pharmaceutical companies. Although there is no standard rate for consulting fees, one Texas institution of higher education limits the amount of consulting fees a professor may accept to 25% of their base salary. The

⁵ Data from *National Medical Consultants, P.C.*, a physician owned and operated company representing a panel of over 2700 medical experts who are distinguished specialists in all areas of medicine.

capped amount is considerably greater than the \$60,000 - \$75,000 honoraria paid to CPRIT Review Council Chairs.

Review Committee Chairs

Each peer review committee is led by a Committee Chair. The CPRIT model for peer review is unique. Other grant-making programs typically use committee chairs only to preside at committee meetings; CPRIT engages preeminent experts in their field for the Committee Chair positions to advise CPRIT on program aspects, including the short-term and long-term direction of the program, the review process itself, and the award portfolio composition. This work is done in addition to the administrative tasks associated with chairing peer review committee meetings. Committee Chairs are also members of the Review Council for the program. Duties of the committee chair include:

- recruiting reviewers for their review panels
- assigning applications to their panel members
- becoming familiar with the abstracts of all applications assigned to their panel
- determining order of review for applications for panel discussion
- chairing panel discussions
- reviewing full applications to participate in programmatic review meetings
- evaluating CPRIT Scholar recruitment grants (Scientific Review Committee chairs)
- assessing due diligence and intellectual property reports for product development applications (Product Development Review Committee chairs)
- ranking grant applications and developing a list of recommended grant awards and supporting information for consideration by the CPRIT Program Integration Committee
- reviewing annual progress reports and milestone funding decisions (Product Development review committee chairs)
- participating in meetings with CPRIT staff to provide advice on future program directions, processes, evaluation criteria, and other related issues

Estimated Annual Time Commitment: The amount of time spent on committee chair activities varies depending on the program. Scientific and Product Development Review Committee chairs are expected to commit approximately 200 hours to CPRIT-related activities in FY2015, and Prevention Review Committee chairs will commit 125 hours. **Table 2** provides a detailed analysis of the activities, hours, and units used to project the committee chair workload. The information in Table 2 is based upon 2009 – 2012 review cycle information and the projected workload for FY2015.

Hourly Rate Proxy: Honorarium is paid for the annual service of the Review Committee chair and is not based on an hourly wage structure. However for comparison, the honoraria paid to Committee chairs equates to a \$200/hour fee. This is in line with hourly rates paid for skilled professional services in other industries and less than the \$500/hour rate paid for medical experts in malpractice cases.⁶ The hourly rate used by CPRIT is also likely to be less than rates used to

⁶ Data from *National Medical Consultants, P.C.*, a physician owned and operated company representing a panel of over 2700 medical experts who are distinguished specialists in all areas of medicine.

calculate consultant fees for physicians and scientists who advise pharmaceutical companies. Although there is no standard rate for consulting fees, one Texas institution of higher education limits the amount of consulting fees a professor may accept to 25% of their base salary. The capped amount is considerably greater than the \$25,000 - \$40,000 honoraria paid to CPRIT Review Committee Chairs.

Review Committee Members

The number of peer review committees varies by program, generally based on the volume of grant applications submitted. Peer reviewers are responsible for individually reviewing, scoring and critiquing 6-10 applications per cycle, as well as participating in panel discussions about grant applications assigned to the peer review committee. A full review of a single application generally takes a reviewer 6-8 hours, but substantially more time may be required for complex, highly technical applications. A typical CPRIT grant application averages about 40 pages in length with additional supporting documentation. Applications for multi-million dollar collaborative research projects and product development project may be much more extensive.

Estimated Time Commitment per Review Cycle: Peer reviewer activity varies by program and number of applications assigned. Scientific peer reviewers are expected to commit approximately 85 hours per review cycle. Prevention peer reviewers will commit 55-70 hours per cycle. Product Development peer reviewers will commit 100 hours per cycle. **Table 3** provides a detailed analysis of the activities, hours, and units used to project the peer review workload. The information in Table 3 is based upon 2009–2012 review cycle information and the projected workload for FY2015.

Hourly Rate Proxy: Honorarium is paid for the service of Scientific and Prevention peer reviewers for a given review cycle and is not based on an hourly wage structure. However for comparison, honoraria paid to Scientific and Prevention peer reviewers equates to a rate of \$50/hour. Honoraria paid to Product Development peer reviewers is \$65/hour. These reviewers must have both scientific and product development backgrounds and are more difficult to recruit. While the hourly rates are significantly less than those paid to professionals of this caliber, the rate is appropriate given the workload and responsibilities compared to Review Council and Committee chairs.

Comparison to other Grant Making Organizations

Grant-making organizations use various models and methods for compensating peer review committee members. A survey of 21 cancer granting organizations reported wide variation among programs such that an average compensation scheme for panel members was not possible. The disparity among organizations makes it difficult to devise a benchmark compensation method or amount. Reported compensation practices may fail to include intangible benefits available to reviewers in addition to monetary compensation, which further complicates the ability to make a meaningful comparison between CPRIT and other grant-making organizations. As discussed earlier, these non-monetary incentives are largely unavailable to CPRIT reviewers because of CPRIT's policy to use highly qualified, experienced, out-of-state reviewers.

- International Cancer Research Partners (ICRP) surveyed 31 of its partner organizations and 21 responded. The report found that organizations commonly paid different honoraria depending on the role of the reviewer. Chairs often received more than committee members, and teleconference or online reviewers typically received less compensation than those members who participated in-person. An average could not be computed on the basis of the supplied data.⁷
- CPRIT's third party grant administrator reports that two other clients pay reviewers \$1,250 and \$2,000 per review meeting.
- NCI's website reports that NCI pays \$200 per day of review in addition to travel expenses.

⁷ The report did not include a range but when the survey sponsors were asked they indicated the range for compensation for panel members was \$150-\$3,000 per day.

Table 1. Council Chair Activities

Table 1 - Review Council Chair Activities, Hours, Units						
Scientific Review		Prevention Review		Product Development Review		
Units	Activity	Units	Activity	Units Chair	Deputy	Activity
5	Consult with staff on vision and direction for the program; bi-weekly calls with staff	5	Consult with staff on vision and direction for the program; bi-weekly calls with staff	5	5	Consult with staff on vision and direction for the program; bi-weekly calls with staff
2	Help select and recruit Committee Chairs	2	Help select and recruit Committee Chairs	2	2	Help select and recruit Committee Chairs
2	Advise on peer review and other processes as needed	2	Advise on peer review and other processes as needed	2	2	Advise on peer review and other processes as needed
4	Review draft RFAs, propose new ones, etc.	4	Review draft RFAs, propose new ones, etc.	6	0	Review draft RFAs, propose new ones, etc.
4	Communicate with Committee Chairs prior to peer review & programmatic mtg	1	Communicate with Committee Chairs prior to peer review & programmatic mtg	6	6	Communicate with Committee Chairs prior to peer review & programmatic mtg
4	Prepare for Programmatic meetings; review materials	2	Prepare for Programmatic meetings; review materials	4	4	Prepare for Programmatic meetings; review materials
2	Lead programmatic review	6	Lead programmatic review	5	5	Lead programmatic review
4	Prepare slate recommendations for ED	1	Prepare slate recommendations for ED	4	0	Prepare slate recommendations for ED
15	Review recruitment applications, become familiar with applications to be discussed	15	Review abstracts, attend portions of panel meetings, back up for panel Chair	12	12	Review abstracts, attend portions of panel meetings, back up for panel Chair
4	Lead quarterly discussion on recruitment awards	4	Collaborate on articles for publication	4	0	Analyze data for Product Development program
4	Analyze data for Research program	4	Analyze population and other data for Prevention program	12.5	12.5	Review annual and final progress reports, including milestone achievement reports, advise on activities of funded product development grants
50		4	Review Annual and Final progress reports	62.5	48.5	
\$ 1,200	Unit cost	50			\$1,200	Unit cost
\$ 250	Hourly rate	\$1,200	Unit cost		\$250	Hourly rate
\$60,000	Annual honoraria	\$250	Hourly rate	\$75,000		Annual honoraria Chair
		\$60,000	Annual honoraria	\$58,200		Annual honoraria Deputy Chair

See Table 4 for an explanation of the correlation between units and hours.

Table 2. Committee Chair Activities

Table 2 - Committee Chair Activities, Hours, Units					
Scientific Review		Prevention Review		Product Development Review	
Units	Activity	Units	Activity	Units	Activity
2	Select/recruit committee members	1	Select/recruit committee members	2	Select/recruit committee members
2	Review draft RFAs and provide input (as needed)	1	Review draft RFAs and provide input (as needed)	1	Review draft RFAs and provide input (as needed)
10	Read abstracts; assign grants to reviewers	10	Read abstracts assigned to their committee	15	Read abstracts assigned to their committee
1	Assist with follow up of delinquent reviewers	1	Assist with follow up of delinquent reviewers	1	Assist with follow up of delinquent reviewers
6	Chair the assigned committee review process via conference call or in person meeting	6	Chair the assigned committee review process via conference call or in person meeting	3	Chair the assigned Screening Teleconference committee via conference call
2	Prepare for Programmatic meetings; review materials	2	Prepare for Programmatic meetings; review materials	10	Chair the assigned committee review process via 2-day, in-person peer review meeting
2	Participate in Chair's programmatic review meetings	6	Participate in Chair's programmatic review & debriefing meetings	2	Participate in debriefing sessions, discussion of future direction of program, development of new RFAs
2	Participate in debriefing sessions, discussion of future direction of program, development of new RFAs	2	Participate in debriefing sessions, discussion of future direction of program, development of new RFAs	11	Review annual and final progress reports, including milestone achievement reports, advise on activities of funded product development grants.
15	Review recruitment applications				
3	Participate in quarterly review of recruitment applications				
45		29		45	
\$875	Unit cost	\$875	Unit cost	\$875	Unit cost
\$200	Hourly	\$200	Hourly	\$200	Hourly
\$39,375	\$40 K Annual honoraria	\$25,375	\$25K Annual honoraria	\$39,375	\$40K Annual honoraria

See Table 4 for an explanation of the correlation between units and hours.

Table 3. Peer Reviewer Activities per Cycle

Table 3 - Peer Reviewers Activity by Program					
Product Development Review:~30 reviewers		Prevention Review:~ 33 reviewers		Scientific Review: ~ 105 reviewers	
Units	Activity	Units	Activity	Units	Activity
8	Preparation of full critiques	8	Preparation of full critiques	10	Preparation of critiques
2	Screening teleconference	3	one meeting by phone, one in- person	3	Travel to/from on-site meeting
3	Travel to/from on-site meeting	2	Participation at meeting	3	Participation at meeting
4	Participation at meeting	1	Post-meeting discussion	1	Post-meeting discussion
1	Post-meeting discussion				
1	Review of due diligence and intellectual property evaluations				
1	Teleconference discussion of due diligence and intellectual property evaluation				
	\$325 Unit cost \$65 avg. hourly rate \$6,500 per cycle		\$250 Unit cost \$50 avg. hourly rate \$2,750 teleconference \$3,500 in person per cycle		\$250 Unit cost \$50 avg. hourly rate \$4,250 per cycle

See Table 4 for an explanation of the correlation between units and hours.

NOTE: As reflected in the table, key activities are assigned a unit cost. Peer reviewers are paid only for activities in which they participate. For example, participation at an in-person research peer review meeting is 3 units (11-15 hours) and each unit is valued at \$250; thus, the amount paid to a research peer reviewer for attendance at an in-person meeting is \$750. If the reviewer was unable to attend the meeting, then \$750 would be subtracted from the honorarium paid to the reviewer.

Table 4. Hours and Units Calculation

PARTICIPATION (HOURS)	UNITS		Council Chairs	Committee Chairs	Peer reviewers
1-5	1		Unit Cost		
6-10	2		\$1200	\$875	\$250-\$325
11-15	3		Average Hourly Rate		
16-20	4		\$250	\$200	\$50-\$65
21-25	5		Honoraria		
26-30	6		\$60 - \$75K annually	\$25 - \$40K Annually	\$2,750 - \$6,500 per cycle
31-35	7				
36-40	8				
41-45	9				
46-50	10				
51-55	11				
56-60	12				
61-65	13				
66-70	14				
71-75	15				



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE CHAIR DR. WILLIAM RICE
FROM: WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT: SECTION 102.1062 WAIVER – MARGARET L. KRIPKE, PH.D.
DATE: AUGUST 20, 2014

Waiver Request and Recommendation:

I request that the Oversight Committee approve a renewal of the conflict of interest waiver for Dr. Margaret L. Kripke, CPRIT's Chief Scientific Officer, pursuant to Health & Safety Code Section 102.1062 "Exceptional Circumstances Requiring Participation." The waiver is necessary for Dr. Kripke to continue to effectively perform her duties as Chief Scientific Officer. Together with the waiver's proposed limitations, adequate protections are in place to mitigate the opportunity for the award of grant funds to be driven by anything other than merit and established criteria.

Background:

The Oversight Committee approved Dr. Kripke's conflict of interest waiver for the 2014 fiscal year. Dr. Kripke's husband, Dr. Isaiah J. Fidler, is employed by The University of Texas M. D. Anderson Cancer as a professor in the Department of Cancer Biology and holds an endowed chair.¹ Therefore, Dr. Kripke continues to have the same conflict of interest and requires a renewal of the conflict of interest waiver for the 2015 fiscal year. The recommendations and limitations in the waiver renewal remain the same as previously approved by the Oversight Committee.

Health & Safety Code Section 102.106(c)(3) mandates that a professional conflict of interest exists if a CPRIT employee's spouse is an employee of an entity applying to receive or receiving CPRIT funds. Furthermore, CPRIT's administrative rule 702.13(c) categorizes this type of professional conflict of interest as one that raises the presumption that the existence of the conflict may affect the impartial review of all other grant applications submitted pursuant to the same grant mechanism in the grant review cycle. A person involved in the review process that holds one of conflicts included in the Section 702.13(c) "super conflict" category must be recused from participating in the "review, discussion, scoring, deliberation and vote on all grant applications competing for the same grant mechanism in the entire grant review cycle, unless a waiver has been granted..."

¹ Dr. Fidler does not have a recognized administrative or leadership position at M.D. Anderson, nor has he ever applied for or received CPRIT funding.

Due to M.D. Anderson's wide-ranging involvement in cancer prevention and cancer research activities in Texas it is reasonable to expect that the same conflict will affect Dr. Kripke's participation in more than one grant review cycle in this fiscal year as well as other grant monitoring activities she will undertake. CPRIT's administrative rule Section 702.17(3) authorizes the Oversight Committee to approve a waiver that applies for all activities affected by the conflict during the fiscal year.

Exceptional Circumstances Requiring Dr. Kripke's Participation

In order to approve a waiver, the Oversight Committee must find that there are exceptional circumstances justifying the conflicted individual's participation in the review process. As explained below, there are compelling reasons warranting Dr. Kripke's continued participation in the review process when she would otherwise be excluded because of the conflict. The proposed limitations and CPRIT's existing process and procedures will substantially mitigate any potential for bias.

One of the principal duties for a CPRIT program officer is serving as the Oversight Committee's expert-in-residence for his or her particular grant program. Dr. Kripke is a respected scientist and administrator who has been recognized both nationally and internationally for her work as a cancer researcher. Her nine-year tenure on the President's Cancer Panel has given her a comprehensive overview of the cancer problem and exceptional insight into the needs and future directions of cancer research. She was recruited to CPRIT as its Chief Scientific Officer following an extensive national search and was deemed to be an ideal candidate for the position.

Dr. Kripke's expertise and experience is important not only to address scientific and technical questions but also when she act as the Oversight Committee's "eyes and ears" into the peer review process. Peer review committees are primarily responsible for the work necessary to evaluate grant applications and recommend awards. CPRIT employees may attend peer review meetings but are expressly prohibited from actively participating in the peer review panel's discussion or scoring of grant applications. By attending the peer review committee meetings, Dr. Kripke will continue to credibly relay the peer reviewers' impression of the grant applications and to effectively address questions the Oversight Committee may have related to a grant recommendation. Without the waiver Dr. Kripke will be unable to attend peer review committee meetings and effectively perform her job.

Dr. Kripke's attendance at peer review meetings is valuable even for those applications that are not recommended for a grant award. Grant applicants often contact the program officer after receiving the peer reviewers' written comments and overall score for their applications. Because Dr. Kripke was able to attend the peer review committee meeting when the application was discussed, she will be able to provide meaningful guidance and feedback to the applicant on the proposal's strengths and weaknesses.

Another important role for the program officer is to recruit and retain members of the program's review council. These review council members serve as strategic advisors for CPRIT's grant

programs as well as being responsible for recruiting high-quality reviewers to the peer review committees chaired by each council member. Texas has established a gold-standard peer review process directly dependent on CPRIT's scientific leader, the Chief Scientific Officer. Dr. Kripke's stature in the cancer research arena provides Texas access to the premier cancer researchers in the world—since these are Dr. Kripke's peers. The Chairs of CPRIT review panels are all highly distinguished in their respective fields and bring enormous stature to the peer review process. Having panel chairs of this caliber distinguishes CPRIT's peer review process from all others.

The review council members and peer reviewers that serve on the CPRIT peer review panels are ineligible to receive CPRIT awards; a main attraction to serving as CPRIT peer reviewers is the opportunity for intellectual interactions with their scientific colleagues. These interactions do not occur without the leadership of the Chief Scientific Officer, Dr. Kripke.

Proposed Waiver and Limitations

In granting the waiver of the conflict of interest set forth in Section 102.106(c)(3), I recommend that Dr. Kripke be permitted to continue to perform the following activities and duties of the Chief Scientific Officer:

1. Assign grant applications, including M.D. Anderson grant applications, to various peer review committees for peer review evaluation;
2. Attend scientific research peer review committee meetings as an observer, including meetings where M.D. Anderson application are discussed;
3. Attend and participate fully in the Program Integration Committee (PIC) meetings, subject to the limitation set forth under "Limitations."
4. Have access to grant application information developed during the grant review process, including information related to M.D. Anderson applications;
5. Provide information about grant applications recommended for grant awards to the Oversight Committee or CPRIT personnel, including answering questions raised by the Oversight Committee or CPRIT personnel about M.D. Anderson grant applications. To the extent that information is provided by Dr. Kripke on her own initiative (e.g. the Chief Scientific Officer's summary of the recommended awards) and not in response to a specific question or request, it should be general information related to the overall grant application process and not advocate specifically for grant application submitted by M.D. Anderson.
6. Following the Oversight Committee's approval of a grant award to M.D. Anderson by the Oversight Committee, Dr. Kripke may review and approve programmatic requests associated with M.D. Anderson grant contracts and grant monitoring activities.

With regard to item number 2, Dr. Kripke will be required to follow CPRIT's established policy that CPRIT employees are prohibited from actively participating in peer review committee meetings. This means that Dr. Kripke may attend the peer review committee meetings as an observer, but may not participate in the substantive discussion of any grant application, may not score any application,

and may not vote on any application. CPRIT contracts with an independent third-party observer to document that CPRIT's observer policy is followed. The independent third-party observer report will be made available to the Oversight Committee prior to any action taken related to the grant award recommendations. Following Oversight Committee action, the independent third-party observer report will be publicly available.

LIMITATION ON DUTIES AND ACTIVITIES

Dr. Kripke is a member of the PIC. As a PIC member, Dr. Kripke is called upon to exercise discretion related to whether applications proposed for grant awards by the peer review committees should be recommended to the Oversight Committee for final approval. Dr. Kripke shall not vote on any award recommendations related to M.D. Anderson.

CPRIT's Compliance Officer is statutorily required to attend PIC meetings to document compliance with CPRIT's rules and processes, including adherence to this limitation.

Important Information Regarding this Waiver and the Waiver Process

- The Oversight Committee may amend, revoke, or revise this waiver, including but not limited to the list of approved activities and duties and the limitations on duties and activities. Approval for any change to the waiver granted shall be by a vote of the Oversight Committee in an open meeting.
- This waiver is limited to the conflict of interest specified in this request. To the extent that Dr. Kripke has a conflict of interest with an application that is not the conflict identified in Section 102.106(c)(3), then Dr. Kripke will follow the required notification and recusal process.



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE CHAIR DR. WILLIAM RICE
FROM: WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT: SECTION 102.1062 WAIVER – DAVID L. LAKEY, M.D.
DATE: AUGUST 13, 2014

Waiver Request and Recommendation:

I request that the Oversight Committee approve a renewal of the conflict of interest waiver for Program Integration Committee (PIC) member Dr. David L. Lakey, pursuant to Health & Safety Code Section 102.1062 "Exceptional Circumstances Requiring Participation." The waiver is necessary for Dr. Lakey to continue to participate in CPRIT's review process as a PIC member. Together with the waiver's proposed limitations, adequate protections are in place to mitigate the opportunity for the award of grant funds to be driven by anything other than merit and established criteria.

Background:

The Oversight Committee approved Dr. Lakey's conflict of interest waiver for the 2014 fiscal year. Dr. Lakey is the Commissioner of the Department of State Health Services (DSHS); DSHS is also a CPRIT grant recipient, having received a grant award in September 2009. Therefore, Dr. Lakey continues to have the same conflict of interest and requires a renewal of the conflict of interest waiver for the 2015 fiscal year. The recommendations and limitations in the renewal remain the same as previously approved by the Oversight Committee.

The DSHS Commissioner is a statutorily designated member of the PIC. As a PIC member, Dr. Lakey is called upon to exercise discretion related to whether applications proposed for grant awards by the peer review committees should be recommended to the Oversight Committee for final approval. DSHS is a CPRIT grant recipient. Health & Safety Code Section 102.106(c)(3) mandates that a professional conflict of interest exists if a PIC member is an employee of an entity applying to receive or receiving CPRIT funds. Furthermore, CPRIT's administrative rule 702.13(c) categorizes this type of professional conflict of interest as one that raises the presumption that the existence of the conflict may affect the impartial review of all other grant applications submitted pursuant to the same grant mechanism in the grant review cycle. A person involved in the review process that holds one of the conflicts included in the Section 702.13(c) "super conflict" category must be recused from participating in the "review, discussion, scoring, deliberation and vote on all grant applications

competing for the same grant mechanism in the entire grant review cycle, unless a waiver has been granted...”

CPRIT’s administrative rule Section 702.17(3) authorizes the Oversight Committee to approve a waiver that applies for all activities affected by the conflict during the fiscal year.

Exceptional Circumstances Requiring Dr. Lakey’s Participation

In order to approve a conflict of interest waiver, the Oversight Committee must find that there are exceptional circumstances justifying the conflicted individual’s participation in the review process. Dr. Lakey’s participation in the review process is compelled by the statute. In order to fulfill legislative intent that the DSHS Commissioner serve as a PIC member, the proposed waiver must be granted. The proposed limitations will substantially mitigate any potential for bias.

Proposed Waiver and Limitations

In granting the waiver of the conflict of interest set forth in Section 102.106(c)(3), I recommend that Dr. Lakey be permitted to continue to perform the following activities and duties associated with CPRIT’s review process subject to the stated limitations:

1. Attend and participate fully in the PIC meetings except that Dr. Lakey shall not participate in the PIC’s discussion or vote on grant award recommendations to be made to DSHS;
2. Have access to grant application information developed during the grant review process, except for information related to DSHS applicants, if any; and
3. Provide information to the Oversight Committee or CPRIT personnel about the grant review process and applications recommended by the PIC for grant awards, including answering questions raised by the Oversight Committee or CPRIT personnel. To the extent that information is provided by Dr. Lakey on his own initiative in a review cycle in which DSHS is a grant applicant, the information provided by Dr. Lakey should be general information related to the overall grant application process and not advocate specifically for a grant application submitted by DSHS.

CPRIT’s Compliance Officer is statutorily required to attend PIC meetings to document compliance with CPRIT’s rules and processes, including adherence to this limitation. The Compliance Officer shall report to the Oversight Committee any violation of this waiver prior to the Oversight Committee’s action on the PIC recommendations.

Important Information Regarding this Waiver and the Waiver Process

- The Oversight Committee may amend, revoke, or revise this waiver, including but not limited to the list of approved activities and duties and the limitations on duties and activities. Approval for any change to the waiver granted shall be by a vote of the Oversight Committee in an open meeting.

- This waiver is limited to the conflict of interest specified in this request. To the extent that Dr. Lakey has a conflict of interest with an application that is not the conflict identified in Section 102.106(c)(3), then Dr. Lakey will follow the required notification and recusal process.



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: HEIDI MCCONNELL
SUBJECT: 2014 INTERNAL AUDIT PROGRAM
DATE: AUGUST 14, 2014

FY 2014 Internal Audit Implementation

Grant Thornton, LLP, CPRIT's internal auditor, has completed field work for all 15 audits scheduled in the Internal Audit Plan. CPRIT has received draft reports for the five agency operational audits and is awaiting draft reports for the 10 grantee audits. Two of the operational audits, *Expenditures Internal Audit Report* and *SRA International Managed Information System Internal Audit Report*, have been finalized and copies are attached.

Expenditures Internal Audit Report

Report #2014-100

June 9, 2014



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

Table of Contents

Table of Contents.....	2
Executive Summary.....	3
Background Information	4
<i>Background.....</i>	<i>4</i>
<i>Audit Objectives.....</i>	<i>4</i>
<i>Scope.....</i>	<i>5</i>
<i>Testing Methodology and Approach</i>	<i>5</i>
<i>Statement of Auditing Standards</i>	<i>5</i>
Observations, Findings, and Recommendations.....	6
<i>Accounts Payable.....</i>	<i>6</i>
<i>Purchasing Contracts.....</i>	<i>7</i>
<i>Employee Travel and Expenses.....</i>	<i>7</i>
<i>Payroll.....</i>	<i>7</i>
<i>Capital Assets.....</i>	<i>8</i>

Executive Summary

As part of the implementation of the FY2014 Internal Audit Plan, an audit of the CPRIT expenditure processes was conducted in March 2014. This audit focused on activity within the accounts payable, purchasing, travel, payroll, and capital asset activities. Internal fiscal procedures provide guidance for the agency's expenditures cycle activities. A three-tiered approval workflow is described in the policy so CPRIT expenditures are requested, approved, and disbursed by separate individuals. Currently, all expenses are approved by the Chief Operating Officer. This policy applies equally to expenditures made for goods, services, supplies, equipment, and employee travel expenses.

CPRIT continues to work towards establishing leading practices to become more efficient and effective in their expenditure approval process. During the internal audit, the following exceptions were noted:

- Three invoices in the sample (8%) were not paid timely, as described in CPRIT's internal policy and procedures
- One of the capital assets selected for testing (6%) could not be verified

Greater detail around these findings and recommendations can be found within the "Observations, Findings, and Recommendations" section of this report. Overall, based on the results of our review and testing, controls provide reasonable assurance that CPRIT's internal expenditure processes are performed accurately and in accordance with agency policies and procedures.

Background Information

Background

Texas voters approved a constitutional amendment in 2007 establishing the Cancer Prevention and Research Institute of Texas (CPRIT) and authorized the state to issue \$3 billion in bonds to fund groundbreaking cancer research and prevention programs and services in Texas. To date, CPRIT has funded over 500 grants totaling more than \$1 billion.

CPRIT's goals are to:

- Create and expedite innovation in the area of cancer research, thereby enhancing the potential for a medical or scientific breakthrough in the prevention of cancer and cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in this State; and
- Continue to develop and implement the Texas Cancer Plan by promoting the development and coordination of effective and efficient statewide public and private policies, programs, and services related to cancer and by encouraging cooperative, comprehensive, and complementary planning among the public, private, and volunteer sectors involved in cancer prevention, detection, treatment, and research.

Audit Objectives

The objectives of the audit were to assess current practices and opportunities to improve efficiency and effectiveness in the expenditure process.

The specific audit objectives were:

- Determine if the controls surrounding the CPRIT expenditures process, including accounts payable, purchasing, travel, payroll, and capital assets, are operating effectively
- Verify that payments are properly documented and processed according to agency requirements
- Validate that assets are accounted for and properly recorded
- Validate that the internal controls at CPRIT help mitigate the risk of fraudulent activity

In order to assess the expenditure activities, Internal Audit reviewed the following:

- Agency invoices paid during the testing period
- Vendor selection process documentation
- Travel reimbursement requests
- Payroll registers
- Capital assets log

Scope

The audit performed was designed to evaluate and test compliance with established policies and procedures as of March 2014. Internal Audit interviewed staff and completed field work on a sample of expenditures for the time period July 1, 2013 – February 28, 2014.

Testing Methodology and Approach

In order to meet the audit objectives stated above, Internal Audit conducted interviews with the responsible management or staff member, evaluated controls over the expenditures review and approval processes, and reviewed agency policies and procedures for compliance. Internal Audit examined and reviewed supporting documentation and performed selected test work as deemed necessary. Statistical sampling was used as part of the test steps performed, and when appropriate, judgmental sampling was used to verify the conclusions drawn in the audit.

Our procedures included discussions with the following CPRIT personnel:

Name	Title
Heidi McConnell	Chief Operating Officer
Alfonso Royal	Finance Manager
Lisa Nelson	Operations Manager
Michelle Huddleston	Accountant

Statement of Auditing Standards

This internal audit was conducted in accordance with generally accepted government auditing standards (GAGAS). The internal audit also follows the guidelines set forth by the Institute of Internal Auditors (IIA) and conforms to the Standards for the Professional Practice of Internal Auditing, the code of ethics contained in the Professional Practices Framework as promulgated by the IIA.

Although due professional care in the performance of this audit was exercised, this should not be construed to imply that unreported irregularities do not exist. The deterrence of fraud is the responsibility of management. Audit procedures alone, even when executed with professional care, do not guarantee that fraud will be detected. Specific areas for improvement are addressed later in this report.

Observations, Findings, and Recommendations

Accounts Payable

For the time period July 1, 2013 – February 28, 2014, Internal Audit judgmentally selected a sample of disbursements made during the testing period. The judgmental sample included a selection of 37 out of 360 invoices (~10%) that were paid during the testing period.

Each disbursement was tested to verify:

- invoices or receipts were provided as supporting documentation,
- purchase vouchers were created,
- invoice was paid thirty days after receipt,
- the amounts on the purchase vouchers matched the amounts on the supporting documentation,
- purchase vouchers were approved by the appropriate personnel, and
- any changes made to the purchase vouchers were documented and reviewed and approved, as necessary.

Internal audit identified five invoices that were paid 30 days after receipt of the original invoice. Three of the five invoices were due to errors and miscalculations of the dates. As a result, CPRIT was required to pay an additional interest charge, totaling \$18.29. Two invoices required revisions of the original receipt, and were paid accordingly after the revision was made. Internal Audit noted an exception for the three invoices paid after 30 days.

Recommendation: To ensure payments are paid in a timely manner, CPRIT should consider using an automated tool to calculate when invoices should be paid. Additionally, payments that are late, and require a late fee/interest to be charged to that particular invoice, should be reviewed and approved by Management on a monthly basis.

Management Response:

The Accountant will use the payment due date-interest calculator tool in “eXpendit” to schedule payments greater than \$5,000 on the 30-day due date as required by the prompt payment law to avoid interest payments to vendors. The Accountant is also now better able to focus on processing vendor and grant payments because the agency has hired a Purchaser and additional Grant Reimbursement staff to perform duties that the Accountant had been performing in conjunction with processing payments, appropriations reconciliation, and cash management.

Person Responsible: Heidi McConnell / Alfonso Royal / Michelle Huddleston

Target Date for Implementation: Implemented

Purchasing / Contract Management

For the time period July 1, 2013 – February 28, 2014, Internal Audit selected a sample of the top ten vendors with the greatest total expenditures. Each vendor was tested for existence of purchasing contracts, and each contract was tested to verify:

- evidence that bid documentation was received from multiple providers,
- statement of reasons for the award were present and reasonable,
- proper approval of award was appropriate,
- notice of award was provided, and
- resulting purchase order was created and approved by the agency director (or designee).

For the vendors selected for testing, Internal Audit obtained the bid documentation, contracts, and amendments to the contracts, where applicable. Internal Audit noted that vendors with a multi-year renewal option did not require new bid documentation but needed signed and approved amendments to the original contract.

For five vendors in the sample, CPRIT used previously negotiated statewide contracts which required no agency bid process. For these five contracts, Internal Audit verified that a purchase order was created, signed and approved by the appropriate CPRIT personnel.

For the remaining vendors, Internal Audit verified that adequate documentation existed for the competitive bid and proposal process. Documentation evidenced CPRIT management review of the responses from vendors and their award decision based on the pre-defined criteria. The reason for the award was present and seemed reasonable.

Employee Travel Expenses

For the time period July 1, 2013 – February 28, 2014, Internal Audit judgmentally selected a sample of seven (~30%) travel reimbursement vouchers and five (~30%) employee reimbursements to test. Each reimbursement voucher was tested to verify:

- invoices or receipts were provided as supporting documentation,
- stated purpose and amount seemed reasonable and in compliance with CPRIT policies,
- the amounts on the reimbursement vouchers matched the amounts on the supporting documentation,
- reimbursement vouchers were approved by the appropriate personnel, and
- any changes made to the reimbursement vouchers were documented, reviewed, and approved, as necessary.

Internal Audit confirmed that each report submitted was in accordance with the travel expense policy and verified that no issues were identified related to employee travel and expenses during the audit.

Payroll

An interagency contract is in place with the Texas Health and Human Services Commission (HHSC) to provide payroll and limited human resources support to CPRIT. HHSC processes the payroll after it is certified by CPRIT management. For the time period July 1, 2013 – February 28, 2014, Internal Audit judgmentally selected a sample of 2 payroll runs to test (~10%). Each payroll change was tested to verify:

- new employees are added to the payroll timely,

- employees that transfer to different departments are modified in payroll timely,
- terminated employees are removed from the payroll timely, and
- all changes to payroll follow the internal policies and procedures.

Internal Audit obtained the listing of employees (including new and terminated) from July 1, 2013 – February 28, 2014 and reviewed the related payroll registers for the testing period. Internal Audit verified that the total hours paid agreed to the actual amount of hours the terminated employee worked for during the last month of employment. Internal Audit also noted that the new and terminated employees were properly authorized and approved by the COO and the CEO. Internal Audit verified that no issues were identified related to payroll during the audit.

Capital Assets

Internal Audit obtained CPRIT's asset listing as of February 28, 2014, and randomly selected 17 out of 34 (50%) capital assets to test. Each sample selected was tested to verify:

- capital assets exist,
- ID numbers attached to the asset match those recorded in the ledger, and
- assets match the recorded descriptions.

Internal Audit reconciled the State Property Accounting Report (SPA) for CPRIT to the asset listing spreadsheet maintained by the agency and verified that the descriptions and asset cost matched on both lists. Internal Audit was able to physically observe 14 of 17 assets in the Austin, TX office. The three remaining assets are located outside of Austin, TX. For two of the three remaining assets, Internal Audit examined copies of the Temporary Use of Equipment agreement in lieu of physically observing the asset. The Temporary Use of Equipment agreement describes the asset and identifies the serial number associated with the asset. Internal Audit verified that the items matched accordingly. However, Internal Audit was not able to verify one asset which we were informed is located in a storage room in Dallas, TX. Because evidence of the asset's existence was not provided, Internal Audit noted this as an exception.

Recommendations: CPRIT should consider reconciling the capital assets on an annual or semi-annual basis to ensure all assets are properly accounted for.

Management Response:

CPRIT has implemented procedures to review capital assets on a quarterly basis. With respect to the asset located in storage in Dallas, Texas, the agency will be bringing all of the stored items to Austin when it moves in August 2014. After the move, these items will be available for physical verification and reconciliation with SPA and the asset listing.

Person Responsible: Heidi McConnell / Lisa Nelson

Target Date for Implementation: September 1, 2014

SRA International Managed Information Systems Internal Audit Report

Report #2014-03

June 18, 2014



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

Table of Contents

Executive Summary	3
Background Information.....	4
<i>Background</i>	<i>4</i>
<i>Audit Objectives</i>	<i>4</i>
<i>Scope.....</i>	<i>5</i>
<i>Testing Approach</i>	<i>5</i>
<i>Testing Methodology</i>	<i>7</i>
<i>Statement of Auditing Standards.....</i>	<i>7</i>
Observations and Recommendations	8
<i>Common Criteria – Organization and Management.....</i>	<i>8</i>
<i>Common Criteria – Communications</i>	<i>10</i>
<i>Common Criteria – Risk Management and Design and Implementation of Controls</i>	<i>11</i>
<i>Common Criteria – Monitoring of Controls.....</i>	<i>12</i>
<i>Common Criteria – Logical and Physical Access Controls.....</i>	<i>13</i>
<i>Common Criteria – System Operations</i>	<i>15</i>
<i>Common Criteria – Change Management</i>	<i>16</i>
<i>Processing Integrity.....</i>	<i>17</i>
Appendix A: Systems Supporting CPRIT	19

Executive Summary

In response to two findings from the State Auditor's Report, Internal Audit has been asked to perform a review of two proprietary information systems operated by SRA International, Inc.'s (SRA), the third-party vendor under contract with CPRIT to provide pre- and post-award grants management services. These information systems allow applicants to submit grant applications, peer reviewers to submit application critiques and scores, grantees to submit financial and progress reports, and CPRIT to track, monitor, and maintain all grantee reports.

An internal audit was conducted in May 2014 to understand internal controls at SRA as they relate to the American Institute of Certified Public Accountants (AICPA) Trust Service Principles. The review was performed using the AICPA Guide: *Reporting on Controls at a Service Organizations Relevant to Security, Availability, Processing Integrity, Confidentiality, or Privacy* focusing on the following trust principles:

- Common Criteria
 - § Organization and Management
 - § Communications
 - § Risk Management and Design and Implementation of Controls
 - § Monitoring of Controls
 - § Logical and Physical Access Controls
 - § System Operations
 - § Change Management
- Processing Integrity

During the internal audit of SRA, no findings or observations were noted that would significantly impact the processing capability of SRA's applications, as related to services provided to CPRIT. While no significant findings were noted during this audit, CPRIT should continue to require SRA to validate their control environment and re-perform this audit periodically.

It is not feasible for all of the control objectives relating to the processing of data to be completely achieved through SRA's implemented controls. While SRA achieves some objectives, procedures performed by CPRIT contribute significantly to the overall achievement of control objectives. See section "CPRIT Control Responsibilities" for more details around CPRIT's responsibilities.

Background Information

Background

Texas voters approved a constitutional amendment in 2007 establishing the Cancer Prevention and Research Institute of Texas (CPRIT) and authorized the state to issue \$3 billion in bonds to fund groundbreaking cancer research and prevention programs and services in Texas. To date, CPRIT has funded over 500 grants totaling over \$1 billion.

CPRIT's goals are to:

- Create and expedite innovation in the area of cancer research, thereby enhancing the potential for a medical or scientific breakthrough in the prevention of cancer and cures for cancer;
- Attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in this State; and
- Continue to develop and implement the Texas Cancer Plan by promoting the development and coordination of effective and efficient statewide public and private policies, programs, and services related to cancer and by encouraging cooperative, comprehensive, and complementary planning among the public, private, and volunteer sectors involved in cancer prevention, detection, treatment, and research.

Applications for grants are submitted through the CPRIT Application Receipt System (CARS), an online application receipt system that is managed by SRA International, Inc. Peer reviewers utilized the Program and Peer Review Management Information System (P²RMIS), an online portal that supports grant evaluation activities. Once applications are approved as grant awards and move towards the executed contract stage, CPRIT's grants management system, CGMS, which is a customization on the CARS information system platform tracks the contract, correspondence, and other compliance documentation for each grant. CGMS was put into production on October 4, 2012. Additional functionality will continue to be developed on an as needed basis. Refer to Appendix A for an illustration of the SRA enabled processes.

Audit Objectives

Our overall objectives of the internal audit were to:

- Understand the policies and procedures in place at SRA
- Understand the control activities in place at SRA
- Map the control activities to the relevant trust principle and determine whether these are sufficient to address the relevant trust principle
- Test the control activities for design effectiveness.
- Identify any gaps or deficiencies.

The policies and procedures reviewed and the testing performed focused on SRA's environment as it relates to services provided to CPRIT.

Scope

The audit performed was designed to evaluate compliance with the relevant trust service principles established by the AICPA. The two principles that this audit focused on are Common Criteria and Processing Integrity. Internal Audit interviewed SRA staff and completed testing on the identified control activities as of May 2014.

Testing Approach

To accomplish the audit objectives, Internal Audit focused on the following areas:

- **Organization Management**
 - Defined organizational structures, reporting lines, authorities, and responsibilities for the design, development, implementation, operation, monitoring, and maintenance of the system enabling it to meet its commitments and requirements as they relate to security, availability and processing integrity
 - Responsibility and accountability for designing, developing, implementing, operating, monitoring, maintaining, and approving the entity's system controls are assigned to individuals within the entity with authority to ensure policies and other system requirements are effectively promulgated
 - Personnel responsible for designing, developing, implementing, operating, monitoring, and maintaining the system have the qualifications and resources to fulfill their responsibilities
 - The entity has established employee conduct standards, implemented employee candidate background screening procedures, and conducts enforcement procedures to enable it to meet its commitments and requirements as they relate to security and processing integrity
- **Communications**
 - Information regarding the design and operation of the system and its boundaries has been prepared and communicated to authorized internal and external system users to permit users to understand their role in the system and the results of system operation
 - The entity's commitments are communicated to external users, as appropriate, and those commitments and the associated system requirements are communicated to internal system users to enable them to carry out their responsibilities
 - Internal and external system users have been provided with information on how to report security, availability and processing integrity failures, incidents, concerns, and other complaints to appropriate personnel
- **Risk Management and Design and Implementation of Controls**
 - The entity (1) identifies potential threats that would impair system security, availability and processing integrity commitments and requirements, (2) analyzes the significance of risks associated with the identified threats, and (3) determines mitigation strategies for those risks (including controls and other mitigation strategies)
 - The entity designs, develops, and implements controls, including policies and procedures, to implement its risk mitigation strategy
 - The entity (1) identifies and assesses changes (for example, environmental, regulatory, and technological changes) that could significantly impact the system of internal control for security, availability and processing integrity and reassesses risks and mitigation strategies based on the changes and (2) reassesses the suitability of the design and deployment of

control activities based on the operation and monitoring of those activities, and updates them as necessary

- **Monitoring of Controls**
 - The design and operating effectiveness of controls are periodically evaluated against security, availability, confidentiality and processing integrity commitments and requirements
- **Logical and Physical Access Controls**
 - Logical access security software, infrastructure, and architectures have been implemented to support (1) identification and authentication of authorized users; (2) restriction of authorized user access to system components, or portions thereof, authorized by management, including hardware, data, software, mobile devices, output, and offline elements; and (3) prevention and detection of unauthorized access
 - Physical access to facilities housing the system (for example, data centers, backup media storage, and other sensitive locations as well as sensitive system components within those locations) is restricted to authorized personnel
 - The transmission, movement, and removal of information is restricted to authorized users and processes, and is protected during transmission, movement, or removal enabling the entity to meet its commitments and requirements as they relate to security, availability, confidentiality and processing integrity
- **System Operations**
 - Vulnerabilities of system components to security and availability breaches and incidents due to malicious acts, natural disasters, or errors are monitored and evaluated and countermeasures are implemented to compensate for known and new vulnerabilities.
 - Security and availability incidents, including logical and physical security breaches, failures, concerns, and other complaints, are identified, reported to appropriate personnel, and acted on in accordance with established incident response procedures
- **Change Management**
 - Security, availability, and process integrity commitments and requirements, are addressed, during the system development lifecycle including design, acquisition, implementation, configuration, testing, modification, and maintenance of system components.
 - Changes to system components are authorized, designed, developed, configured, documented, tested, approved, and implemented in accordance with security and processing integrity commitments and requirements

Testing Methodology

In order to meet the objectives stated above, Internal Audit conducted interviews, evaluated controls and reviewed selected policies and procedures. Judgmental sampling was used to improve the overall efficiency of the assessment.

Our procedures included discussions with the following SRA personnel:

Name	Title
Jennifer Boothe	SRA – Project Manager
Karen Wan	SRA – Product Owner and Technical Manager
Mike Wingo	SRA – IT Manager

Statement of Auditing Standards

This assessment was conducted in accordance with AICPA Guide: *Reporting on Controls at a Service Organizations Relevant to Security, Availability, Processing Integrity, Confidentiality, or Privacy*. The internal audit also follows the guidelines set forth by the Institute of Internal Auditors (IIA) and conforms to the Standards for the Professional Practice of Internal Auditing, the code of ethics contained in the Professional Practices Framework as promulgated by the IIA. Grant Thornton was not engaged to perform audit or attest services under AICPA auditing or attestation standards or to provide any form of attest report or opinion under such standards in conjunction with this engagement.

Although due professional care in the performance of this audit was exercised, this should not be construed to imply that unreported irregularities do not exist. The deterrence of fraud is the responsibility of management. Audit procedures alone, even when executed with professional care, do not guarantee that fraud will be detected.

Observations and Recommendations

AICPA Trust Service Principles Criteria, Control Activities, and Testing Results

This section presents the specific control activities specified by SRA to achieve the trust principle criteria. Our review addressed controls pertaining to the following scope areas:

Common Criteria

- Organization and Management
- Communications
- Risk Management and Implementation of Controls
- Monitoring
- Logical and Physical Access
- System Operations
- Change Management

Processing Integrity

- Data Processing
- Data Retention

Also, included in this section is the following information:

- A description of the testing performed by the Internal Audit to determine whether SRA's controls were operating with sufficient effectiveness to achieve the specified criteria,
- The results of the tests of operating effectiveness and any exceptions noted.

Common Criteria – Organization and Management

AICPA Criteria	Control #	Control Activity	Testing Results
CC1.1 - The entity has defined organizational structures, reporting lines, authorities, and responsibilities for the design, development, implementation, operation, monitoring, and maintenance of the system enabling it to meet its commitments and requirements as they relate to security, availability and processing integrity	CC1.1	SRA has established a Security policy which covers assigning responsibility for system security. The company has defined an organizational structure and posted an organizational chart to the company website. The organizational chart is reviewed and updated at least once every two years.	No exception noted.

AICPA Criteria	Control #	Control Activity	Testing Results
CC1.2 - Responsibility and accountability for designing, developing, implementing, operating, monitoring, maintaining, and approving the entity's system controls are assigned to individuals within the entity with authority to ensure policies and other system requirements are effectively promulgated.	CC1.2	Company policies are documented, posted to the company website for employee access, and reviewed once every two years by management.	No exception noted.
CC1.3 - Personnel responsible for designing, developing, implementing, operating, monitoring, and maintaining the system affecting [insert the principle(s) being reported on; for example, security, availability, processing integrity, and confidentiality] have the qualifications and resources to fulfill their responsibilities.	CC1.3-01	Job requirements are documented in the job descriptions and are available for employee access.	No exception noted.
	CC1.3-02	The company has defined an organizational structure and posted an organizational chart to the company website. The organizational chart is reviewed and updated at least annually.	No exception noted.
	CC1.3-03	New and updated system access requests are approved by management prior to access being granted.	No exception noted.
CC1.4 - The entity has established employee conduct standards, implemented employee candidate background screening procedures, and conducts enforcement procedures to enable it to meet its commitments and requirements as they relate to security and processing integrity.	CC1.4-01	SRA has established a Background Check Policy for all the employees.	No exception noted.
	CC1.4-02	All employees must attend annual training in order to comply with current and updated company policies relevant to their job responsibilities.	No exception noted.
	CC1.4-03	New employees sign an acknowledgement form, indicating that they have read and agree to company policies relevant to their job responsibilities.	No exception noted.

Common Criteria – Communications

AICPA Criteria	Control #	Control Activity	Testing Results
CC2.1 - Information regarding the design and operation of the system and its boundaries has been prepared and communicated to authorized internal and external system users to permit users to understand their role in the system and the results of system operation.	CC2.1	Company policies are documented, posted to the company website for employee access, and reviewed annually by management. (Refer to CC1.2)	No exception noted.
CC2.2 - The entity's commitments are communicated to external users, as appropriate, and those commitments and the associated system requirements are communicated to internal system users to enable them to carry out their responsibilities.	CC2.2-01	All employees must attend annual training in order to comply with current and updated company policies relevant to their job responsibilities. (Refer to CC1.4)	No exception noted.
	CC2.2-02	New employees sign an acknowledgement form, indicating that they have read and agree to company policies relevant to their job responsibilities. (Refer to CC1.4)	No exception noted.
CC2.5 - Internal and external system users have been provided with information on how to report security, availability and processing integrity failures, incidents, concerns, and other complaints to appropriate personnel.	CC2.5	Tracking of incidents (including complaints and disputes) and security breaches of Company policies are monitored through the JIRA ticketing system.	No exception noted.
CC2.6 - System changes that affect internal and external system user responsibilities or the entity's commitments and requirements relevant to security, availability, and process integrity are communicated to those users in a timely manner.	CC2.6	Appropriate groups are notified prior to or within one business day of the implementation of an application change, if necessary.	No exception noted.

Common Criteria – Risk Management and Design and Implementation of Controls

AICPA Criteria	Control #	Control Activity	Testing Results
CC3.1 - The entity (1) identifies potential threats that would impair system security, availability and processing integrity commitments and requirements, (2) analyzes the significance of risks associated with the identified threats, and (3) determines mitigation strategies for those risks (including controls and other mitigation strategies).	CC3.1-01	SRA has a continuous monitoring program in place to identify and minimize risks including Quarterly vulnerability scans, a patch management program and regularly scheduled re-assessment of security controls.	No exception noted.
	CC3.1-02	Network availability and capacity is monitored via monitoring tools which are configured to send alerts if a system or device reaches configured thresholds.	No exception noted.
	CC3.1-03	An intrusion prevention system is in place to monitor and prevent unauthorized access to the network and applications.	No exception noted.
	CC3.1-04	Anti-virus software is installed on employee workstations and updated on a daily basis.	No exception noted.
CC3.2 - The entity designs, develops, and implements controls, including policies and procedures, to implement its risk mitigation strategy.	CC3.2-01	Company policies are documented, posted to a network share folder for employee access, and reviewed annually by management. (Refer to CC1.2)	No exception noted.
	CC3.2-02	The Company's Disaster Recovery and Business Continuity Plan is tested on a quarterly basis and any issues identified are documented and resolved.	No exception noted.
	CC3.2-03	SRA has a continuous monitoring program in place to identify and minimize risks including Quarterly vulnerability scans, a patch management program and regularly scheduled re-assessment of security controls. (Refer to CC3.1)	No exception noted.
CC3.3 - The entity (1) identifies and assesses changes (for example, environmental, regulatory, and technological changes) that could significantly impact the system of internal control for security, availability and processing integrity and reassesses risks and mitigation strategies based on the changes and (2) reassesses the suitability of the design and deployment of control activities based on the operation and monitoring of those activities, and updates them as necessary.	CC3.3	SRA has a continuous monitoring program in place to identify and minimize risks including Quarterly vulnerability scans, a patch management program and regularly scheduled re-assessment of security controls. (Refer to CC3.1)	No exception noted.

Common Criteria – Monitoring of Controls

AICPA Criteria	Control #	Control Activity	Testing Results
CC4.1 - The design and operating effectiveness of controls are periodically evaluated against security, availability, confidentiality and processing integrity commitments and requirements.	CC4.1-01	SRA has a continuous monitoring program in place to identify and minimize risks including Quarterly vulnerability scans, a patch management program and regularly scheduled re-assessment of security controls. (Refer to CC3.1)	No exception noted.
	CC4.1-02	Network availability and capacity is monitored via monitoring tools which are configured to send alerts if a system or device reaches configured thresholds. (Refer to CC3.1)	No exception noted.
	CC4.1-03	An intrusion prevention system is in place to monitor and prevent unauthorized access to the network and applications. (Refer to CC3.1)	No exception noted.
	CC4.1-04	The Company's Disaster Recovery and Business Continuity Plan is tested on a quarterly basis and any issues identified are documented and resolved. (Refer to CC3.2)	No exception noted.

Common Criteria – Logical and Physical Access Controls

AICPA Criteria	Control #	Control Activity	Testing Results
CC5.1 - Logical access security software, infrastructure, and architectures have been implemented to support (1) identification and authentication of authorized users; (2) restriction of authorized user access to system components, or portions thereof, authorized by management, including hardware, data, software, mobile devices, output, and offline elements; and (3) prevention and detection of unauthorized access.	CC5.1-01	SRA has established a Security Policy which covers preventing unauthorized access. A valid user ID and password is required to access the SRA applications.	No exception noted.
	CC5.1-02	Administrative access to the network is restricted to the Hosting group and administrative access to the application software is restricted to the Project team.	No exception noted.
	CC5.1-03	Password rules are configured on the network to enforce the following: 1. 8 minimum length 2. 90 day expiration 3. Complexity required	No exception noted.
	CC5.1-04	An intrusion prevention system is in place to monitor and prevent unauthorized access to the network and applications. (Refer to CC3.1)	No exception noted.
	CC5.1-05	Firewall rules are configured to restrict access to the network.	No exception noted.
CC5.2 - New internal and external system users are registered and authorized prior to being issued system credentials, and granted the ability to access the system. User system credentials are removed when user access is no longer authorized.	CC5.2-01	New employee's access to the SRA applications and related databases must be approved by the project manager through the HelpDesk ticketing system JIRA to verify access is appropriate based on the user's job responsibilities.	No exception noted.
	CC5.2-02	Terminated employees' access is removed within one business day.	No exception noted.
CC5.3 - Internal and external system users are identified and authenticated when accessing the system components (for example, infrastructure, software, and data).	CC5.3-01	A valid user ID and password is required to access the SRA applications. (Refer to CC5.1)	No exception noted.
	CC5.3-02	SRA has established a Security Policy which covers preventing unauthorized access. A valid user ID and password is required to access the SRA applications. (Refer to CC5.1)	No exception noted.

AICPA Criteria	Control #	Control Activity	Testing Results
CC5.4 - Access to data, software, functions, and other IT resources is authorized and is modified or removed based on roles, responsibilities, or the system design and changes to them.	CC5.4-01	Administrative access to the SRA applications and related databases is appropriately restricted based on job function.	No exception noted.
	CC5.4-02	Terminated employees' access is removed within one business day. (Refer to CC5.2)	No exception noted.
	CC5.4-03	User accounts are reviewed for appropriateness by management on a semi-annual basis.	No exception noted.
CC5.5 - Physical access to facilities housing the system (for example, data centers, backup media storage, and other sensitive locations as well as sensitive system components within those locations) is restricted to authorized personnel.	CC5.5-01	Physical access to the data center housing SRA systems and storage devices and media is restricted to authorized individuals via key-cards, biometrics, man-traps, locked cages, camera coverage and 24X7 video monitoring.	No exception noted.
	CC5.5-02	Terminated employees' physical access is removed within one business day.	No exception noted.
	CC5.5-03	Physical access is reviewed by management on a quarterly basis.	No exception noted.
CC5.6 - Logical access security measures have been implemented to protect against unauthorized security and confidentiality threats from sources outside the boundaries of the system.	CC5.6	Firewall rules are configured to restrict access to the network. (Refer to CC5.1)	No exception noted.
CC5.8 - Controls have been implemented to prevent or detect and act upon the introduction of unauthorized or malicious software.	CC5.8	Symantec is loaded on workstations and servers to help mitigate the risk of virus threats.	No exception noted.

Common Criteria – System Operations

AICPA Criteria	Control #	Control Activity	Testing Results
CC6.1 - Vulnerabilities of system components to security and availability breaches and incidents due to malicious acts, natural disasters, or errors are monitored and evaluated and countermeasures are implemented to compensate for known and new vulnerabilities.	CC6.1	SRA I/T personnel performs security and vulnerability assessments quarterly.	No exception noted.
CC6.2 - Security and availability incidents, including logical and physical security breaches, failures, concerns, and other complaints, are identified, reported to appropriate personnel, and acted on in accordance with established incident response procedures.	CC6.2	Tracking of incidents (including complaints and disputes) and security breaches of Company policies are monitored through the JIRA ticketing system. (Refer to CC2.5)	No exception noted.

Common Criteria – Change Management

AICPA Criteria	Control #	Control Activity	Testing Results
CC7.1 - Security, availability, and process integrity commitments and requirements, are addressed, during the system development lifecycle including design, acquisition, implementation, configuration, testing, modification, and maintenance of system components.	CC7.1	A documented policy is in place that provides testing and approval requirements for change management.	No exception noted.
CC7.2 - Infrastructure, data, software, and procedures are updated as necessary to remain consistent with the system commitments and requirements as they relate to [insert the principle(s) being reported on; for example, security, availability, processing integrity, and confidentiality]	CC7.2	Company policies are documented, posted to the company website for employee access, and reviewed once in two years by management. (Refer to CC1.2)	No exception noted.
CC7.3 - Change management processes are initiated when deficiencies in the design or operating effectiveness of controls are identified during system operation and monitoring.	CC7.3	Change requests are sent to CPRIT and documented through the change management system.	No exception noted.
CC7.4 - Changes to system components are authorized, designed, developed, configured, documented, tested, approved, and implemented in accordance with security and processing integrity commitments and requirements.	CC7.4-01	Changes must be approved and reviewed by CPRIT prior to implementation into production.	No exception noted.
	CC7.4-02	Changes are developed and tested in a segregated environment from production.	No exception noted.
	CC7.4-03	Programmers are denied access to production libraries, unless a firewall exception is obtained for temporary access.	No exception noted.
	CC7.4-04	Changes are tested prior to implementation into production.	No exception noted.
	CC7.4-05	Changes are promoted to production by authorized personnel.	No exception noted.

Processing Integrity

AICPA Criteria	Control #	Control Activity	Testing Results
PI1.1 - Procedures exist to prevent, detect, and correct processing errors to meet processing integrity commitments and requirements.	PI1.1-01	A data retention policy is maintained and updated on an annual basis. (Refer to CC1.2)	No exception noted.
	PI1.1-02	Daily incremental and weekly full backups are performed.	No exception noted.
	PI1.1-03	A restoration test is performed on backup data on a bi-monthly basis	No exception noted.
	PI1.1-04	Backup results are monitored on a daily basis and failures or issues are resolved.	No exception noted.
PI1.4 - Data is stored and maintained completely and accurately for its specified life span in accordance with processing integrity commitments and requirements.	PI1.4-01	A data retention policy is maintained and updated on an annual basis. (Refer to CC1.2)	No exception noted.
	PI1.4-02	Daily incremental and weekly full backups are performed. (Refer to PI1.1)	No exception noted.
	PI1.4-03	A restoration test is performed on backup data on a bi-monthly basis. (Refer to PI1.1)	No exception noted.
	PI1.4-04	Backup results are monitored on a daily basis and failures or issues are resolved. (Refer to PI1.1)	No exception noted.
Modification of data is authorized, using authorized procedures in accordance with processing integrity commitments and requirements.	PI1.6-01	Administrative access to the network and SRA applications is restricted to personnel whose job functions require it.	No exception noted.
	PI1.6-02	User accounts are reviewed for appropriateness by management on an annual basis.	No exception noted.
	PI1.6-03	Changes are requested and documented through the change management system.	No exception noted.
	PI1.6-04	Changes must be approved by management prior to implementation into production. (Refer to CC7.4)	No exception noted.

CPRIT Control Responsibilities

It is not feasible for all of the control objectives related to data processing to be achieved entirely by SRA's implemented controls. While SRA can achieve most objectives, procedures performed by CPRIT contribute significantly to the overall achievement of control objectives.

Other control objectives may be defined by and must be performed solely by CPRIT.

- CPRIT is responsible for ensuring that CPRIT specific data is complete and accurate prior to submission to SRA International.
- CPRIT notifies SRA of employee transfer activities stating what access needs to be enabled or disabled.
- CPRIT has controls in place to ensure changes follow the established change management processes by approving changes to the SRA applications prior to implementation, maintaining a list of pre-approved changes and conducting periodic change controls meetings.

Appendix A: Systems Supporting CPRIT



P²RMIS (Program and Peer Review Management Information System)

- SRA-owned proprietary system that provides robust functionality supporting the Peer Review of grant applications
- After closing of a receipt cycle, application data is transferred from CARS to P²RMIS
- Data output from the peer review process will be transferred to CGMS upon completion of the peer review process. **Note:** this is planned functionality that is currently being priced for CPRIT approval.



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: HEIDI MCCONNELL
SUBJECT: CONTRACTS REQUIRING APPROVAL
DATE: AUGUST 14, 2014

CPRIT staff is seeking authorization to proceed with executing contracts for the services outlined below. Because all of these contracts will exceed \$100,000, CPRIT must also request approval from the Legislative Budget Board before proceeding with executing these contracts.

Due Diligence Services Contract

Since 2010, the Product Development Program has had a business management-regulatory due diligence report and an intellectual property due diligence report on every company applicant considered by the Product Development Review Council for a grant award recommendation. These due diligence reports are not a re-review of the grant application but provide an independent analysis of the company applicant's potential to commercially develop the proposed, drug, device, diagnostic, technology, or service, which the Product Development Review Council uses to finalize their grant award recommendations.

Staff estimate that the Product Development Review Council will request due diligence on three to five company applicants per grant application cycle. There may be up to three application cycles in fiscal year 2015.

For the business-management-regulatory due diligence, CPRIT has subcontracted with a firm through the grants management contract with SRA International, Inc. to perform this evaluation on applicants that have proceeded through the initial Product Development Peer Review panels' review and recommendation for funding. Business administration and regulatory due diligence review involves an in-depth evaluation of a company's management team, regulatory affairs, clinical trial design, manufacturability of the proposed product, market for the proposed product, marketing and so forth. Instead of subcontracting for this service through the SRA International contract, CPRIT has issued a Request for Proposal (RFP) for the business management-regulatory due diligence services. Responses to the RFP are due on August 22, 2014.

CPRIT staff would like authorization to award a four-year contract (one-year base contract with up to three one-year renewal options) with one or more firms to provide business management-regulatory due diligence all totaling up to \$350,000 per year, with a potential value of \$1.4 million over four years.

Based on past history, the cost of each report has not exceeded \$25,000. Staff recommends procuring more than one firm to perform these due diligence evaluations following the model we have used with legal firms performing intellectual property due diligence. This is done to allow the agency to alternate between firms if one has a conflict with an applicant that must undergo CPRIT due diligence.

Outside Legal Services Contract

CPRIT seeks approval of two contracts for outside counsel services. CPRIT relies on outside legal counsel with expertise in intellectual property to conduct a review of companies' intellectual property estate as part of the due diligence process. Two firms, Vinson & Elkins and Yudell Isidore Ng Russell, were selected following a review process initiated by CPRIT. The original Request for Qualifications was issued in July 2012 and permits a series of renewals through 2017.

CPRIT staff would like authorization to exercise the agency's option to renew the two contracts through August 31, 2015 in amounts not to exceed:

- \$200,000 for the Vinson & Elkins contract, and
- \$100,000 for the Yudell Isidore Ng Russell contract.

Outside counsel contracts must be approved by the Office of the Attorney General. Generally, outside counsel contracts are permissible only in special circumstances when the agency legal counsel and Attorney General legal staff do not have expertise in the particular area.

Pre- and Post-Award Grants Management Support Contract

CPRIT issued a Statement of Work (SOW) request to SRA International, Inc. on July 3, 2014, based on the contract terms already negotiated with the State of Texas through the Comptroller's Texas Multiple Award Schedules (TXMAS) program. TXMAS vendors have negotiated rates for services with the State of Texas based on the federal General Services Administration procurement contracts for these services with most favored customer prices.

CPRIT has augmented its staff with pre- and post-award grant management support services since July 2009. The contract with the current vendor for these services expires on August 31, 2014. CPRIT continues to have a need for these services given the limited size of its staff, now 32 FTEs. The contract augments CPRIT's staff resources for grant applications processing, peer review meeting support, and programmatic review of grant award progress reports, provides support for arranging travel for CPRIT's peer reviewers for the peer review meetings, provides support for processing payments for peer reviewer travel and honoraria for CPRIT's approximately 200 peer reviewers, and provides logistical support for peer review meeting arrangements.

After refining the SOW requirements and service assumptions, SRA's final proposed cost is \$11,509,011 for FY 2015. CPRIT staff seeks authorization to contract with SRA for \$11,509,011 for the year ending August 31, 2015. Please note that the SOW included an option for CPRIT to extend the contract after August 31, 2015 by up to 12 months, if necessary.

Peer Review Monitoring Contract

CPRIT has contracted for independent monitoring of all peer review meetings since May 2012. At peer review meetings, the monitoring work is limited to observations of the following:

- a. CPRIT's established procedure for panelists who have declared a conflict of interest are followed during the meeting (e.g., reviewers hang up from the teleconference or leave the room when a proposal with which there is a conflict is discussed);
- b. CPRIT program staff participation at meetings is limited to offering general points of information when asked by peer review panel members;
- c. CPRIT program staff do not engage in the panel's discussion on the merits of applications; and
- d. The peer review panel discussion is focused on the established scoring criteria and/or making grant award recommendations.

The observations do not include an evaluation of the appropriateness or rigor of the peer review panel's discussion of scientific, technical or programmatic aspects of the applications. At the conclusion of each peer review panel and Review Council meeting, the monitor provides a written report to the Chief Compliance Officer to document the results of the observations and the procedures followed in the observation process. CPRIT estimates there will be 86 peer review panel and Review Council meetings in FY 2015.

CPRIT issued an Invitation for Bid for these services on August 4, 2014, and responses are due on August 18, 2014.

Based on past history, the cost of these services is not anticipated to exceed \$100,000 in a year. CPRIT staff would like authorization to award a four-year contract (one-year base contract with up to three one-year renewal options) for up to \$100,000 per year, with a potential value of up to \$400,000 over four years.

Independent Financial Audit Contract

CPRIT is required by Texas Health and Safety Code § 102.053 to audit its financial statements every year. For a state agency the financial statement is the Annual Financial Report (AFR). The format and content of the AFR is prescribed by the Comptroller's Office which consolidates the financial statements of every state agency into the Comprehensive Annual Financial Report (CAFR) for the state. The audited financial statement is due to the Comptroller's and CPRIT's other oversight offices by December 20 of each year.

These services have been provided by accounting firms on the TXMAS procurement program administered by the Comptroller's Office. The services require an audit delegation authorization

from the State Auditor. CPRIT can request the audit delegation once a firm and a cost for the services has been determined through the procurement process.

In previous years, this audit has cost approximately \$35,000-40,000. Responses to the procurement opportunity are due on August 19, 2014. The Invitation for Bid allows CPRIT to award the contract for FY 2015 with three one-year renewal options.

CPRIT staff would like authorization to proceed with awarding a contract to the vendor that provides the best value to the state up to a total value of \$160,000 for the four-year contract term.



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: AMY MITCHELL, BOARD GOVERNANCE SUBCOMMITTEE INTERIM CHAIR
SUBJECT: PROPOSED ADOPTION OF UNIVERSITY ADVISORY COMMITTEE CHARTER
DATE: AUGUST 13, 2014

Summary and Recommendation:

The Board Governance subcommittee recommends that the Oversight Committee vote to approve the University Advisory Committee (UAC) charter. The Board Governance subcommittee is responsible for providing guidance to the Oversight Committee regarding approval of organizational documents. The Board Governance Subcommittee discussed the proposed UAC charter with CPRIT's General Counsel, Kristen Doyle, at its meeting on August 13, 2014.

Background:

The UAC is a statutorily-created committee to advise the Oversight Committee regarding the role of institutions of higher education in cancer research. CPRIT's administrative rule §701.13(6) requires the UAC to create a committee charter for Oversight Committee approval that delineates the UAC's role and expected activities. The UAC approved its charter on August 5, 2014 and submitted it for Oversight Committee approval.



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

THE CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS UNIVERSITY ADVISORY COMMITTEE CHARTER

BACKGROUND

Texas Health and Safety Code §102.154 establishes the University Advisory Committee (“UAC”) to advise the Cancer Prevention and Research Institute of Texas (“Institute”). This Charter (“UAC Charter”), adopted by the UAC members and approved by the Oversight Committee of the Cancer Prevention and Research Institute of Texas (“Oversight Committee”) on _____, supersedes any other documents relating to the UAC.

PURPOSE

The primary purpose of the UAC is to advise the Oversight Committee and each Scientific Research and Prevention Program Peer Review Committee regarding the role of institutions of higher education in cancer research, including early stage product development.

COMPOSITION

The UAC shall be composed of at least nine members representing all public university systems and private research universities in the state of Texas. Appointed by their respective chancellors and presidents (generally referred to as “Appointing Authority”), membership shall be assigned in the following manner:

- Two members appointed by the chancellor of The University of Texas System to represent The University of Texas Southwestern Medical Center, The University of Texas Medical Branch at Galveston, The University of Texas Health Science Center at Houston, The University of Texas Health Science Center at San Antonio, The University of Texas Health Science Center at Tyler, or The University of Texas M.D. Anderson Cancer Center;
- One member appointed by the chancellor of The Texas A&M University System to represent the Texas A&M University System Health Science Center or the teaching hospital for the Texas A&M Health Science Center College of Medicine;
- One member appointed by the chancellor of the Texas Tech University System to represent the Texas Tech University Health Sciences Center;

- One member appointed by the chancellor of the University of Houston System to represent the system;
- One member appointed by the chancellor of the Texas State University System to represent the system;
- One member appointed by the chancellor of the University of North Texas System to represent the system;
- One member appointed by the president of Baylor College of Medicine; and
- One member appointed by the president of Rice University.

Additional members may be appointed at the discretion of the Institute's Chief Executive Officer. UAC members serve for terms as determined by the appropriate Appointing Authority. Once appointed, a UAC member serves until the member resigns or the Appointing Authority appoints a new member as a replacement for the UAC member.

ELECTION OF OFFICERS

A UAC Chairperson and a Vice Chairperson shall be elected by a majority of UAC members present and able to vote at the first regular meetings of the UAC held in May and June, 2014. The UAC Chairperson and Vice Chairperson shall serve two-year terms, at the conclusion of which the Vice Chairperson shall assume the position of UAC Chairperson.

Beginning in 2016 and then in every even-numbered year thereafter, the UAC shall elect a new Vice Chairperson by a majority of UAC members present and able to vote at the first regular meeting of the UAC held on or after September 1.

In the event a Chairperson or Vice Chairperson fails to complete a full two-year term, the UAC shall elect by majority vote a member to complete the term of the vacant position. An election may occur when there is a majority of members present and able to vote. In the event that the Chairperson fails to complete a full two-year term, nothing prevents the UAC from electing the Vice Chairperson to complete the term of the Chairperson; however, no individual may hold both positions simultaneously.

MEETINGS AND QUORUM

The UAC shall meet as often as deemed necessary by the UAC Chairperson. At a minimum, the UAC shall meet annually to compose a report to send to the Oversight Committee and to conduct any other business required by this Charter, statutes, or administrative rules.

A meeting of the UAC requires a quorum of members. Such meeting may take place in person or by teleconference. A quorum exists when at least a majority of appointed members of the UAC are present or available via telephone. If there is an even number of currently appointed members, then half that number plus one member constitutes a quorum.

The UAC Vice Chairperson or his/her designate shall record the minutes for each UAC meeting. The UAC Vice Chairperson shall forward the final meeting minutes to the Institute's Chief Executive Officer for retention and distribution to the Oversight Committee members.

An office copy of the UAC meeting minutes will be retained at CPRIT headquarters and available to the public on request. The Institute's CEO will distribute the minutes to the Oversight Committee members on or before the Oversight Committee meeting following the date that the minutes were submitted to CPRIT.

DUTIES AND RESPONSIBILITIES

The UAC shall have the following duties and responsibilities:

- Annual Report – The UAC shall report, at least annually, to the Oversight Committee regarding the work undertaken by the UAC for the previous year and the UAC's recommendations for the Institute. The Oversight Committee may direct the UAC to address specific topics in the UAC Annual Report. Such direction shall be provided in writing by the Oversight Committee's Presiding Officer to the UAC Chairperson.

The UAC Annual Report shall be submitted by the end of each calendar year to the Oversight Committee's Presiding Officer for distribution to the Oversight Committee. Prior to submission of the final UAC Annual Report, a draft report may be provided to the Institute's Prevention Subcommittee, Scientific Research Subcommittee, and/or Product Development Subcommittee for review.

The UAC Chairperson shall present the UAC Annual Report on behalf of the UAC at the first regular meeting of the Oversight Committee following the submission of the report. If the UAC Chairperson is unable to attend the meeting, the Vice-Chairperson, or

another designated member if the Vice-Chairperson is unable to attend, shall present the report.

In addition, the UAC may provide to the Oversight Committee on-going advice, input and support related to the development of programs that will have a lasting impact on cancer research and prevention efforts in Texas, including the following:

- Advise the Subcommittees of the Oversight Committee – The UAC may work with the subcommittees of the Oversight Committee as needed pursuant to direction provided by the Institute.
- Advise the Institute Regarding Prevention and Research Grant Mechanisms – The UAC may provide input regarding the impact of the Institute’s grant mechanisms on Texas institutions of higher education and propose new areas to be addressed by future grant mechanisms. The UAC’s recommendations may be compiled in the UAC Annual Report or provided to the Oversight Committee as a separate report.
- Assist in the Identification of Institute Success Metrics - The UAC may recommend Institute priorities and opportunities that enhance the ability of the Institute to achieve its mission and to implement the Texas Cancer Plan. In addition, the UAC may provide guidance as to how the Institute can best achieve compliance when working with the institutions of higher education that have received grants.

OTHER DUTIES

In addition to duties and responsibilities stated herein, the Oversight Committee’s Presiding Officer may authorize additional, official duties of the UAC.

AMENDING OR REPEALING THE CHARTER

The UAC retains the ability to make, alter, amend, or repeal the UAC Charter in order to best conduct business. Proposed changes to the UAC Charter shall be made pursuant to a majority vote of the UAC members. Proposed changes are final once approved by a vote of the Oversight Committee.

CHARTER APPROVAL

As reflected by the signatures of the UAC Chairperson and Oversight Committee’s Presiding Officer, the UAC was adopted and approved in compliance with the process specified herein on the dates stated below.

Adopted by the UAC

Approved by the Oversight Committee

Cheryl Lyn Walker, Ph.D.
Chair, UAC

William Rice, M.D.
Presiding Officer, Oversight Committee

Date: _____

Date: _____

STATEMENT OF REVISIONS: None

DRAFT



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

Advisory Committee on Childhood Cancers Proposed Members

Gail Tomlinson, M.D., Ph.D.

Interim Director
Greehey Children's Cancer Research Institute
The University of Texas Health Science Center
in San Antonio

C. Patrick Reynolds, M.D., Ph.D.

Cancer Center
School of Medicine
Texas Tech Health Sciences Center

David Poplack, M.D.

Director, Texas Children's Cancer Center
Elise C. Young Professor of Pediatric Oncology
Head, Hematology-Oncology Section,
Department of Pediatrics
Baylor College of Medicine

Karen Albritton M.D.

Director Adolescent and Young Adult Oncology
Program Cook Children's Hospital

Daniel Bowers, M.D.

Medical Director, Pediatric Neuro-Oncology
The University of Texas Southwestern Medical
Center/ Children's Medical Center Dallas

Brad H. Pollock, M.P.H., Ph.D.

Professor and Chairman
Henry B. Dielmann Distinguished University
Chair
School of Medicine
University of Texas Health Science Center
Department of Epidemiology and Biostatistics

Tim Culliver

Adam's Angels Ministry
Brenham, Texas

Annette Leslie

Executive Director
Carson Leslie Foundation
Dallas, Texas

Eugenie Kleinerman M.D.

Professor and Head, Division of Pediatrics
Mary V. and John A. Reilly Distinguished Chair
The University of Texas M.D. Anderson Cancer
Center

Stephen X. Skapek, M.D.

Director, Division of Pediatric
Hematology/Oncology
The University of Texas Southwestern Medical
Center *and*
Medical Director, Pauline Allen Gill Center
for Cancer and Blood Disorders
Children's Medical Center, Dallas

Susan Blaney, M.D.

Professor
Deputy Director, Texas Children's Cancer Center
and Hematology Service
Texas Children's Clinical Care Center



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: AMY MITCHELL, BOARD GOVERNANCE SUBCOMMITTEE INTERIM CHAIR
SUBJECT: INTENTION TO RECOMMEND APPROVAL OF THE FINAL ORDERS ADOPTING ADMINISTRATIVE RULE CHANGES
DATE: AUGUST 13, 2014

Summary and Recommendation:

The Board Governance subcommittee recommends that the Oversight Committee vote to approve changes to CPRIT administrative rules at its August 20, 2014 meeting. The Board Governance Subcommittee discussed the rule changes with CPRIT's General Counsel, Kristen Doyle, at its meeting on August 13, 2014.

Discussion:

Texas Health and Safety Code § 102.108 authorizes the Oversight Committee to implement rules to administer CPRIT's statute. Pursuant to the Oversight Committee's Bylaws, the Board Governance Subcommittee is assigned the responsibility of considering changes to CPRIT's administrative rules. The Board Governance Subcommittee met with Ms. Doyle, on August 13, 2014, to discuss the administrative rule changes proposed for adoption.

The changes made to CPRIT's administrative rules implement State Auditor recommendations and adapt agency practices to legislative requirements enacted by Senate Bill 149. The proposed administrative rule changes were provisionally approved by the Oversight Committee at the May 21, 2014, meeting. The proposed rules were published in the *Texas Register* in June and were posted on CPRIT's website. No public input was received.

The Board Governance Subcommittee recommends that the Oversight Committee approve the final orders formally adopting the changes in Chapters 702 and 703.

TITLE 25. HEALTH SERVICES

PART 11. CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CHAPTER 702. Institute Standards on Ethics and Conflicts, Including the Acceptance of Gifts and Donations to the Institute

The Cancer Prevention and Research Institute of Texas (Institute) adopts an amendment to § 702.7 regarding the Institute's gift reporting requirements. The proposed amendment to § 702.7 was published in the June 13, 2014, issue of the Texas Register (39 TexReg 4614).

Reasoned Justification

The amendment clarifies when a gift falls under an exception from the Institute's reporting requirement. Language is changed to mirror language found in other, corresponding statutes in order to reduce confusion.

The Texas Health and Safety Code, § 102.106 directs the CPRIT Oversight Committee to adopt conflict of interest rules to apply to the Oversight Committee, the Program Integration Committee, and Institute employees. In addition, these amendments are adopted pursuant to and in satisfaction of the provisions of Texas Government Code, Chapters 572 and 2255, Texas Health and Safety Code, Chapter 102, and other relevant statutes.

The Institute accepted public comments in writing and by fax through July 14, 2014. No comments were received concerning the proposed amendment to § 702.7. The amendment to § 702.7 will be adopted as published in the June 13, 2014 edition of the *Texas Register* and will not be republished.

The Oversight Committee approved the final order adopting the amendments to Chapter 702 rules on August 20, 2014.

The rules are adopted under the authority of the Texas Health and Safety Code Annotated, § 102.106, which directs the Oversight Committee to adopt conflict of interest rules and §§ 102.108 and 102.109, which provides the Institute with broad authority to adopt rules to administer the chapter.

The Institute hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

To be filed with the Secretary of State on August 21, 2014.

TITLE 25. HEALTH SERVICES

PART 11. CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CHAPTER 703. Grants for Cancer Research and Prevention

The Cancer Prevention and Research Institute of Texas (Institute) adopts the amendments to §§ 703.3, 703.6, 703.8, 703.11, 703.13, 703.14, 703.20, and 703.21. The proposed amendments for Chapter 703 were published in the June 13, 2014, issue of the *Texas Register* (39 TexReg 4616).

Reasoned Justification

These amendments allow for the designation of co-chairpersons by either a Peer Review Panel chairperson or Review Council chairperson and specify that it is the chief executive officer, rather than the chief compliance officer, who is responsible for recommending corrective actions for variances in the grant review process. The amendments clarify document submission requirements for grant recipients. Specifically, these proposed amendments provide more explanation regarding requirements, deadlines, and consequences for late submission of required documents including audits, close out documents, financial status reports, grant progress reports, and tranche progress reports. Amended language also clarifies when reimbursement costs may be waived for grant recipients who have received advance payment of funds. The amendments are adopted pursuant to and in satisfaction of the provisions Texas Health and Safety Code, Chapter 102, and other relevant statutes.

The Institute accepted public comments in writing and by fax through July 14, 2014. No comments were received concerning the proposed amendments for Chapter 703. The amendments to Chapter 703 rules will be adopted as published in the June 13, 2014 edition of the *Texas Register* and will not be republished.

The Oversight Committee approved the final order adopting the amendments to Chapter 703 rules on August 20, 2014.

The rules are proposed under the authority of the Texas Health and Safety Code Annotated, §§ 102.8, 102.251, 102.255, 102.260, which provide the Institute with the authority to adopt rules and the Oversight Committee to establish procedures for the grant award process.

The Institute hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

To be filed with the Office of Secretary of State on August 21, 2014.

Summary of Proposed Administrative Rule Changes to be Adopted August 20, 2014

Chapter 702

§702.7(f)(4)(B)-(C) These subsections are part of a list of items that are not subject to CPRIT's gift reporting requirement as it applies to an Oversight Committee Member, Institute Employee, or Program Integration Committee Member. Changes are made to track language found in Chapter 36 of the Penal Code and Section 3.104 of the Business & Commerce Code.

§702.7(f)(5)(B) This subsection is part of a list of items that are that are not subject to CPRIT's gift reporting requirement if a Scientific Research and Prevention Programs Committee Member receives a gift by a Grant Applicant or Recipient. Changes are made to track language found in Chapter 36 of the Penal Code and Section 3.104 of the Business & Commerce Code.

§702.7(6)(A)-(C) While a member of an Advisory Committee participates in the Grant Review Process, he or she is required to report gifts, grants, or other consideration received from a Grant Applicant or Recipient. These subsections list out gifts that are not subject to CPRIT's reporting requirement. Changes are made to track Chapter 36 of the Penal Code and Section 3.104 of the Business & Commerce Code.

Chapter 703

§703.3(d) Clarifying language added to read an "otherwise qualified applicant" is only eligible for Grant Mechanism in RFA.

§703.3(j) Language added to require Grant Applicant to indicate if ineligible to receive state grant funds in addition to federal grant funds. Currently, only federal funds are listed.

§703.6(e)(1)(C) Corrects title to read Peer Review Panel chairperson.

§703.6(k) A new subsection that allows either a Peer Review Panel chairperson or Review Council chairperson who cannot carry out duties to designate a co-chairperson. This designation must be in writing and contain the specific time and extent of designation.

§703.8(1)(B) and (2) Allows the Chief Executive Officer, instead of the Chief Compliance Officer, to recommend "corrective actions" for variances that occurred in grant review process. The Oversight Committee must approve the actions by a simple majority of members present and voting.

§703.11(c)(5)(C) Removes requirement that Chief Executive Officer must approve the allowance for unrecovered Indirect Costs because electronic grants management records make requirement superfluous.

§703.11(i) When a Grant Recipient does not match funds, this subsection allows CPRIT to take action not specifically listed in §703.11(h). Language is added so that the Chief Executive Officer must approve such action.

§703.13(a)(3) Clarifying change requiring Grant Recipients to submit independent audit within 30 days of receiving audit. This is consistent with Uniform Grant Management Standards. Instead of nine months as currently written, the Grant Recipient has 270 days following the end of their fiscal year to submit this audit. This change is due to the fact that CPRIT's Grant Management System counts time by days instead of months.

§703.13(a)(3)(B) If Grant Recipients cannot meet audit deadline, they may ask CPRIT for more time. This subsection clarifies that period of time. The grantees must submit request no later than the 270th day after the end of their fiscal year.

§703.13(d) Language changed to achieve consistency within the statute. If a grantee is delinquent under §703.13 then the grantee is not eligible "to be awarded" a new grant or a "continuation Grant Award." If a grantee has been approved by CPRIT for more time, the grantee remains eligible "to be awarded" a new grant or "continuation Grant Award."

§703.14(c)(5) This is a new subsection that allows CPRIT, before 180 days prior to termination date of a Grant Contract, to approve an amendment to the Grant Contract extending the termination date via something other than a no cost extension request. There must be a finding of good cause.

§703.14(d) Clarifies that final Financial Status Report, final Grant Progress Report, and any other documents are collectively referred to as "close out documents."

§703.14(d)(1) New language that clarifies waiver of reimbursement costs as it relates to the final Financial Status Report and other close out documents. As it appears now, the grantee may submit a late Financial Status Report and still be reimbursed. The new language fixes this in two ways. First, if the Grant Recipient submits the final Financial Status Report but no other close out documents, then final reimbursement will not be paid until all close out documents are submitted. Second, if the Grant Recipient does not submit the final Financial Status Report within 30 days after the deadline, reimbursement of costs incurred during that reporting period will be waived.

§703.14(d)(2) New language that imposes a stricter penalty on a Grant Recipient that does not submit close out documents. If close out documents are not submitted within 180 days of termination, the Grant Recipient will be ineligible to receive new grants or continued grants. CPRIT may waive final submission of documents if requested by Grant Recipient.

§703.14(d)(2)(A)-(C) New subsections to lay out the process of granting a waiver of late close out document submission. The Chief Executive Officer must grant the approval. The Oversight Committee will be notified of both the waiver request by the Grant Recipient and the decision of the Chief Executive Officer. The decision of the Chief Executive Officer will be final unless overturned by a simple majority of Oversight Committee members present and voting.

§703.20(2) Requires a Grant Recipient to show good cause for not certifying adoption and enforcement of a Tobacco-free workplace policy.

§703.21(b)(2) New language added to clarify that this subsection also applies to Grant Recipients that received advanced funds. If a Grant Recipient does not timely submit Financial Status Reports within 30 days of due date, reimbursement of projects costs for that time period are waived.

§703.21(b)(2)(A)-(B) New language clarifying Financial Status Report due date of 90 days following the end of the state fiscal quarter. Language is also added to clarify when Grant Recipient must submit request to defer reimbursement request.

§703.21(b)(3)(G)-(H) Both are new subsections that implement penalty for not timely submitting the Grant Progress Report. If a Grant Recipient does not submit the Grant Progress Report within 60 days of anniversary of effective date of Grant Contract, CPRIT will not disperse funds until the report is filed. Additionally, Product Development Grant Recipients must submit “Tranche Grant Progress Reports,” along with other reports required by CPRIT. If this is not timely done, funds for the next tranche as per the Grant Contract will not be disbursed until reports reviewed and approved.



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: AMY MITCHELL, BOARD GOVERNANCE SUBCOMMITTEE INTERIM CHAIR
SUBJECT: INTENTION TO RECOMMEND APPROVAL OF PROPOSED ADMINISTRATIVE RULE CHANGES
DATE: AUGUST 13, 2014

Summary and Recommendation:

The Board Governance subcommittee recommends that the Oversight Committee vote to approve proposed changes to CPRIT's administrative rules at its August 20, 2014 meeting. The Board Governance Subcommittee discussed the new rules and rule changes with CPRIT's General Counsel, Kristen Doyle, at its meeting on August 13, 2014.

Discussion:

Texas Health and Safety Code § 102.108 authorizes the Oversight Committee to implement rules to administer CPRIT's statute. Pursuant to the Oversight Committee's Bylaws, the Board Governance Subcommittee is assigned the responsibility of considering changes to CPRIT's administrative rules. The Board Governance Subcommittee met with Ms. Doyle, on August 13, 2014, to discuss the proposed changes to the administrative rules.

The Board Governance Subcommittee has considered the proposed changes and recommends that the Oversight Committee approve publication of the proposed changes in the *Texas Register*. The proposed changes provide guidance regarding agency policies and grantee requirements.



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: KRISTEN DOYLE, GENERAL COUNSEL
SUBJECT: PUBLICATION APPROVAL FOR PROPOSED CHANGE TO RULE §703.13
DATE: AUGUST 1, 2014

Summary and Recommendation:

Representatives from public universities have requested additional guidance regarding 25 T.A.C. § 703.13 concerning audits and investigations. The proposed amendment provides additional clarity that an agreed upon procedures engagement, as defined by the American Institute of Certified Public Accountants, fulfills the audit requirement. The Oversight Committee should approve the proposed amendment for publication in the *Texas Register* for public comment.

Discussion:

CPRIT initially revised § 703.13 to implement recommendations made by the State Auditor's Office in its January 2013 report, *Grant Management at the Cancer Prevention and Research Institute of Texas and Selected Grantees*. The State Auditor advised that CPRIT's practice of allowing state institutions to use the Statewide Single Audit did not comply with the single audit requirement of the Uniform Grant Management Standards (UGMS) because the Statewide Single Audit does not include a review of the state-funded grant awards, such as the CPRIT grants. To implement the State Auditor's recommendation, CPRIT revised its administrative rules to require a grantee expending \$500,000 or more in state awards during its fiscal year to obtain either an annual single independent audit or a program specific independent audit. The rules clarified that a single audit is required if funds from more than one state program are spent by the grantee.

Following the Oversight Committee's approval of administrative rule changes earlier this year, representatives from the state institutions of higher education contacted CPRIT staff with questions about the appropriateness of using an agreed upon procedures engagement to fulfill the revised audit requirements. They provided additional information about the impact of the provision requiring that all CPRIT-funded entities receiving \$500,000 or more in state awards to obtain a single audit. State institutions of higher education are exempted by state law from having to comply with UGMS. To avoid any conflict with state law, the change to this section clarifies that state institutions of higher education do not have to obtain a single audit if they expend more than \$500,000 in state grants and allows them to satisfy the audit requirement by obtaining either a program specific audit or an agreed upon procedures engagement as defined by the American Institute of Certified Public Accountants.

The Oversight Committee's consideration and approval for publishing the proposed rule amendment in the next edition of the *Texas Register* (likely to be the September 5, 2014, edition) is the first step in the process to adopt final rule. Once the proposed rule amendment is published, the public has 30 days to submit written comments to CPRIT before the rule can be brought back to the Oversight Committee for final approval. The rule, along with a summary of the input received from the public and any recommended changes, will be brought to the Oversight Committee for final approval and adoption at its next open meeting.

TITLE 25. HEALTH SERVICES

PART 11. CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CHAPTER 701. Policies and Procedures

The Cancer Prevention and Research Institute of Texas (Institute) proposes a new § 701.35 to Chapter 701, Texas Administrative Code.

Background and Justification

Chapter 2001, Texas Government Code, requires state agencies to prescribe by rule the form and procedure for accepting, considering, and disposing of such petitions. The proposed new rule sets forth the procedure an interested must follow to petition the Institute for consideration of a proposed administrative rule. The proposed new rule describes the Institute's process for considering the petition.

Fiscal Note

Kristen Pauling Doyle, General Counsel for the Cancer Prevention and Research Institute of Texas has determined that for the first five-year period the rule is in effect there will be no foreseeable implications relating to costs or revenues for state or local government as a result of enforcing or administering the rule.

Public Benefit and Costs

Ms. Doyle also has determined that for each year of the first five years the rule is in effect the public benefit anticipated as a result of enforcing the rule will be clarification of the policies and procedures the Institute will follow to implement its statutory duties. There are no anticipated economic costs to persons who are required to comply with the rule as proposed.

Small Business and Micro-business Impact Analysis

Ms. Doyle has determined that the rule shall not have an effect on small businesses or on micro businesses.

Written comments on the proposed rule may be submitted to Ms. Kristen Pauling Doyle, General Counsel, Cancer Prevention and Research Institute of Texas, P. O. Box 12097, Austin, Texas 78711 no later than **October 6, 2014**. Parties filing comments are asked to indicate whether or not they support the new rule proposed by the Institute and, if changes are requested, to provide specific text proposed to be included in the rule. Comments may be submitted electronically to kdoyle@cprit.state.tx.us. Comments may be submitted by facsimile transmission to 512/475-2563.

Statutory Authority

The rule is proposed under the authority of the Texas Health and Safety Code Annotated, § 102.108, which provides the Institute with the authority to adopt rules to administer the chapter.

There is no other statute, article or code that is affected by this rule.

RULE §701.35 Petition for Adoption of Rules

- (a) An interested party may petition the Institute to adopt a rule by submitting a proposed rule in writing either by electronic or regular mail to the Chief Executive Officer and the General Counsel of the Institute. Each proposed rule must be submitted to the Institute in a separate petition for adoption.
- (b) The petition must include the following information:
 - (1) the full name, mailing address, email address, and phone number of the petitioner;
 - (2) the complete text of the new proposed rule, if the proposed rule alters text of a current Institute rule then changes shall be shown in the following manner, deletion of current text shall be marked by striking through the text, addition of new text shall be marked by underlining the text;
 - (3) an explanation of how the proposed rule benefits the public, including supporting information or data demonstrating the need for the proposed rule;
 - (4) a statement of the legal authority for the proposed rule; and
 - (5) any other information required by the Institute.
- (c) The General Counsel of the agency shall review the petition for adoption and confirm it complies with subsection (b) of this section, if not in compliance the petition for adoption may be denied. On or before the 60th day after receipt of the proposed rule, the Chief Executive Officer shall either deny the petition for adoption in writing stating reasons for denial or direct the General Counsel to initiate a rulemaking procedure pursuant to Chapter 2001, Texas Government Code.

TITLE 25. HEALTH SERVICES

PART 11. CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CHAPTER 703. Grants for Cancer Prevention and Research

The Cancer Prevention and Research Institute of Texas (Institute) proposes amendments to §§ 703.11 and 703.13, regarding matching fund and audit requirements.

Background and Justification

The Institute permits a grant recipient that is a public or private institution of higher education, as defined by §61.003, Texas Education Code, to credit toward the grant recipient's matching funds obligation the dollar amount equivalent to the difference between the indirect cost rate authorized by the federal government for research grants awarded to the grant recipient and the five percent (5%) indirect cost limit imposed by §102.203(c), Texas Health and Safety Code. The proposed amendment to § 703.11(b) provides guidance for calculating the federal indirect cost rate applicable for subcontracted work on the grant project.

The Institute requires grant recipients that expend \$500,000 or more in state awards during its fiscal year to obtain an annual audit as a condition of the grant award. The purpose of the proposed amendment to § 703.13 is to clarify that an agreed upon procedures engagement, as defined by the American Institute of Certified Public Accountants, fulfills the audit requirement. This amendment is proposed pursuant to and in satisfaction of the provisions Texas Health and Safety Code, Chapter 102, and other relevant statutes.

Fiscal Note

Kristen Pauling Doyle, General Counsel for the Cancer Prevention and Research Institute of Texas has determined that for the first five-year period the rules are in effect there will be no foreseeable implications relating to costs or revenues for state or local government as a result of enforcing or administering the rules.

Public Benefit and Costs

Ms. Doyle has determined that for each year of the first five years the rules are in effect the public benefit anticipated as a result of enforcing the rules will be clarification of policies and procedures the Institute will follow to implement its statutory duties. Probable economic cost to persons required to comply with the rule will be for the institutions of higher education expending \$500,000 or more in state grants to avoid incurring costs for a single audit.

Small Business and Micro-business Impact Analysis

Ms. Doyle has determined that the rule shall not have an effect on small businesses or on micro businesses.

Written comments on the rules may be submitted to Ms. Kristen Pauling Doyle, General Counsel, Cancer Prevention and Research Institute of Texas, P. O. Box 12097, Austin, Texas 78711 no later than **October 6, 2014**. Parties filing comments are asked to indicate whether or not they support the rule revisions proposed by the Institute and, if a change is requested, to provide specific text proposed to be included in the rule. Comments may be submitted electronically to kdoyle@cprit.state.tx.us. Comments may be submitted by facsimile transmission to 512/475-2563.

Statutory Authority

The rules are proposed under the authority of the Texas Health and Safety Code Annotated, §102.8, which provides the Institute with broad rule-making authority to administer the chapter. Kristen Pauling Doyle, the Institute's General Counsel, has reviewed the proposed amendment and certifies the proposal to be within the Institute's authority to adopt.

There is no other statute, article or code that is affected by these rules.

RULE §703.11 Requirement to Demonstrate Available Funds for Cancer Research Grants

(a) Prior to the disbursement of Grant Award funds, the Grant Recipient of a Cancer Research Grant Award shall demonstrate that the Grant Recipient has an amount of Encumbered Funds equal to one-half of the Grant Award available and not yet expended that are dedicated to the research that is the subject of the Grant Award. The Grant Recipient's written certification of Matching Funds, as described in this section, shall be included in the Grant Contract. A Grant Recipient of a multiyear Grant Award may certify Matching Funds on a year-by-year basis for the amount of Award Funds to be distributed for the Project Year based upon the Approved Budget. A Grant Recipient receiving multiple Grant Awards may provide certification at the institutional level.

(b) For purposes of the certification required by subsection (a) of this section, a Grant Recipient that is a public or private institution of higher education, as defined by §61.003, Texas Education Code, may credit toward the Grant Recipient's Matching Funds obligation the dollar amount equivalent to the difference between the indirect cost rate authorized by the federal government for research grants awarded to the Grant Recipient and the five percent (5%) Indirect Cost limit imposed by §102.203(c), Texas Health and Safety Code, subject to the following requirements:

(1) The Grant Recipient shall file certification with the Institute documenting the federal indirect cost rate authorized for research grants awarded to the Grant Recipient; ~~and~~

(2) To the extent that the Grant Recipient's Matching Funds credit does not equal or exceed one-half of the Grant Award funds to be distributed for the Project Year, then the Grant Recipient's Matching Funds certification shall demonstrate that a combination of the dollar amount equivalent credit and the funds to be dedicated to the Grant Award project as described in subsection (c) of this section is available and sufficient to meet or exceed the Matching Fund requirement-; ~~and~~

(3) Calculation of the portion of federal indirect cost rate credit associated with subcontracted work performed for the Grant Recipient shall be in accordance with the Grant Recipient's established internal policy.

(c) For purposes of the certification required by subsection (a) of this section, Encumbered Funds may include:

(1) Federal funds, including, but not limited to American Recovery and Reinvestment Act of 2009 funds, and the fair market value of drug development support provided to the recipient by the National Cancer Institute or other similar programs;

(2) State of Texas funds;

(3) funds of other states;

(4) Non-governmental funds, (including private funds, foundation grants, gifts and donations; and

(5) Unrecovered Indirect Costs not to exceed ten percent (10%) of the Grant Award amount, subject to the following conditions:

(A) These costs are not otherwise charged against the Grant Award as the five percent (5%) indirect funds amount allowed under §703.12(c) of this chapter (relating to Limitation on Use of Funds);

(B) The Grant Recipient must have a documented federal indirect cost rate or an indirect cost rate certified by an independent accounting firm;

(C) The allowance for unrecovered Indirect Costs must be specifically approved by the Chief Executive Officer; and

(D) The Grant Recipient is not a public or private institution of higher education as defined by §61.003 of the Texas Education Code.

(d) For purposes of the certification required by subsection (a) of this section, the following items do not qualify as Encumbered Funds:

(1) In-kind costs;

(2) Volunteer services furnished to the Grant Recipient;

(3) Noncash contributions;

(4) Income earned by the Grant Recipient that is not available at the time of Grant Award;

(5) Pre-existing real estate of the Grant Recipient including building, facilities and land;

(6) Deferred giving such as a charitable remainder annuity trust, a charitable remainder unitrust, or a pooled income fund; or

(7) Other items as may be determined by the Oversight Committee.

(e) To the extent that a Grant Recipient of a multiyear Grant Award elects to certify Matching Funds on a yearly basis, the failure to provide certification of Encumbered Funds at the appropriate time for each Project Year shall serve as grounds for terminating the Grant Contract.

(f) In no event shall Grant Award funds for a Project Year be advanced or reimbursed, as may be appropriate for the Grant Award and specified in the Grant Contract, until the certification required by subsection (a) of this section is filed and approved by the Institute.

(g) No later than 60 days from the anniversary of the Effective Date of the Grant Contract, the Grant Recipient shall file a form with the Institute reporting the amount of Matching Funds spent for the preceding Project Year.

(h) If the Grant Recipient failed to expend Matching Funds equal to one-half of the actual amount of Grant Award funds distributed to the Grant Recipient for the same period, the Institute shall:

(1) Carry forward and add to the Matching Fund requirement for the next Project Year the dollar amount equal to the deficiency between the actual amount of Grant Award funds distributed and the actual Matching Funds expended, so long as the deficiency is equal to or less than twenty percent (20%) of the total Matching Funds required for the same period and the Grant Recipient has not previously had a Matching Funds deficiency for the project;

(2) Suspend distributing Grant Award funds for the project to the Grant Recipient if the deficiency between the actual amount of Grant Funds distributed and the Matching Funds expended is greater than twenty percent (20%) but less than fifty percent (50%) of the total Matching Funds required for the period.

(A) The Grant Recipient will have no less than eight months from the anniversary of the Grant Contract's effective date to demonstrate that it has expended Encumbered Funds sufficient to fulfill the Matching Funds deficiency for the project.

(B) If the Grant Recipient fails to fulfill the Matching Funds deficiency within the specified period, then the Grant Contract shall be considered in default and the Institute may proceed with terminating the Grant Award pursuant to the process established in the Grant Contract;

(3) Declare the Grant Contract in default if the deficiency between the actual amount of Grant Award funds distributed and the Matching Funds expended is greater than fifty percent (50%) of the total Matching Funds required for the period. The Institute may proceed with terminating the Grant Award pursuant to the process established in the Grant Contract; or

(4) Take appropriate action, including withholding reimbursement, requiring repayment of the deficiency, or terminating the Grant Contract if a deficiency exists between the actual amount of Grant Award funds distributed and the Matching Funds expended and it is the last year of the Grant Contract;

(i) Nothing herein shall preclude the Institute from taking action other than described in subsection (h) of this section based upon the specific reasons for the deficiency. To the extent that other action not described herein is taken by the Institute, such action shall be documented in writing and included in Grant Contract records. The options described in subsection (h)(1) and (2) of this section may be used by the Grant Recipient only one time for the particular project. A second deficiency of any amount shall be considered an event of default and the Institute may proceed with terminating the Grant Award pursuant to the process established in the Grant Contract.

(j) The Grant Recipient shall maintain adequate documentation supporting the source and use of the Matching Funds reported in the certification required by subsection (a) of this section. The Institute shall conduct an annual review of the documentation supporting the source and use of Matching Funds reported in the required certification for a risk-identified sample of Grant Recipients. Based upon the results of the sample, the Institute may elect to expand the review of supporting documentation to other Grant Recipients. Nothing herein restricts the authority of the Institute to review supporting documentation for one or more Grant Recipients or to conduct a review of Matching Funds documentation more frequently.

RULE §703.13 Audits and Investigations

(a) Upon request and with reasonable notice, an entity receiving Grant Award funds directly under the Grant Contract or indirectly through a subcontract under the Grant Contract shall allow, or shall cause the entity that is maintaining such items to allow the Institute, or auditors or investigators working on behalf of the Institute, including the State Auditor and/or the Comptroller of Public Accounts for the State of Texas, to review, inspect, audit, copy or abstract its records pertaining to the specific Grant Contract during the term of the Grant Contract and for the three year period following the end of the Grant Recipient's fiscal year during which the Grant Contract was terminated.

(b) Notwithstanding the foregoing, a Grant Recipient expending \$500,000 or more in state awards during its fiscal year shall obtain either an annual single independent audit, ~~or~~ a program specific independent audit, or an agreed upon procedures engagement as defined by the American Institute of Certified Public Accountants.

(1) A single audit is required if funds from more than one state program are spent by ~~the a~~ Grant Recipient that does not meet the definition of an institution of higher education in Texas Education Code, Sec. 61.003.

(2) The audited time period is the Grant Recipient's fiscal year.

(3) The audit must be submitted to the Institute no later than nine (9) months following the close of the Grant Recipient's fiscal year and shall include a corrective action plan that addresses any weaknesses, deficiencies, wrongdoings, or other concerns raised by the audit report and a summary of the action taken by the Grant Recipient to address the concerns, if any, raised by the audit report.

(A) The Grant Recipient may seek additional time to submit the required audit and corrective action plan by providing a written explanation for its failure to timely comply and providing an expected time for the submission.

(B) The Grant Recipient's request for additional time must be submitted on or before the due date of the required audit and corrective action plan.

(C) Approval of the Grant Recipient's request for additional time is at the discretion of the Institute. Such approval must be granted by the Chief Executive Officer.

(c) No reimbursements or advances of Grant Award funds shall be made to the Grant Recipient if the Grant Recipient is delinquent in filing the required audit and corrective action plan. A Grant Recipient that has received approval from the Institute for additional time to file the required audit and corrective action plan may receive reimbursements or advances of Grant Award funds during the pendency of the delinquency unless the Institute's approval declines to permit reimbursements or advances of Grant Award funds until the delinquency is addressed.

(d) A Grant Recipient that is delinquent in submitting to the Institute the audit and corrective action plan required by this section is not eligible to apply for a Grant Award until the required audit and corrective action plan is submitted. A Grant Recipient that has received approval from the Institute for additional time to file the required audit and corrective action plan may remain eligible to apply for a Grant Award unless the Institute's approval declines to continue eligibility during the pendency of the delinquency.



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: AMY MITCHELL, BOARD GOVERNANCE SUBCOMMITTEE INTERIM CHAIR
SUBJECT: PROPOSED CHANGES TO CODE OF CONDUCT
DATE: AUGUST 13, 2014

Summary and Recommendation:

The Board Governance subcommittee recommends that the Oversight Committee vote to approve two proposed changes to the Code of Conduct at its August 20, 2014 meeting. The Board Governance Subcommittee discussed the proposed changes to Sections II.E. and V. of the Code of Conduct with CPRIT's General Counsel, Kristen Doyle, at its meeting on August 13, 2014. Both proposed changes are clarifying and are intended to set due dates for certain annual reports or filings. Establishing specific due dates allows the agency to take action to ensure compliance with applicable state laws and agency policies, such as sending calendar reminders.



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CODE OF CONDUCT and ETHICS

I. OVERVIEW

A. Authority

Pursuant to Section 572.051(c) of the Government Code and Section 102.109 of the Health & Safety Code, the Cancer Prevention and Research Institute of Texas (CPRIT) promulgates the following Code of Conduct and Ethics (Code).

B. General Principles

(1) This Code recognizes CPRIT's unique role as the steward of taxpayer funds in furtherance of CPRIT's mission and the ultimate beneficiaries of the funds, the citizens of the State of Texas and sets forth the basic principles and guidelines for Oversight Committee Members, PIC Members, and Employees.

(2) Oversight Committee Members, PIC Members, and Employees are expected to discharge their duties in a manner that promotes and preserves public trust, proper stewardship, and confidence in the integrity of CPRIT and be guided by the basic principles of loyalty, prudence, honesty and fairness in conducting CPRIT's affairs.

C. Definitions

In this Code:

(1) "Audit Subcommittee" means the standing Audit Subcommittee of the Oversight Committee established by CPRIT bylaws.

(2) "Business entity" means any entity recognized by law through which business for profit is conducted, including a sole proprietorship, partnership, firm, corporation, holding company, joint stock company, receivership, or trust. Tex. Gov't Code Ann. § 572.002(2).

(3) "CPRIT" means the Cancer Prevention and Research Institute of Texas.

(4) "CEO" means the Chief Executive Officer of CPRIT.

(5) “Employee” means a person working for CPRIT in an employer-employee relationship.

(6) “Grant Applicant” means the public or private institution of higher education, as defined by §61.003, Education Code, research institution, government organization, non-governmental organization, non-profit organization, other public entity, private company, individual, or consortia, including any combination of the aforementioned, that submits a grant application to CPRIT. Unless otherwise indicated, this term includes the Principal Investigator or Program Director.

(7) “Grant Recipient” means the entire legal entity responsible for the performance or administration of the CPRIT grant. Unless otherwise indicated, this term includes the Principal Investigator, Program Director, or Company Representative.

(8) “Oversight Committee Member” means a member of the CPRIT Oversight Committee.

(9) “Oversight Committee” means CPRIT’s governing body, composed of the nine individuals appointed by the Governor, Lieutenant Governor, and the Speaker of the House of Representatives.

(10) “Program Integration Committee” (PIC) means the group composed of the Chief Executive Officer, the Chief Scientific Officer, the Chief Product Development Officer, the Commissioner of State Health Services, and the Chief Prevention Officer that is responsible for submitting to the Oversight Committee the list of grant applications the PIC recommends for grant awards.

(11) “PIC Member” means a member of the PIC.

(12) “Relative” means a person related within the second degree by consanguinity or affinity determined in accordance with Sections 573.021 – 573.025, *Government Code*. For purposes of this definition:

(A) examples of an individual within the second degree by consanguinity are a child, grandchild, parent, grandparent, brother, sister, uncle, aunt, niece, or nephew;

(B) examples of an individual within the second degree by affinity are a spouse, a person related to a spouse within the second degree by consanguinity, or a spouse of such a person;

(C) an individual adopted into a family is considered a Relative on the same basis as a natural born family member; and

(D) an individual is considered a spouse even if the marriage has been dissolved by death or divorce if there are surviving children of that marriage.

D. Enforcement

(1) The Oversight Committee shall enforce this Code with respect to Employees through the CEO. The CEO is responsible for implementing this Code with respect to Employees and PIC Members. An Employee who violates any provision of the Code is subject to termination of the employee's employment or another employment-related sanction.

(2) The Oversight Committee shall enforce this Code with respect to individual Oversight Committee Members through resolutions of reprimand, censure, or other appropriate parliamentary measures, including requests for resignation.

(3) An Oversight Committee Member, PIC Member, or Employee who violates any applicable federal or Texas law or rule may be subject to civil or criminal penalties in addition to any employment-related sanction.

II. STANDARDS OF CONDUCT

A. Expected Conduct of Oversight Committee Members, PIC Members, and Employees

All Oversight Committee Members, PIC Members, and Employees shall:

(1) familiarize themselves with the Code and should be specifically knowledgeable of Chapter 102, *Health & Safety Code*, Chapter 572, *Government Code*, and Sections 36.02 (Bribery), 36.07 (Acceptance of Honorarium), 36.08 (Gift to Public Servant), 39.02 (Abuse of Official Capacity), and 39.06 (Misuse of Official Information), *Penal Code*;

(2) abide by all applicable federal and Texas laws, administrative rules, and CPRIT conduct policies, including this Code. The Code does not supersede any applicable federal or Texas law or administrative rule;

(3) perform his or her official duties in a lawful, professional, and ethical manner;

(4) practice responsible stewardship of CPRIT resources; and

(5) report any conduct or activity that the employee believes to be in violation of this Code of Conduct policy to the Chief Compliance Officer or the General Counsel, as may be appropriate. Retaliatory action may not be taken against a person who makes a good faith report of a violation involving another person.

B. Prohibited Conduct

An Oversight Committee Member, a PIC Member, an Employee, or the spouse of an Oversight Committee Member, a PIC Member, or an Employee shall not:

- (1) accept or solicit any gift, favor, or service that could reasonably tend to influence member or employee in the discharge of official duties, or that the member, employee, or spouse of the member or employee knows or should know is being offered with the intent to influence the member's or employee's official conduct;
- (2) intentionally or knowingly solicit, accept, or agree to accept any benefit for exercising the member's official powers or performing the member's or employee's official duties in favor or another;
- (3) disclose confidential information, information that is excepted from public disclosure under the Texas Public Information Act, or information that has been ordered sealed by a court, that was acquired by reason of the member's or employee's official position, or accept other employment, including self-employment, or engage in a business, charity, nonprofit organization, or professional activity that the member or employee might reasonably expect would require or induce the member or employee to disclose confidential information, information that is excepted from public disclosure under the Texas Public Information Act, or information that has been ordered sealed by a court, that was acquired by reason of the employee's official position;
- (4) accept other employment, including self-employment, or compensation that could reasonably impair the member's or employee's independent judgment in the performance of the official duties;
- (5) make personal investments or have a financial interest that could reasonably create a substantial conflict between the member's or employee's private interest and the member's or employee's official duties;
- (6) utilize state time, property, facilities, or equipment for any purpose other than official state business, unless such use is reasonable and incidental and does not result in any direct cost to the state or CPRIT, interfere with the member's or employee's official duties, and interfere with CPRIT functions;
- (7) utilize the member's or employee's official position, or state issued items, such as a badge, indicating such position for financial gain, obtaining privileges, or avoiding consequences of illegal acts;
- (8) knowingly make misleading statements, either oral or written, or provide false information, in the course of official state business;
- (9) engage in any political activity while on state time or utilize state resources for any political activity.

(10) lease, directly or indirectly, any property, capital equipment, employee or service to a Grant Recipient;

(11) submit a grant application to CPRIT;

(12) participate in a matter before CPRIT that involves a business, contract, property, or investment held by the person if it is reasonably foreseeable that CPRIT action on the matter would confer a benefit to the person by or through the business, contract, property, or investment;

(13) recommend or cause discretionary CPRIT business to be transacted with or for the benefit of a Relative;

(14) represent any person in any action or proceeding before or involving the interests of CPRIT except as a duly authorized representative or agent of CPRIT;

(15) serve on a CPRIT Grant Recipient's board of directors or similar committee that exercises governing powers over the Grant Recipient. This prohibition also applies to serving on the board of directors or similar committee of a non-profit foundation established to benefit the Grant Recipient;

(16) use confidential information, or knowledge of non-public decisions related to CPRIT Grant Applicants, received by virtue of the individual's employment or official duties associated with CPRIT, to make an investment or take some other action to realize a personal financial benefit; or

(17) copyright or patent any work produced or developed as part of the individual's service to or employment with CPRIT when the work is related to a CPRIT goal, project, or concern.

C. Special Provisions

(1) An Oversight Committee Member, an Employee, or the spouse of an Oversight Committee Member shall not be employed by or participate in the management of a business entity or other organization receiving money from CPRIT.

(2) An Oversight Committee Member, an Employee, or the spouse of an Oversight Committee Member shall not own or control, directly or indirectly, an interest in a business or entity or other organization receiving money from CPRIT, except that the prohibition does not apply to ownership of shares in a publicly traded mutual fund or similar investment vehicle in which the person does not exercise any discretion regarding the investment of the assets of the fund or other investment vehicle.

(3) An Oversight Committee Member or Employee shall not have an office in a facility

owned by a business entity or other organization receiving or applying to receive money from CPRIT.

(4) An Oversight Committee Member or Employee shall not solicit, agree to accept, or accept an honorarium in consideration for services the Oversight Committee Member or the Employee would not have been asked to provide but for the person's official position.

(5) An Oversight Committee Member or the spouse of an Oversight Committee Member shall not use or receive a substantial amount of tangible goods, services, or money from CPRIT other than reimbursement authorized for Oversight Committee Members attendance or expenses.

(6) A former Oversight Committee Member or former CEO may not make any communication to or appearance before a current Oversight Committee Member or Employee before the second anniversary of the date the former Oversight Committee Member or former CEO ceased to be an Oversight Committee Member or CEO if the communication is made:

(a) with the intent to influence a decision or with intent to cause any action or inaction; and

(b) on behalf of any person or business entity in connection with any matter on which the former Oversight Committee Member or former CEO seeks action by CPRIT.

(7) A former Oversight Committee Member or former Employee may not represent any person or entity, or receive compensation for services rendered on behalf of any person or entity, regarding a particular matter in which the former Oversight Committee Member or Employee participated during the period of state service or employment, either through personal involvement or because the case or proceeding was a matter within the Oversight Committee Member's or Employee's official responsibility.

(a) This subsection applies to an Employee who is compensated, as of the last date of state employment, at or above the amount prescribed by the General Appropriations Act for step 1, salary group 17, of the position classification salary schedule, including an employee who is exempt from the state's position classification plan.

(b) For purposes of this subsection, the term "participated" means to have taken action through decision, approval, disapproval, recommendation, giving advice, investigation, or similar action.

(c) For purposes of this subsection, the term "particular matter" means a specific investigation, application, request for a ruling or determination, rulemaking proceeding, contract, claim, accusation, charge, arrest, or judicial or other proceeding, except that the

prohibition of this subsection does not apply to a rulemaking proceeding that was conducted before the Oversight Committee Member's or Employee's service or employment ceased.

(8) CPRIT may not enter into an agreement or transaction with a former Oversight Committee Member or former Employee, or a business entity or other organization in which a former Oversight Committee Member or former Employee owns or controls an interest or serves on the governing board, on or before the first anniversary of the date the person ceased to be an Oversight Committee Member or Employee. Nothing herein prevents a business entity or organization that would otherwise be prohibited from entering into an agreement or transacting with CPRIT under this subsection from applying for or receiving grant funds.

D. Nepotism

(1) Except as provided in subsection (2), CPRIT may not employ a person who is a Relative of an Oversight Committee Member or Employee. For purposes of this section, the prohibition on employment includes employment as a consultant to CPRIT.

(2) This subsection does not prohibit the continued employment of a person who has been working for CPRIT for at least 90 consecutive days before the date of the related Oversight Committee Member's appointment.

E. Outside Employment or Business Activity

(1) An Employee may not engage in outside employment, business, or other activities that detract from the individual's ability to reasonably fulfill responsibilities to CPRIT.

(2) An Employee (other than the CEO) must obtain advance written approval from the CEO for any outside employment or business activity, including service on the board of directors of a business or non-profit organization. The CEO shall notify the Audit Subcommittee in writing concerning any approval given for outside employment or other business activity by Employees, including the nature of the employment or other business activity.

(3) The CEO must obtain advance approval from the Oversight Committee if the CEO intends to engage in outside employment or other business activities, including service on the board of directors for a business or non-profit organization.

(4) The CEO shall report to the Oversight Committee annually all approved outside employment or business activities of Employees. The report shall be submitted to the Oversight Committee no later than September 30.

III. CONFLICTS OF INTEREST

A. Decision-Making Based on Merit.

Oversight Committee Members, PIC Members, and Employees shall base CPRIT business transactions on professional integrity and competence, financial merit and benefit to CPRIT, and, as required, in accordance with procurement laws for state agencies.

B. Conflict of Interest Requirements.

(1) The Oversight Committee adopts herein by reference the statutory requirements regarding conflicts of interest, Sections 102.106 – 102.1064, *Health & Safety Code*, and CPRIT's administrative rules, Section 702.11 – 702.17, and any updates thereto.

(2) The conflict of interest statutory and administrative rule provisions apply to any decision to commit CPRIT funds, whether or not the commitment is part of the grant award process or to a Grant Applicant.

IV. GIFTS AND ENTERTAINMENT

A. Prohibition Against Acceptance of Gifts or Consideration

Except as provided herein, Oversight Committee Members, PIC Members, and Employees may not accept gifts, benefits, consideration or anything reasonably regarded as a financial gain or advantage.

B. Exceptions

The prohibition against acceptance of a gift or consideration does not apply to the following items so long as the acceptance of such an item does not violate Section II(B)(1) or any other applicable law and the Oversight Committee, PIC Member, or Employee has no reason to believe that a gift or consideration that would otherwise be prohibited is being offered through an intermediary:

(1) an item with a value less than \$50, excluding cash or a negotiable instrument as described by 3.104, Business & Commerce Code or a gift or other benefit conferred on account of kinship;

(2) gifts or consideration of any value provided to the Oversight Committee Member, PIC Member, or Employee by a personal friend or colleague, so long as:

(a) The gift or consideration is given based solely on an existing personal, professional, or business relationship independent of the Oversight Committee Member's, PIC

Member's, or Employee's official status;

(b) The personal friend or colleague, or a Relative of the personal friend or colleague, is not an employee or the member of the governing board of an entity receiving or applying to receive money from CPRIT; and

(c) The Oversight Committee Member, the PIC Member, or the Employee has no reason to believe that the gift or consideration is being offered through the personal friend or colleague as an intermediary; and

(3) payments to which the Oversight Committee Member, PIC Member, or Employee is lawfully entitled in a capacity other than the individual's official status;

(4) a political contribution as defined by Title 15, Election Code;

(7) items issued by CPRIT or other governmental entities to the Oversight Committee Member, PIC Member, or Employee that allow the use of property or facilities owned, leased, or operated by CPRIT or other governmental entity;

(6) food, lodging, transportation, or entertainment accepted as a guest with the donor present, and, if the done is required by law to report those items, reported by the done in accordance with that law;

(7) Lodging, transportation, and meals described by Chapter 36, Section 36.07(b) (Acceptance of Honorariums), Penal Code;

(8) books, pamphlets, articles, or other similar materials that contain information directly related to the job duties of an Oversight Committee Member, Employee, or PIC Member and that are accepted by the individual on behalf of CPRIT for use in performing the individual's job duties; and

(9) registration or admittance fees for seminars, conferences, or other sponsored events that may involve entertainment or recreation. If the seminar, conference, or other sponsored event is hosted or paid for by a business entity or organization applying for or receiving CPRIT funds, prior written approval to attend the event is required and the entity sponsoring or paying for the event must attend. For Oversight Committee Members, approval may be provided by the Oversight Committee chair (or vice chair if the chair is seeking approval). For a PIC Member or Employee, approval may be provided by the CEO (or the Oversight Committee chair if the CEO is seeking approval.)

C. Gifts or Consideration from Lobbyists

An Oversight Committee Member, PIC Member, or Employee shall immediately report to the

Chief Compliance Officer any gift or consideration if the gift or consideration is provided by a registered lobbyist.

D. Return of Prohibited Gifts or Consideration

An Oversight Committee Member, PIC Member, or Employee who receives a prohibited gift or other prohibited consideration shall make every effort to return the gift or consideration to its source or, if that is not possible or feasible, donate the gift or consideration to a recognized tax-exempt charitable organization formed for educational, religious, or scientific purposes.

E. Reporting Requirements

An Oversight Committee Member, PIC Member, or Employee shall report to CPRIT's Chief Compliance Officer any gift, grant, or consideration provided to the individual as soon as possible, but no later than thirty (30) days after receipt of the gift, grant or consideration.

- (1) The individual shall provide the name of the donor, the date of receipt, and amount of the gift, grant, or consideration.
- (2) The reporting requirement applies to any gifts, grants, or other consideration provided to an Oversight Committee Member, PIC Member, or Employee, except for those specified in subsection (B).
- (3) Notwithstanding the foregoing, information related to subsections (B)(7) and (9) shall be reported to the Chief Compliance Officer.

V. FINANCIAL DISCLOSURE AND COMPLIANCE STATEMENTS

Unless otherwise directed, the following statements and certifications shall be completed and returned to the Chief Compliance Officer. Unless otherwise specified, the statements and certifications shall be filed with the Chief Compliance Officer no later than 30 days following the date of the member's or employee's appointment or employment and then annually thereafter on or before September 30th. The CEO may postpone a filing deadline for not more than 60 days on the written request of an Oversight Committee Member, PIC Member, or Employee, or for an additional period for good cause.

A. Financial Disclosure Statements.

- (1) An Oversight Committee Member and the CEO shall file a financial disclosure statement with the Chief Compliance Officer not later than the 30th day after the date of appointment or employment, and not later than April 30 of each year thereafter.
- (2) CPRIT must maintain a financial disclosure statement for at least five years after the date

it is filed.

(3) Oversight Committee Members who are required to file disclosure statements with the Texas Ethics Commission shall file those statements in the form and time prescribed by law.

B. Ethics Compliance Statements.

An Oversight Committee Member, PIC Member, or Employee, including an interim Employee, must sign, date, and file an ethics compliance statement acknowledging that the individual has received and read this Code, that the individual will comply with its provisions, and that it is the individual's duty to report knowledge of any act or failure to act that is a violation of this Code.

C. Conflict of Interest Compliance Statements.

An Oversight Committee Member, PIC Member, or Employee, including an interim Employee, must sign, date, and file a conflict of interest compliance statement acknowledging that the individual has received and read the statutory and administrative rules related to conflicts of interest, that they will comply with its provisions, and that it is their duty to report when they have knowledge of any act or failure to act that is a violation of the conflict of interest statutes or rules.

D. Non-Disclosure Agreements

An Oversight Committee Member, PIC Member, or Employee, including an interim Employee, must sign, date, and file a non-disclosure agreement.

E. Certification of No Financial Interest.

(1) Before the Oversight Committee votes on proposed grant awards, each Oversight Committee Member shall certify that he or she does not have a financial interest in a business entity or other organization applying for or receiving CPRIT funds.

(2) For purposes of this certification, "financial interest" means:

(a) ownership of stock or shares of the business entity; or

(b) ownership of any sum of the fair market value of the business entity; or

(c) receipt of any sum of the person's gross income for the preceding calendar year from the business entity; or

(d) any private investment in the business entity, such as debt obligation or equity interest that is not a publicly traded security.

(3) Oversight Committee Members shall sign, date, and file the certification not later than the day preceding the date of the Oversight Committee meeting scheduled to consider the proposed grant awards.

(4) An Oversight Committee Member is prohibited from participating in any action taken regarding the proposed grant awards if the member fails to file the required certification prior to the day preceding the Oversight Committee meeting. However, upon a showing of good cause, the Oversight Committee may vote to allow the Oversight Committee Member to participate in action taken related to the proposed grant awards, so long as the member certifies for the record in the open meeting that the member does not have a financial interest in a business entity or other organization applying for or receiving grant funds. Immediately following the meeting, the Oversight Committee Member must complete the certification.

F. Statement of No Communication.

(1) Before the Oversight Committee awards a grant, each Oversight Committee Member and PIC Member shall certify that he or she has not communicated with any Grant Applicant for CPRIT funds regarding the substance of a pending application. The period of the restricted communication begins on the first day that grant applications are accepted by CPRIT until the Grant Applicant receives notice regarding a final decision on the grant application.

(2) In addition to the certification required in subsection (1), each PIC Member must also certify that the PIC Member did not communicate individually with one or more Oversight Committee members about a pending grant recommendation prior to the time that the PIC submits its list of recommendations to the Oversight Committee and the CEO has submitted the affidavits required by statute. Communication that involves one or more PIC members responding to a question raised by an Oversight Committee Member does not constitute a prohibited communication so long as the question and the response is provided in writing to all Oversight Committee Members contemporaneously.

G. Disclosure of Political Contributions Pursuant to Health & Safety Code § 102.101(f)

Each Oversight Committee member shall submit the information required by Health & Safety Code 102.101(f) to the Chief Compliance Officer no later than January 31 of each year. After the initial disclosure is made, each subsequent disclosure by the Oversight Committee member shall update the information for the previous calendar year.



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: CYNTHIA MULROW, MD
SUBJECT: DIVERSITY SUBCOMMITTEE REPORT
DATE: AUGUST 13, 2014

The subcommittee met and discussed items on the attached agenda.

Agency administrative efforts related to Historically Underutilized Businesses (HUB)

Charlotte Craig, Purchaser, is charged with making sure that CPRIT's existing HUB plan conforms to new guidance distributed by the Comptroller of Public Accounts (CPA) and that CPRIT implements the plan. Charlotte discussed specifics of the agency's HUB Plan (attached) and efforts to increase HUB use by CPRIT. These include using the CPA's Centralized Master Bidders List and HUB search to ensure a good faith concerted effort is made to increase awards of goods and services contracts to HUBs. Internal agency meetings with HUB vendors and attending HUB Forums where various state agencies meet with vendors to discuss procurement opportunities will be implemented and attended. One possibility to increase participation is to use HUB resellers instead of buying directly from a manufacturer, for instance with respect to Dell information technology acquisitions.

Previous agency annual HUB reports were reviewed and the agency's difficulties in meeting statewide goals were discussed. For "Other Services", the agency's success has been 5% or less between 2010 and 2012 when the goal is 24.6%. The disparity is due to the large services contract with SRA International which manages CPRIT's award opportunity solicitations, applications, peer review, Program Integration and Oversight Committee reviews, contracting, and post-award monitoring. No HUB vendors offer comparable services and the SRA contract amounts overwhelm other HUB services contracts for reporting purposes. CPRIT did switch to a HUB vendor for its 2013 annual financial report. CPRIT has had success in meeting the statewide goal of 21% for "Commodity Purchasing" (18% in 2010, 41% in 2011, and 20% in 2012). The 2013 HUB report is due at the end of September 2014.

Programmatic Ethnicity Data

Ramona Magid, Senior Program Manager for Prevention, discussed ethnicity data from CPRIT's three programs (see "Program Ethnicity Data" handout attached). Across all programs, the ethnicity of the principal investigators is 56% White, 30% Asian, with small percentages for Blacks and Hispanics. In Research, 95% of the recruited scholars are either White or Asian. Blacks and Hispanics together make up only 5%. The ethnicity of the principal investigator is predominately White (62%). Asians make up 33%, Hispanics 5%, and less than 1% is Black.

Most prevention projects serve all ethnicities. Of those that specify populations served, 28% serve Hispanic communities, 9% Black, and 7% Asian. While prevention focuses on populations served by the grants, project director ethnicity shows over 50% White, 28% Hispanic, 13% Asian, and 4% Black. Four percent did not report ethnicity in their applications. Principal investigator ethnicity is heavily skewed – 93% White and 7% Asian, with no Hispanic or Black representation.

Scientific Research Program

Michael Brown, Senior Program Manager for Research, discussed diversity in the Research Training Award programs and discussions within the University Advisory Committee. The Scientific Research Office is currently compiling diversity data and success stories for the training award programs. Preliminary data have been collected for all except one training program and are listed in the chart below. The percentage of ethnic minorities that have been recruited as participants in the training programs is higher than that of principal investigators of research grants; however it remains low in comparison to Whites and Asians participating in the same programs. While all of the programs have plans in place to recruit underserved populations, the pipeline of minorities for recruitment is not as plentiful as that of other groups. There were suggestions presented for how to develop further requests for applications to include a requirement for a “Minority Recruitment Plan” that would be evaluated by peer reviewers as part of the next training award RFA. Additionally, review criteria could be expanded to emphasize the importance of the recruitment of minorities through a series of targeted questions posed to panel members as they review applications.

Trainee Category	Number of Applicants Enrolled	Number of Applicants Supported by this Grant	Number of Males	Number of Females	Number of Black or African Americans	Number of Asian, native Hawaiian, or Pacific Islanders	Number of Caucasian or Whites	Number of Hispanic or Latinos	Number of Native Americans	Number of others*
Postdoctoral	206	112	66	46	4	59	37	9	0	3
Predoctoral	158	91	39	40	1	46	22	8	0	1
Undergraduate	669	324	126	200	19	96	153	53	1	0
Total	1033	527	231	286	24	201	212	70	2	4
			Training Program Participant Totals		5%	38%	40%	13%	0%	1%
			Undergrad Training Participants		6%	30%	47%	16%	0%	0%
			Overall Research Program		1%	33%	62%	5%	0%	0%

*Non-Black African/Middle Eastern

The University Advisory Committee has met twice and had brief discussions regarding minority issues. The discussions centered on how increasing the diversity of researchers and trainees could be achieved through CPRIT funding mechanisms.

Their suggestions included:

- ensuring that the review committees understand that the recruitment of underserved populations is a high priority for CPRIT,
- targeting research applications on cancers prevalent in minority populations, and
- awarding supplements to research grants for support of underserved students and postdoctoral trainees.

The UAC has subsequently developed a whitepaper that captured these recommendations.

Discussion

The subcommittee is initially inclined to support adding weights to encourage programmatic improvement in the numbers of participants from underrepresented population groups as discussed for Research Programs. However, compliance with all applicable state and federal requirements concerning promotion of individuals from underrepresented population groups should be assured. Consideration of using “socioeconomic status” instead of ethnic classification is a possible alternative that could achieve the same purpose without conflicting with legal provisions.

Other than agency operational HUB activities, emphasis on diversity and improving programmatic participation may need to be added to the charge of each programmatic subcommittee (prevention, research, product development) to ensure proper emphasis and implementation.

Regardless, diversity must be promoted. Since awardees generally are part of larger organizations (especially research) with similar diversity requirements and goals, CPRIT should avoid infringing upon other entities’ responsibilities. However, CPRIT staff needs to continue its efforts to improve data collection from its awardees concerning their use of HUB vendors, ethnicity and gender data of investigators and their staff, and employment at private sector entities receiving CPRIT product development awards.

Recommendation(s)

The subcommittee has requested that staff investigate the issue of using “socioeconomic status” as a more suitable indicator than “underrepresented population group” to target training and education efforts. No action is needed on this matter at this time. This should be discussed at the next subcommittee meeting.

In addition, along those same lines, the subcommittee is interested in finding ways to target some of CPRIT’s educational/training activities to younger individuals in high schools and community colleges with high numbers of individuals from lower socioeconomic groups. Doing so could impact positively the “pipeline” issue of an insufficient number of these individuals for advanced institutions of higher education to incorporate in their programs.

No additional recommendations at this time other than to endorse efforts underway in the Scientific Research Program provided the Scientific Research Oversight Subcommittee concurs. The Diversity Subcommittee will continue to monitor progress in facilitating diversity among the three programs and agency operations.

Attachments

Agenda, Diversity Subcommittee, August 8, 2014
CPRIT Historically Underutilized Business Plan
Program Ethnicity Data



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

Diversity Subcommittee

August 8, 2014, 10:30am Meeting Agenda

1. Call to Order
2. Agency Historically Underutilized Businesses (HUB) Activities
3. Programmatic Ethnicity Data
4. Scientific Research Program
 - a. Training Grants
 - b. University Advisory Committee Discussion
5. Other Discussion
6. Adjourn



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: DIVERSITY SUBCOMMITTEE MEMBERS
FROM: HEIDI MCCONNELL
SUBJECT: CPRIT HUB PLAN AND IMPLEMENTATION
DATE: AUGUST 5, 2014

Charlotte Craig has been CPRIT's Purchaser since June 1, 2014. She is a Certified Texas Purchasing Manager (CTPM) and a Certified Texas Contract Manager (CTCM) with extensive experience working at state agencies. Since Ms. Craig has come on board she ensures that CPRIT's existing HUB Plan continues to conform to new guidance distributed by the Comptroller of Public Accounts (CPA) and that CPRIT implements the plan. Changes in implementation that are occurring since Charlotte joined CPRIT are:

1. Posting information about CPRIT procurement on the agency's website under a landing page, *Doing Business With CPRIT*, with contact information to the CPA's Statewide HUB Program, and
2. Attending HUB vendor forums to inform certified HUB state vendors about specific CPRIT procurement opportunities.

With respect to some policies changes to the Statewide HUB Program, "Veterans" have been added as a category. In addition, the CPA has recently issued some changes to the administrative rules which are available for public comment.

CPRIT's HUB Plan and the *Doing Business With CPRIT* document are attached.



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

Historically Underutilized Business Plan

The Historically Underutilized Businesses (HUB)

The HUB program is governed by the Texas Government Code, Title 10, Subtitle D, Chapter 2161. The purpose of the program is to increase contracting opportunities with the State of Texas for minority and women-owned businesses.

HUB Participation

Work to continuously develop strategies to increase the agency's HUB participation and to ensure that the agency complies in fact and spirit, with the laws, and rules established for the HUB program.

HUB Outreach

Focus on the manner in which awards are distributed among the various ethnic HUB groups. Agency goal is to ensure that contract awards are distributed among all HUB groups and not concentrated within just one or two ethnic HUB groups. Distribute agency information regarding the HUB program at various HUB events.

HUB Goal

To make a good faith effort to award procurement opportunities to businesses certified as historically underutilized.

HUB Objective

To make a good faith effort to increase utilization of historically underutilized businesses.

- Complying with HUB planning and reporting requirements;
- Utilizing the CPA's Centralized Master Bidders List (CMBL), and HUB search to ensure that a good faith effort is made to increase the award of goods and services contracts to HUBs;
- Adhering to the HUB purchasing procedures and requirements established by the CPA's Texas Procurement and Support Services division;
- Informing staff of procurement procedures that encourage HUBs to compete for state contracts;
- Holding internal agency meetings with HUB vendors;
- Attending HUB Workgroup Discussion (HWD), meetings, HUB small business trainings and HUB Forums;
- Utilizing HUB resellers from the Department of Information Resources' contracts as often as possible; and
- Promoting historically underutilized businesses in the competitive bid process on all goods and services.



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

DOING BUSINESS WITH CPRIT

Cancer Prevention & Research Institute of Texas Mission

The Texas Cancer Prevention & Research Institute of Texas (CPRIT) creates and expedites innovation in the area of cancer research to enhance the potential for a medical or scientific breakthrough in the prevention of cancer and cures for cancer; attracts, creates, or expands research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in this state; and develops and implements the Texas Cancer Plan.

The goods and services procured for agency use include but are not limited to the following:

- Supplies and equipment
- Contracts for the purchase of goods and services
- Temporary personnel needs
- Consulting services
- Contract labor
- Maintenance contracts
- Interagency contracts

Centralized Master Bidders List (CMBL)

The CMBL is a mailing list for vendors to receive bids based on the products or services which can be provided to the State of Texas. Registration on the CMBL is an effective tool for businesses to use to market their products and services to state agencies and institutions of higher education. The CMBL can be accessed at the following link:

www.cpa.state.tx.us/procurement/prog/cmb1

Registration is online at: http://cmb1reg.cpa.state.tx.us/login_cmb1_only.cfm or by submitting an application with a \$70.00 annual registration fee.

Historically Underutilized Business (HUB)

The Comptroller of Public Accounts (CPA) administers Texas' Statewide Historically Underutilized Business (HUB) Program in accordance with Texas Government Code (TGC), Chapter 2161 and Texas Administrative Code (TAC), Title 34, Part 1, Chapter 20, Subchapter B.

The HUB program is designed to facilitate the participation of minority and women owned businesses in State agency procurement opportunities. To apply for HUB certification, contact the Statewide HUB Program at:

Statewide HUB Program
Texas Comptroller of Public Accounts
<http://www.window.state.tx.us/procurement/prog/hub>
Email: cpa.hub@cpa.state.tx.us
Phone: (512) 463-5872 or (888) 863-5881

Electronic State Business Daily (ESBD)

The ESBD was created pursuant by Texas Government Code, S 2155.074(I) and the Administrative Procedures Act as a means for all state agencies to give notice directly and electronically on the Internet before making procurement with a value exceeding \$25,000. The ESBD can be accessed at: <http://esbd.cpa.state.tx.us>

CPRIT Information:

CPRIT Website: <http://www.cprit.state.tx.us>

Purchasing and HUB Contact: Charlotte Craig, CTPM, CTCM

Email: ccraig@cprit.state.tx.us

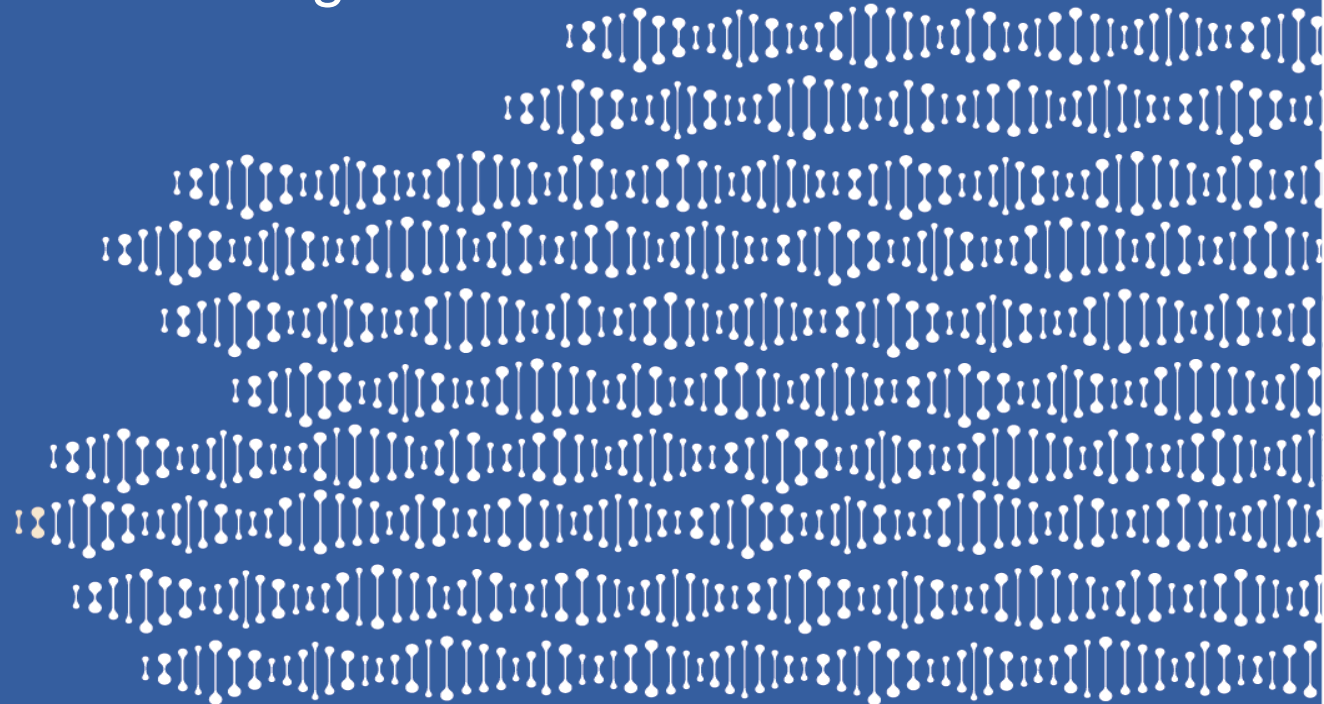
Phone: 512-305-8498 Fax: 512-475-2563



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

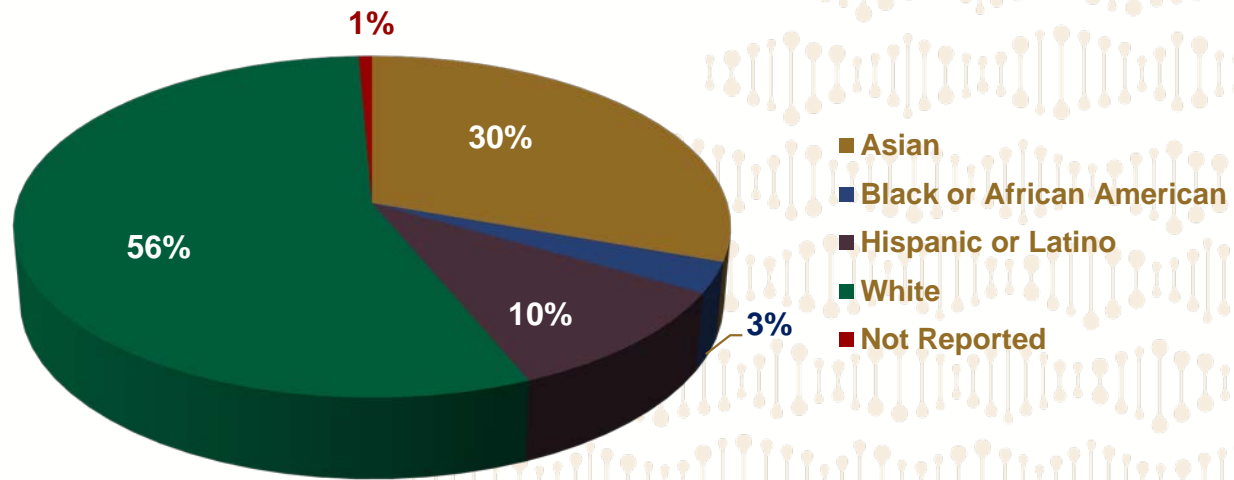
Programmatic Ethnicity Data

Presented by: Ramona Magid



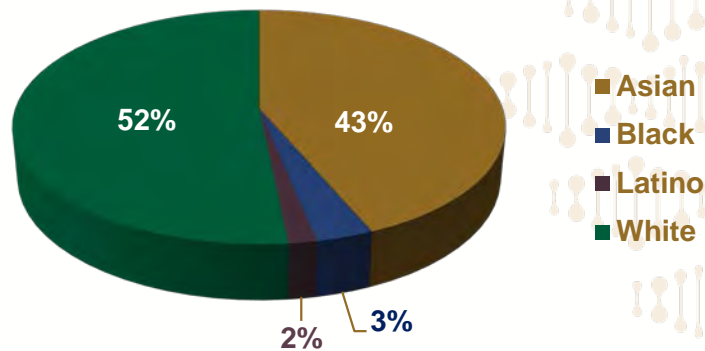
All Programs

Ethnicity of PI/PD

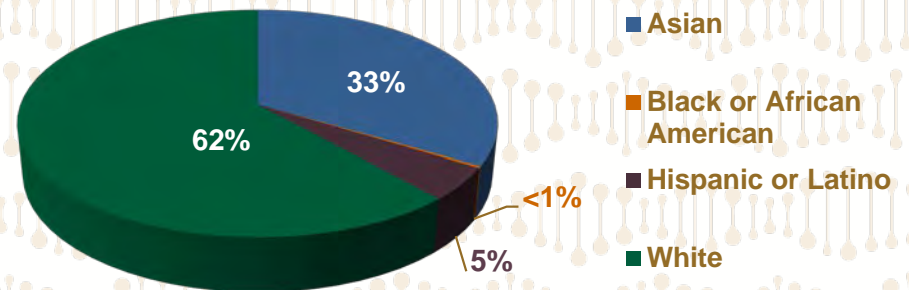


Research

**CPRIT Scholars --
Ethnicity**

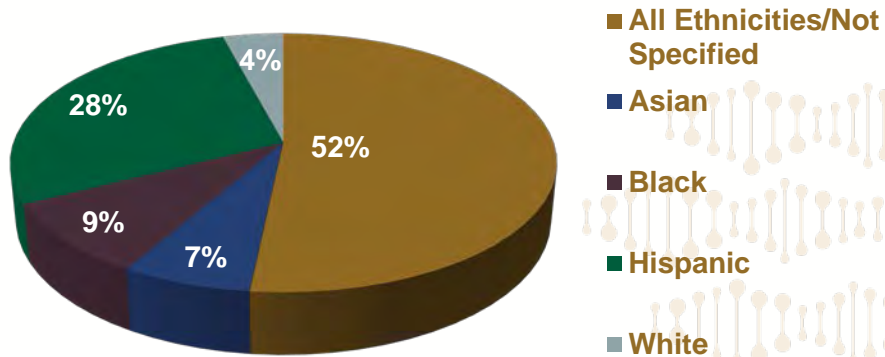


**Ethnicity of Principal
Investigator - Research**

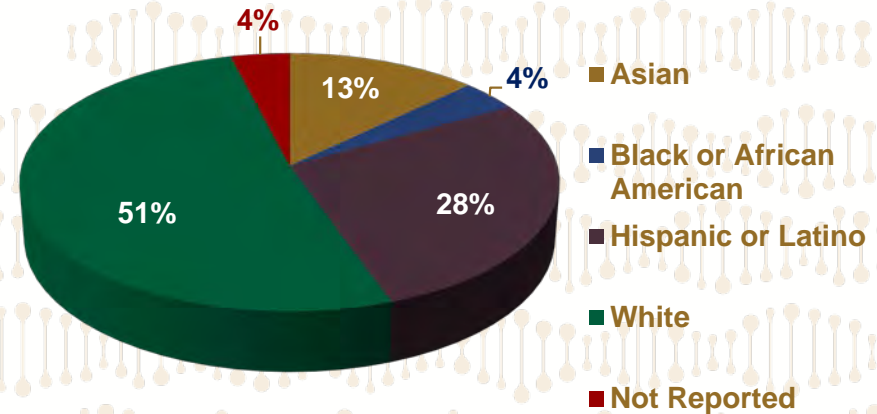


Prevention

Populations Served -- Prevention Projects



Prevention -- Ethnicity of Project Director



Product Development

Ethnicity of Principal Investigator - Product Development

