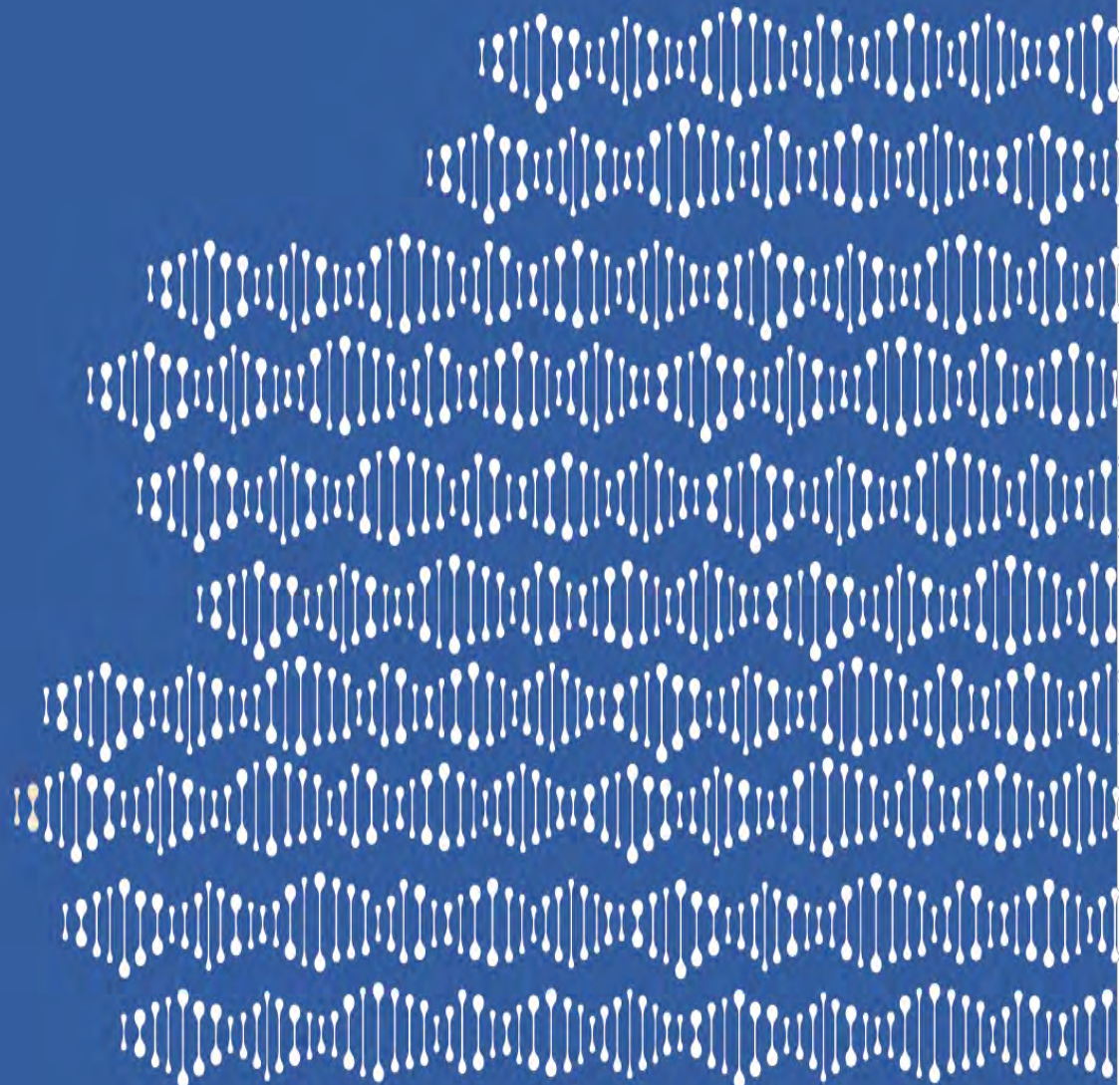




CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Meeting

November 19, 2014





Summary Overview of the November 19, 2014, Oversight Committee Meeting

Please find enclosed the packet for the next meeting of the CPRIT Oversight Committee to be held on Wednesday, November 19, 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, the recent meeting of the joint newly formed Advisory Committee for Product Development (ACPD) and Economic Terms subcommittee, and other issues as appropriate.

Chief Compliance Officer Report

David Reisman will report on the status of required grantee reports, desk reviews, and grantee training.

Chief Operating Officer Report

Heidi McConnell will present the FY2014 year-end financial report including key performance measures, FY2015 operating budget, and debt issuance for FY2014.

Programs Priority Project

Mr. Roberts and the Prevention, Scientific Research, and Product Development Officers will present the draft Program Priorities Report that incorporates final recommendations from each of the program subcommittees. The public input on the program priorities will also be discussed. The Oversight Committee must set program priorities annually pursuant to Texas Health & Safety Code §102.107 and consider those priorities when awarding grants.

Chief Prevention and Communications Officer Report and Grant Award Recommendations

Dr. Becky Garcia will provide an update regarding the communications initiatives, including plans for the 2015 CPRIT Conference. In addition, Dr. Garcia will present the Program Integration Committee's recommendations for five 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 eight recruitment awards and provide an update regarding the current review process. In addition, Dr. Kripke will deliver the Scientific Review Council's recommendations regarding increased funding for two grant projects previously approved for grant awards. Dr. Kripke will also report on the September meeting of the Advisory Committee on Childhood Cancer (ACCC) and the ACCC's proposed charter.

*Oversight Committee: William Rice, M.D., Chair | Angelos Angelou | Gerald Geistweidt | Pete Geren | Ned Holmes
Amy Mitchell | Will Montgomery | Cynthia D. Mulrow, M.D., MSc., MACP | Craig Rosenfeld, M.D.*

Chief Product Development Officer Program Overview and Grant Award

Recommendations

Dr. Tom Goodman will provide an update on the Product Development program and present the Program Integration Committee's recommendations for 20 Early Translational Research Awards. Dr. Goodman will also provide an update related to the process for establishing revenue sharing terms for product development awards.

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.

Appointments to the Scientific Research and Prevention Programs Committee and the Advisory Committee on Product Development (ACPD)

Mr. Roberts has appointed two new members to the CPRIT's Scientific Research and Prevention Programs Committees, as well as nine members to the newly formed ACPD. Texas Health & Safety Code §102.151 requires the CEO's appointments to be approved by the Oversight Committee. A biographical sketch for each appointee is included in the board packet.

Annual Review of the CEO

The Oversight Committee will conduct the annual performance evaluation of the CEO, led by the Board Governance subcommittee, at its February 2015 meeting. Dr. Bill Rice, Oversight Committee Chair, will present the proposed process for discussion.

Internal Audit Reports, Internal Audit Plan, and Internal Audit Services Contract

Several audit-related items will be offered for Oversight Committee approval. Grant Thornton, LLP, CPRIT's internal auditor, will present recently completed operational audits and grantee audits. CPRIT's FY2015 Internal Audit Plan, FY2014 Internal Audit Annual Report will also be reviewed. Ms. McConnell will address CPRIT staff's recommendation for FY2015 internal audit services.

Changes to Agency Administrative Rules

Kristen Doyle, General Counsel, will present proposed changes to the agency's administrative rules. Texas Health and Safety Code § 102.108 authorizes the Oversight Committee to implement rules to administer CPRIT's statute.

- Rule changes recommended for final adoption include new rule § 701.35, which addresses a statutory requirement that CPRIT provide a process for the public to request initiation of a rulemaking project and amendments to §§ 703.11 and 703.13 that provide clarity for grantees regarding required reports. These changes were initially discussed at the August 20 meeting and no comments from the public were received.
- Proposed rule changes recommended for publication in the *Texas Register* will affect §703.6 to incorporate the Chief Compliance Officer in the review panel process and §703.11 to provide additional clarity regarding matching fund requirements. Once the public has had the opportunity to provide input regarding the changes, the rule changes will be brought back to the Oversight Committee in February 2015 for adoption.



Oversight Committee Meeting Agenda

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

November 19, 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 August 20 and September 3, 2014 meetings

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
 - 2015 Biennial Conference

TAB 2

TAB 3

TAB 4

TAB 5

Program Activities

9. Program Priorities Project Pursuant to §102.107(2)
10. Chief Prevention and Communications Officer Report
 - Grant Award Recommendations
11. Chief Scientific Officer Report
 - Grant Award Recommendations
 - Budget Increase Approval for Grant ID RP130256 and RP130397
12. Chief Product Development Officer Report
 - Grant Award Recommendations
13. Scientific Research and Prevention Program Committee Appointments

TAB 6

TAB 7

TAB 8

TAB 9

TAB 10

Agency Business

- | | |
|--|---------------|
| 14. Personnel Action – Annual Review of Chief Executive Officer | TAB 11 |
| 15. Internal Audit Reports | TAB 12 |
| • Governance Internal Audit Report | |
| • Grants Management Internal Audit Report | |
| • IT Internal Audit Report | |
| 16. Internal Audit Plan for FY 2015 | TAB 13 |
| 17. Internal Audit Services Contract for FY 2015 | TAB 13 |
| 18. Internal Audit Report FY 2014 | TAB 13 |
| 19. Biennial Conference Contract | TAB 14 |
| 20. Advisory Committee on Childhood Cancers Charter | TAB 15 |
| 21. Advisory Committee on Product Development Membership | TAB 16 |
| 22. Final Order Approving Amendments to 25 T.A.C. Chapters 701 – 703 | TAB 17 |
| 23. Proposed Amendments to 25 T.A.C. Chapter 703 and Authorization to Publish in the <i>Texas Register</i> | TAB 18 |
| 24. Subcommittee Business | TAB 19 |
| 25. Consultation with General Counsel | |

Closing

26. Future Meeting Dates and Agenda Items
27. 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 & RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Meeting Minutes

August 20, 2014

1. Meeting Called to Order

A quorum being present, Dr. Rice called the Oversight Committee to order at 10:02 A.M.

2. Roll Call /Excused Absences

Ms. Mitchell called the roll. All present except Dr. Rosenfeld. Ms. Mitchell announced that Dr. Rosenfeld had notified CPRIT he would be unable to attend.

MOTION:

Dr. Rice asked for a motion to approve an excused absence for Dr. Rosenfeld.

Motion by: Montgomery

Seconded by: Geren

MOTION CARRIED UNANIMOUSLY

3. Adoption of Minutes from the May 21, 2014 meeting

Dr. Rice informed the committee that the meeting packet included the minutes from the May 21, 2014, meeting. There were no comments.

MOTION:

Dr. Rice called for a motion to approve the minutes.

Motion by: Montgomery

Seconded by: Mulrow

MOTION CARRIED UNANIMOUSLY

4. Public Comments

Dr. Rice informed the committee that no requests for public comment had been received.

5. Chief Executive Officer Report

Dr. Rice recognized Mr. Roberts to present the Chief Executive Officer Report. Mr. Roberts reported the following:

New Employees

Employees that joined CPRIT since the May Oversight Committee meeting were introduced. Cathy Allen, David Escamilla, and Mark McCollum are grant specialists and Wilfredo “Freddy” Ruiz, is a grant accountant.

Dashboard Update

The dashboard was presented with two new elements included. Mr. Roberts called attention to item 6, Revenue Sharing Payments Received. CPRIT recently received a lump sum payment of \$1.2 million from a grantee, Visualase. The payment was triggered by the grant award contract, which permitted Visualase to buy out their ongoing revenue sharing obligation to CPRIT by repaying the grant funds already received from CPRIT plus interest. Visualase exercised this option due to acquisition by another entity.

Kristen Doyle, Chief Advisor and General Counsel, stated that Visualase was awarded the grant in 2010 and the company had received approximately \$1.4 million in grant payments from CPRIT to date. In addition to the \$1.2 lump sum payment, Visualase has already made payments to CPRIT pursuant to the company’s revenue sharing obligations. The total amount paid by Visualase to CPRIT and deposited in the State Treasury over the course of the grant is approximately \$2.1 million.

Facilities Update

CPRIT employees will begin the move to the Wells Fargo Building on August 21. The move must be completed by noon August 22, 2014. Unpacking will occur on August 25 and CPRIT will be fully operational by August 26.

Legislative Activities

The House Select Committee on Economic Development Incentives will hold a meeting at 10:00 A.M. on Wednesday, September 24th on the University of Houston campus in Houston. CPRIT will give a 10 minute overview of its economic incentives and how they will benefit Texas. This overview will largely focus on the Product Development program.

On August 14, CPRIT presented an overview to the Senate Health and Human Service Committee. Hearing materials were distributed to the Oversight Committee. This is the core material to be used during the upcoming session, updated periodically to include items of interest to the legislative members or committees being addressed. The supplemental book contains items of interest, but not necessarily things that will be discussed each meeting.

The meeting with the Senate committee went smoothly. Senator Nelson asked if CPRIT is satisfied with the statutory tools provided to manage the agency, to which Mr. Roberts said he was. Mr. Roberts told the Oversight Committee that he is not satisfied with progress on compliance, but is encouraged by recent developments in the metrics indicating greater compliance. Getting good measures on reporting status is a positive step on which the agency can act. Getting good measures has been difficult with one

hindrance being agency staffing levels. Several positions were left open until the Chief Executive Officer was permanently hired, and he has since moved deliberately to fill new positions and those resulting from routine staff turnover. Mr. Roberts thinks that when CPRIT reaches the full 32 FTE's currently allowed, the current number of compliance staff will not be sufficient to accomplish the compliance level expected. When Mr. Roberts arrived at CPRIT in December 2012, only three employees were reviewing expenditure reimbursement requests and other administrative reports required of nearly 500 grantees. This matter will be discussed with the CPRIT Oversight Committee Audit Subcommittee (Dr. Rice clarified that the compliance, post award process, not the peer review process, is under discussion. Mr. Roberts said he was satisfied with the peer review process.) Of those three employees, two were contract workers. This observation became the basis for Mr. Roberts' legislative request for eight new positions for compliance and to add redundancy in other areas to mitigate risk. CPRIT has more than 500 active awards, each required to submit at least 12 reports yearly. Of the resulting 6,400 required reports each year, 2,100 are financial status reports. As of today, CPRIT's administrative expenses are low: 4.4% - program operation; 1.5% - indirect administration; for a total of 5.9% for overhead. Overhead that is too low can put the enterprise at risk.

On August 15, CPRIT received the Weaver and Tidwell report, which is discussed later, giving a possible approach to enhancing the existing compliance program. Staff hasn't been able to review sufficiently for a meaningful discussion today of its merits and possible shortcomings. Mr. Roberts intends to have a strong compliance program and believes the best compliance program is one in which potential compliance issues are addressed before the issues develop into reportable problems. This means that compliance staff, and everyone in CPRIT, work with grantees to make sure they understand CPRIT requirements, identify issues before they become problems, and operate as partners with our grantees to ensure compliance. It serves no one if CPRIT rejects funding reimbursement to grantees in such a way that thwarts a research or prevention project. Doing so for any reason other than fraud, waste or abuse, will be considered a shortcoming on CPRIT's part.

Since May, Heidi McConnell, Chief Operating Officer, restructured the financial status report (FSR) review process and added more grant accountants. Previously one person was responsible for final approval of all reports. After the restructuring, each grant recipient is permanently assigned to one of three grant accountants. Each accountant is responsible for reviewing and processing the reports submitted by their assigned entity. Every report receives a second review by someone other than the original reviewer. The restructuring and additional staffing distributed workloads, thereby eliminating the bottleneck created by the single-approver process.

CPRIT has early indications that this restructuring is working. In May CPRIT processing time for an FSR was 66 days. By early August the processing time was down to 14 days and some were processed within 24 hours. CPRIT is more responsive to grantees with this new system, answering questions, and reaching out to grantees who have issues with pending reports. For the month of June, CPRIT issued 156 grant vouchers totaling

\$10.4 million dollars. During roughly the same period between mid-July and mid-August, CPRIT issued 312 vouchers totaling \$33.1 million. CPRIT doubled the number of vouchers and tripled amount of reimbursements issued.

Another development since May was the hiring of three grant specialists in addition to a grant accountant, and repositioning Sandra Balderrama as the grant specialists' manager. The first project they undertook was determining the number of delinquent reports: in May, Chief Compliance Officer David Reisman could not determine the number of delinquent FSR's. Since then, that number has been determined to be 180. Now, delinquencies are 157—a direct result of grant specialists opening every active grant to determine the number of delinquent FSR's. Sixty grant projects at 11 entities are at least one FSR behind—some more. Determining these numbers was a month-long effort to open every files for every award CPRIT has ever given. The grants specialists identified reports that were missing in the electronic system, located hard copies in our files, and reported that information to the third party grant management system.

The second project undertaken by the grant specialists and the grant accountants is to reduce the number of delinquent reports, including FSR's. In this regard, staff is working with the individual grantees to notify them of required reports that have not been submitted and provide assistance as the grantees prepare the reports. In early August the total number of delinquent reports was 535. After staff undertook the intensive communications outreach, the number of late reports dropped to 387 in one week. Mr. Roberts said he believes this summary indicates that staff takes noncompliance seriously and aggressively addresses noncompliance issues. Additional steps will be taken and further enhancement to the compliance program will be discussed with the Audit Subcommittee and then the full Oversight Committee. Mr. Roberts concluded by reaffirming that CPRIT's role is to fund and facilitate world class projects and address our mission to mitigate cancer in our lifetimes. This must be done transparently, with accountability and strict documentation to measure that accountability.

Dr. Rice clarified that if an institution gets behind on FSR reports, it must catch up one at a time. Faster turnaround of review means that grantees can catch up faster. Mr. Roberts said the goal is to reach zero delinquencies because they won't be reimbursed if they don't keep in compliance. Mr. Montgomery asked if a zero policy is realistic. Mr. Roberts said there will probably always be some delinquencies, but it will be low and the goal remains zero. Mr. Montgomery asked if the form is too complicated or if staff just don't complete the reports. Ms. Doyle noted that grantees at universities that receive grants from the federal government are also required to file reports each year, although CPRIT requires more backup information, particularly for the financial reports. Restructuring the review and approval process for FSR's has allowed the grant accountants to ask for more information instead of rejecting the entire report, which may expedite the overall review process. Ms. Doyle said the 30-day grace period to file late FSR's after the due date will help with giving time for report preparation before the grantee is at risk for waiving reimbursement. Mr. Montgomery asked if an incomplete report is considered delinquent. Ms. Doyle responded that a report is considered delinquent if no report was filed with CPRIT; an incomplete report filed by the due date

would not be delinquent. Ms. Doyle also said grantees can request a deferral in emergencies to submit a 6-month report instead of a 3-month report. Mr. Geren said many grantees operate in a culture that doesn't put a premium on punctual reporting. He feels it would be beneficial to get inside their systems and see what their processes are and then work with them to reform from the inside. Mr. Roberts said he doesn't feel the institutions consider reporting unimportant, but they have limitations on staffing. Their bookkeeping is such that funds are comingled in a way that researchers get paid for their work but allocation to appropriate grant accounts may linger. Ms. McConnell monitors CPRIT's available funds to be sure sufficient money exists to fund current grants and to make new ones. Mr. Roberts said the compliance program is designed to ensure grantees report as required by the grant contract and state law and administrative rules. Mr. Roberts will be contacting university presidents when it appears a funding cut off could occur. Mr. Geren agreed that speaking with the head of the institutions would be beneficial.

Mr. Montgomery asked about the grantee compliance/delinquent visits reported on the dashboard and if this item would go down over time. Mr. Roberts said yes, that the job of grant specialists and grant accountants is to train the grantees and once trained, periodic but less frequent training will occur.

Dr. Mulrow stated that CPRIT needs more active methods of monitoring, like frequent site visits, and wants it better understood by the grantees who is in charge of issues dealing with compliance, i.e., is one person in the agency responsible or multiple contacts across the agency. Mr. Roberts said currently it is multiple people. Grant accountants are in fiscal operations, reporting to Ms. McConnell. Grant specialists, for administrative purposes, direct report to Ms. Doyle, but also share direct reporting responsibilities to Mr. Reisman. The Chief Compliance Officer is responsible for reporting findings in regard to delinquencies and non-compliance. It is less of his role operationally to address the delinquencies. The Weaver report suggests some changes in these roles. Dr. Rice stated he appreciates the work being done and looks forward to receiving reports showing the reduction in delinquencies.

6. Chief Compliance Officer Report

Dr. Rice recognized Mr. Reisman to present the Chief Compliance Officer Report.

Monitoring Submission Status of Required Grant Recipient Reports

Mr. Reisman explained why the numbers for delinquent reporting of FSR's are high. He noted that the total number of delinquencies has dropped significantly. He said that most of the backup was the result of the moratorium. During that time, no grants were contracted. When the moratorium was lifted, contracts went into effect as of the date of the original award, making the effective date in the past and all reports were automatically due and considered late in the system. Since the reports could only be accepted and approved one at a time, it is difficult for an entity to get current quickly. CPRIT is catching up now due to the work of multiple grant specialists and accountants.

Approval processing time was 66 days and is now down to hours in some instances. The number of delinquencies is anticipated to continue to decline.

Mr. Reisman discussed briefly the enhancements to the system: the new grant specialists and accountants, and the multi-approver process.

Dr. Rice asked about the 35 delinquent FSR's on one report versus the 147 reported elsewhere. Mr. Reisman explained it was due to entities having multiple reports in the queue.

Mr. Montgomery asked how long Mr. Reisman expected before delinquencies would be down to acceptable rates. Mr. Reisman said that at the current rate of reduction, the FSR's will be done by October.

Dr. Mulrow asked if there is any monitoring of FSR reports and what information is in the reports. Mr. Reisman said that backup information is reviewed, then another specialist reviews the report to be sure it's properly done. This ensures both the reporting time and the information in the reports are correct. Mr. Roberts said that SRA also reviews annual grant progress reports through expert reviewers.

Dr. Rice asked if senior staff was required to analyze or summarize the qualitative information coming in from grantees by the required reports. Mr. Roberts said that we are working with grantees and the grant management system to improve the quality and standardize the information from the reports.

Mr. Geren noted that the issue is not so much on the front end, but that when a researcher at an institution is working on six different grants, there may be internal pressure on that researcher to allocate time on those grants where the report is due and it may not reflect accurately how that person has spent time. Therefore the qualitative side is important. He noted that it's hard and may be more labor intensive than is justified. He requested more information on the reports and Mr. Roberts affirmed he would get more information. *(Note: Staff will report on the number and content of reports at subsequent meetings and subcommittees.)*

Mr. Reisman noted that interaction with grantees has improved and it's reflected in the decreasing number of delinquencies.

Compliance Program Design Recommendations

Mr. Reisman said Weaver submitted their final report of a proposed design for CPRIT's compliance program. The report will be reviewed by the Audit Subcommittee.

Ethics Training

CPRIT staff has received ethics training. In addition, the Oversight Committee needs training. Mr. Reisman suggested scheduling 30-minute sessions to occur twice annually, possibly occurring immediately preceding an Oversight Committee meeting. The Oversight Committee member training would cover timely and relevant ethics and

compliance topics. Dr. Rice suggested that the sessions might be offered before several different meetings so everyone has an opportunity to receive the training at their convenience without trying to coordinate all schedules for one meeting. Mr. Reisman informed the committee that three different forms attesting to compliance with ethics regulations must now be submitted by each CPRIT employee annually. He noted that Oversight Committee members had each been given the three to be filled out and returned to him today.

7. Chief Operating Officer Report

Dr. Rice recognized Ms. McConnell to present the Chief Operating Officer Report.

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. Out of that about \$8.1 million was expended for operations between grant review and award operations and the indirect cost strategies we have. The remaining amount was for the obligations CPRIT made in grant awards through the meeting in May.

Debt Issuance History

With respect to the debt issuance, another \$60.3 million was issued in June. This was the final issuance for FY 2014, and brought the total commercial paper notes issued to \$162.5 million. Ms. McConnell drew attention to the fact that in the dashboard metric, the grant reimbursements that were processed through the entire year were \$141.3 million, so there is a correlation between what we're issuing now and what we're processing. The remainder between the \$162.5 million and \$141.3 million is operating costs and transfer to the Texas Cancer Registry. Given the discussion earlier about grantees needing to expend funds so that CPRIT can issue the money and expend it is important. Ms. McConnell also pointed out that the Texas Public Finance Authority (TPFA) exchanged \$261.2 million of issued commercial paper notes into long-term general obligation bonds, which is done as TPFA deems appropriate. CPRIT expects approval of the \$300 million for FY2015 and issuances to begin again in September.

Dr. Rice asked why the materials show 2014 appropriated at \$261 million and budgeted at \$252 million, a \$9 million difference. Ms. McConnell said it is due to transfers from the research awards budget line item to operating costs and for the agency move, which has not yet been authorized by the LBB.

8. Chief Prevention and Communications Officer Report

Dr. Rice recognized Dr. Rebecca Garcia to present the Chief Prevention and Communications Officer report.

Communications

Key articles from the past quarter were provided in the Communications Update section of the committee materials. Some of the articles published were a result of media interviews the communications staff scheduled for CPRIT leadership.

The May grant awards were announced in a press release to local, regional, and national media. New funding opportunities were also publicized as they became available. When CPRIT completed the implementation of the State Auditor's Report, an announcement was sent to the Texas Legislature.

With the support of Hahn Public Communications, a new CPRIT logo and standard design templates were created and are in the process of being rolled out. In addition to the branding materials, key messages are being developed to effectively communicate the work that CPRIT and the grantees are doing.

Planning the CPRIT 2015 Conference is one of Communication's responsibilities. An RFP for a hotel venue was released on August 13, with proposals due back by September 30, 2014. Once proposals are received, the budget will be refined and recommendations submitted to the Audit Subcommittee for consideration.

CPRIT is in discussions with the Texas Public Broadcasting System to explore options to participate in the release in Texas of the Ken Burns' new documentary on *The Emperor of all Maladies: A Biography of Cancer*.

Mr. Montgomery asked if it was worth considering having Hahn Public Communications actively placing CPRIT's messages in key publications. Dr. Garcia affirmed that was a part of the Communications strategy.

9. Program Priorities Project

Dr. Rice called on Dr. Garcia and Mr. Roberts to update the committee on the Program Priorities Project. Dr. Garcia reported that the subcommittee meetings in July led to substantive discussions on establishing program priorities, guidelines for making grant decisions and ideas for priorities across programs. Mr. Robert Mittman facilitated those discussions. On August 15 the subcommittee chairs continued the discussion of across-program guidelines for decision making. The work that has occurred to date is to prepare for the September 3, 2014, work session on priorities. At those discussions, there will be an opportunity for public comment. Additionally, the University Advisory Committee and the Childhood Cancer Advisory Committee have been invited to comment. After the September 3 meeting, a draft report will be prepared and made available for public comment through the CPRIT website. The goal is to collect comments and have a final draft prepared for the November Oversight Committee meeting.

Mr. Montgomery asked what the final document would contain. Dr. Garcia said it's expected to have the program priorities and guidelines that the Oversight Committee

selects to help guide funding decisions. The content will be determined by the Oversight Committee at the September meeting.

Ms. Mitchell noted that the University Advisory Committee has already provided comments.

10. Prevention Program Report and Grant Recommendations

Dr. Rice called on Dr. Garcia to report on the prevention program and grant recommendations.

Prevention Program Update

For the update to the Prevention Program, Dr. Garcia referred members to the memo behind Tab 7 in their committee materials.

Grant Recommendations

CPRIT issued three Requests for Application (RFAs) in December 2013. The Evidence-Based Cancer Prevention (EBP) Services, the Health Behavior Change through Public Education, and the Competitive Continuation/Expansion RFAs. In February CPRIT received 50 applications, 47 of which went through full review and three were withdrawn for administrative reasons. Twenty-three of those went on to be discussed at the two panel meetings. The Prevention Review Council is recommending 15 grants for approximately \$17.6 million.

From 40 approved reviewers, the Prevention Council Chairs recruited 27 to be on two panels. Recommendations for awards are being presented from EBP Services mechanisms and the Continuation/Expansion mechanisms. There are no funding recommendations from the Public Education mechanism.

The six Evidence Based Prevention projects were:

Appl. ID	Title	PD	Organization	Total Recommended Budget
PP140208	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
PP140183	Multi-component Interventions to Increase HPV Vaccination in a Network of Pediatric	Vernon, Sally W	The University of Texas Health Science Center at Houston	\$1,495,388

Appl. ID	Title	PD	Organization	Total Recommended Budget
	Clinics			
PP140211	Tiempo de vacunarte! Time to get vaccinated!	Penaranda, Eribeth K	Texas Tech University System Health Sciences Center at El Paso	\$1,499,993
PP140176	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
PP140018	Improving Access to Colorectal Cancer Screening in East Texas	Sauter, Edward	The University of Texas Health Center at Tyler	\$1,269,216
PP140209	Building a Healthy Temple Cancer Primary Prevention Program amongst Hispanics	He, Meizi	The University of Texas at San Antonio	\$573,095

The nine Continuation/Expansion projects were:

Appl. ID	Title	PD	Organization	Total Recommended Budget
PP140026	Bridging Access to Breast Healthcare Services	Letman, Vanessa L	The Bridge Breast Network	\$1,497,357
PP140171	Navigating Rural Highways II: Expanding Access to Breast Cancer Screening and the Care Continuum for Underserved Texas Women	Joseph, Bernice	The Rose	\$539,144
PP140033	Access to Breast and Cervical Care for West Texas (ABC24WT)	Layeequr Rahman, Rakshanda	Texas Tech University Health Sciences Center	\$1,499,670

Appl. ID	Title	PD	Organization	Total Recommended Budget
PP140205	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
PP140028	Empowering the Medically Underserved Through a Community Network for Cancer Prevention	Jibaja-Weiss, Maria	Baylor College of Medicine	\$1,499,234
PP140164	ACCION 2: Against Colorectal Cancer in our Neighborhoods: El Paso and Hudspeth County	Shokar, Navkiran LK	Texas Tech University Health Sciences Center at El Paso	\$1,499,438
PP140182	Population Based Screening for Hereditary Breast and Ovarian Cancer Syndrome and the Lynch Syndrome in the Underserved	Argenbright, Keith E	The University of Texas Southwestern Medical Center	\$1,499,872
PP140049	Educating Hispanic Adolescents and their Families on Cervical Cancer Prevention and HPV Vaccination in Community and Clinic Settings	Morales-Campos, Daisy	The University of Texas Health Science Center at San Antonio	\$149,985
PP140210	Cancer Genomics Training Program for a Competent Texas Health Education Workforce	Chen, Lei-Shih	Texas A&M University	\$149,991

Dr. Garcia pointed out that one of CPRIT's legislative measures is to cover 100% of the 11 regions in Texas. With this slate of awards, 100 % of the regions of Texas will be covered, and 80% of Texas' 254 counties.

Dr. Rice referred to the synopsis of the 15 awards is on pages 7 and 8 in the Oversight Committee's Grant Award Recommendations and Supporting Information book that accompanied the meeting packet. He commented that Dr. Garcia had said in the past that the Prevention Program has touched approximately 1.6 million Texans. With this slate, he asked for a general sense of the overall number of people that are anticipated to be affected. Dr. Garcia said that the grantees are required to state in their application how many people they expect to reach. From the first mechanism they expect 905,000 people.

They distinguish between reached and served because reached can be through passive means, but then they are asked to state actual numbers to which they provide services. These are estimates from their application. When they submit quarterly reports, actual data on people and services are collected. So for these 15 applications, they anticipate 594,000 people will be touched.

Compliance Certification (David Reisman)

Regarding the Evidence-Based Prevention Award Slate, the Continuation/Expansion Grants Award Slate, and the Health Behavior Change Through Public Education Applications, Mr. Reisman reviewed the grant documentation including third party observer reports for the Peer Review Meetings and is satisfied that the application review process resulted in the nine applications recommended followed applicable laws and agency administrative rules. He noted that the background information could be found starting on page 15 of the Oversight Committee's Grant Award Recommendations and Supporting Information book. He then certified the two award slates, the Evidence Based Cancer Prevention Award Slate and the Competitive Continuation/Expansion Grants Award Slate for Oversight Committee approval.

CONFLICT OF INTEREST NOTIFICATIONS

Dr. Rice noted for the record that Oversight Committee members have reported conflicts of interest with the some of the applications to be considered. Specifically, Ms. Mitchell and Mr. Montgomery both report conflicts with applications submitted by the following institutions:

- Texas A&M University
- The University of Texas Health Science Center at Tyler
- The University of Texas Health Science Center at Houston
- The University of Texas Health Science Center at San Antonio
- The University of Texas at San Antonio
- The University of Texas Southwestern Medical Center

Ms. Mitchell also reported conflicts of interest with applications submitted by Baylor College of Medicine, Texas Tech University Health Sciences Center and Texas Tech University Health Sciences Center at El Paso.

In accordance with CPRIT's rules, Dr. Rice noted that Ms. Mitchell and Mr. Montgomery were recused from the discussion or action on the applications where they have reported a conflict of interest that arises from their firms' relationships with those entities.

Dr. Rice stated the list of the application ID numbers that members report conflicts with was included in the Supporting Information book. He stated copies of the list are available to the public attending the meeting. Dr. Rice noted that he would sign the list and require that the list be included in the certified copy of the minutes for this meeting. Dr. Rice asked if there were any other conflict of interest declarations for Oversight Committee members that had not be previously noted. None was heard.

APPROVAL PROCESS – Evidence-Based Cancer Prevention and Competitive Continuation/ Expansion Grant Awards

Dr. Rice stated that members had the list of applications and grant amounts recommended by the PIC for Evidence-Based Cancer Prevention and Competitive Continuation/ Expansion grant awards.

He noted that the PIC's recommendation would be approved if two-thirds of the Oversight Committee members present and able to vote approved the PIC's funding recommendations. Rather than taking up each recommendation individually, Dr. Rice asked for a vote for the awards and award amounts as listed on pages 7 and 8 of the letter from the PIC Chair dated August 4, 2014.

He stated the vote would be taken in three groups. The first group was the group of applications that both Ms. Mitchell and Mr. Montgomery are in conflict.

MOTION:

Dr. Rice called for a motion to approve each of the PIC's recommendations for grant awards and award amounts for applications submitted by:

- Texas A&M University
- The University of Texas Health Science Center at Tyler
- The University of Texas Health Science Center at Houston
- The University of Texas Health Science Center at San Antonio
- The University of Texas at San Antonio
- The University of Texas Southwestern Medical Center

Motion by: Mulrow

Seconded by: Holmes

MOTION CARRIED UNANIMOUSLY

Dr. Rice noted for the record that Ms. Mitchell and Mr. Montgomery abstained from voting.

MOTION:

Dr. Rice called for a motion to approve each of the PIC's recommendations for grant awards and award amounts for applications submitted by Baylor College of Medicine, Texas Tech University Health Sciences Center and Texas Tech University Health Sciences Center at El Paso.

Motion by: Angelou

Seconded by: Mulrow

MOTION CARRIED UNANIMOUSLY

Dr. Rice noted for the record that Ms. Mitchell abstained from voting.

MOTION:

Dr. Rice called for a motion to approve each of the PIC's recommendations for grant awards and award amounts for applications submitted by Legacy Community Health

Services, Asian American Health Coalition of Greater Houston, The Bridge Breast Network, and The Rose.

Motion by: Mulrow

Seconded by: Mitchell
MOTION CARRIED UNANIMOUSLY

MOTION:

Having approved the PIC recommendations, Dr. Rice called for 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 CPRIT.

Motion by: Mulrow

Seconded by: Angelou
MOTION CARRIED UNANIMOUSLY

11. Chief Scientific Officer Report and Grant Award Recommendations

Dr. Rice recognized Dr. Margaret Kripke to present the Chief Scientific Officer Report and Grant Award Recommendations.

Dr. Kripke said CPRIT has received the grant applications for the next set of RFA's, the untargeted Individual Investigator Awards and the two targeted ones for prevention and early detection and the other for childhood and adolescent cancers. Those RFA's have closed now so we know that there were 57 applications submitted for the childhood cancer awards and 66 applications submitted for prevention and early detection research. Most of them appear to be for early detection and some for prevention.

Dr. Rice asked what volume was seen for the Individual Investigator awards. Dr. Kripke said the total was 404, so it was a little less than 300—compared to the 483 applications submitted for Individual Investigator awards for today's awards. It was believed that the high number of applications submitted last time was a result of pent up demand, and that appears to have been borne out in the smaller number of applications submitted for the current RFA.

These applications are currently being assigned to various reviewers and will be addressed by the Peer Review Panels at the end of October and beginning of November. These applications will come to the February 2015 Oversight Committee meeting.

Also, the newest set of RFA's has been released, this time for Multi-Investigator Research Awards, Core Facilities Awards, and another round of the High Impact-High Risk grants. Those have not yet closed and will be reviewed next spring.

Dr. Kripke stated that Mr. Montgomery had requested a schedule of the research grant funding cycles and that schedule was on page two of Tab 8 in the Oversight Committee meeting packet. Grant mechanism 14.1 is the one being dealt with today. Staff is putting these cycles on a schedule for the Oversight Committee. In the future, research grants will only be brought to the Oversight Committee in February and May.

Dr. Kripke indicated that the Recruitment awards are handled differently. Those are open continuously. CPRIT has now increased the reviews by the Scientific Review Council to once a month. This was done at the suggestion of the University Advisory Committee (UAC), who requested it be done more often than quarterly because of the difficulty of recruitment and the need to move quickly on new recruits. The most important time for that group to have decisions made is in March and April, since most of the recruiting at the universities happen July1-September 1. This may necessitate a special meeting of the Oversight Committee to deal with recruitment applications during that time, depending on the number of applications received.

Dr. Rice noted that Mr. Holmes attended the UAC meeting and his presence was greatly appreciated. Dr. Rice noted that the Oversight Committee did not want its meeting schedule to impede the ability to recruit the finest people available, so adding a meeting to the schedule is a good suggestion.

Applications recommended for funding by the CPRIT Scientific Review Council (SRC) have been reviewed and approved by the Program Integration Committee. Applications were submitted in response to two scientific research award Requests for Applications (RFAs): Individual Investigator Research Award (RFA R-14-IIRA-1), and High Impact/High Risk (RFA R-14-HIHR-1). One hundred applications were received for the HIHR award mechanisms, and 484 were received for the IIRA mechanism. No applications were administratively rejected, one was withdrawn by the applicant, and 583 were reviewed. Seventy-six applications are being recommended for funding, for a combined amount of \$54,277,535.

Individual Investigator Research Award (RFA R-14-IIRA-1)

Applications Receiving Preliminary Evaluation	483
Applications Receiving Full Review	220
Applications Recommended:	61
Total Funding Request:	\$51,279,773

The majority (52%) of those applications are for research in cancer biology (studying basic mechanisms in cancer, identifying altered genes, and looking at mechanisms of cancer spread). Another 25% are on new approaches to treatment, trying new drugs and finding new compounds for further development. About 10% are for early detection, diagnosis, and prognosis. The remaining few are in etiology of cancer, and one each in model systems and cancer control.

High Impact/High Risk (RFA R-14-HIHR-1)

Applications Reviewed:	100
Applications Recommended:	15
Total Funding Request:	\$2,997,762

The application success rate was 15%. These are small grants at a maximum of \$100,000 per year for two years. These are “idea” grants that don’t require preliminary data as long the application makes sense and is feasible.

Among these grants, four are gene discovery; three are identifying targets for therapy; three are new immunotherapy approaches to treat cancer; two are on viruses in cancers; two are on the development of new technologies; and one is on studying proton therapy. Three of the grants are go to Baylor, three to UT-Austin, two to UT-Southwestern, two to Texas Tech, two to Texas A&M, one to M.D. Anderson, one to Scott and White, and one to UT-San Antonio. Thus, there is a good spectrum of recipients and of projects.

The list of grants is as follows:

App ID	Award Type	Organization	Application Title	Budget
RP140244	IIRA	The University of Texas M. D. Anderson Cancer Center	Regulation of MDM2-mediated oncogenesis and anti-tumor immunity by USP15	\$870,156
RP140412	IIRA	The University of Texas Southwestern Medical Center	Endotrophin and the Obesity/Cancer Nexus: Role in Growth and Chemoresistance	\$899,997
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
RP140655	IIRA	The University of Texas Southwestern Medical Center	Evaluation of the role of tumor suppressor candidate NPRL2 in cell growth control	\$596,265
RP140350	HIHR	Baylor College of Medicine	Integrated Human Herpesvirus 6 as a Novel Heritable Risk Factor for Glioma	\$199,298
RP140606	IIRA	The University of Texas M. D. Anderson Cancer Center	Optimizing therapy for glioblastoma through genomic profiling of treatment failure	\$900,000
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
RP140402	IIRA	The University of Texas Southwestern Medical Center	Novel targets for acute myeloid leukemia treatment	\$900,000
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
RP140612	IIRA	The University of Texas M. D. Anderson Cancer Center	Collateral Genomic Deletions As Targetable Vulnerabilities in Cancer	\$900,000
RP140469	IIRA	Baylor College of Medicine	Novel Small Molecule Probes Targeting IDH Mutated Glioma	\$695,527

App ID	Award Type	Organization	Application Title	Budget
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
RP140408	IIRA	The University of Texas M. D. Anderson Cancer Center	Identificaiton of a novel mechanism of mTORC1 and autophagy regulation for cancer therapy.	\$900,000
RP140462	IIRA	The University of Texas M. D. Anderson Cancer Center	Systematic Investigation of Clinically Relevant Expressed Pseudogenes in Cancer	\$870,539
RP140132	IIRA	Rice University	Towards Point-of-Care Nucleic Acid Cancer Diagnostics	\$900,000
RP140517	IIRA	The University of Texas at Dallas	Optimal Biomarkers for Personalized Cancer Therapy: A Network-Based Approach	\$490,689
RP140285	IIRA	The University of Texas Southwestern Medical Center	Noninvasive Identification of Prostate Tumor Hypoxia as a Prognostic Biomarker of Radiation Response	\$895,820
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
RP140329	HIHR	The University of Texas M. D. Anderson Cancer Center	Opening the central nervous system to immunotherapy by blocking TREK1	\$198,957
RP140181	IIRA	Baylor College of Medicine	Mechanisms of CTC Biomarkers in Breast Cancer Brain Metastasis	\$899,968
RP140252	IIRA	Baylor College of Medicine	Investigating and preclinical targeting molecular drivers of muscle-invasive bladder cancer	\$827,451
RP140262	IIRA	The University of Texas M. D. Anderson Cancer Center	Intrinsic Reward Sensitivity & Smoking Cessation with Varenicline or Patch NRT	\$899,505
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
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
RP140298	IIRA	Texas Tech University	Engineering microfluidic devices for multimodal mechanical phenotyping of tumor cells in flow	\$674,465
RP140152	IIRA	The University of Texas Southwestern Medical Center	Natural Product for Treatment of Non-Small Cell Lung Cancer	\$772,368
RP140218	IIRA	The University of Texas M. D. Anderson Cancer Center	Inhibiting Oxidative Phosphorylation: A Novel Strategy in Leukemia	\$826,744

App ID	Award Type	Organization	Application Title	Budget
RP140522	IIRA	The University of Texas M. D. Anderson Cancer Center	Reversing vaccination-induced impairment of anti-CTLA-4-based cancer therapy.	\$899,991
RP140233	IIRA	The University of Texas Southwestern Medical Center	Structure-guided Kinase Inhibitor Design for Cancer Therapy	\$900,000
RP140648	IIRA	The University of Texas at Austin	New Therapeutic Strategies for Metastatic Melanoma	\$900,000
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
RP140840	HIHR	Texas Tech University	New Technology for Ultra High Throughput Enumeration of Circulating Tumor Cells	\$199,993
RP140001	IIRA	Baylor College of Medicine	Role of DNA METHYLTRANSFERASE 3A in Hematologic Malignancies	\$900,000
RP140468	IIRA	The University of Texas M. D. Anderson Cancer Center	TARGETING OF CHRONIC LYMPHOCYTIC LEUKEMIA BY DESIGNER T CELLS	\$900,000
RP140449	HIHR	The University of Texas Southwestern Medical Center	A new Cancer Target: AMPylation machinery	\$200,000
RP140271	IIRA	The University of Texas M. D. Anderson Cancer Center	Targeting p53 in cancer through manipulation of p63 and p73	\$900,000
RP140140	IIRA	The University of Texas Southwestern Medical Center	Turn ON the Tumor Contrast for Surgical Resection of Head and Neck Cancers	\$900,000
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
RP140141	IIRA	The University of Texas Southwestern Medical Center	Targeting HER2 for cancer therapy	\$892,989
RP140179	IIRA	Baylor College of Medicine	Targeting self-renewal in leukemic stem cells through the inactivation of KLF4	\$813,789
RP140430	IIRA	The University of Texas M. D. Anderson Cancer Center	Synaptic Mechanisms of Cognitive Decline after Cranial Radiation	\$836,557
RP140563	IIRA	The University of Texas M. D. Anderson Cancer Center	PAF, a Novel Wnt Signaling Regulator, in Colorectal Cancer	\$900,000
RP140223	HIHR	Baylor College of Medicine	Viral MicroRNAs in Ovarian Cancer Growth and Metastasis	\$199,995

App ID	Award Type	Organization	Application Title	Budget
RP140224	IIRA	The University of Texas M. D. Anderson Cancer Center	PPAR-delta Regulation of Wnt/B-catenin to Drive Colon Cancer	\$890,003
RP140315	IIRA	The Methodist Hospital Research Institute	Accurate and High Throughput Detection of Breast and Ovarian Cancer Cells in Whole Blood	\$900,000
RP140649	HIHR	The University of Texas at Austin	Realizing Personalized and Precision Medicine for Melanoma: A Rapid Assay for Measuring ERK Activity	\$200,000
RP140222	IIRA	The University of Texas M. D. Anderson Cancer Center	Direct Roles for RB and E2F1 in DNA Repair	\$900,000
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
RP140500*	IIRA	The University of Texas M. D. Anderson Cancer Center	Toward the Cure of Myelodysplastic Syndrome: Interfering with Innate Immunity Alterations in Human and Mouse Systems	\$900,000
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
RP140842	IIRA	The University of Texas at Austin	Determining the Functional Role of microRNAs in Viral Tumorigenesis.	\$604,624
RP140478	HIHR	Texas Tech University	Computational Chemistry Determination of DNA Damage Mechanisms in Proton Cancer Therapy to Optimize Its Clinical Use	\$200,000
RP140544	IIRA	The University of Texas at Dallas	Mapping Acidic Tumor Microenvironment with Renal Clearable pH Nanoindicators	\$900,000
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
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
RP140399	IIRA	Baylor University	Targeting Hypoxia in Breast Cancer with Highly Potent Small-Molecule Anticancer Prodrugs	\$900,000

App ID	Award Type	Organization	Application Title	Budget
RP140320	HIHR	The University of Texas Southwestern Medical Center	DISSECTING A Necrotic Signaling Pathway in Human Cancer Cells	\$200,000
RP140661	IIRA	The University of Texas Southwestern Medical Center	Analyses of the regulatory mechanisms of tankyrase and its role in tumorigenesis	\$876,751
RP140367	IIRA	The University of Texas Southwestern Medical Center	Targeting BRD4 in Breast Cancer	\$900,000
RP140678	HIHR	Scott & White Healthcare	Novel, humanized single-chain CD123xCD3 bispecific antibodies for eliminating leukemia stem cells and leukemic cells	\$199,959
RP140800	IIRA	The University of Texas Health Science Center at Houston	The Role of Alternative Polyadenylation in Glioblastoma Tumor Progression	\$848,491
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
RP140542	IIRA	The University of Texas M. D. Anderson Cancer Center	Biology and Therapy of Basal Bladder Cancers	\$865,587
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
RP140479	HIHR	Texas A&M University	Screening for melanoma genes using natural hybrid incompatibilities	\$199,993
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
RP140553	IIRA	Baylor College of Medicine	Translational Discovery of Resistance Genes and Cancer Gene Functions	\$900,000
RP140616	IIRA	Baylor College of Medicine	Tenascin-C and Metastatic Prostate Cancer Progression	\$827,806
RP140429	IIRA	The University of Texas M. D. Anderson Cancer Center	The Role of DIRAS3 (ARHI) in Initiating Autophagy and Tumor Dormancy	\$900,000
RP140411	IIRA	The University of Texas M. D. Anderson Cancer Center	Targeting Tumor Cell Invasion in Glioblastoma	\$900,000
RP140258	IIRA	Baylor College of Medicine	The Intersection between Childhood Cancer and Congenital Anomalies: Identifying Novel Cancer Predisposition Syndromes	\$874,964
RP140781	HIHR	Texas A&M University	High-Field Open MRI: Cost-Effective Screening for Early Detection of Breast Cancer	\$200,000
RP140328	HIHR	The University of Texas at Austin	Synthetic protein degradation agents to clear oncogenic proteins from cells	\$199,852

App ID	Award Type	Organization	Application Title	Budget
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
RP140767	IIRA	Baylor College of Medicine	Toll-like receptors, gut microbiota, and risk of colorectal adenoma	\$899,131
RP140609	IIRA	The University of Texas M. D. Anderson Cancer Center	A missing link between obesity and cancer: Adipose derived stem cells	\$610,704

Dr. Rice recapped the requests that Dr. Kripke presented: Individual Investigator – 61 awards at \$51 million; High Impact/High Risk – 15 awards at \$2.9 million; Established Investigator – 1 award at \$6 million; Rising Stars – 1 at \$4 million; and First Time Tenure Track – 6 awards at \$12 million. That totals to \$84 million in research grants.

Compliance Certification (David Reisman)

With regard to the High Impact High Risk Award Slate; Individual Investigator Award Slate; Recruitment of First-Time, Tenure-Track Faculty Members Award Slate; Recruitment of Rising Stars Award Slate; and Recruitment of Established Investigators Award Slate, Mr. Reisman stated he conferred with staff at CPRIT and SRA International (SRA), CPRIT's contracted third-party grant administrator, and studied the supporting grant review documentation, including third-party observer reports for the peer review meetings. He expressed satisfaction that the application review process that resulting in the grants recommended by the Chief Executive Officer followed applicable laws and agency administrative rules. Mr. Reisman certified these award slates for the Oversight Committee's consideration.

CONFLICT OF INTEREST NOTIFICATIONS

Dr. Rice noted for the record that Oversight Committee members have reported conflicts of interest with the some of the applications to be considered.

Specifically, Ms. Mitchell and Mr. Montgomery both report conflicts with applications submitted by the following institutions:

- Rice
- Texas A&M University
- Methodist Hospital Research Institute
- The University of Texas at Austin
- The University of Texas at Dallas
- The University of Texas Health Science Center at Houston
- The University of Texas Health Science Center at San Antonio
- The University of Texas M.D. Anderson Cancer Center
- The University of Texas Southwestern Medical Center

In addition, Ms. Mitchell also reported conflicts of interest with applications submitted by Baylor College of Medicine, Baylor Research Institute, Baylor University, Scott & White Healthcare, and Texas Tech University.

Dr. Rice stated that in accordance with CPRIT's rules, Ms. Mitchell and Mr. Montgomery were recused from the discussion or action on the applications where they have reported a conflict of interest.

Dr. Rice referred members to the Supporting Information books for the list of application ID numbers for awards that members reported conflicts. He stated that copies of this list are available for the public attending the meeting. Dr. Rice stated he would sign the list at the end of this meeting and require that the list be included in the certified copy of the minutes for this meeting.

Dr. Rice asked if there were any other conflict of interest declarations for Oversight Committee members that had not been previously noted. None was heard.

APPROVAL PROCESS – Individual Investigator and High-Impact High Risk Grant Awards

Dr. Rice informed the members they had the list of applications and grant amounts recommended by the PIC for Individual Investigator and High-Risk High Impact grant awards.

He noted the PIC's recommendation would be approved if two-thirds of the Oversight Committee members present and able to vote approved the PIC's funding recommendations

Dr. Rice said that rather than taking up each recommendation individually, members would vote for the awards and award amounts as listed on pages 2 through 6 of the letter from the PIC Chair dated August 4, 2014.

Dr. Rice stated the members were going to take this vote in two groups. The first group included applications that Ms. Mitchell and Mr. Montgomery have conflict.

MOTION:

Dr. Rice called for a motion to approve each of the PIC's recommendations for grant awards and award amounts for applications submitted by:

- Rice
- Texas A&M University
- Methodist Hospital Research Institute
- The University of Texas at Austin
- The University of Texas at Dallas
- The University of Texas Health Science Center at Houston
- The University of Texas Health Science Center at San Antonio

- The University of Texas M.D. Anderson Cancer Center
- The University of Texas Southwestern Medical Center

Motion by: Angelou

Seconded by: Holmes

MOTION CARRIED UNANIMOUSLY

Dr. Rice noted for the record that Ms. Mitchell and Mr. Montgomery abstained from voting.

MOTION:

Dr. Rice called for a motion to approve each of the PIC's recommendations for grant awards and award amounts for applications submitted by:

- Baylor College of Medicine
- Baylor Research Institute
- Baylor University
- Scott and White Healthcare
- Texas Tech University

Motion by: Mulrow

Seconded by: Angelou

MOTION CARRIED UNANIMOUSLY

Dr. Rice noted for the record that Ms. Mitchell abstained from voting.

APPROVAL PROCESS – Recruitment Grant Awards

Dr. Rice noted that members had the list of applications and grant amounts recommended by the PIC for Recruitment grant awards.

The PIC's recommendation would be approved if two-thirds of the Oversight Committee members present and able to vote approve the PIC's funding recommendations.

Dr. Rice stated that rather than taking up each recommendation individually, the members would vote for the awards and award amounts as listed on page 6 of the letter from the PIC Chair dated August 4, 2014.

Dr. Rice stated for the record that Ms. Mitchell and Mr. Montgomery indicated that they had conflicts with all of the applications being recommended for recruitment grant awards.

MOTION:

Dr. Rice called for a motion to approve each of the PIC's recommendations for recruitment grant awards and award amounts.

Motion by: Angelou

Seconded by: Holmes

MOTION CARRIED UNANIMOUSLY

Dr. Rice noted for the record that Ms. Mitchell and Mr. Montgomery abstained from voting.

MOTION:

Having approved the PIC recommendations for the Individual Investigator, High-Impact, High Risk and Recruitment grant awards, Dr. Rice called for 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.

Motion by: Mulrow

Seconded by: Angelou

MOTION CARRIED UNANIMOUSLY

12. Chief Product Development Officer Report and Revised Contract Terms

Dr. Rice noted that Dr. Rosenfeld, Chair of the Product Development Subcommittee, provided the subcommittee's recommendation to the board behind Tab 9 in the meeting packet. He then recognized Dr. Thomas Goodman to present the revised contract terms that the Oversight Committee ratified in May and the PIC recommendations for Product Development grants.

Dr. Goodman began by stating that CPRIT had received 30 grant applications for product development awards in Cycle 15.1. Of these 17 were advanced to in-person presentations last week. The review panel recommended that the applications of nine different companies be moved forward to due diligence. The total amount of support requested is less than \$100 million. This shows that CPRIT has had robust interest in its company-related programs and an increasing percentage of high-quality applications are moving forward.

The Early Translation Research Applications (ETRA's) were previously administered as part of the research program. Dr. Kripke recommended and Dr. Goodman agreed that these might be better evaluated by product development review panels. He reported that CPRIT has received 46 applications that have been assigned to reviewers. They will be discussed by the review panels in October and will come before the Oversight Committee in November.

Dr. Goodman noted that for the first time CPRIT requires the ETRA award recipients to prepare business plans. This activity should focus on converting academic research into products beneficial to cancer patients.

The next cycle of product development new company relocation/established companies requests for applications was released in July and will close on September 29, 2014. Any award recommendations resulting from this cycle will be presented to the Oversight Committee for approval in May of 2015.

Revenue Sharing

Dr. Goodman stated that revenue sharing provisions are required in all CPRIT grant applications and grant award contracts. Health and Safety Code, Section 102.256, requires that the Oversight Committee establish standards and require that all grant awards be subject to intellectual property agreements that allow the state to collect royalty income and other benefits including interest and proceeds resulting from securities and equity ownership that are realized as a result of the projects that funded by CPRIT. However, Dr. Goodman noted that the statute also indicates that the Oversight Committee must balance the opportunity of the state to benefit from patents, royalties, licenses, and other benefits, with ensuring essential medical research is not unreasonably hindered and a disincentive for follow-on investment by others is not created.

Several companies that had been approved for grant contracts contacted CPRIT about the revenue sharing terms presented at the May 21 Oversight Committee meeting. Their concerns were transmitted to the Product Development Subcommittee; Dr. Goodman reported that some issues had merit. After discussion by the subcommittee, Dr. Goodman reported that three important concerns can be addressed through the revisions to the revenue sharing terms previously presented.

Dr. Goodman presented the recommended revisions to the previously approved revenue sharing terms:

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, it is recommended that 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 shortage of venture capital funding for early-stage, life sciences companies in Texas is problematic. Previously approved buyout terms create potential negotiating problems with future investors. For example, a company required to pay off a grant award at the same time it is negotiating a new round of financing may be difficult. Although the company had three years to plan for the buyout - essentially the term of the CPRIT contract, this amount of time may be inadequate.

Given this, it is recommended that 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 credited against the buyout amount.

3. Accounting for Licensing Royalties

While the present proposed contract allows adjustment of the revenue sharing percentages as a result of other contributions to the product development, it does not consider potential licensing royalties that might have to be paid to allow product sales.

Given this, the addition of a stacking provision is recommended. 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 otherwise would be.

Dr. Goodman stated that should the Oversight Committee approve these recommended terms, CPRIT would offer any company that has already been approved for a grant award and is currently pending execution of a final contract the option to proceed pursuant to the contract terms that were approved at the May 21 Oversight Committee meeting or the contract terms approved today. Companies that were approved for contract execution at the May meeting and have already executed a contract will be offered the option of accepting these newly approved terms through a contract amendment. The terms adopted today would be used for the grant contracts for companies approved for grant awards at this meeting.

Dr. Rice commented for clarity that the Oversight Committee discussed the matrix in May and then, as a result of the feedback received from potential grantees, Dr. Goodman is asking the Oversight Committee, through a three-step process, to accept this new construct of deal-making terms to be uniformly applied. The Oversight Committee's action will potentially affect three classes of companies: those that are being brought forth now that have been through the process; those that had been approved in May and have

been in contract negotiations; and those that were approved at the February 2014 Oversight Committee meeting and have already signed a final contract that will be offered these new terms as an addendum to their contract. This means everyone would have been given the same terms throughout the whole year. Dr. Goodman agreed that this was a correct summation, although the grantees that previously executed contracts would have the option, not the requirement, to take the new terms.

Mr. Montgomery said it is difficult to evaluate this proposal in the abstract and wanted to know how proposed rates compare to the market.

Dr. Goodman replied there is a requirement for fair compensation to the state; however, there is also a goal to present terms that don't hinder follow-on funding from the private sector. He stated that CPRIT's proposed terms were attractive to small companies in that they did not require equity to be given up by the company. A venture capitalist investor could, under some circumstances, take up to 75% of the company in equity.

Mr. Geren stated this buyout option seems inconsistent with what he understood the Legislature's intent that CPRIT would participate in the occasional successful product, as investors in this kind of high risk activity would typically do. However, this proposal being discussed today limits CPRIT to a maximum 9% return on investment.

Mr. Roberts stated that one must blend the goal to receive an appropriate return on investment with other considerations that a conventional venture company does not take into account, such as trying to build an under-represented industry to Texas.

Dr. Rice asked why we would have a buyout clause.

Mr. Holmes responded that there was much discussion on this matter in the subcommittee. Mr. Holmes stated that the buyout provision was developed to allow the small and growing company to access additional capital that the state is not prepared to provide.

Ms. Doyle added from a legal perspective that CPRIT's statute was changed in 2011 to allow CPRIT to take equity in companies. There are many issues with taking equity, which can be subject to discussion on another day. CPRIT does not have the capital necessary for a company to bring a product from discovery to market, the funding provided by CPRIT is intended for the company to create data to show early success in Phase 1 and 2 trials that should make the company attractive to larger investors that can invest the money necessary to further develop the drug or product. Ms. Doyle noted that CPRIT's primary objective is to get cancer cures to the market.

After considerable discussion, the Oversight Committee directed Dr. Goodman and CPRIT staff to refine the contract terms to address the Oversight Committee concerns raised at this meeting for reconsideration at the Oversight Committee meeting that will be held September 3. Mr. Holmes summarized the Oversight Committee's request: eliminate the buyout provision and set the wind down from 4% to 2% as a result of the

stacking provision. He also asked Dr. Goodman to provide information on using gross versus net revenues.

No further action was taken on contracts with AERase and Mirna.

Product Development – New Company Product Development Award Recommendations

Dr. Goodman presented the PIC recommendations for approval of two product development grant proposals totaling \$13,580,185. The recommended grant proposals were submitted in response to the New Company Product Development Request for Applications. The PIC concurred with recommendations made by the Product Development Review Council. The two companies are Curtana Pharmaceuticals and OncoNano Medicine. The total requested was \$13,580,185.

Curtana is developing the first truly targeted small molecule drug for treatment of glioblastoma, the most common and deadliest of malignant brain tumors in adults, and diffuse intrinsic pontine glioma, an extremely deadly pediatric brain tumor. This fits CPRIT's mission to expedite innovation in areas of new product development and attract companies that will create jobs in Texas. This award will bridge the translational research gap and address an important medical need in patients. The CPRIT funding request recommended for approval is about \$7.6 million. This amount will be matched by \$3.8 million of company-contributed funds for a total project cost of \$11.4 million.

Dr. Mulrow asked if it was usual for companies to have concerns noted by the independent scientific evaluation, i.e., lack of oncological expertise; the assumption about the need for a pre-IMD meeting; and an unrealistic budget. Dr. Goodman responded that it is not unusual for a young company to need to hire more expertise and get regulatory professionals involved.

There being no further questions, Dr. Goodman discussed OncoNano Medicine. The company is a Dallas-based, The University of Texas Southwestern Medical Center spinout developing a nano technology enabled probe to help cancer surgeons visualize tumors during surgery. This probe responds to the pH conditions present within the cancer cells and becomes fluorescent, thus making it possible for the surgeon to excise the tumor more precisely. Over 500,000 cancer surgeries are performed every year in the United States and a major challenge is getting the entire cancer out to prevent regrowth and metastasis, without removing good tissue. The company is will operate in the UT-Southwestern Incubator and is expected to create high quality research jobs and recruit talent. The CPRIT grant amount request is for \$6 million that will be matched with an additional \$3 million of company supplied funds, for a total project cost of \$9 million.

The list of grants is as follows:

App ID	Company Name	Project	Budget*
DP140034	Curtana Pharmaceuticals, Inc.	Preclinical Drug Discovery and Development of Novel, First-In-Class, Small Molecule Compounds	\$7,580,185
DP140072	OncoNano Medicine, Inc.	Transforming Cancer Surgery by Tumor Illumination	\$6,000,000

Dr. Rice stated that though Dr. Rosenfeld could not be at the meeting, Dr. Rosenfeld's memo emphasize the need to get adequate licensing of the technology from Southwestern before proceeding.

Dr. Rice noted that in response to this RFA, about 25 companies applied with these two being the top two: OncoNano scored the highest at 2.2, and Curtana scored 2.4.

Compliance Certification (David Reisman)

Mr. Reisman stated that with regard to New Company Product Development awards, he conferred with staff at CPRIT and SRA International (SRA), CPRIT's contracted third-party grant administrator, and studied the supporting grant review documentation, including third-party observer reports for the peer review meetings. He stated he was satisfied that the process that resulted in the grants recommended by the Chief Executive Officer followed applicable laws and agency administrative rules. Mr. Reisman certified these award slates for the Oversight Committee's consideration.

CONFLICT OF INTEREST NOTIFICATIONS

Dr. Rice noted for the record that Oversight Committee members have reported conflicts of interest with the some of the applications to be considered.

Specifically, Ms. Mitchell and Mr. Montgomery both report conflicts with application ID number DP140072. In accordance with CPRIT's rules, Ms. Mitchell and Mr. Montgomery were recused from the discussion and action on this application. There were no other conflicts reported.

CONSIDERATION OF NEW COMPANY PRODUCT DEVELOPMENT GRANTS

MOTION:

Dr. Rice called for a motion to approve the PIC's recommendation for Curtana Pharmaceuticals to receive a New Company Product Development Award in an amount not to exceed \$7,580,185.

Motion by: Geistweidt

Seconded by: Geren

MOTION CARRIED UNANIMOUSLY

Dr. Rice noted for the record that Ms. Mitchell and Mr. Montgomery abstained from voting.

MOTION:

Dr. Rice called for a motion to approve the PIC's recommendation for OncoNano Medicine to receive a New Company Product Development Award in an amount not to exceed \$6,000,000.

Motion by: Holmes

Seconded by: Angelou
MOTION CARRIED UNANIMOUSLY

MOTION:

Having approved these companies for product development awards, Dr. Rice called for a motion to delegate contract negotiation authority to the Chief Executive Officer and CPRIT Staff. He noted that Dr. Rosenfeld's memo indicated that the Product Development Subcommittee recommended approval contingent upon the companies demonstrating they have ownership of or license to the intellectual property underlying the projects.

Motion by: Angelou

Seconded by: Holmes
MOTION CARRIED UNANIMOUSLY

Authorization to Disburse Grant Funds by Advance Payment

Dr. Rice stated that Mr. Roberts had notified the Board by letter sent August 4 indicating that he seeks authority to disburse grant funds in advance of incurring expenses to the two companies approved for awards today.

Mr. Holmes asked if this would be done before the September 3 meeting and Mr. Roberts responded it would not. Ms. Doyle clarified that payment of grant funds is contingent upon an executed contract. No grant funds will be paid until a contract is signed.

MOTION:

Dr. Rice called for a motion, pursuant to the General Appropriations Act, Article IX, Section 4.03(a), to authorize CPRIT to disburse grant fund via advance payments to the two Product Development Awards approved today, recognizing that there are never any advances until there is an executed contract.

Motion by: Geistweidt

Seconded by: Holmes
MOTION CARRIED UNANIMOUSLY

13. Appointments to Scientific Research and Prevention Program Committees

Dr. Rice recognized Nominations Subcommittee Chair Ned Holmes to lay out the subcommittee's recommendations.

Mr. Holmes stated the Nominations Subcommittee met on August 15 and discussed the Chief Executive Officer's new appointments to the Scientific Research and Prevention Programs Committee. The subcommittee recommended approval of the CEO's 24 appointments.

There were no questions or discussion by members.

MOTION:

Dr. Rice called for a motion to approve the Chief Executive Officer's appointments to the Scientific Research and Prevention Programs Committee.

Motion by: Geistweidt

Seconded by: Holmes

MOTION CARRIED UNANIMOUSLY

14. FY 2015 Honoraria Policy

Dr. Rice recognized Mr. Roberts, CEO, to present the FY 2015 honoraria policy.

Mr. Roberts stated that 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 FY 2015 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. Creation of the deputy position is due to the number of applications submitted to the program having increased, necessitating two review panels to meet several times during the cycle. The deputy would head up one of the two review panels. The 2015 policy identified this deputy's responsibilities to justify the honoraria amount associated with the time commitment. The breakdown of those activities can be found on page 8 of the attachment to the memo in the meeting packet. Mr. Roberts recommended approval of the FY 2015 honoraria policy.

There were no questions or discussion by members.

MOTION:

Dr. Rice called for a motion to approve the Chief Executive Officer's FY 2015 Honoraria Policy.

Motion by: Montgomery

Seconded by: Mitchell

MOTION CARRIED UNANIMOUSLY

15. Texas Health and Safety Code § 102.1062 Waivers

Dr. Rice recognized Mr. Roberts to present his formal request to the Oversight Committee for consideration of Conflict of Interest Waivers for Dr. Kripke, Dr. Lakey, and Mr. Montgomery.

Mr. Roberts stated the first two waivers are identical to the ones approved last year. Dr. Kripke's waiver is necessary for her to continue to effectively perform her duties of Chief Science Officer. The rationale and explanation can be found in the memo that has been posted on CPRIT's website and is public record. Mr. Roberts pointed out that granting the waiver in no way prohibits the Oversight Committee from amending, revoking, or revising the waiver in the future, including but not limited to the list of approved activities and duties of the limitations. The waiver is limited to the conflict of interest specified in the request. To the extent to which Dr. Kripke has a conflict of interest with an application that is not the conflict identified in this waiver, she will have to follow the required notification and recusal process. She is also required to follow all other restrictions and prohibitions upon staff activities during the peer review process.

Mr. Roberts next spoke to Dr. Lakey's waiver, which he stated is identical to the one presented last year. Dr. Lakey heads up an agency that receives prevention grants from CPRIT, but by statute he is a member of the PIC. In order to operate as envisioned by the statute, this waiver is necessary for his participation.

The third waiver request, Mr. Roberts stated, is new. The waiver request is for Oversight Committee member, Will Montgomery, and is necessary for him to fully participate in the grant award approval process. 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. By way of background, Mr. Montgomery is a partner at Jackson Walker, a long-time Texas-based law firm that employs more than 350 attorneys. Mr. Montgomery legal practice focuses on disputes related to the financial services industry, including regulatory investigations, enforcement proceedings, and internal investigations related to securities, options, derivatives, commodities, and futures. Mr. Montgomery does not personally represent CPRIT grant recipients; however, some lawyers employed by Jackson Walker do provide legal services to 12 grant recipients, which are: Rice, Texas A&M University System, the A&M System Technology Commercialization, the A&M Institute for Biosciences and Technology, the Methodist Hospital System of Houston, UT-

Southwestern, UT School of Public Health, UT Medical Branch in Galveston, Children's Medical Center Research Institute, UT-San Antonio, UT-Austin, and UT Health Science Center at Houston. To approve the waiver, the Oversight Committee must find exceptional circumstances justifying Mr. Montgomery's participation in the review process. One of the principle duties of an Oversight Committee member is to approve grant awards recommendations submitted by the Program Integration Committee. The statute requires a two-thirds vote of the committee to approve a grant award. Excluding Mr. Montgomery from participation in the decision-making process related to grant awards reduces the number of committee members that are able to perform the critical tasks of reviewing information about potential grantees in the review process associated with the recommendations. The Oversight Committee may amend, revoke or revise this waiver, which is limited to the conflict of interest specified in this request and based upon the circumstances stated. If circumstances change such that Mr. Montgomery is required to personally represent one of the entities listed herein or to supervise the work of someone representing the entity, he will be required to notify CPRIT's Chief Executive Officer and the presiding officer of the Oversight Committee.

Dr. Rice called for questions or discussion. None was heard.

MOTION:

Dr. Rice called for a motion finding that exceptional circumstances exist and to approve the waiver proposed for Dr. Kripke that will waive the conflict of interest specified in Texas Health and Safety Code Section 102.106(c)(3).

Motion by: Mulrow

Seconded by: Angelou

MOTION CARRIED UNANIMOUSLY

MOTION:

Dr. Rice called for a motion finding that exceptional circumstances exist and to approve the waiver proposed for Dr. David Lakey that will waive the conflict of interest specified in the Texas Health and Safety Code Section 102.106(c)(3).

Motion by: Mulrow

Seconded by: Holmes

MOTION CARRIED UNANIMOUSLY

MOTION:

Dr. Rice called for a motion finding that exceptional circumstances exist and to approve the waiver proposed for Oversight Committee member Will Montgomery that will waive the conflict of interest specified in Texas Health and Safety Code Section 102.106(c)(4).

Motion by: Mulrow

Seconded by: Holmes

MOTION CARRIED UNANIMOUSLY

Dr. Rice noted that Mr. Montgomery did not participate in this vote on his waiver. He also noted that the waivers will be publicly posted on CPRIT's website and will be provided to the Governor, Lt. Governor, and Speaker of the House, as well as to the statutorily designated legislative committees with oversight for CPRIT operations. Mr. Roberts confirmed that this will be done.

16. Personnel Action – Manager of Internal Audits

Closed Session

Dr. Rice stated that at this time the Oversight Committee would go into closed session pursuant to Texas Open Meetings, Act Sections 551.071 and 551.074 to discuss personnel issues as listed on the posted agenda and to consult with its attorney. At the request of the chair, Mr. Roberts, Ms. Doyle, and Lisa Nelson, CPRIT's Operations Manager (HR), attended the closed session. The time: 1:47 p.m.

Dr. Rice reconvened the meeting after closed session and called the time: 3:11 p.m.

Dr. Rice stated that CPRIT staff did not have a recommendation for the position of Manager of Internal Audits to be considered by the committee at this time. Dr. Rice stated that no further action would be taken at this time.

17. Internal Audit Reports

Dr. Rice recognized Ms. McConnell to present the Internal Audit Reports.

Ms. McConnell stated that there were five internal audits related to the operations of the agency on which Grant Thornton, CPRIT's internal auditor, is working on. Two of the audits are completed and are under Tab 13 in the Oversight Committee Meeting book: Expenditures Internal Audit Report and Third-Party SRA International Managed Information Systems Internal Audit Report. Two findings for the Expenditures report are: (1) 3 of 35 payments were not paid on time, resulting in additional interest charges, and (2) 1 of 17 capital assets did not have sufficient evidence of the asset's existence. Management is addressing both these concerns.

The Third-Party SRA Managed Information Systems audit was done according to American Institute of Certified Public Accountants Trust Service Principles. Grant Thornton examined those that were specific to the systems at SRA. No exceptions were noted.

Ms. McConnell gave an update on the status of the 10 grantee field audits. The field work for five of them is being completed: UT-Southwestern, The Nurses Foundation, Molecular Templates, Texas A&M Health Science Center, and UT Health Science Center—Houston. The other five are: UT-Austin, UT Health Science Center—San Antonio, the Methodist Hospital Research Institute, Texas AgriLife Extension Service, and Rice University. The final reports will be ready for the November meeting.

No questions were voiced. Dr. Rice asked Mr. Angelou, Chair of the Audit Subcommittee, to present the subcommittee recommendations.

Mr. Angelou stated the Audit Subcommittee met on August 7 and recommended the Oversight Committee accept the audits as presented.

MOTION:

Dr. Rice called for a motion to accept the Expenditures Internal Audit Report and the SRA International Managed Information System Internal Audit Report.

Motion by: Montgomery

Seconded by: Mulrow

MOTION CARRIED UNANIMOUSLY

Dr. Rice stated that these audits will be posted on the CPRIT website. Ms. McConnell affirmed. Dr. Rice asked Ms. McConnell if the website reports will contain explanations of some of the findings that might lead the public to believe there is a larger problem than there is, i.e., one finding is for only \$18. Ms. McConnell said she would include clarification in the executive summary of the reports. Mr. Roberts pointed out the report includes CPRIT's responses on how the findings are being addressed.

18-22. Approval of Operational and Services Contracts

Due Diligence Services Request for Proposal: CPRIT has had due diligence services performed since 2010 in the product development program. This is a business management regulatory review and evaluation, and is separate from intellectual property due diligence covered by the outside legal services contract. This is an independent analysis of the company applicant's potential to commercially develop their proposed drug device, diagnostic technology or service. The Product Development Review Council uses these reports, as referred to in the Chief Product Development Officers reports. In the past three years, these services have been subcontracted through SRA, but CPRIT is now going to handle and manage this contract. CPRIT requests authorization to award a one-year base contract with up to three one-year renewal options, to potentially two firms totaling up to \$350,000. This amount assumes 12 due diligence evaluations performed at approximately \$25,000 each. Having two firms addresses any potential conflicts of interest. The RFP for these services is active and responses are due by August 22, so there are not recommendations to discuss. Staff requests approval to move forward with contracting because these services are critical for the product development evaluation process.

Outside Legal Services Contract: These two contracts are for intellectual property due diligence that is part of the product development evaluation. Having two firms addresses any potential conflicts of interest. Ms. Doyle works with outside counsel to assign due diligence work. This is an ongoing contract so CPRIT would be exercising the renewal option for the second year.

The Pre- and Post-Award Grants Management Support Services Statement of Work:

This contract is for SRA International. This contract includes their labor estimated to be \$6.6 million, the honoraria they pay to peer reviewers estimated to be \$2.4 million, travel to the peer review meetings estimated to be \$400,000, the peer review costs of hotels and meeting room space estimated to be \$635,000, and labor SRA subcontracts estimated to be \$1 million.

Mr. Geren asked about the \$6 million SRA labor costs and how many FTE's that equals. Dr. Rice confirmed this did not include software costs, just labor. Mr. Geren asked if CPRIT has compared what is paid to SRA to what it would cost to do the work in-house. Ms. McConnell said the comparison had been done. The costs are for SRA scientific personnel (7-8 FTE's), editors, and IT staff.

Dr. Mulrow asked if SRA was based in Texas. Ms. McConnell stated they are based in Maryland. Mr. Geren asked if the contract was competitively bid. Ms. McConnell responded that it was originally bid through a request for proposals, but their services for FY 2015 were procured through the Comptroller's TXMAS program.

Mr. Roberts stated that this contract is for one year where previously the contracts had been multi-year. CPRIT is in the process of getting the services structured so they can be transferred to another vendor if warranted, through a competitive bidding process to occur next year. Dr. Rice stated SRA appears to be an impressive group. Mr. Roberts stated CPRIT is satisfied with their services, but since the original contract was let years ago, there are now other possibilities to be considered. Dr. Rice asked for a breakout of the FTE's to see how the \$6 million is allotted and would like to know if software is included in the fee structure. Ms. McConnell responded that our grants management system uses their proprietary software, which SRA enhances to fit CPRIT needs each time an RFA is issued or a change in process occurs. CPRIT pays an annual licensing fee of approximately \$8,000 a month.

Peer Review Monitoring Services Invitation for Bid: The peer review monitoring contract is for independent monitoring of CPRIT peer review meetings. This type of service has existed since May 2012. It is estimated that this year 86 peer review panel and review council meetings will be needed, costing up to \$100,000. CPRIT requests authorization to award a one-year base contract with up to three one-year renewal options, totaling \$400,000.

Independent Financial Audit Services Statement of Work: This contract is for a statutorily required report that must be submitted to the State Comptroller and other CPRIT oversight offices by December 20 of every year. CPRIT contracts through the Comptroller's TXMAS program and must get delegation from the State Auditor's Office for these services. In the past this audit has cost approximately \$35,000 to \$40,000; therefore, CPRIT is asking authorization to procure a firm to provide these services for up to \$40,000 a year or up to \$160,000 for four years.

No further questions or discussion was heard.

Service	Period Under Consideration	Notes about Contract	Annual Contract Amount	Period	Total Value of Contract
Due Diligence Services Request for Proposal	Award 4-year contract, initial year FY 2015	Award to one or more firms	\$350,000	maximum per year among firms	\$1,400,000
Outside Legal Services: Vinson & Elkins	5-year Contract in place, exercise 2nd Renewal Option	One of two firms	\$200,000	FY 2015	\$1,000,000
Outside Legal Services: Yudell Isidore Ng Russell	5-year Contract in place, exercise 2nd Renewal Option	One of two firms	\$100,000	FY 2015	\$500,000
Pre- and Post-Award Grants Management Support Services Statement of Work	Award 1-year contract (option for up to 12 additional months)	Comptroller's Texas Multiple Award Schedules (TXMAS) program	\$11,509,011	FY 2015	\$11,509,011
Peer Review Monitoring Services Invitation for Bid	Award 4-year contract, initial year FY 2015		\$100,000	estimated maximum per year	\$400,000
Independent Financial Audit Services Statement of Work	Award 4-year contract, initial year FY 2015	Comptroller's Texas Multiple Award Schedules (TXMAS) program	\$40,000	estimated maximum per year	\$160,000

MOTION:

Dr. Rice called for a motion to authorize CPRIT to execute these service contracts as presented by the Chief Operating Officer and upon appropriate approval from the Legislative Budget Board.

Motion by: Holmes

Seconded by: Mulrow

MOTION CARRIED UNANIMOUSLY

23. University Advisory Committee Charter

Dr. Rice stated that Dr. Kripke described earlier the work of the University Advisory Committee. He then recognized Ms. Doyle to present the recommendation on the committee charter that is in the Oversight Committee meeting packet under Tab 15.

Ms. Doyle stated the University Advisory Committee (UAC) is required to have a charter that is approved by the Oversight Committee. This charter was drafted by the UAC to address their roles and activities. There is at least one report required by statute at the

first meeting after the start of the year, but others could be necessary. The UAC requests approval of this charter.

There were no questions or discussion.

MOTION:

Dr. Rice called for a motion to approve the University Advisory Committee charter.

Motion by: Geistweidt

Seconded by: Mulrow

MOTION CARRIED UNANIMOUSLY

24. Advisory Committee on Childhood Cancers

Dr. Rice stated the Oversight Committee is served by another committee, the Advisory Committee on Childhood Cancers. This committee is required by CPRIT's statute and has been serving the Oversight Committee since 2010. The Oversight Committee is responsible for appointing the members of the committee. Dr. Rice called on Mr. Holmes, Chair of the Nominations Subcommittee, to present the subcommittee recommendations.

Mr. Holmes reported that the Nominations Subcommittee met on August 15 to review the eleven proposed members of the Advisory Committee on Childhood Cancers. The subcommittee recommended that the Oversight Committee approve the members as listed in their meeting packet under Tab 16.

There were no questions or discussion.

MOTION:

Dr. Rice called for a motion to approve the members of the Advisory Committee on Childhood Cancers

Motion by: Geren

Seconded by: Holmes

MOTION CARRIED UNANIMOUSLY

25. Final Order Approving Amendments to 25 T.A.C. Chapters 701-703

Dr. Rice recognized Ms. Doyle to address agenda item 25, the final orders approving changes to CPRIT's administrative rules. The rules are under Tab 17 of the Oversight Committee meeting book.

Ms. Doyle stated this is the first of two actions to be taken today related to CPRIT's administrative rules. This agenda item concerns adopting final rule amendments. At the May meeting, members approved proposed rule changes for publication in the Texas Register to solicit public comment. In addition to publishing the rule changes in the Texas Register, CPRIT also distributed a listserve notice about the proposed changes to

more than a 1,000 people. No input was received from the public. Therefore, the rule changes originally proposed at the May meeting and subsequently published in the Texas Register are presented for final adoption. The final orders adopting the rule changes will be provided to the Secretary of State.

No questions or discussion was heard.

MOTION:

Dr. Rice called for a motion to approve the final orders adopting CPRIT's rule changes and to direct staff to file the orders with the Secretary of State.

Motion by: Geren

Seconded by: Mulrow

MOTION CARRIED UNANIMOUSLY

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

Dr. Rice noted that the proposed rule changes are under Tab 18 of the committee meeting packet, with the changes to the text in red. He called on Ms. Doyle to present this item.

Ms. Doyle stated that action on this agenda item will begin the formal rulemaking process for three proposed rule changes. The rule changes are recommended for publication in the *Texas Register*. Ms. Doyle explained the first change, proposed new Rule 701.35, which addresses the process to be followed if a member of the public seeks to initiate a rule change. CPRIT is required by statute to have a process for the public to suggest administrative rules and this new rule fulfills that requirement. Ms. Doyle indicated that the other two rule changes are in Chapter 703, which deals primarily with grantees, both from the grant application and post award perspective. The two proposed changes to Chapter 703, if adopted, will affect grantees. One change provides additional guidance with respect to the federal indirect cost rate that academic institutions are able to use for their matching fund credit. The other rule change involves a change to CPRIT's audit requirements that responds to an issue related to required audits for state institutions of higher education. Ms. Doyle referred the Oversight Committee to the explanation for the proposed change in the memo behind Tab 18 and responded that it is intended addresses inefficiencies arising from the current audit requirements.

Ms. Doyle explained that she will report at the November meeting regarding any public input related to the proposed changes and, based on the input received; recommend possible final action to the Oversight Committee at that time.

No questions or discussion was heard.

MOTION:

Dr. Rice called for a motion to instruct staff to publish the proposed rule amendments to Chapters 701 and 703 in the Texas Register in accordance with the requirements of the Administrative Procedure Act.

Motion by: Geren

Seconded by: Mulrow

MOTION CARRIED UNANIMOUSLY

27. Proposed Amendments to the Code of Conduct

Dr. Rice recognized Ms. Doyle to present amendments to the Code of Conduct, found under Tab 19 in the meeting packet.

Ms. Doyle stated the proposed changes are administrative. During the process of compiling a list of annual reporting requirements and due dates for Oversight Committee members and for CPRIT employees, Staff determined that due dates were not specified for some reports, which may make it difficult to ensure compliance. The changes proposed for consideration would add due dates for the CEO's yearly report on outside employment of CPRIT employees and for the annual filing of Oversight Committee member political contributions exceeding \$1000 to state and federal candidates.

There were no questions or comments heard.

MOTION:

Dr. Rice called for a motion to adopt the amendments to CPRIT's Code of Conduct as proposed

Motion by: Angelou

Seconded by: Mulrow

MOTION CARRIED UNANIMOUSLY

28. Subcommittee Business

Dr. Rice recognized Dr. Mulrow to present the Diversity Subcommittee report, located under Tab 20 in the committee meeting packet.

Dr. Mulrow reported the subcommittee met on August 13 and discussed the agency's administrative efforts related to historically underutilized businesses. The subcommittee also received and discussed a report on programmatic ethnicity data and made some recommendations on how to prioritize diversity by the agency. She stated there are no actions for today and the subcommittee will continue to discuss the topic.

29. Consultation with General Counsel

This agenda item was previously taken up. See agenda item 16.

30. Future Meeting Dates and Agenda Items

Dr. Rice reported that the next regular Oversight Committee meeting is scheduled for November 19. CPRIT staff will circulate a tentative agenda prior to the meeting.

The Oversight Committee will convene in Austin on September 3 for a working session to address the Programs Priority Project. In addition, consistent with the discussion today, the Oversight Committee will consider Product Development grant contracts and terms at the September 3 meeting. An agenda will be posted.

31. Adjourn

There being no further business, Dr. Rice called for a motion to adjourn.

Motion by: Geren

Seconded by: Mulrow

MOTION CARRIED UNANIMOUSLY

Meeting adjourned at 3:23 p.m.

Signature

Date



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

Conflict of Interest Disclosure – Oversight Committee Members For Applications Recommended for Consideration at August 20, 2014 Open Meeting

Conflict of Interest Disclosure - Amy Mitchell

Product Development (1)

DP140072

Prevention (11)

PP140018, PP140028, PP140033, PP140049, PP140164, PP140176, PP140182, PP140183,
PP140209, PP140210, PP140211

Scientific Research (84)

RP140001, RP140132, RP140140, RP140141, RP140143, RP140152, RP140179, RP140181,
RP140216, RP140218, RP140222, RP140223, RP140224, RP140233, RP140244, RP140252,
RP140258, RP140262, RP140271, RP140285, RP140298, RP140315, RP140320, RP140323,
RP140328, RP140329, RP140350, RP140367, RP140399, RP140402, RP140408, RP140411,
RP140412, RP140429, RP140430, RP140435, RP140449, RP140452, RP140456, RP140462,
RP140464, RP140468, RP140469, RP140473, RP140478, RP140479, RP140482, RP140500,
RP140515, RP140517, RP140522, RP140542, RP140544, RP140553, RP140556, RP140563,
RP140594, RP140597, RP140606, RP140609, RP140612, RP140616, RP140648, RP140649,
RP140655, RP140661, RP140664, RP140672, RP140678, RP140685, RP140767, RP140781,
RP140784, RP140800, RP140840, RP140842, RR140061, RR140071, RR140072, RR140073,
RR140077, RR140081, RR140082, RR140084

Conflict of Interest Disclosure – Will Montgomery

Product Development (1)

DP140072

Prevention (7)

PP140018, PP140049, PP140176, PP140182, PP140183, PP140209, PP140210

Scientific Research (65)

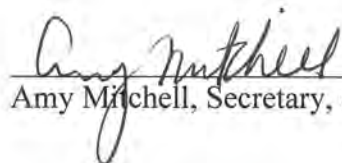
RP140132, RP140140, RP140141, RP140143, RP140152, RP140218, RP140222, RP140224, RP140233, RP140244, RP140262, RP140271, RP140285, RP140315, RP140320, RP140323, RP140328, RP140329, RP140367, RP140402, RP140408, RP140411, RP140412, RP140429, RP140430, RP140435, RP140449, RP140452, RP140462, RP140464, RP140468, RP140473, RP140479, RP140482, RP140500, RP140515, RP140517, RP140522, RP140542, RP140544, RP140556, RP140563, RP140594, RP140597, RP140606, RP140609, RP140612, RP140648, RP140649, RP140655, RP140661, RP140664, RP140672, RP140685, RP140781, RP140800, RP140842, RR140061, RR140071, RR140072, RR140073, RR140077, RR140081, RR140082, RR140084

By my signature, this list of reported conflicts of interest shall be included as the official record of conflicts of interest reported by Oversight Committee members for grant award recommendations considered at the August 20, 2014, Oversight Committee meeting.



Dr. William Rice, Presiding Officer, Oversight Committee

8-20-14 (date)



Amy Mitchell, Secretary, Oversight Committee

9-3-14 (date)



W. R. Roberts 8-20-14
Amy M. Mitchell 9/3/14

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

August 4, 2014

Dear Oversight Committee Members:

I am pleased to present the Program Integration Committee's (PIC) unanimous recommendations for funding 101 grant applications totaling \$107 million in grants. The PIC recommendations for 84 scientific research grant awards, 15 prevention awards and two product development awards are attached.

Dr. Margaret Kripke, CPRIT's Chief Scientific Officer, Dr. Becky Garcia, CPRIT's Chief Prevention Officer, and Dr. Tom Goodman, CPRIT's Product Development Officer, have prepared overviews of the scientific research, prevention, and product development program slates to assist your evaluation of the recommended awards. The overviews are intended to provide a comprehensive summary of the recommended proposals with enough detail that you should be able to understand the substance of the proposal and the reasons endorsing grant funding.

In addition to the comprehensive overviews, all of the information reviewed by the Review Councils is available by clicking on the appropriate link in the portal. This information includes the full application, peer reviewer critiques, and the CEO affidavit for each proposal.

The approval of these grant recommendations is governed by a statutory process that requires 2/3 of the members present and voting to approve each recommendation. David Reisman, CPRIT's Chief Compliance Officer, will certify that the review process for the recommended grants followed CPRIT's award process prior to any Oversight Committee action.

The award recommendations will not be considered final until the Oversight Committee meeting on Wednesday, August 20, 2014. Consistent with the non-disclosure agreement that all Oversight Committee members have signed, the recommendations should be kept confidential and not be disclosed to anyone until the award list is publicly announced at the Oversight Committee meeting. I request that Oversight Committee members not print, email or save to your computer's hard drive any material on the portal. I appreciate your assistance in taking all necessary precautions to protect this information.

If you have any questions or would like more information on the review process or any of the projects recommended for an award, CPRIT's staff, including myself, Dr. Kripke, Dr. Garcia, and Dr. Goodman, are always available. Please feel free to contact us directly should you have any questions. The programs that will be supported by the CPRIT awards are an important step in our efforts to mitigate the effects of cancer in Texas. Thank you for being part of this endeavor.

Sincerely,
Wayne R. Roberts
Chief Executive Officer

Academic Research Award Recommendations –

The PIC unanimously recommends approval of 84 academic grant proposals totaling \$76,277,535. The recommended grant proposals were submitted in response to one of five grant mechanisms: Individual Investigator Research Awards, High Impact-High Risk Research Awards, Recruitment of Established Investigators, Recruitment of Rising Stars, and Recruitment of First-Time Tenure-Track Faculty Members. The PIC followed the recommendations made by the Scientific Review Council (SRC). The SRC provided the prioritized list of recommendations for Individual Investigator Research Award and High Impact-High Risk Research Awards to the presiding officer of the PIC and the Oversight Committee on June 24, 2014. The SRC provided the prioritized list of recommendations for the Recruitment awards to the presiding officers on July 12, 2014.

The PIC is required to give funding priority, to the extent possible, to applications that meet one or more criteria set forth in V.T.C.A., TEX. HEALTH & SAFETY CODE § 102.251(a)(2)(C). The PIC determined that these academic research proposals met the following CPRIT funding priorities:

- could lead to immediate or long-term medical and scientific breakthroughs in the area of cancer prevention or cures for cancer;
- strengthen and enhance fundamental science in cancer research;
- ensure a comprehensive coordinated approach to cancer research [Individual Investigator Research Awards];
- address federal or other major research sponsors' priorities in emerging scientific or technology fields in the area of cancer prevention or cures for cancer;
- are matched with funds available by a private or nonprofit entity and institution or institutions of higher education;
- have a demonstrable economic development benefit to this state [Individual Investigator Research Awards, Recruitment Awards];
- enhance research superiority at institutions of higher education in this state by creating new research superiority, attracting existing research superiority from institutions not located in this state and other research entities, or enhancing existing research superiority by attracting from outside this state additional researchers and resources [Recruitment Applications]; and
- address the goals of the Texas Cancer Plan.

Individual Investigator and High Impact-High Risk Grant Award Recommendations

App ID	Award Type	Organization	Application Title	Budget
RP140244	IIRA	The University of Texas M. D. Anderson Cancer Center	Regulation of MDM2-mediated oncogenesis and anti-tumor immunity by USP15	\$870,156
RP140412	IIRA	The University of Texas Southwestern Medical Center	Endotrophin and the Obesity/Cancer Nexus: Role in Growth and Chemoresistance	\$899,997
RP140597	IIRA	The University of Texas M. D. Anderson Cancer Center	Role of TJPI in Sensitivity and Resistance to Proteasome Inhibitors in Myeloma	\$900,000
RP140655	IIRA	The University of Texas Southwestern Medical Center	Evaluation of the role of tumor suppressor candidate NPRL2 in cell growth control	\$596,265
RP140350	HIHR	Baylor College of Medicine	Integrated Human Herpesvirus 6 as a Novel Heritable Risk Factor for Glioma	\$199,298

RP140606	IIRA	The University of Texas M. D. Anderson Cancer Center	Optimizing therapy for glioblastoma through genomic profiling of treatment failure	\$900,000
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
RP140402	IIRA	The University of Texas Southwestern Medical Center	Novel targets for acute myeloid leukemia treatment	\$900,000
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
RP140612	IIRA	The University of Texas M. D. Anderson Cancer Center	Collateral Genomic Deletions As Targetable Vulnerabilities in Cancer	\$900,000
RP140469	IIRA	Baylor College of Medicine	Novel Small Molecule Probes Targeting IDH Mutated Glioma	\$695,527
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
RP140408	IIRA	The University of Texas M. D. Anderson Cancer Center	Identificaiton of a novel mechanism of mTORC1 and autophagy regulation for cancer therapy.	\$900,000
RP140462	IIRA	The University of Texas M. D. Anderson Cancer Center	Systematic Investigation of Clinically Relevant Expressed Pseudogenes in Cancer	\$870,539
RP140132	IIRA	Rice University	Towards Point-of-Care Nucleic Acid Cancer Diagnostics	\$900,000
RP140517	IIRA	The University of Texas at Dallas	Optimal Biomarkers for Personalized Cancer Therapy: A Network-Based Approach	\$490,689
RP140285	IIRA	The University of Texas Southwestern Medical Center	Noninvasive Identification of Prostate Tumor Hypoxia as a Prognostic Biomarker of Radiation Response	\$895,820
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
RP140329	HIHR	The University of Texas M. D. Anderson Cancer Center	Opening the central nervous system to immunotherapy by blocking TREK1	\$198,957
RP140181	IIRA	Baylor College of Medicine	Mechanisms of CTC Biomarkers in Breast Cancer Brain Metastasis	\$899,968
RP140252	IIRA	Baylor College of Medicine	Investigating and preclinical targeting molecular drivers of muscle-invasive bladder cancer	\$827,451
RP140262	IIRA	The University of Texas M. D. Anderson Cancer Center	Intrinsic Reward Sensitivity & Smoking Cessation with Varenicline or Patch NRT	\$899,505
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
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
RP140298	IIRA	Texas Tech University	Engineering microfluidic devices for multimodal mechanical phenotyping of tumor cells in flow	\$674,465
RP140152	IIRA	The University of Texas Southwestern Medical Center	Natural Product for Treatment of Non-Small Cell Lung Cancer	\$772,368
RP140218	IIRA	The University of Texas M. D. Anderson Cancer Center	Inhibiting Oxidative Phosphorylation: A Novel Strategy in Leukemia	\$826,744

RP140522	IIRA	The University of Texas M. D. Anderson Cancer Center	Reversing vaccination-induced impairment of anti-CTLA-4-based cancer therapy.	\$899,991
RP140233	IIRA	The University of Texas Southwestern Medical Center	Structure-guided Kinase Inhibitor Design for Cancer Therapy	\$900,000
RP140648	IIRA	The University of Texas at Austin	New Therapeutic Strategies for Metastatic Melanoma	\$900,000
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
RP140840	HIHR	Texas Tech University	New Technology for Ultra High Throughput Enumeration of Circulating Tumor Cells	\$199,993
RP140001	IIRA	Baylor College of Medicine	Role of DNA METHYLTRANSFERASE 3A in Hematologic Malignancies	\$900,000
RP140468	IIRA	The University of Texas M. D. Anderson Cancer Center	TARGETING OF CHRONIC LYMPHOCYTIC LEUKEMIA BY DESIGNER T CELLS	\$900,000
RP140449	HIHR	The University of Texas Southwestern Medical Center	A new Cancer Target: AMPylation machinery	\$200,000
RP140271	IIRA	The University of Texas M. D. Anderson Cancer Center	Targeting p53 in cancer through manipulation of p63 and p73	\$900,000
RP140140	IIRA	The University of Texas Southwestern Medical Center	Turn ON the Tumor Contrast for Surgical Resection of Head and Neck Cancers	\$900,000
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
RP140141	IIRA	The University of Texas Southwestern Medical Center	Targeting HER2 for cancer therapy	\$892,989
RP140179	IIRA	Baylor College of Medicine	Targeting self-renewal in leukemic stem cells through the inactivation of KLF4	\$813,789
RP140430	IIRA	The University of Texas M. D. Anderson Cancer Center	Synaptic Mechanisms of Cognitive Decline after Cranial Radiation	\$836,557
RP140563	IIRA	The University of Texas M. D. Anderson Cancer Center	PAF, a Novel Wnt Signaling Regulator, in Colorectal Cancer	\$900,000
RP140223	HIHR	Baylor College of Medicine	Viral MicroRNAs in Ovarian Cancer Growth and Metastasis	\$199,995
RP140224	IIRA	The University of Texas M. D. Anderson Cancer Center	PPAR-delta Regulation of Wnt/B-catenin to Drive Colon Cancer	\$890,003
RP140315	IIRA	The Methodist Hospital Research Institute	Accurate and High Throughput Detection of Breast and Ovarian Cancer Cells in Whole Blood	\$900,000
RP140649	HIHR	The University of Texas at Austin	Realizing Personalized and Precision Medicine for Melanoma: A Rapid Assay for Measuring ERK Activity	\$200,000
RP140222	IIRA	The University of Texas M. D. Anderson Cancer Center	Direct Roles for RB and E2F1 in DNA Repair	\$900,000
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
RP140500*	IIRA	The University of Texas M. D. Anderson Cancer Center	Toward the Cure of Myelodysplastic Syndrome: Interfering with Innate Immunity Alterations in Human and Mouse Systems	\$900,000

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
RP140842	IIRA	The University of Texas at Austin	Determining the Functional Role of microRNAs in Viral Tumorigenesis.	\$604,624
RP140478	HIHR	Texas Tech University	Computational Chemistry Determination of DNA Damage Mechanisms in Proton Cancer Therapy to Optimize Its Clinical Use	\$200,000
RP140544	IIRA	The University of Texas at Dallas	Mapping Acidic Tumor Microenvironment with Renal Clearable pH Nanoindicators	\$900,000
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
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
RP140399	IIRA	Baylor University	Targeting Hypoxia in Breast Cancer with Highly Potent Small-Molecule Anticancer Prodrugs	\$900,000
RP140320	HIHR	The University of Texas Southwestern Medical Center	DISSECTING A Necrotic Signaling Pathway in Human Cancer Cells	\$200,000
RP140661	IIRA	The University of Texas Southwestern Medical Center	Analyses of the regulatory mechanisms of tankyrase and its role in tumorigenesis	\$876,751
RP140367	IIRA	The University of Texas Southwestern Medical Center	Targeting BRD4 in Breast Cancer	\$900,000
RP140678	HIHR	Scott & White Healthcare	Novel, humanized single-chain CD123xCD3 bispecific antibodies for eliminating leukemia stem cells and leukemic cells	\$199,959
RP140800	IIRA	The University of Texas Health Science Center at Houston	The Role of Alternative Polyadenylation in Glioblastoma Tumor Progression	\$848,491
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
RP140542	IIRA	The University of Texas M. D. Anderson Cancer Center	Biology and Therapy of Basal Bladder Cancers	\$865,587
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
RP140479	HIHR	Texas A&M University	Screening for melanoma genes using natural hybrid incompatibilities	\$199,993
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
RP140553	IIRA	Baylor College of Medicine	Translational Discovery of Resistance Genes and Cancer Gene Functions	\$900,000
RP140616	IIRA	Baylor College of Medicine	Tenascin-C and Metastatic Prostate Cancer Progression	\$827,806
RP140429	IIRA	The University of Texas M. D. Anderson Cancer Center	The Role of DIRAS3 (ARHI) in Initiating Autophagy and Tumor Dormancy	\$900,000
RP140411	IIRA	The University of Texas M. D. Anderson Cancer Center	Targeting Tumor Cell Invasion in Glioblastoma	\$900,000

RP140258	IIRA	Baylor College of Medicine	The Intersection between Childhood Cancer and Congenital Anomalies: Identifying Novel Cancer Predisposition Syndromes	\$874,964
RP140781	HIHR	Texas A&M University	High-Field Open MRI: Cost-Effective Screening for Early Detection of Breast Cancer	\$200,000
RP140328	HIHR	The University of Texas at Austin	Synthetic protein degradation agents to clear oncogenic proteins from cells	\$199,852
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
RP140767	IIRA	Baylor College of Medicine	Toll-like receptors, gut microbiota, and risk of colorectal adenoma	\$899,131
RP140609	IIRA	The University of Texas M. D. Anderson Cancer Center	A missing link between obesity and cancer: Adipose derived stem cells	\$610,704

* Note the changed title from the original SRC recommendations sent by SRC Chair Dr. Richard Kolodner on June 24, 2014. Dr. Kolodner corrected the title for RP140500 in a letter dated July 10, 2014.

Recruitment Grant Award Recommendations

Application ID	Nominator Organization	Candidate	Mechanism*	Budget Requested
RR140082	The University of Texas Southwestern Medical Center	Daniela Nicastro	RRS	\$4,000,000
RR140084	The University of Texas Southwestern Medical Center	David McFadden	RFT	\$2,000,000
RR140071	The University of Texas M. D. Anderson Cancer Center	Yiwen Chen	RFT	\$2,000,000
RR140061	The University of Texas Southwestern Medical Center	Andrew Hsieh	RFT	\$2,000,000
RR140072	The University of Texas Health Science Center at San Antonio	Kexin Xu	RFT	\$2,000,000
RR140081	Rice University	Gang Bao	REI	\$6,000,000
RR140077	The University of Texas M. D. Anderson Cancer Center	George Eisenhoffer	RFT	\$2,000,000
RR140073	Rice University	Aryeh Warmflash	RFT	\$2,000,000

*RRS = Recruitment of Rising Star, RFT = Recruitment of First Time Tenure Track, REI = Recruitment of Established Investigator

Prevention Award Recommendations -

The PIC unanimously recommends approval of 15 prevention grant proposals totaling \$17,568,470. The recommended grant proposals were submitted in response to one of two grant mechanisms: Evidence-Based Cancer Prevention Services and Competitive Continuation/Expansion Grants. The PIC followed the recommendations made by the Prevention Review Council.

The PIC is required to give funding priority, to the extent possible, to applications that meet one or more criteria set forth in V.T.C.A., TEX. HEALTH & SAFETY CODE § 102.251(a)(2)(C). The PIC determined that these prevention proposals met the following CPRIT funding priorities:

- ensure a comprehensive coordinated approach to cancer research;
- address federal or other major research sponsors' priorities in emerging scientific or technology fields in the area of cancer prevention or cures for cancer;
- are collaborative between any combination of private and nonprofit entities, public or private agencies or institutions in this state, and public or private institutions outside this state [Evidence-Based Cancer Prevention Services];
- have a demonstrable economic development benefit to this state; and
- address the goals of the Texas Cancer Plan.

Evidence-Based Cancer Prevention Services and Competitive Continuation/Expansion Grant Award Recommendations

App ID	Award Type	Title	Organization	Budget
PP140208	EBP	Increasing HPV Vaccinations in Harris and Jefferson Counties Using Combined Evidence-Based Approaches in a Federally Qualified Health Center	Legacy Community Health Services	\$1,500,000
PP140205	CCE EBP	Eliminating Cancer Disparities in Medically Underserved Immigrant and Refugee Populations in Houston Texas	Asian American Health Coalition of Greater Houston, Inc., dba Hope Clinic	\$1,496,840
PP140033	CCE EBP	Access to Breast and Cervical Care for West Texas (ABC24WT)	Texas Tech University Health Sciences Center	\$1,499,670
PP140183	EBP	Multi-component Interventions to Increase HPV Vaccination in a Network of Pediatric Clinics	The University of Texas Health Science Center at Houston	\$1,495,388
PP140049	CCE PubEd	Educating Hispanic adolescents and their families on cervical cancer prevention and HPV vaccination in community and clinic settings	The University of Texas Health Science Center at San Antonio	\$149,985
PP140176	EBP	SMS Cessation Service for Young Adult Smokers in South Texas	The University of Texas Health Science Center at San Antonio	\$1,400,045
PP140211	EBP	Tiempo de vacunarte! Time to get vaccinated!	Texas Tech University Health Sciences Center at El Paso	\$1,499,195
PP140018	EBP	Improving Access to Colorectal Cancer Screening in East Texas	The University of Texas Health Center at Tyler	\$1,269,216
PP140164	CCE EBP	ACCION 2: Against Colorectal Cancer in our Neighborhoods: El Paso and Hudspeth County	Texas Tech University Health Sciences Center at El Paso	\$1,499,438
PP140209	EBP	Building a Healthy Temple Cancer Primary Prevention Program amongst Hispanics	The University of Texas at San Antonio	\$573,095
PP140210	CCE ProfEd	Cancer genomics training program for a competent Texas health education workforce	Texas A&M University	\$149,991
PP140026	CCE EBP	Bridging Access to Breast Healthcare Services	The Bridge Breast Network	\$1,497,357
PP140028	CCE EBP	Empowering the Medically Underserved Through a Community Network for Cancer Prevention	Baylor College of Medicine	\$1,499,234

PP140182	CCE EBP	Population Based Screening for Hereditary Breast and Ovarian Cancer Syndrome and the Lynch syndrome in the Underserved	The University of Texas Southwestern Medical Center	\$1,499,872
PP140171	CCEE BP	Navigating Rural Highways II: Expanding Access to Breast Cancer Screening and the Care Continuum for Underserved Texas Women (NRH II)	The Rose	\$539,144

Product Development Award Recommendations –

The PIC unanimously recommends approval of two product development grant proposals totaling \$13,580,185. The recommended grant proposals were submitted in response to the New Company Product Development Request for Applications. The PIC followed the recommendations made by the Product Development Review Council.

The PIC is required to give funding priority, to the extent possible, to applications that meet one or more criteria set forth in V.T.C.A., TEX. HEALTH & SAFETY CODE § 102.251(a)(2)(C). The PIC determined that these product development proposals met the following CPRIT funding priorities:

- could lead to immediate or long-term medical and scientific breakthroughs in the area of cancer prevention or cures for cancer ;
- strengthen and enhance fundamental science in cancer research [DP140034];
- are interdisciplinary or interinstitutional [DP140072];
- address federal or other major research sponsors' priorities in emerging scientific or technology fields in the area of cancer prevention or cures for cancer;
- are matched with funds available by a private or nonprofit entity and institution or institutions of higher education;
- are collaborative between any combination of private and nonprofit entities, public or private agencies or institutions in this state, and public or private institutions outside this state;
- have a demonstrable economic development benefit to this state;
- expedite innovation and product development, attract, create, or expand private sector entities that will drive a substantial increase in high-quality jobs, and increase higher education applied science or technology research capabilities; and
- address the goals of the Texas Cancer Plan.

Product Development Grant Award Recommendations

App ID	Company Name	Project	Budget*
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
DP140072	OncoNano Medicine, Inc.	Transforming Cancer Surgery by Tumor Illumination	\$6,000,000

* CPRIT will seek Oversight Committee approval at the August 20, 2014, meeting to authorize advancing grant award funds to both companies, subject to contract negotiation. The timing, amounts, and conditions of funding advancement will be presented to the Oversight Committee for review and approval.



Oversight Committee Meeting Minutes

September 03, 2014

- 1) Chairman Rice called the meeting to order at 8:30 a.m.
- 2) Secretary Mitchell called roll. All were present.
- 3) Chairman Rice noted that the following two witnesses signed up for public comment: Linda McCaul, wife of Congressman Michael McCaul; and C. Patrick Reynolds, MD, PhD, Cancer Center Director, Texas Tech University Health Sciences Center, School of Medicine
- 4) Contract Terms for Product Development Grants

Chairman Rice called on Dr. Tom Goodman, Chief Product Development Officer, and Wayne Roberts, CEO, to present contract terms for product development grants for the Oversight Committee's approval. Mr. Roberts proposed the Oversight Committee consider adoption in principle of the guidance presented by Dr. Goodman on economic terms and the establishment of an Oversight Committee subcommittee to focus on economic terms. Mr. Roberts also stated CPRIT staff would identify members for a Product Development Advisory Committee to counsel CPRIT in establishing economic terms and other product development issues.

MOTION:

Chairman Rice called for a motion to adopt in principle the guidance presented by Mr. Goodman on economic terms for contracts already in process.

Motion by: Mulrow

Seconded by: Rosenfeld

MOTION CARRIED UNANIMOUSLY

MOTION:

Chairman Rice called for a motion to establish an Oversight Committee Subcommittee on Economic Terms with membership of Dr. Craig Rosenfeld, Mr. Will Montgomery, Ms. Amy Mitchell, and Mr. Pete Geren.

Motion by: Mulrow

Seconded by: Montgomery

MOTION CARRIED UNANIMOUSLY

4) Program Priorities Project Work Session

Chairman Rice called on Mr. Roberts to introduce the work session on program priorities. Mr. Roberts introduced Mr. Robert Mittman, who guided the group through the following steps:

- a. Measures of Success for CPRIT
- b. Prevention program priorities
- c. Scientific Research program priorities
- d. Product Development program priorities
- e. Cross-programs priorities

After the program discussions, Dr. Rice stated that a report will be prepared from the day's priorities discussion, including comments submitted by the University Advisory Committee, and posted for public comment. Those public comments will be collected and the report presented to the Oversight Committee for approval at their regularly scheduled meeting in November.

5) Public testimony was provided by Dr. Reynolds regarding the importance of childhood cancer research. Mrs. McCaul was unable to attend.

6) Adjourn

There being no further business, Chairman Rice adjourned the meeting and work session at 2:35 p.m.

Signature

Date



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: CPRIT OVERSIGHT COMMITTEE MEMBERS
FROM: WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT: AGENDA ITEM 5: CHIEF EXECUTIVE OFFICER REPORT
DATE: NOVEMBER 10, 2014

Behind this memo are copies of the October 3 and November 3, 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 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 November 19, 2014, Oversight Committee meeting includes the following:

New Employees and Job Postings

Three new employees are starting work with CPRIT over the next two weeks. With these hires, the agency will have 28 full-time equivalent (FTE) employees; CPRIT is authorized to employ 32 FTEs. These new employees will be introduced to the Oversight Committee on November 19:

- Donald Brandy, Purchaser
- Dina Fletcher, Grant Accountant
- Jeff Hillery, Communications Specialist

The position for Program Manager for Product Development closed on October 31. Screening for the 26 applications has begun. This person will assist Dr. Goodman and work directly with product development grantees and grant applicants, as well as take on special assignments related to product development activities. An Operations Specialist position is posted until November 12. This person will assist Lisa Nelson, Operations Manager, with personnel, office management, and grants management.

Once these two positions are filled, CPRIT will have two remaining FTE positions to fill: Information Technology and the Manager of Internal Audits. The internal audit manager position may be re-designated for another purpose.

Facilities Update

Construction at the Travis Building is reported to be on schedule for the February office relocation. Initial inspections may occur in late December or early January.

Joint Meeting - Advisory Committee for Product Development and Oversight Committee Subcommittee on Economic Terms

At the last Oversight Committee meeting, the Oversight Committee voted to establish a new subcommittee to address issues related to contract terms, particularly related to economic expectations and revenue sharing obligations for grantees. The most immediate goal for the new subcommittee is to recommend contract terms for product development awards to the full Oversight Committee. To assist the new Economic Terms subcommittee, CPRIT staff committed to establishing a new Advisory Committee for Product Development (ACPD) to provide advice and input related to the product development program, including revenue sharing options.

The ACPD membership has been constituted, and the Oversight Committee will be asked to formally approve membership of the ACPD at the November 19 meeting. One of the primary charges for the ACPD is to clarify life science venture capital trends and practices that can be transferred to and used by CPRIT with its multiple goals of cancer mitigation, high quality job creation, and providing an appropriate rate of return on CPRIT's product development investments.

The provisional members of the ACPD met by conference call on November 6 as part of a joint meeting with the Economic Terms subcommittee. The purpose of this joint meeting was to receive feedback from ACPD members regarding options and expectations CPRIT should consider when establishing revenue sharing terms. To help guide the discussion, meeting attendees were asked to provide their perspectives on the following issues:

- Reasonable revenue sharing terms for a public entity like CPRIT investing in an early stage company - Is there an acceptable range? How might these terms change as the company matures? (Note: CPRIT is not a traditional venture capital firm. Rate of return is one consideration in our investments, but as a public entity, CPRIT also has social goals such as getting products, devices, and drugs to the bedside to treat people with cancer ASAP, enticing companies to Texas, growing a currently underrepresented industry in Texas, and creating good high paying jobs. These goals must be blended.)
- Advantages and disadvantages of a buyout clause - How does one benefit the company? How does one benefit the investor (CPRIT)? How is fair market value determined at the time of the buyout?
- “Home Runs” in the venture capital world - What is the expected rate of return on a blockbuster company investment?

Another meeting of the Economic Terms subcommittee is expected to be held sometime this month. No deadline for the committee's work has been established as of this writing.

Other Topics May be Added as Warranted



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT: SEPTEMBER ACTIVITIES UPDATE
DATE: OCTOBER 3, 2014

Topics in this update include: CPRIT staffing, the Program Priorities Project, Program updates, Compliance Plan Design status, advisory committees, operations (including contracts and audits), and outreach efforts.

New Hires and Job Openings

The agency now has 26 full-time equivalent (FTE) employees and is authorized to employ up to 32 FTEs. A job offer has been extended to fill the Program Manager for Product Development. The Program Manager will assist Dr. Goodman and work directly with product development grantees and grant applicants, as well as take on special assignments related to product development activities.

Job postings for three positions (Grant Accountant, Purchasing Specialist, and Communications Specialist) will close October 3. Interviews with qualified candidates for these positions will take place in October. A position for an operations specialist will be posted this month.

Office Relocation and Move to Temporary Offices

In late August CPRIT completed the first of two scheduled moves. Our temporary offices are located at 400 West 15th Street. (Austinites may know this building as the Wells Fargo Building, although the bank is no longer a tenant.)

CPRIT's move to state-owned space in the William B. Travis Building is still on target to occur in February 2015. It is less than ideal to move the entire office twice in the six months (a period that covers four Oversight Committee meetings and the start of the 84th Legislative Session); however, CPRIT staff has managed the first move with a minimum of disruption in our operations.

Compliance Program Design Project

The Audit Subcommittee met on September 10 to discuss the report from Weaver and Tidwell LLP, a Texas-based assurance, tax and advisory firm, who developed a compliance program design plan for CPRIT pursuant to a \$99,000 consulting contract approved by the Governor's Office in June. The Subcommittee considered the analysis underlying recommendations of the report and asked for additional information. The Subcommittee will meet on October 6 to discuss further research related to compliance programs at other similar grant programs and state entities and to consider initial program ideas.

Delinquent Reports

Since reported at the last Oversight Committee meeting, the number of current delinquent reports has steadily and markedly decreased from 483, as of August 8, to 186 as of September 26. These numbers do not include the total number of Financial Status Reports (FSRs) that must be filed, which are those that are in line for filing after current delinquent FSRs are filed. That number has declined as well, from 180 as of August 8 to 142 as of September 26. While the decline does not appear to be relatively substantial, it should be taken into account that August 29 was an FSR filing deadline for all grantees, which resulted in an additional FSR added to each grantee total who already had one or more delinquent FSRs pending.

There remains more work to be done in eliminating the delinquent reports. However, the grantees have been working diligently to file past due reports, while staff has been working together, and with the grantees, to find better and more efficient ways to process the reports filed.

Program Priority Setting Project

Robert Mittman facilitated a meeting of the Oversight Committee September 3 in Austin. The Oversight Committee discussed the long-term vision for CPRIT's product development, scientific research and prevention activities as well as high-level priorities and guidelines for grant-making decisions within and across the three programs. A report based on this discussion is being drafted and, after review by the subcommittees, it will be posted for public input in October. A second draft will be presented to the Oversight Committee on November 19.

Scientific Research Program Update

Much of the work for the Scientific Research program in September related to the peer review of applications submitted for Individual Investigator Research Awards and Recruitment awards.

- FY2015 Individual Investigator Research Award (IIRA) Applications: The review process is ongoing for the proposals submitted in June in response to three RFAs. In addition to the 271 applications submitted for the traditional IIRA, 66 applications were submitted for a targeted

cancer prevention research IIRA and 56 applications were submitted for a targeted childhood and adolescent cancer IIRA. The traditional IIRA applications were subjected to preliminary evaluation, which eliminated 37% of those applications. The targeted IIRAs and IIRA renewal applications are not subject to preliminary evaluation. This leaves a total of 247 applications that will undergo full review out of the 393 applications submitted in June.

The peer review panels will meet at the Hyatt Regency in Dallas on October 27, 28, 31, and November 3, 6, and 11. Oversight Committee members are invited to attend one or more of the peer review meetings. The grants recommended by the review panels, the Scientific Review Council (SRC), and PIC will come to the Oversight Committee meeting for approval at its meeting in February.

- FY2015 Recruitment Awards: The SRC is reviewing ten applications submitted by five institutions for Recruitment Awards. Of the ten applications under review, four are for First Time, Tenure-Track Awards, three are Rising Star applications, and three are Established Investigator applications. Candidates are from Harvard University Medical School or Broad Institute, NIH, Weill Cornell Medical School, UC San Diego, McGill University and the University of Maryland. The SRC will meet in October to decide the final recommendations, which will be forwarded to the PIC, and presented for Oversight Committee consideration at the November 19 meeting.
- 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.
- Advisory Committee on Childhood Cancer (ACCC) Meeting - CPRIT's Scientific Research Program hosted a meeting of the ACCC on September 2, along with the Oversight Committee Chair and CPRIT's CEO. The ACCC appointed Dr. Gail Tomlinson as interim chair and Dr. Patrick Reynolds as co-chair and approved their charter. Dr. Kripke presented an overview of the Scientific Research program's grant portfolio; this was followed by a discussion of priorities for the Scientific Research program and the focus of the Committee's annual report to the Oversight Committee.

Product Development Program Update

The Product Development Program is currently reviewing applications submitted for FY2015 product development awards and constituting an Advisory Committee on Product Development.

- FY2015 Cycle 1 Product Development Grant Applications: Following in-person presentations made by the 17 companies invited to address the full product development review panels in Dallas August 12 – 15, the review panels approved nine companies to move forward for due diligence evaluation. Due diligence review did not take place in September due to a delay in approval of the third-party contract by the Legislative Budget Board. Although the FY2015 Cycle 1 Product Development award recommendations were expected to be presented for approval at the November 19 Oversight Committee meeting, the delay has pushed back consideration until at least the February 2015 Oversight Committee meeting.
- FY2015 Cycle 2 Bridging the Gap: Early Translational Research Awards (ETRA) Request for Applications: The Product Development review panels will meet October 7 and 8 to consider the 46 ETRA applications submitted in August. This is the first time that consideration of the ETRA applications will be undertaken 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. However, after consultation with the Product Development Review Council, CPRIT staff elected to close the RFAs before the application deadline while CPRIT evaluates appropriate revenue sharing terms and sets its program priorities. This was the third application cycle to open in eight months, and there are 15 companies for whom awards have been announced and contracts are pending. CPRIT's next cycle is scheduled to begin in December 2014 with the release of RFAs.
- Advisory Committee on Product Development: Following up on a commitment made at the September 3 Oversight Committee meeting, we have been seeking input from Oversight Committee members, staff, and others regarding potential candidates for the newly created Advisory Committee on Product Development. As of this writing, 22 individuals have been

recommended for consideration as committee members. The committee is expected to provide expert advice to the Oversight Committee regarding Product Development program issues, including: 1.) Using a common template for contractual revenue sharing provisions that provides a fair return for the State of Texas while not discouraging follow-on funding from other sources; 2.) Appropriate portfolio mix of product development awards by stage of company and size of award; and 3.) Strategies to expand and encourage relocation of high quality companies to Texas. We are hopeful that the new committee will be in place and have had its first meeting before the Oversight Committee meeting in November.

Prevention Program Update

In September, the Prevention Program peer reviewer panels continued reviewing applications submitted for the first round of FY 2015 grant awards, and Requests for Applications (RFAs) for the second round of FY 2015 grant awards were released.

- FY2015 Cycle 1: CPRIT received 16 applications in response to two RFAs, Evidence-Based Cancer Prevention Services and Competitive Continuation/Expansion. Review of these applications took place October 1 and 2 via teleconference. The Prevention Review Council will forward their recommendations to the Program Integration Committee (PIC) after conducting their programmatic review on October 24. The PIC's recommendations will be forwarded for consideration by the Oversight Committee at its November 19 meeting.
- FY2015 Cycle 2: We released four prevention RFAs on September 25, 2014, two of which are new. Applications are due December 4, 2014.
 - Competitive Continuation/Expansion - Evidence-Based Cancer Prevention Services Supports the continuation or expansion of previously funded cancer prevention and control clinical services that have demonstrated exemplary success.
 - Evidence-Based Cancer Prevention Services Supports the delivery of evidence-based cancer prevention and control clinical services.
 - **(New)** Evidence-Based Cancer Prevention Services-Colorectal Cancer Prevention Coalition Supports the delivery of colorectal cancer prevention and control services through simultaneous implementation in multiple clinical sites.
 - **(New)** Cancer Prevention Promotion and Navigation to Clinical Services Supports public education and outreach and navigation to cancer screening and preventive services.

- Upcoming Webinar for Applicants: Dr. Garcia and Ramona Magid will host a webinar on October 22 for potential applicants to ask questions regarding the four award mechanisms and the online CPRIT Application Receipt System (CARS).

Communications

- The new CPRIT logo (with the state seal) has been incorporated into the website and materials and templates for use with the new logo were distributed to all staff and grantees.
- Hahn Public Communications and senior staff continue to work on creating a comprehensive CPRIT message platform which will ultimately be used across all audiences and communications activities of the agency.
- We received one proposal from Austin area hotels (due September 30) for the 2015 Conference and are reviewing its viability. We plan to submit a recommendation, with a revised budget if appropriate, to the Audit Subcommittee on November 10 before being presented to the full Oversight Committee on November 19.
- Announcements regarding the release of new Prevention RFAs were sent out via our available communications channels.
- CPRIT is continuing its 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.

Operations and Finance (Contracts, RFPs, Internal Audit)

CPRIT's operations staff has been primarily involved with the office relocation, processing grant reimbursements, and working with the internal auditors to complete several reports.

On September 27, CPRIT received approval from the Legislative Budget Board (LBB) to transfer \$9,160,324 from the cancer research line item in the budget to the agency's two administrative line items. Of the total, \$8,804,882 is transferred to the grant review and award operations line items to fund the salaries of all of the staff and service contracts that support pre- and post-award grants management, and \$355,442 is transferred to the indirect administration line item primarily for services contracts, like strategic communications and internal audit, that support general agency operations.

In the same letter, the LBB also approved several contracts exceeding \$100,000 that the Oversight Committee approved at its meeting on August 20. Among them are the contract for pre- and post-award

grants management support services with SRA International, the two contracts for intellectual property due diligence with two legal firms, and the peer review monitoring services contract with Grant Thornton LLP. The LBB did not approve the contract for business management-regulatory due diligence until CPRIT completes the procurement process and has identified a vendor to perform the services. CPRIT operations staff has been moving forward with finalizing contracts for those approved.

Legislative Activities

The Capitol is starting to look ahead to the 84th Legislative Session in January. CPRIT staff testified before two legislative committees in September. I also met with legislative staff about CPRIT's activities in preparation for the upcoming session. This work will intensify next month once the elections are over and attention shifts toward 2015.

- Joint Public Budget hearing with the Governor's Office Budget, Planning and Policy and the Legislative Budget Board: On September 11, Heidi McConnell and I testified before the staff of the Governor's Office Budget, Planning and Policy and the Legislative Budget Board regarding CPRIT's legislative appropriations request for FY 2016 – 2017.
- Select House Committee on Economic Development Incentives: Dr. Tom Goodman, Dr. Margaret Kripke, and I testified before the Select House Committee on Economic Development Incentives on September 24. The Select Committee's charge is to determine the types of economic development projects that offer the most benefit to the state and suggest opportunities to focus on such projects. It will also discuss how to make programs more efficient. A copy of the presentation material was provided to you on September 25 and is posted on our website. Follow up information concerning committee questions was forwarded to the committee today. The Oversight Committee is copied on the letter and it will be posted on our website.
- Congressional Childhood Cancer Caucus: I traveled to Washington D.C. on September 18 to attend a reception honoring Congressmen Michael McCaul (R – Texas) and Chris Van Hollen (D – Maryland) for their work as Co-Chairs of the Congressional Childhood Cancer Caucus. On September 19, I attended the 5th Annual Childhood Cancer Summit: "Pediatric Cancer: Major Advances, Major Challenges". Dr. Ronald DePinho, the President of MD Anderson Cancer Center, was one of the speakers.
- Legislative Staff Meetings: I met with legislative staff for Senator Nelson, committee directors for Senate Health and Human Services and Senate Finance, and the assigned staff of the House Committee on Appropriations, this month.

Staff Presentations/Meetings

- Society of Physician Entrepreneurs: Dr. Goodman gave a presentation to the Society of Physician Entrepreneurs (SoPE) in Houston on September 10. SoPE's mission is "to provide a rich platform for Houston based doctors/healthcare providers transforming their ideas to innovation and developing integrated innovation business models to the global market." The goal at SoPE is to accelerate healthcare innovation and get ideas to patients faster.
- Texas A&M University Training: CPRIT staff traveled to College Station on September 15 to participate in a training session for the Texas A&M University System Sponsored Programs staff.
- NCI and Methodist Research Institute in Houston Workshop: Dr. Kripke was an invited participant at a workshop held September 18-19 on "Current Topics in Cancer Systems Biology: Multi-Scale Imaging for Cancer Biology," sponsored by NCI and Methodist Research Institute in Houston. A white paper will be forthcoming from this event outlining research needs in this area, one of which is in computational biology and mathematical modeling. Dr. Kripke presented CPRIT's Scientific Research program, with an emphasis on how CPRIT might help facilitate this agenda. As a follow up, we are exploring opportunities for partnering with NCI on this important initiative to support work on multimodality imaging in Texas.
- Texas Health and Bioscience Institute (THBI): On September 25, I presented an update on CPRIT activities to THBI membership. THBI is an industry professional association and key supporter of CPRIT.
- Breast Cancer Awareness Month Kick-Off Celebration: On October 1 CPRIT staff participated in the 17th Annual Breast Cancer Awareness Month Kick-Off Celebration at the State Capitol. CPRIT was a state-agency sponsor of the event, along with the Governor's Commission for Women and the Texas Department of State Health Services. Sandra Balderrama, CPRIT's Grant Specialist Manager, serves as the agency's liaison and was involved in planning the event.
- Baylor College of Medicine Training: CPRIT staff will travel to Baylor College of Medicine on October 9 to participate in a training session for Sponsored Programs staff and new grantees.
- Texas Fresh AIR 2014 Annual Conference: Dr. Goodman is invited to present to the Texas Fresh AIR (Academia Industry Roundtable) meeting attendees on October 23. Attendees will include research innovators from various Texas universities and industry partners from the biopharmaceutical space. The meeting will focus on immune-oncology.

Standing Subcommittee Meetings in November

If you or your assistant did not receive a calendar invite from Mary Gerdes for subcommittee meeting dates in November 2015, please contact Mary at mgerdes@cprit.state.tx.us.

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

Board Governance –	November 6 at 10:00
Diversity –	November 7 at 10:00
Audit –	November 10 at 10:00
Prevention –	November 11 at 10:00
Scientific Research –	November 12 at 10:00
Product Development –	November 13 at 10:00
Nominations –	November 14 at 10:00

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

CPRIT has awarded **785** grants totaling **\$1,084,121 billion**

- 130 prevention awards totaling \$114.3 million
- 655 academic research and product development awards totaling \$970 million

Of the \$970 **million** in academic research and product development awards

- 30.2% of the funding (\$292.7 million) supports clinical research projects
- 25.6% of the funding (\$248.0 million) supports translational research projects
- 24.0% of funding (\$232.5 million) supports recruitment awards
- 17.2% of the funding (\$167.2 million) supports discovery stage research projects
- 3.0% of funding (\$29.5 million) supports training programs.

CPRIT has 10 Requests for Applications (RFAs) that are open:

- 4 Prevention applications
- 6 Scientific Research applications



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

To: OVERSIGHT COMMITTEE MEMBERS
From: WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
Subject: CPRIT ACTIVITIES UPDATE - OCTOBER
Date: NOVEMBER 3, 2014

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

Preparation for the November 19 Oversight Committee Meeting

The Oversight Committee will meet November 19 at 10:00 in the Texas Capitol Extension. The final agenda for Oversight Committee will be posted by November 11; 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 will meet November 4 to review the grant award recommendations made by the Scientific Research, Product Development and Prevention Review Councils to consider a list of more than 30 award recommendations totaling approximately \$71 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 by November 6, 2014. The portal will have supporting documentation regarding each project proposed for an award, including the application, CEO affidavit, summary statement, and grant pedigree. 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.

We plan to distribute the agenda packet to Oversight Committee members electronically by COB November 12. CPRIT will hand deliver hard copies of the agenda packet to all members residing in Austin. Hard copies will be available for the Oversight Committee meeting for all out-of-town members.

New Hires and Job Openings

Jeff Hillery has been hired as the new Communications Specialist and will start on November 14. Jeff comes to us from the Secretary of State's Office where he was Deputy Director of Communications. Prior to that he was Communications Director for a Texas state senator among other significant related positions.

Job offers have been accepted by a fourth and final Grant Accountant and a Purchasing Specialist. The new grant accountant and purchaser will start on November 17. With these hires, the agency will have 28 full-time equivalent (FTE) employees; CPRIT is authorized to employ 32 FTEs.

The position for Program Manager for Product Development was reposted until October 31. This person will assist Dr. Goodman and work directly with product development grantees and grant applicants, as well as take on special assignments related to product development activities.

The position of Operations Specialist is posted until November 12. This person will assist Lisa Nelson, Operations Manager with personnel, office management, and grants management.

Program Priority Setting Project

The draft Program Priority report was posted on CPRIT's website for public input October 3. CPRIT solicited feedback on the draft priorities using an online survey; 47 respondents completed the survey and entered comments for Scientific Research, Prevention, and Product Development priorities by the October 28 deadline. The public input received and recommendations for revision will be presented to the Oversight Committee on November 19.

In addition, the CPRIT Oversight Committee's Advisory Committee on Childhood Cancer provided a white paper with recommendations on priority areas for funding. A copy of this paper will be distributed to the Oversight Committee for discussion on November 19.

Compliance Program Design Project

The Audit Subcommittee met on October 6 to discuss additional research related to compliance programs at other similar grant programs and state entities and to consider initial staff proposals for a compliance program design plan. As you will recall, CPRIT received a plan designed by Weaver and Tidwell LLP, a Texas-based assurance, tax, and advisory firm, pursuant to a consulting contract approved by the Governor's Office in June. Using the Weaver report, staff proposed adopting a 53 percent compliance coverage which could require four to five new contract positions in addition to nine agency staff.

The Audit Subcommittee directed CPRIT staff to develop a Request for Proposals (RFP) for the subcommittee's and Oversight Committee's approval. Since development of the RFP will require the assistance of the new Purchasing Specialist that will join CPRIT November 17,

finalization of the draft RFP may not occur until after the November 19 Oversight Committee meeting. If that is the case, it may be necessary to authorize the Audit Subcommittee to authorize issuance of the RFP after November 19 in order to keep the project on schedule. Full Oversight Committee approval of the successful proposal will be required as well as that of the Legislative Budget Board since the contract cost will exceed \$100,000.

Delinquent Reports

The positive momentum reported in the September briefing memo continues. At the time of the August 20 Oversight Committee meeting there were 483 delinquent reports. By the end of September, the number of delinquent reports fell to 186. As of October 29, the delinquent report count stands at 69. This consistent downward trend is due to the sustained effort of CPRIT's Grant Specialist and Grant Accountant Teams contacting and working with grantees to submit delinquent reports for review and approval.

It is worth noting that additional resources and a restructured approach have resulted in much faster processing times for grantee financial status reports over the past several months, dropping from 66 days to less than 10 days for an FSR that has submitted all back up information. As the number of delinquent reports have declined, the Grant Specialist Team has begun preparing processes and procedures for the new grant compliance program which entails desk, field, and programmatic reviews. Desk reviews have begun with two completed to date and more underway.

The first of an expected five compliance and rules/regulations training videos is being prepared in November by David Reisman in conjunction with Hahn Texas.

Required Reports Project

At recent Oversight Committee meetings, members have sought clarity regarding the number of reports that grantees must file with CPRIT each year and how the CPRIT reporting process compares to the NIH reporting process. CPRIT Staff Attorney Cameron Eckel has led a project to compile the information collected and evaluated by CPRIT for each program. Ms. Eckel also researched NIH reporting requirements and interviewed sponsored program office representatives to compare the NIH and CPRIT reporting processes. Her findings will be discussed by the Board Governance and Audit subcommittees and shared with Oversight Committee members.

Scientific Research Program Update

In addition to the preparing the slate of eight recruitment recommendations for review and approval by the PIC and the Oversight Committee, the Scientific Research Program is currently involved in peer review for Individual Investigator grant proposals.

- SRC Recommendations for FY 2015 Recruitment Applications: The SRC met to consider 10 recruitment award applications. The applications included four for First-Time Faculty awards, three for Rising Star awards, and three for Established Investigator awards. On October 8 SRC Chair Dr. Richard Kolodner sent a letter to the Oversight Committee Presiding Officer and the PIC with the SRC's recommendations to award eight recruitment grants totaling \$30 million. The eight recruitment grant award recommendations will be reviewed by the PIC. PIC recommendations will be presented at the November 19 Oversight Committee meeting.
- FY 2015 Individual Investigator Research Award (IIRA) Applications: Peer reviews of the responses to three scientific research Requests for Applications (RFAs) are underway. The RFAs were for untargeted Individual Investigator Research Awards (IIRA) with 271 applications; IIRAs for Prevention and Early Detection with 66 applications; and IIRAs for Cancers of Children and Adolescents with 56 applications, for a total of 393 applications. New IIRA applications were subjected to preliminary evaluation, which eliminated 37 percent of those applications. IIRA-P, IIRA-CCA, and IIRA renewal applications were not subject to preliminary evaluation. This left a total of 247 applications for full review. The peer review panels are meeting October 27, 28, 31 and November 3, 6, and 11 in Dallas. Interested members of the OC are invited to attend. Favorably reviewed applications will be presented at the February 2015 Oversight Committee meeting for approval.
- Funding Reconsideration for Two FY 2013 Core Facility Support Awards: The Oversight Committee approved a process at its December 5, 2012, meeting for resolving irregularities related to budget approval that occurred during the review for two FY 2013 Core Facility applications. Although the two grantees were approved for Core Facilities grant awards, the peer review panels reduced the budgets for both projects from the amount originally requested in the applications. Peer review panels may cut proposed budgets; however it was unclear whether unauthorized comments made by a CPRIT staff person during the review process may have influenced the peer reviewers' decisions related to the budgets. The process approved by the Oversight Committee permits the two grantees to request approval to restore the full budget included in their applications. Pursuant to the approved process, the SRC must review the budget request in conjunction with submission of the first progress report to determine whether full funding should be approved. This review is in progress, and if additional funding is recommended, a recommendation may come to the November 19 meeting for consideration and approval by the Oversight Committee.
- FY 2015 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.

- FY 2015 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 work in October focused on finalizing a staff recommendation for standard revenue sharing terms to be included in product development grant contracts, constituting an Advisory Committee on Product Development, and reviewing Early Translational Research Award (ETRA) applications.

- FY 2015 Cycle 2 Bridging the Gap: Early Translational Research Awards (ETRA) Request for Applications: The Product Development review panels met October 7 and 8 to consider the ETRA applications submitted in August. Of the 46 proposals submitted for review, the review panels recommended 20 for grant award consideration. On October 28 PDRC Chair Dr. Jack Geltosky sent a letter to the Oversight Committee Presiding Officer and the PIC with the PDRC's recommendations to award grants to the 20 ETRA applications identified by the review panels, with a total anticipated outlay of nearly \$34 million.

This is the first time that consideration of the ETRA applications has been undertaken 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. ETRA grant recommendations will be considered by the PIC; approved proposals will be considered by the Oversight Committee on November 19.

- FY 2015 Cycle 4 Product Development Request for Applications: CPRIT plans to release released three RFAs for Company Relocation, Established Company, and New Company product development awards on December 1.
- Advisory Committee on Product Development: Pursuant to discussion at the September 3, 2014, Oversight Committee, a new advisory committee has been assembled to assist the Oversight Committee and staff by providing input on product development matters. Nominations for members were made by Oversight Committee members and knowledgeable individuals unaffiliated with CPRIT. The committee currently has ten members with expertise in the biolife sciences, venture capital investment, university technology transfer offices, and regulatory matters. Four members are non-Texans. The first meeting of the advisory committee will occur in conjunction with the new Oversight Committee Subcommittee for Contract Terms on November 6 to discuss economic and revenue sharing issues related to approved grants pending contract completion. The Oversight Committee

will be asked to approve the new committee members subject to review and recommendation by the Nominations Subcommittee on November 14.

Prevention Program Update

In late September and October, the Prevention Program peer reviewer panels continued reviewing applications submitted for the first round of FY 2015 grant awards, and Requests for Applications (RFAs) for the second round of FY 2015 grant awards were released.

- FY 2015 Review Cycle 1: CPRIT received 16 applications in response to two RFAs, Evidence Based Cancer Prevention Services and Competitive Continuation/Expansion. On October 24, 2014, the Prevention Review Council completed its review of the applications forwarded by the review panels and Prevention Review Council Chair Dr. Stephen Wyatt submitted the PRC's recommendations to the Oversight Committee chair and PIC chair on October 28. Five projects may be recommended for approval by the Oversight Committee at the November 19 meeting.
- FY 2015 Review Cycle 2: We released four prevention RFAs on September 25, 2014, two of which are new. Applications are due December 4, 2014.
 - Competitive Continuation/Expansion - Evidence-Based Cancer Prevention Services
Supports the continuation or expansion of previously funded cancer prevention and control clinical services that have demonstrated exemplary success.
 - Evidence-Based Cancer Prevention Services
Supports the delivery of evidence-based cancer prevention and control clinical services.
 - New: Evidence-Based Cancer Prevention Services-Colorectal Cancer Prevention Coalition
Supports the delivery of colorectal cancer prevention and control services through simultaneous implementation in multiple clinical sites.
 - New : Cancer Prevention Promotion and Navigation to Clinical Services
Supports public education and outreach and navigation to cancer screening and preventive services.

Meetings are scheduled October 27-29 with five Prevention program grantees in the Dallas/Fort Worth area. The purpose of these meetings is to review the projects' status and explore components of projects that may be candidates for replication by others.

Communications

- Work has begun on the statutorily required *2014 Annual Report* due by the end of January 2015. In conjunction with the annual report, we intend to create a new report to highlight accomplishments resulting from CPRIT's grants programs.
- CPRIT received one proposal from an Austin area hotel in response to the Request for Proposals for the 2015 Biennial Conference. Recommendations and a proposed conference budget will be submitted to the Audit Subcommittee on November 10 before being presented to the full Oversight Committee on November 19.
- As a result of discussions with Texas Public Broadcasting System (PBS) concerning CPRIT participation in the premiere of Ken Burn's new documentary, *The Emperor of All Maladies: A Biography of Cancer*, CPRIT is investigating interest in having a special 30 minute screening of the documentary at the Capitol complex, perhaps the Extension Auditorium. A thirty minute panel discussion could follow the screening. Invitations to this advance screening and discussion would be extended to legislators, their staff, and cancer advocacy organizations.

Operations and Finance (Contracts, RFPs, Audit)

- Dr. Goodman, Heidi McConnell, and Kristen Doyle evaluated three proposals CPRIT received for business-regulatory due diligence reviews of product development grant proposals, and determined that ICON Clinical Research located in North Wales, Pennsylvania with expertise in the commercial and regulatory environment of cancer drugs is best qualified to provide this service to CPRIT. This contract would be for a not-to-exceed amount of \$350,000 for FY 2015. CPRIT has requested authorization from the Legislative Budget Board to enter in to this contract and received approval October 31.
- Since engaging McConnell & Jones LLP to conduct the financial audit for FY 2014, CPRIT staff has been addressing the auditors' document requests. McConnell & Jones auditors will be on site at the CPRIT office during the first week of November to sample documents for the audit.
- During the October 10, 2014, meeting of the Audit Subcommittee, Dr. Rice requested preparation of a succession plan for agency management in the event of a sudden, unexpected vacancy in the position of Chief Executive Officer. This plan could be activated on an interim basis to ensure stable, effective management control of the agency while the Oversight Committee undertakes a formal competitive recruitment of a permanent CEO. Developing this plan is underway and has been expanded to include sudden vacancies in all senior management positions. Although a time frame for this

project was not stipulated, the plan may be presented to the Audit Subcommittee by mid-December.

Staff Presentations/Meetings/Training

- Baylor College of Medicine Training: CPRIT Legal, Compliance and Finance staff conducted an on-site training session at Baylor College of Medicine on October 9. Topics covered included new administrative rules affecting grantees and common financial errors made when submitting FSRs. Following the presentation, CPRIT staff answered grantee questions for more than an hour. Attendees included sponsored program office staff, principal investigators/program directors, accountants and other grants administrators.
- The Big C Finale: I attended the The Big C Finale competition sponsored by LIVESTRONG on October 17. This global competition brings together entrepreneurs, fashion experts, technologists, healthcare and medical enthusiasts to present innovative products or services to improve the lives of those facing cancer.
- American Cancer Society (ACS): Dr. Garcia met with ACS on October 20 to discuss possible collaboration on colorectal cancer initiatives. The Society will inform the clinics and partners they work with in Texas about CPRIT's new colorectal cancer prevention RFA. CPRIT and ACS will also explore other partnership opportunities.
- Prevention Grant Applicant Webinar: Dr. Garcia and Ramona Magid presented a webinar to over 100 participants on October 22. The webinar allowed potential applicants to inquire about the four award mechanisms and the online CPRIT Application Receipt System (CARS).
- Texas Fresh AIR 2014 Annual Conference: Dr. Goodman presented to the Texas Fresh AIR (Academia Industry Roundtable) in Houston on October 23. Attendees included research innovators from various Texas university and industry partners from the biopharmaceutical sector. Networking connections were made with meeting attendees.
- CPRIT Training Webinar: CPRIT Legal, Compliance and Finance staff conducted a training webinar on October 30. Topics included recent administrative rule changes that impact grantees, common financial errors made when submitting FSRs, the grant specialist program, and a preview of Compliance Program activities, including the desk review and site review process. Over 180 grantees from across Texas included sponsored principal investigators/program directors, accountants and other recipient grant administrators.

- College of American Pathologists: Dr. Garcia and Ramona Magid continued discussion with the College of American Pathologists about partnering to expand their *See, Test, and Treat Program* on breast and cervical cancer in Texas. They also met with the College's executive director and foundation chair on September 27 to observe a program that was held in Austin.
- Texas Healthcare and Bioscience Institute (THBI): THBI has invited Dr. Garcia to present at **LeadTexas** in Edinburg, Texas on November 5. **LeadTexas** is a project to join corporations, communities, economic development entities, foundations, academic institutions, and individuals to create jobs in the bioscience industry.
- Houston Technology Center (HTC): the program chiefs and I will go to Houston on December 10 for a follow up to our presentation on July 10 to the HTC. This visit will update their membership on CPRIT activities since our visit and to brief them on the Program Priority Project.

Standing Subcommittee Meetings in November

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

Board Governance –	November 6 at 10:00
Diversity –	November 7 at 10:30
Audit –	November 10 at 10:00
Prevention –	November 11 at 10:00
Scientific Research –	November 12 at 10:00
Product Development –	November 13 at 10:00
Nominations –	November 14 at 10:30

In addition to the standing subcommittee meetings listed above, the newly formed Contract Terms subcommittee will meet on November 6 at 1:00 and November 11 at 1:30.

An agenda, call-in information and supporting material will be sent to the subcommittee one week prior to the meeting date. If you or your assistant did not receive a calendar invite from Mary Gerdes for subcommittee meeting dates in November, please contact Mary at mgerdes@cprit.state.tx.us.

CPRIT has awarded **785** grants totaling **\$1,084,121 billion**

- 130 prevention awards totaling \$114.3 million
- 655 academic research and product development awards totaling \$970 million

Of the \$970 **million** in academic research and product development awards

- 30.2% of the funding (\$292.7 million) supports clinical research projects
- 25.6% of the funding (\$248.0 million) supports translational research projects
- 24.0% of funding (\$232.5 million) supports recruitment awards
- 17.2% of the funding (\$167.2 million) supports discovery stage research projects
- 3.0% of funding (\$29.5 million) supports training programs.

CPRIT has 10 Requests for Applications (RFAs) that are open:

- 4 Prevention applications
- 6 Scientific Research applications

**CPRIT MANAGEMENT DASHBOARD
FISCAL YEAR 2014**

	SEPT	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	CUMULATIVE (ANNUAL)	CUMULATIVE (YTD)
ACCOUNTABILITY														
Announced Grant Awards			10		3	17			16			101	147	
New Grant Contracts Signed			31	1	28	36	2	37	15	2	3	0	155	
New Grant Contracts In Negotiation					44	20	0	0	8	0	0	99	171	
Grant Reimbursements Processed (#)	216	138	86	85	78	261	1	215	105	156	198	162	1701	
Grant Reimbursements Processed (\$)	\$ 15,708,608	\$ 7,679,038	\$ 5,812,765	\$ 6,461,722	\$ 5,518,045	\$ 23,916,847	\$ 2,355	\$ 14,816,629	\$ 14,386,666	\$ 10,473,161	\$ 24,534,667	\$ 11,957,318	\$ 141,267,820	
Revenue Sharing Payments Received	\$ -	\$ 34,817			\$ 86,802	\$ 171,930	\$ -	\$ 7,202	\$ 149,857	\$ -	\$ 7,323	\$ 1,310,858	\$ 1,768,789	\$ 2,166,742
Total Grants Contracted (\$)			\$ 33,140,223	\$ 1,061,827	\$ 24,524,765	\$ 35,951,078	\$ 1,235,069	\$ 39,152,279	\$ 9,683,570	\$ 852,407	\$ 28,813,623	\$ -	\$ 174,414,841	
Grants Awarded (#)/Applications Rec'd (#)	14%	14%	15%	15%	15%	13%	13%	13%	13%	12%	12%	14%		
Debt Issued (\$)/Funding Awarded (\$)	40%	40%	46%	52%	52%	47%	52%	52%	48%	54%	54%	51%		
Grantee Compliance Trainings/Monitoring Visits						0	0	0	0	0	0	0	0	
Awards with Delinquent Reimbursement Submission (FSR)			5		52	20			42			36		
Awards with Delinquent Matching Funds Verification												103		
Awards with Delinquent Progress Report Submission			3		2	7			10			5		
IA Agency Operational Recommendations Implemented	0	0	0	0	0	0	0	0	0	0	0	8		
IA Agency Operational Recommendations In Progress	18	18	18	18	18	18	18	18	18	18	18	10		
IA Grantee Recommendations Implemented	0	0	0	0	0	0	0	0	0	0	0			
IA Grantee Recommendations In Progress	7	7	7	7	7	7	7	7	7	7	7			
Open RFAs				10	13	8	11	11	11	9	12	10		
Prevention Applications Received				0	0	50	0	0	0	0	16	0	66	505
Product Development Applications Received				0	0	43	0	0	30	0	0	46	119	252
Research Applications Received				0	12	584	27	0	0	424	0	0	1,047	3,783
Help Desk Calls/Emails	151	113	147	290	746	360	217	254	298	390	344		3,310	
MISSION														
RESEARCH PROGRAM														
Number of Research Grant Awarded (Annual)					3	11			14			84	112	
Scientists Recruited (Cumulative)														55
Published Articles on CPRIT-Funded Projects (#)												2,997	2,997	
Jobs Created & Maintained (#)												4,583	4,583	
Trainees in CPRIT-Funded Training Programs (#)												1,087	1,087	

CPRIT MANAGEMENT DASHBOARD
FISCAL YEAR 2014

Open Clinical Trials (#)														
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	SEPT	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	CUMULATIVE (ANNUAL)	CUMULATIVE (YTD)
Number of Patents Resulting from Research												18	18	
Number of Patent Applications												41	41	
Number of Investigational New Drugs														

PRODUCT DEVELOPMENT PROGRAM														
Number of Product Development Grant Awarded (Annual)					0	6			2			2	10	
Life Science Companies Recruited (in TX)												0	0	1
Published Articles on CPRIT-Funded Projects												37	37	
Number of Jobs Created & Maintained												211	211	
Number of Patents Resulting from Research												2	2	
Number of Investigational New Drugs												4	4	
PREVENTION PROGRAM														
Number of Prevention Grant Awarded (Annual)			10		0	0			0			15	25	
People Served by CPRIT-Funded Prevention and Control Activities			88,285			74,925			128,786			128,742	420,738	
People Served through CPRIT-Funded Education and Training			45,018			32,006			46,128			35,093	158,245	
People Served through CPRIT-Funded Clinical Services			43,267			42,919			82,658			93,649	262,493	
TRANSPARENCY														
Total Website Hits	3,900	5,313	6,445	7,634	11,276	7,630	6,003	8,726	9,620	8,507	6,791	10,610	92,455	
Total Unique Visitors to Website	2,895	3,876	4,219	5,077	6,544	4,998	4,249	6,123	6,185	5,383	4,730	7,055	61,334	

**CPRIT MANAGEMENT DASHBOARD
FISCAL YEAR 2015**

	SEPT	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	CUMULATIVE (ANNUAL)	CUMULATIVE (YTD)
ACCOUNTABILITY														
Announced Grant Awards													0	
New Grant Contracts Signed	11	14	20										45	
New Grant Contracts In Negotiation	0	0	0										0	
Grant Reimbursements Processed (#)	2	434											436	
Grant Reimbursements Processed (\$)	\$ 3,919,524	\$ 30,454,155	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 34,373,679	
Revenue Sharing Payments Received	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 2,166,742
Total Grants Contracted (\$)	\$ 8,316,567	\$ 21,311,777	\$23,347,423	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 52,975,767	
Grants Awarded (#)/Applications Rec'd (#)	12%	12%	\$ -											
Debt Issued (\$)/Funding Awarded (\$)	51%	51%												
Grantee Compliance Trainings/Monitoring Visits	1	1											2	
Awards with Delinquent Reimbursement Submission (FSR)														
Awards with Delinquent Matching Funds Verification			16											
Awards with Delinquent Progress Report Submission			10											
IA Agency Operational Recommendations Implemented	2	2												
IA Agency Operational Recommendations In Progress	13	13												
IA Grantee Recommendations Implemented														
IA Grantee Recommendations In Progress														
Open RFAs	7	13												
Prevention Applications Received	0	0											0	505
Product Development Applications Received	0	0											0	252
Research Applications Received	10	0											10	3,793
Help Desk Calls/Emails	230	240											470	
MISSION														
RESEARCH PROGRAM														
Number of Research Grant Awarded (Annual)													0	
Scientists Recruited (Cumulative Year to Date)														
Published Articles on CPRIT-Funded Projects (#)													0	
Jobs Created & Maintained (#)													0	

CPRIT MANAGEMENT DASHBOARD
FISCAL YEAR 2015

Trainees in CPRIT-Funded Training Programs (#)													0	
Open Clinical Trials (#)													0	

	SEPT	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	CUMULATIVE (ANNUAL)	CUMULATIVE (YTD)
Number of Patents Resulting from Research													0	
Number of Patent Applications													0	
Number of Investigational New Drugs													0	

PRODUCT DEVELOPMENT PROGRAM														
Number of Product Development Grant Awarded (Annual)													0	
Life Science Companies Recruited (in TX)														1
Published Articles on CPRIT-Funded Projects													0	
Number of Jobs Created & Maintained													0	
Number of Patents Resulting from Research													0	
Number of Investigational New Drugs														
PREVENTION PROGRAM														
Number of Prevention Grant Awarded (Annual)													0	
People Served by CPRIT-Funded Prevention and Control Activities													0	
People Served through CPRIT-Funded Education and Training													0	
People Served through CPRIT-Funded Clinical Services													0	
TRANSPARENCY														
Total Website Hits	6,610	7,275											13,885	
Total Unique Visitors to Website	4,811	5,143											9,954	



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: CPRIT OVERSIGHT COMMITTEE MEMBERS
FROM: DAVID A. REISMAN, CHIEF COMPLIANCE OFFICER
SUBJECT: CHIEF COMPLIANCE OFFICER REPORT
DATE: NOVEMBER 10, 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. CPRIT's Administrative 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 November 10, 2014, the date the report was run, information regarding delinquent grant recipient reports was as follows:

- 26 grant projects, either active or in close out, at six 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 36 grant projects had not filed required FSRs by the deadline.

At the last Oversight Committee meeting it was noted that in addition to those above, other FSRs were pending filing upon submission and approval of the currently delinquent FSR. The total number of past due FSRs at the last meeting was 180, at this meeting it is 46.

- Nine 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 grant specialists and the grant accountants have continued reviewing and processing incoming reports and reaching out to

grantees to expeditiously resolve filing issues. As a result, significant progress has been made in identifying and processing these past due reports.

At the last meeting, a total of 483 outstanding reports existed. As of November 7, 2014, the date this report was run, that number has been reduced to 76. It should be noted that the grants management software (CGMS) that the agency uses to manage the filing of reports has been undergoing a reconciliation and grantees have been unable to file select annual financial reports for several weeks. This reconciliation is expected to be completed within the week.

Grantee Desk Reviews

The grant specialists have initiated desk reviews of grantees. Desk-based financial monitoring/reviews are conducted during the course of grant awards to verify grantees expend funds in compliance with specific grant requirements and guidelines. Desk-based reviews may target the following areas:

- Grantee administrative and/or operating policies and procedures
- Grantee financial policies and procedures
- Project budget and payroll records and time reporting records
- Project accounting records to include general ledger records
- Project financial expenditure records and supporting documentation
- Programmatic reports, financial reports, progress reports, inventory reports
- Single Audit Reports and/or Single Audit Determination forms and records

Desk reviews differ from audits. Desk reviews are preventative to ensure processes are working as intended. Auditing, on the other hand, is corrective and a formal, systematic and disciplined approach designed to evaluate and improve the effectiveness of processes and related controls.

Grantee Training

Since the last Oversight Committee meeting, CPRIT staff have conducted two on-site training presentations for grantees in College Station and in Houston. The trainings covered recently enacted rules, common reporting errors as well as other important issues.

Additionally, CPRIT staff conducted a webinar for all CPRIT grantees attended by over 100 grant recipient staff responsible for grant administration. The webinar is available on the CPRIT website at the Compliance Tab.

Finally, the Chief Compliance Officer, working with the CPRIT communications team, produced a series of short training videos introducing our grantees to the compliance division and covering important rule changes.

Required Reports

Report	Filer	Due Date
Quarterly Financial Status Report	All grant recipients	90 days after the end of the state fiscal quarter Tex. Admin. Code § 703.21(b)(1)
Final Financial Status Report	All grant recipients	90 days after the end of state fiscal quarter Tex. Admin. Code § 703.14(d)
Quarterly Progress Report	Prevention grant recipients	15 days after the end of the state fiscal quarter
Annual Progress Report	All grant recipients	60 days after the anniversary of the grant contract effective date Tex. Admin. Code § 703.21(b)(3)(B)
Tranche Report	Commercialization/ Product Development grant recipients	Upon completion of milestones for specific tranche Tex. Admin Code § 703.21(b)(3)(G)
Final Progress Report	All grant recipients	Within 90 days of grant contract termination date Tex. Admin. Code § 703.21(b)(3)(C)
Matching Funds Certification/ Verification Form	Research grant recipients (including Commercialization/Product Development)	Contract execution (certification), 60 days after the anniversary of the grant contract effective date Tex. Admin. Code § 703.21(b)(3)(B)(x)
Inventory Report	All grant recipients	60 days after the anniversary of the grant contract effective date Tex. Admin. Code § 703.21(b)(3)(B)(iv)
Revenue Sharing Form	All grant recipients	60 days after the anniversary of the grant contract effective date Tex. Admin. Code § 703.21(b)(3)(B)(xi)
HUB/Buy Texas Form	All grant recipients	60 days after the anniversary of the grant contract effective date Tex. Admin. Code § 703.21(b)(3)(B)(vi)
Single Audit Determination Form	All grant recipients	60 days after the anniversary of the grant contract effective date Tex. Admin. Code § 703.21(b)(3)(B)(xii)
Audit	Recipients that expend \$500,000 or more in state awards in the recipient's fiscal year	Within 30 days of receipt, but no more than 270 days after the recipient's fiscal year end Tex. Admin. Code § 703.13(b)(3)
Close Out Documents	All grant recipients	Within 180 days of grant contract termination date Tex. Admin. Code § 703.14(d)

Consequences for Failing to File Required Reports in a Timely Manner

(Note – in addition to the consequences stated below, the failure to timely file required reports may also serve as grounds for contract termination)

Report	Due Date	Consequence
Quarterly Financial Status Report	90 days after the end of the state fiscal quarter The recipient may request to defer submission of the reimbursement request for the current fiscal quarter until the next quarter. The request must be submitted on or before the FSR due date.	Reimbursement of project costs incurred during the reporting period will be waived if the FSR is not submitted within 30 days of the FSR due date. Tex. Admin. Code § 703.21(b)(2)
Final Financial Status Report	90 days after the end of state fiscal quarter	Reimbursement of project costs incurred during the reporting period will be waived if the FSR is not submitted within 30 days of the FSR due date. Tex. Admin. Code § 703.14(d)(1)
Quarterly Progress Report	15 days after the end of the state fiscal quarter	
Annual Progress Report	60 days after the anniversary of the grant contract effective date	No disbursement of grant funds will be made until the progress report is filed. Tex. Admin. Code § 703.21(b)(3)(G)
Tranche Report	Upon completion of milestones for specific tranche	The next tranche of grant funds will not be disbursed until the tranche report is approved. Tex. Admin. Code § 703.21(b)(3)(H)(ii)
Final Progress Report	Within 90 days of grant contract termination date The recipient may request that CPRIT waive the final submission of close out documents for exceptional circumstances. Tex. Admin. Code § 703.14(d)(2)	The final reimbursement of grant expenditures will not be disbursed until the progress report and other close out documents are approved. Failure to submit the progress report within 180 days of the termination date will cause the recipient to be ineligible to receive new grant awards until all information has been submitted or a waiver of final submission is approved by CPRIT. Tex. Admin. Code § 703.14(d)(2)
Matching Funds Certification/ Verification Form	At the time of contract execution (certification), 60 days after the anniversary of the grant contract effective date (verification and certification)	The grant contract will not be executed until the initial certification is submitted by the recipient. Grant funds for the next project year (or tranche, if applicable) will not be disbursed until the matching funds verification for the previous year and certification for the upcoming year has been approved. Tex. Admin. Code § 703.11(f)
Inventory Report	60 days after the anniversary of the grant contract effective date	Grant funds for the next project year will not be disbursed until the other annual financial reports, including the inventory report, have been submitted. Tex. Admin. Code § 703.21(b)(3)(G)
Revenue Sharing Form	60 days after the anniversary of the grant contract effective date	Grant funds for the next project year will not be disbursed until the other annual financial reports, including the revenue sharing form, have been submitted.
HUB/Buy Texas Form	60 days after the anniversary of the grant contract effective date	Grant funds for the next project year will not be disbursed until the other annual financial reports, including the HUB Report/Buy Texas form, have been submitted. Tex. Admin. Code § 703.21(b)(3)(G)
Single Audit Determination Form	60 days after the anniversary of the grant contract effective date	Grant funds for the next project year will not be disbursed until the other annual financial reports, including the single audit determination form, have been submitted. Tex. Admin. Code § 703.21(b)(3)(G)
Audit	Within 30 days of receipt, but no more than 270 days after the recipient's fiscal year end The recipient may request additional time to file the audit and corrective action plan. The request must be submitted on or before the audit due date.	Grant funds will not be disbursed until the delinquent audit and corrective action plan, if any, have been approved. The recipient is ineligible to receive a grant award during the time that the audit and corrective action plan is delinquent. Tex. Admin. Code § 703.13(c) and (d)
Close Out Documents	Within 180 days of grant contract termination date	The final reimbursement of grant expenditures will not be disbursed until the progress report and other close out documents are approved. Failure to submit the progress report and other close out documents within 180 days of the termination date will cause the recipient to be ineligible to receive new grant awards until all information has been submitted or a waiver of final submission is approved by CPRIT. Tex. Admin. Code § 703.14(d)(2)

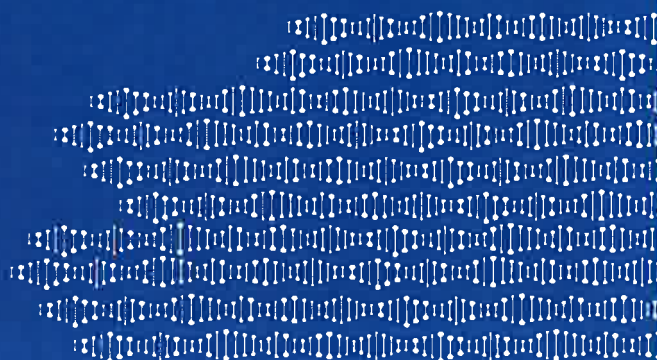


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CPRIT Training Series

Grantee Webinar Training

October 28, 2014



CPRIT Grantee Training Agenda

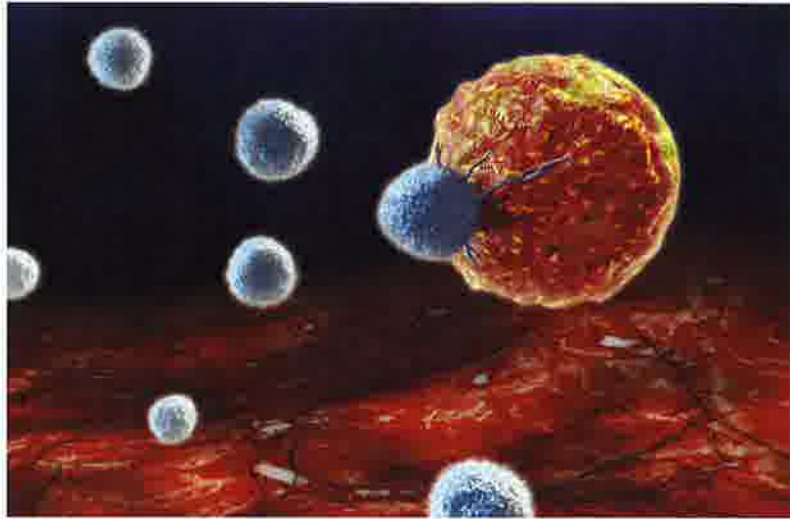
- 1. Webinar Overview**
Kristen Doyle, General Counsel
- 2. Administrative Rule Changes**
Kristen Doyle, General Counsel
- 3. Grant Accountants and Grant Specialists Introduction**
Heidi McConnell, Chief Operating Officer
- 4. Common Errors in Financial Status Reports**
Oralia Huggins, Grant Accountant
- 5. Compliance Program Activities**
David Reisman, Chief Compliance Officer
- 6. Q&A**
CPRIT Staff

Moderator – Ramona Magid
IT Assistance – Therry Simien, Jason Romero



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119,000 Texans newly diagnosed; 44,150 die in 2014.



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3

CPRIT's Unique Role in the Fight Against Cancer

Mission

- Create and expedite innovation in cancer research into prevention and cures
- Attract, create, or expand research capabilities
- Create high-quality new jobs in Texas
- Develop and implement the Texas Cancer Plan



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Action

Award merit-based, peer reviewed grants to Texas-based entities and institutions for cancer-related research, product development and the delivery of cancer prevention programs and services.



4



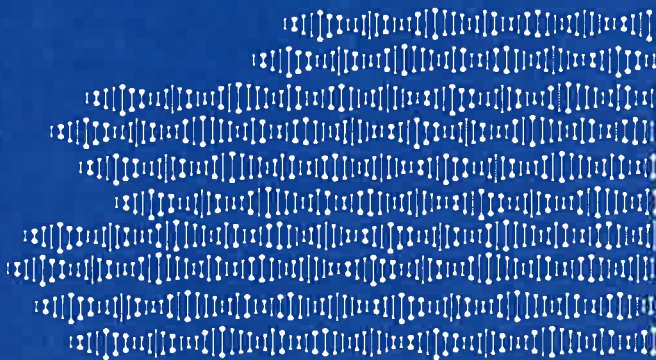
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CPRIT Training Series

Administrative Rule Changes Affecting Grantees

October 2014

Presented By: Kristen Doyle



Introduction

- CPRIT is governed by Health & Safety Code Chapter 102, as well as agency administrative rules.
- New tools to address grantee compliance with state law and administrative rules have been adopted by the CPRIT Oversight Committee.
- The rule changes discussed in this presentation were approved in January and implemented June 1, 2014.
- This overview is not intended as a comprehensive discussion of all administrative rule changes or the consequences a grantee may face in the event of noncompliance.
- Please consult the administrative rules and contact CPRIT with specific questions. (<http://www.cprit.state.tx.us/about-cprit/laws-rules-and-guidelines/>).



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Sources for Grant Requirements

- State and Federal Statutes – primarily [Health & Safety Code Chapter 102](#)
- Administrative Rules – primarily [Chapters 701 - 703](#)
- Grant Contract
- Policies & Procedures Guide
- Request for Applications
- Uniform Grant Management Standards (UGMS)



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JUNE 30, 2014

SUMMARY OF CPRIT'S IMPLEMENTATION OF THE

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JANUARY 2013 STATE AUDITOR'S GRANT MANAGEMENT RECOMMENDATIONS

	Recommendations In Chapter		Recommendations Completed
Chapter 1-A	8	CPRIT should ensure that all grant decisions are free from real or apparent conflicts of interest	8
Chapter 1-B	7	CPRIT should ensure the transparency and accountability of its peer review process	7
Chapter 1-C	2	CPRIT should verify the accuracy and availability of grantees' matching funds	2
Chapter 2-A	2	CPRIT should establish requirements for advance payments and reimbursements it makes to grantees	2
Chapter 2-B	5	CPRIT should improve processes for monitoring grantee expenditures and research progress	5
Chapter 2-C	2	CPRIT should strengthen certain contract management processes	2
Chapter 3	6	CPRIT should improve its management of the CTNet research grant and other administrative practices	6
Chapter 4-A	4	CPRIT should ensure that contracted services and related costs are reasonable and necessary	4
Chapter 4-B	3	CPRIT should ensure that its honorarium payments are appropriate	3
Chapter 5	2	CPRIT should ensure that its outsourced information systems maintain valid and reliable grant management data	2
	10	The Legislature should consider clarifying certain statutory requirements to increase transparency and accountability at CPRIT	10
TOTAL COMPLETED			51

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CPRIT Audit Findings

State Auditor: "...for 85 (84.1 percent) of the 101 reimbursements, or approximately \$9.4 million in reimbursements, CPRIT did not obtain detail to support that reimbursed expenditures such as payroll expenses, travel expenses, purchases, and service expenses were reasonable, necessary, and allowable. For those 85 reimbursements, grantees typically provided CPRIT with spreadsheets that summarized the expenditures they reported were related to the CPRIT grant for the applicable reporting period. **However, CPRIT cannot ensure the accuracy and appropriateness of grantees' reported expenditures without obtaining detailed information and adequate documentation to support the expenditures reported on the spreadsheets.**" (emphasis added)

Internal Auditor: "We recommend that grantees should be required to provide supporting invoices and receipts for all expenses incurred, including transactions that are internal to a grantee's entity, and submitted on the Financial Status Report regardless of dollar amount. We also recommend that a detailed description be provided by the grantee to show how the expenditure is appropriate to the award." (emphasis added)



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CANCER PREVENTION & RESEARCH
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SUMMARY OF CPRIT'S IMPLEMENTATION OF SENATE BILL 149

		Implemented by CPRIT
§102.106- §102.1064 §102.109	Strengthen conflicts of interest policies and code of conduct; ensure that all grant decisions are free from real or apparent conflicts of interest	✓
§102.251	Increase the transparency and accountability of CPRIT's peer review process	✓
§102.107	Enhance policy role of Oversight Committee	✓
§102.252 §102.264	Create the Program Integration Committee and require affirmative approval of grant awards by the Oversight Committee	✓
§102.255	Clarify matching fund requirements and verify the accuracy and availability of grantee matching funds	✓
§102.255	Establish requirements for advance payments and reimbursements it makes to grantees	✓
§102.260	Improve monitoring of grantee expenditures and research progress	✓
§102.263	Employ a Chief Compliance Officer and implement a compliance program	✓
§102.262	Require transparency in gifts made to CPRIT, its employees, its Oversight Committee members, and any foundation created to support CPRIT	✓
§102.251	Prohibit awarding a grant to an applicant who has made a gift to CPRIT or related foundation	✓

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Overview of Administrative Rule Changes

1. Timely Filing of Financial Status Reports
2. Matching Funds and Matching Funds Certification
3. Required Audit and Grantee Eligibility
4. No Cost Extension
5. Submission of Final Close-Out Reports
6. Gifts to CPRIT or Supporting Foundations



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1. Timely Filing of Financial Status Reports

• Waiver of Reimbursement for Failure to Timely File Financial Status Report

Background: A quarterly financial status report's (FSR's) due date is 90 days following the end of the state fiscal quarter.

Consequence: A grantee's failure to timely submit an FSR will result in the grantee waiving the reimbursement of project costs incurred during the reporting period.

- 30-day grace period following FSR due date before waiver of reimbursement
- Deferral requests must be filed on or before the original FSR due date
- Waiver will be implemented for FSR due on November 29, 2014



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Applicable Rule: §703.21

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1. Timely Filing of Financial Status Reports

• Due Date and Grace Period for FSRs

Fiscal Quarter	Period	FSR Due Date	Last Day of Grace Period
Q1	Sept 1 – Nov 30	Feb 28	Mar 30
Q2	Dec 1 – Feb 28	May 29	June 28
Q3	Mar 1 – May 31	Aug 29	Sept 28
Q4	June 1 – Aug 31	Nov 29	Dec 29

- For example, the Q4 FSR is due on or before November 29.
- The request to defer Q4 reporting until the next FSR due date must be filed on or before November 29. Use a standard "Change Request" form to request the deferral.
- If the Q4 FSR is not filed by November 29 and a deferral request is not filed, then the FSR must be filed by December 29 or the reimbursement for Q4 expenses will be waived.



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Applicable Rule: §703.21

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2. Matching Funds and Matching Funds Certification

• Suspension/Termination of Grant for Failure to Expend Matching Funds In Accordance with Matching Funds Certification

Background: All research grantees must certify available matching funds prior to the advance or reimbursement of any grant funds.

Consequence: Failure to expend matching funds equal to one-half of the actual amount of the grant award funds distributed for the same period is considered a matching funds deficiency.

- Grantee must file form with CPRIT verifying matching funds expended for the previous project year no later than 60 days from the anniversary of the contract effective date
- CPRIT may withhold reimbursement, require repayment, or terminate the contract depending upon the size of deficiency and amount of time past due date
- Grantee must provide and maintain adequate documentation showing the source of the matching funds at the time of certification



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Applicable Rule: §703.11

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2. Matching Funds Certification for Public and Private Institutions of Higher Education

H&S Code Chapter 102 was changed to allow the dollar-equivalent of the federal indirect cost rate (FICR) as a credit toward required matching funds.

Example:

- University receives a one year grant totaling \$500,000
- Required Matching Funds = \$250,000 (\$500,000 X 50%)
- University's FICR = 54%
- Of the 50% match required, 49% (54% – 5%) is covered by FICR credit.
- FICR Credit of \$245,000 (\$500,000 X 49%) counted toward match.
- University funds needed for match = \$5,000 (\$500,000 X 1%)

- The matching funds credit is the difference between the FICR and the 5% indirect cost rate allowed by CPRIT
- For any required match amount not covered by FICR credit, grantee must have funds dedicated to the project
- The grantee must file documentation of the FICR with CPRIT and maintain adequate documentation of funds used for match at the time of the certification



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Applicable Rule: §703.11

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3. Required Audit and Grantee Eligibility

- **Grantee is Ineligible to be Awarded a New CPRIT Grant or a Continuation Grant Award if Required Audit is Not Timely Filed**

Background: Grantees expending \$500,000+ in state awards during the grantee's fiscal year must obtain an annual single independent audit or a program specific independent audit.

Consequence: No reimbursement or advances of grant funds shall be made if required audit and corrective action plan is not submitted by due date. Grantees are not eligible to receive a grant award until delinquent audit is submitted.

- Submit audit to CPRIT within 30 days of receipt by grantee, no later than 270 days following close of grantee's fiscal year ("due date of required audit")
- Grantees may request additional time to file required audit
- Extension request must be submitted on or before date audit is due to CPRIT
- CPRIT may authorize continued payment of grant funds and/or maintain the eligibility of the grantee to receive grant awards if extension is approved



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Applicable Rule: §703.13

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3. Proposed Audit Change

Change to Audit Rule Regarding Requirements for Public Universities

Background: State audit advised CPRIT that allowing state institutions to use the Statewide Single Audit did not comply with the single audit requirement in UGMS. CPRIT amended its rules to require an annual independent audit.

Proposed Change: State institutions may satisfy the audit requirement by obtaining a program specific audit or an agreed upon procedures engagement.

- Proposed rule change approved by the Oversight Committee on August 20 for publication in Texas Register
- Proposed change published in Texas Register on October 3
- Comments on the proposed change are due by November 3
- Rule change will be considered for adoption by Oversight Committee in November



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Applicable Rule: §703.13 17

4. No Cost Extension

No Cost Extension (NCE) Submitted at Least 30 Days Prior to the Contract Termination Date

Background: Grantees may ask for additional time to complete work on a grant project via a NCE request. NCE duration is six months unless special circumstances justify more time.

Consequence: A NCE request submitted fewer than 30 days prior to termination date will not be approved.

- Grantees seeking a NCE must submit request no earlier than 180 days and no later than 30 days prior to the termination date of the grant contract.
- Grantee must be in good fiscal and programmatic standing in order to receive NCE approval.



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Applicable Rule: §703.14 18

5. Submission of Final Close-Out Reports

Submission of Final Close-Out Reports

Background: Grantees must file final close-out reports within 90 days of contract termination date.

Consequence: Final reimbursement will not be paid until the close-out reports are filed. Failure to submit all close out documents within 180 days of contract end date results in grantee being ineligible to receive new grant awards or continuation grant awards

- Final close-out report documents include: FSR, progress report, and other required reports as specified in the grant contract
- CPRIT rules consider a grantee to be the institution or organization; thus delinquent reports for one project bars all potential primary investigators, project directors, and company representatives at the institution, organization or company from receiving new grant awards



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Applicable Rule: §703.14

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6. Gifts to CPRIT or Supporting Foundations

Applicant is Ineligible to Receive Grant Awards if Applicant Makes a Gift to CPRIT or a Supporting Foundation

Background: CPRIT may not award a grant to an applicant who has made a gift to CPRIT on or after June 14, 2013.

Consequence: Any application submitted by a grant applicant that has made a gift to CPRIT or a foundation supporting CPRIT will be withdrawn from consideration for a grant award. The donation must be returned to be eligible.

- Grant applicants include: the principal investigator; program director; company representative, senior member or key personnel listed on the application, officer or director of the applicant, spouses and dependent children of the aforementioned
- This prohibition also applies to grantees
- Applicants must certify they have not made a gift to CPRIT at the time of submission and at time of contract execution



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Applicable Rule: §703.3

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CPRIT Administrative Rules – Follow Up

Questions? Contact:

Kristen Doyle, General Counsel,
kdoyle@cprit.state.tx.us, 512/305-8486

Cameron Eckel, Staff Attorney,
ceckel@cprit.state.tx.us, 512/305-8495



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CPRIT Grant Accountants & Grant Specialists

Grant Accountants

Oralia Huggins

Dan Limas

Wilfredo Ruiz

A fourth grant accountant
will be added in November

Grant Specialists

Sandra Balderrama
(Grant Specialist Manager)

Cathy Allen
 David Escamilla
 Mark McCollum

The grant accountants are assigned by entity;
 grant specialists are available to all grantees.



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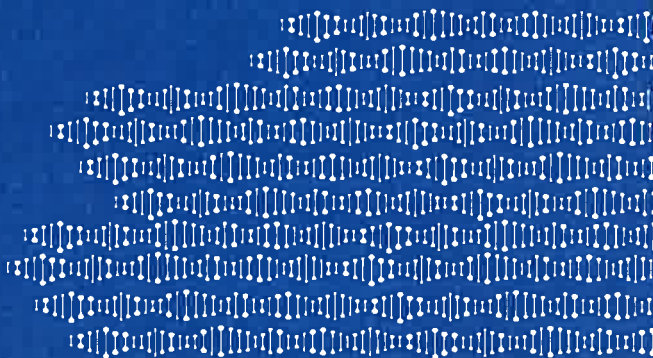
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Grantee Training Series

Common FSR Errors

October 2014

Presented By: Oralia Huggins



Common Errors

1. Submitting accrued expenses.

- All expenses submitted for reimbursement must have been paid during the quarter reported. No accrued expense should be reported on the FSR.



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Common Errors

2. Submitting invoices with dates outside the current reporting period.

- CPRIT will accept invoices with prior dates within 90 days of reporting period only with management justification for late submission.
- Invoices with dates after the reporting period must be reported in the following quarter when they are paid.



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Common Errors

3. Key/Non-Key personnel reported on grant payroll are not listed on the Personnel Level of Effort (PLOE) form in CGMS.

- (New) If you are submitting salary expense for a Key employee on the financial status report make sure their name and title is on the Personnel Level of Effort prior to submitting for payment.
- CPRIT will not reimburse salary for employees not listed on the Personnel Level of Effort.



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Personnel Level of Effort Change Form

- (NEW) Non-Key personnel changes are to be submitted to CPRIT as soon as they occur using CPRIT's Personnel Level of Effort Change Form.
- The Personnel Level of Effort Form is located on the CPRIT web site:
- <http://www.cprit.state.tx.us/funded-grants/grantee-resources/>



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Personnel Level of Effort Change Form

Non-Key CPRIT Grant Personnel Update Form, Page 2

Grant ID:

Employee Name (Last, first, middle initial, etc.)	Initial Date of Employment (MM/DD/YYYY)	End Date of Employment (MM/DD/YYYY) (if applicable)
Employee Name 1: <input type="text"/>	<input type="text"/>	<input type="text"/>
Reason for Update: <input type="text"/>		
Employee Name 2: <input type="text"/>	<input type="text"/>	<input type="text"/>
Reason for Update: <input type="text"/>		
Employee Name 3: <input type="text"/>	<input type="text"/>	<input type="text"/>
Reason for Update: <input type="text"/>		
Employee Name 4: <input type="text"/>	<input type="text"/>	<input type="text"/>
Reason for Update: <input type="text"/>		
Employee Name 5: <input type="text"/>	<input type="text"/>	<input type="text"/>
Reason for Update: <input type="text"/>		

Non-Key CPRIT Grant Personnel Update Form, Page 2

Grant ID:

Employee Name (Last, first, middle initial, etc.)	Initial Date of Employment (MM/DD/YYYY)	End Date of Employment (MM/DD/YYYY) (if applicable)
Employee Name 6: <input type="text"/>	<input type="text"/>	<input type="text"/>
Reason for Update: <input type="text"/>		
Employee Name 7: <input type="text"/>	<input type="text"/>	<input type="text"/>
Reason for Update: <input type="text"/>		
Employee Name 8: <input type="text"/>	<input type="text"/>	<input type="text"/>
Reason for Update: <input type="text"/>		
Employee Name 9: <input type="text"/>	<input type="text"/>	<input type="text"/>
Reason for Update: <input type="text"/>		



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Common Errors

4. Submitting reimbursement for expenses not listed and approved in initial project budget.

- If a major expense is not itemized in the budget, it will not be reimbursed without program management approval, i.e. tuition, stipends, equipment, gift cards, and office furniture.
- For gift card incentives, you must maintain a log of recipients with their signature and date they received the card to submit with the reimbursement request.
- All furniture purchases must be approved by program managers and listed on the project budget.



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Gift Card Certification Form

Gift Card Certification Form for CPRIT Grants

Grantees are required to complete this form for all gift cards distributed to participants or staff. The form is to be completed and submitted to the program manager at the time of the reimbursement request. A separate form is required for gift cards that are distributed to participants or staff for personal use. It is not to be submitted to the program manager.

Program	Grant Number

Date of Gift Card Distribution: _____
 Name of Recipient: _____
 Description of Gift Card: _____
 Amount of Gift Card: _____
 Date of Gift Card Distribution: _____
 Signature of Recipient: _____
 Date of Gift Card Distribution: _____

Instructions:

1. Fill out all information on the form above. Use "N/A" if necessary. Do not leave a blank line.
 2. If the total number of gift cards produced is different than the total number distributed, provide explanation, which is limited to the final disposition of the gift cards that were not distributed. Submit this information with the form.
 3. Attach all information including but not limited to the following to the form: a list of names, dates, and amounts of gift cards distributed to participants or staff.
 4. If the grantee is a grantee of the CPRIT program, the grantee must ensure that all participants received gift cards prior to the end of the grant period. The program manager and grantee both should sign and date the form to certify that the information was completed.

Signature of Recipient: _____ **Name/Title of person receiving information:** _____
Signature of Grantee: _____ **Date:** _____

- Gift Card documentation should include the following:

- List of gift card recipients
- Recipient signature
- Gift Card denomination
- Date and Name of Event

CPRIT will now allow grantees to complete this form with redacted documents, if necessary to avoid HIPAA violations, so long as additional certifications are made.

<http://www.cprit.state.tx.us/funded-grants/grantee-resources/>



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Common Errors

5. Interdepartmental charges not adequately documented.

- CPRIT will accept a form developed by the organization that details the interdepartmental expenses (services/supplies) with dates received and the signature of an individual documenting receipt.



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Common Errors

6. Providing purchase orders instead of vendor invoices.

- Vendor invoices must be provided for all expenses reported on the financial status report.



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Common Errors

7. Submitting incorrect travel documentation.

- The following must be provided for all travel expense reported: receipts for Hotel, Airfare, Car Rental and Travel Mileage Logs, Google Maps showing total travel mileage.
- Tips are unallowable.



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Questions

1. Is there a CPRIT Travel Policy?

- CPRIT uses the State of Texas Travel Guidelines found on the Texas Comptroller's office website: <http://www.window.state.tx.us/procurement/prog/stmp/>
- Texas Administrative Code, Title 34, Part 1 Chapter 20 (f), Rules 20.301 – 20.369
[http://info.sos.state.tx.us/pls/pub/readtac\\$ext.ViewTAC?tac_view=5&ti=34&pt=1&ch=20&sch=F&rl=Y](http://info.sos.state.tx.us/pls/pub/readtac$ext.ViewTAC?tac_view=5&ti=34&pt=1&ch=20&sch=F&rl=Y)



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Questions

2. Currently we have to repeatedly provide justification for the tax charged on leased equipment. Will this continue?

- The Texas Constitution prohibits state agencies and institutions of higher education from paying sales tax.
- <https://fmxcpa.state.tx.us/fm/pubs/purchase/restricted/index.php>



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Questions

3. I wonder if changes of level of effort have to be reported essentially in “real time” or can we just report them at end of quarter?

- As soon as you know who is going to be working on the grant, update the Personnel Level of Effort, (PLOE) form in CGMS. Ensuring only salaries for those employees listed on the PLOE is a reimbursement verification.



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Questions

4. Is it allowable to use Sub-Award funds toward the required match?

- Yes, the subcontractor or subawardee's own funds spent on the CPRIT project may count toward the grantee's required match. The sub's portion of the match for a project year cannot exceed the percentage of the total grant funds paid to the sub for the same project year.
-
- For example:
-
- A grant project has budgeted \$100,000 budget for the project year. Of that amount, \$20,000 of grant funds, or 20% of the total budget for the year, is allocated to be paid to the sub.
-
- The grantee may include up to \$10,000 of the sub's own funds expended on the grant project (20% of the total match required) to demonstrate the \$50,000 matching funds requirement for the project year.
-
- The requirements set forth in Texas Administrative Code 703.11 apply to the use, documentation, and verification of the sub's funds demonstrating the required match.



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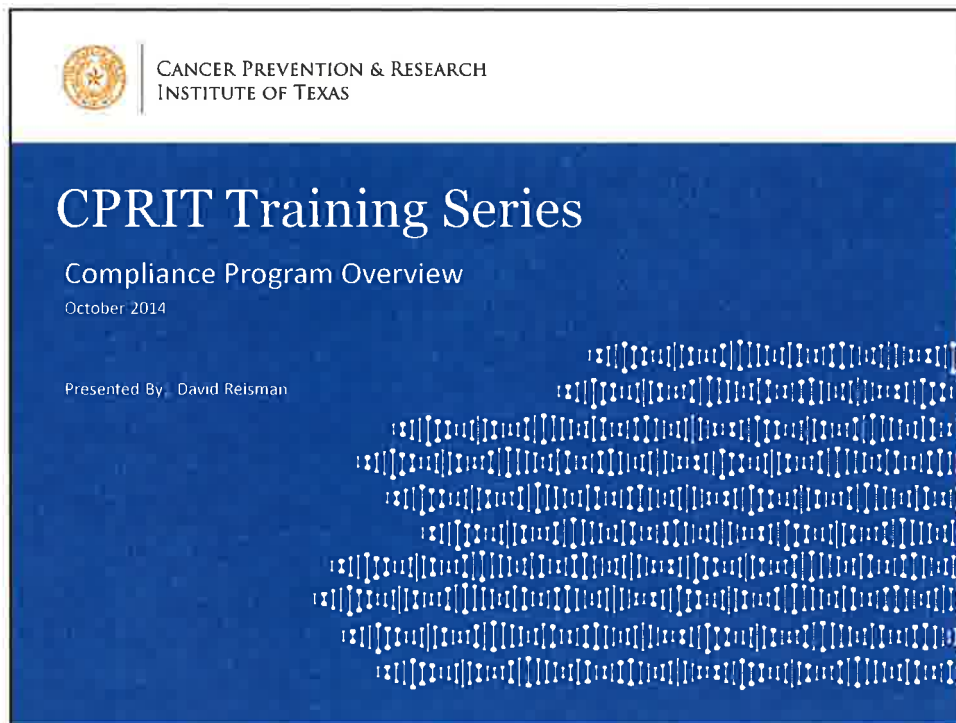
Unallowable Costs - Examples

- Purchase of equipment, if not initially budgeted in the CPRIT proposal, requires prior approval.
- Cost transfers processed after 90 days are unallowable. Cost transfers are allowed to make corrections to bookkeeping errors.
- Invoices posting after the end date of the period of performance may be unallowable; always explain out-of-period invoices unless it is clear from the invoice that the goods/services were received during the period of performance.
- Clothing purchases such as uniforms, lab coats, boots, etc. necessary to perform the project work are allowable but they must be listed in the project budget.
- Personal insurance on a rental car is unallowable. CPRIT will cover insurance costs when insurance is purchased through the car rental agency.
- Cell phone charges paid as supplemental payroll are unallowable. Payments directly to a cell phone provider are allowable.
- Tips are unallowable.



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The slide features a blue background with a white header. The header contains the Cancer Prevention & Research Institute of Texas logo and name. The main title 'CPRIT Training Series' is in large white font, followed by 'Compliance Program Overview' and 'October 2014' in smaller white font. The presenter's name 'Presented By: David Reisman' is in white. A decorative graphic of a DNA double helix is on the right side.

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CPRIT Training Series

Compliance Program Overview

October 2014

Presented By: David Reisman

CPRIT Compliance Program

- 1. Compliance Program Overview**
- 2. Grantee Requirements**
- 3. Grantee Training**
- 4. Fraud Waste & Abuse**

CPRIT Compliance Program Overview

David A. Reisman
Chief Compliance Officer

e-mail: dreisman@cprit.state.tx.us



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CPRIT Compliance Program Overview

**The Compliance Program Ensures CPRIT's
Commitment to:**

- **Our mission**
- **Transparency**
- **Accountability**



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CPRIT Compliance Program Overview

Two Broad Areas of Focus:

- 1. CPRIT Monitoring, Training and Controls**
- 2. Grantee Monitoring, Training, Controls and Customer Service**



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CPRIT Compliance Program Overview

STAFFING

The Compliance Program works jointly with CPRIT's other divisions, Legal, Operations, Human Resources and IT to ensure comprehensive coverage CPRIT compliance activities.



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CPRIT Compliance Program Overview

Grantee Contacts:

Program Managers

Research - Michael Brown
Prevention – Ramona Magid
Product Development - Vacant

Grant Accountants

Oralia Huggins
Dan Limas
Wilfredo Ruiz
Vacant

Grant Specialists

Sandra Balderrama - Manager
Cathy Allen
David Escamilla
Mark McCollum



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Grantee Requirements

There are many Grantee requirements detailed in the laws, rules, policies and contract. The four I'll briefly cover today include:

- MAINTAIN RECORDS
- REPORTING
- CONFLICTS OF INTEREST
- ENSURE STANDARDS OF CONDUCT



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Grantee Requirements

Grantee Monitoring

IMPLEMENTATION OF CPRIT DESK and FIELD REVIEWS



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Grantee Requirements

Monitoring vs. Auditing

Monitoring is preventative: Monitoring is an on-going process that agency management has in place to ensure processes are working as intended.

Auditing is corrective: Auditing is a formal, systematic and disciplined approach designed to evaluate and improve the effectiveness of processes and related controls.



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Grantee Requirements

Types of CPRIT Compliance Monitoring Reviews

Desk Reviews: Desk-based financial monitoring/reviews are conducted during the course of the grant award and seek to verify grantees are expending funds in a compliance with specific grant.

Scope of Desk Reviews:

- Financial and Administrative
- Programmatic/Financial Reporting
- Other Financial Reports
- Single Audit Review



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Grantee Requirements

Types of CPRIT Compliance Monitoring Reviews

On-Site Reviews: An on-site review is the most comprehensive monitoring activity that involves field visits led by compliance grant monitoring staff. Similar to desk-based reviews, on-site monitoring allows CPRIT staff to assess the capability, performance, and compliance of grantees against applicable state regulations and grant/contract requirements.



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Grantee Training

Compliance Training:

- **On-Site**
- **Webinars**
- **Videos**
- **Website Resources**



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Fraud, Waste & Abuse

Fraud

Any act that constitutes fraud under applicable federal or state law, including any intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to that person or some other person.

Waste

Practices that a reasonably prudent person would deem careless or that would allow inefficient use of resources, items or services.

Abuse

Practices that are inconsistent with sound fiscal, business, or medical practices and that result in unnecessary program cost. For example, abuse can include reimbursement for services that are not necessary, or that do not meet professionally recognized standards.



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Fraud, Waste & Abuse

To report fraud, waste and/or abuse,
call the **State Auditor's Office Hotline** at
1-800-TX-AUDIT or go to:

<https://sao.fraud.state.tx.us/hotline.aspx>



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CONCLUSION

QUESTIONS?



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Questions for CPRIT Staff

Ramona Magid will moderate the questions for CPRIT staff

There are two ways to submit questions:

1. Via Chat – Type your question into the chat box on the right side of the screen, click SEND
2. Use your Phone – First “raise your hand” by clicking the Hand button on the left side of the toolbar for the webinar menu. This places you in the queue. Second, when you are called on, UNMUTE your line and ask your question. Once your question has been answered, “lower your hand” by clicking the hand button again.

The slide deck for each presentation is available on CPRIT’s website via the “Compliance” Tab from the homepage.



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MEMORANDUM

TO: CPRIT OVERSIGHT COMMITTEE MEMBERS
FROM: HEIDI MCCONNELL, CHIEF OPERATING OFFICER
SUBJECT: CPRIT FINANCIAL OVERVIEW FOR FISCAL YEAR 2014 AND
OPERATING BUDGET FOR FISCAL YEAR 2015
DATE: NOVEMBER 7, 2014

Fiscal Year 2014 Year End Financial Report

CPRIT expended or obligated approximately \$2.8 million in Indirect Administration through the end of the year. 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 \$9.4 million in Grant Review and Award Operations. The expenditures of \$7.5 million reflected in the Professional Fees and Services category are primarily for the pre/post-award grants management support services provided by SRA International.

CPRIT reported on its six key performance measures to the Legislative Budget Board for FY 2014 and met or exceeded five of those measures. It did not meet the performance measure for company relocations to Texas in the product development program. This measure was affected by the moratorium during FY 2013 when no product development awards were made.

Fiscal Year 2015 Operating Budget

CPRIT's Operating Budget for FY 2015 is \$297,101,446, with the required transfer of \$2,969,554 to the Department of State Health Services for the Texas Cancer Registry operations and estimates of revenue of \$40,000 from company application fees in the product development program and of \$31,000 from the sale of cancer license plates. On September 27, 2014, the Legislative Budget Board approved CPRIT's request to transfer \$9,160,324 from the Cancer Research Grant strategy to the two operating strategies, Grant Review and Award Operations as well as Indirect Operations to support the cost of several major contracts including the pre- and post-award grants management contract with SRA International, the intellectual property evaluation services with Vinson & Elkins and Udell Isidore Ng Russell, and peer review monitoring services with Grant Thornton LLP. With that transfer, there is approximately \$278 million available for prevention, product development, and research grant awards.

Debt Issuance History

CPRIT issued \$162.5 million in commercial paper notes during FY 2014 through the Texas Public Finance Authority (TPFA). On November 5, 2014, TPFA issued \$57.6 million on CPRIT's behalf, bringing the total debt issued to date to approximately \$606.4 million. This debt issuance provides \$7.6 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 \$48.5 million allows CPRIT to make reimbursement payments due to grantees for award expenses.

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

Indirect Administration (B.1.1.)

	2014 Appropriated	2014 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
1001 Salaries and Wages	\$ 1,559,830	\$ 1,286,196		\$ 1,038,610	247,586	81%	\$ 1,038,610	\$ 247,586
1002 Other Personnel Costs	21,400	50,000		36,556	13,444	73%	36,556	13,444
2001 Professional Fees and Services	350,500	969,571		733,579	235,992	76%	733,579	235,992
2003 Consumable Supplies	25,332	22,500		19,670	2,830	87%	19,670	2,830
2004 Utilities	32,600	63,648		57,361	6,287	90%	57,361	6,287
2005 Travel	24,176	34,874		21,721	13,153	62%	21,721	13,153
2006 Rent - Building	427,450	476,075		574,565	(98,490)	121%	574,565	(98,490)
2007 Rent-Machine and Other	16,763	24,150		16,245	7,905	67%	16,245	7,905
2009 Other Operating Expenses	348,824	342,551		277,623	64,928	81%	277,623	64,928
5000 Capital		1,073,200		-	1,073,200	0%	-	1,073,200
Subtotal - Indirect Administration (B.1.1.)	\$ 2,806,875	\$ 4,342,765	1.46%	\$ 2,775,930	\$ 1,566,835	64%	\$ 2,775,930	\$ 1,566,835

Grant Review and Award Operations (A.1.3.)

	2014 Appropriated	2014 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
1001 Salaries and Wages	\$ 1,026,701	\$ 2,377,082		\$ 1,771,306	\$ 605,776	75%	\$ 1,771,306	\$ 605,776
1002 Other Personnel Costs	3,600	100,000		21,895	78,105	0%	21,895	78,105
2001 Professional Fees and Services	4,285,471	8,608,808		7,501,406	1,107,402	87%	7,501,406	1,107,402
2003 Consumable Supplies	27,324	-		-	-	0%	-	-
2005 Travel	24,400	35,430		20,064	15,366	57%	20,064	15,366
2006 Rent - Building	4,867	32,400		37,581	(5,181)	116%	37,581	(5,181)
2007 Rent-Machine and Other	-	7,500		3,670	3,830	49%	3,670	3,830
2009 Other Operating Expenses	1,551,996	-		-	-	0%	-	-
Subtotal - Grant Operations (A.1.3.)	\$ 6,924,359	\$ 11,161,220	3.76%	\$ 9,355,922	\$ 1,805,298	84%	\$ 9,355,922	\$ 1,805,298

Grants

	2014 Appropriated	2014 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
4000 Grants - Prevention (A.1.2)	\$ 29,022,567	\$ 29,022,567		\$ 28,346,692	\$ 675,875	98%	\$ 28,346,692	\$ 675,875
4000 Grants - Research (A.1.1.)	261,262,199	\$ 252,269,894		248,206,283	\$ 4,063,611	98%	248,206,283	4,063,611
Subtotal - Grants	\$ 290,284,766	\$ 281,292,461	94.78%	\$ 276,552,975	\$ 4,739,486	98%	\$ 276,552,975	\$ 4,739,486
Grand Totals	\$ 300,016,000	\$ 296,796,446	100.00%	\$ 288,684,827	\$ 8,111,619	97%	\$ 288,684,827	\$ 8,111,619

* 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

Actual Performance for Outcome and Output/Efficiency Measures for Fiscal Year 2014

Measure	Targeted Performance	QTR 1	QTR 2	QTR 3	QTR 4	Sum of QTRs	% of Mandate Attained
Number of People Served by Institute Funded Prevention and Control Activities	400,000	168,340	147,943	122,144	128,742	567,169	141.79%
Number of Entities Relocating to TX for Cancer Research Related Projects	7.00	0.00	0.00	0.00	0.00	0.00	0.00%
Percentage of Texas Regions w/ Cancer Prevention Services and Activities Initiated	100%	N/A	N/A	N/A	N/A	100%	100%
Annual Age-adjusted Cancer Mortality Rate	176.5	N/A	N/A	N/A	N/A	161.5	91.50%
Number of Published Articles on CPRIT-Funded Research Projects	300	N/A	N/A	N/A	N/A	2997	999.00%
Number of New Jobs Created and Maintained	140	N/A	N/A	N/A	N/A	4794	3424.29%

Variance Explanations

Number of People Served by Institute Funded Prevention and Control Activities
The number of CPRIT grant awards that provide cancer prevention education and screening services vary from year to year depending on what stage they are in from ongoing to completed. The annual projection for this measure is based on the projections from ongoing grant awards as well as an agency projection of the number of new grants that may be awarded in the future that provide these kinds of services and an estimate of the number of potential people served based on past history.
Number of Entities Relocating to TX for Cancer Research Related Projects
CPRIT did not make any relocation awards to companies commercializing cancer research in fiscal year 2013 due to the state leadership imposed moratorium. This output is dependent on the number of companies applying for CPRIT Company Relocation Awards that can successfully advance through CPRIT's rigorous review and evaluation process.
Annual Age-adjusted Cancer Mortality Rate
The rate calculation is affected by annual population adjustments. The calculation for 2014 is based on the age-adjusted mortality rate for all malignant cancer, males and females combined, for 2011. The rate is per 100,000 people and is age-adjusted to the 2000 US Standard Population standard. The population counts used to calculate cancer mortality rates are supplied by the National Center for Health Statistics with support from the NCI. These population counts are based on estimates produced by the US Census Bureau's Population Estimates Program and are adjusted annually.
Number of Published Articles on CPRIT- Funded Research Projects
CPRIT grantees are apparently reporting the cumulative number of published articles during their grants rather than the number of articles published during the reporting period. These numbers will be verified and/or corrected as part of CPRIT's enhanced grant monitoring resulting from implementation of the compliance program beginning in FY 2015.
Number of New Jobs Created and Maintained
The number of new jobs created and maintained reported by scientific and product development research grantees exceeded the projection because CPRIT was using the historical experience from its grants which was limited at the time that the projection was developed. These numbers will be verified and/or corrected as part of CPRIT's enhanced grant monitoring resulting from implementation of the compliance program beginning in FY 2015.
Number of Entities Relocating to TX for Cancer Research Related Projects
CPRIT did not make any relocation awards to companies commercializing cancer research in fiscal year 2013 due to the state leadership imposed moratorium. This output is dependent on the number of companies applying for CPRIT Company Relocation Awards that can successfully advance through CPRIT's rigorous review and evaluation process. Because the measure reflects awards made about one year previously, there is a delay from when a relocation award is made and when it can impact this measure.

Cancer Prevention and Research Institute of Texas

2015 Operating Budget

Method of Finance	AY 2015
Appropriated General Obligation Bond Proceeds	\$ 300,000,000
Transfer for Cancer Registry to Dept. of State Health Services	(2,969,554)
Company Application Fees / Misc Collections	40,000
License Plate Revenue	31,000
Total Appropriated FY 2015	\$ 297,101,446
Items of Appropriation	
Cancer Research Grants	\$ 248,929,227
Cancer Prevention Grants	29,037,567
Grant Review and Award Operations	15,769,241
Institution (Indirect) Administration	3,365,411
Total Appropriated FY 2015	\$ 297,101,446
Object-of-Expense	
Salaries and Wages	\$ 4,226,145
Other Personnel Costs	150,000
Professional Fees and Services	13,809,501
Consumable Supplies	25,750
Utilities	63,648
Travel	59,176
Rent - Building	214,275
Rent-Machine and Other	34,657
Other Operating Expenses	456,500
Capital	95,000
Grants	277,966,794
Total Budgeted	\$ 297,101,446

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				
2015	\$ 300,000,000	November 5, 2014	\$ 57,600,000		Commercial Paper Notes	Series A, Taxable		Footnote 1
				\$ 57,600,000				
TOTAL ISSUED TO DATE				\$ 606,375,000				

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: NOVEMBER 19, 2014

The following report provides an overview of communications activities from August 2014 through October 2014. Over the last quarter the communications team has consisted of Hahn Public Communications and me plus support from Ramona Magid. I am very pleased to report that, as of November 14, Jeff Hillery has joined the team as Communications Specialist.

EARNED MEDIA

The communications team worked with and pitched individual publications and reporters to secure positive coverage for CPRIT, including coordinating an interview with the *Austin American-Statesman* regarding the Oversight Committee's Program Priorities Project.

Grant Awards Announcement: Following the Oversight Committee's approval, on August 20, 2014, CPRIT distributed a press release to and pitched local, regional and national media announcing the awarding of two product development grants, 15 prevention grants and 84 research grants which resulted in some of the coverage as represented below.

Coverage: (August 1, 2014 – October 31, 2014)

- 18 articles featured CPRIT
- 38 additional articles mentioned CPRIT (stories primarily focused on work of grantees)

Coverage Highlights: (see clipped articles following report)

- October 25, 2014, *Austin American-Statesman*, Texas cancer agency shifts funding priorities
- September 8, 2014, *The Cancer Letter*, CPRIT awards round of grants
- September 3, 2014, *D Magazine – Healthcare Daily*, UT Southwestern lands \$26 million in CPRIT grants
- August 22, 2014, *Austin Business Journal*, CPRIT hands out \$170M for anti-cancer projects; Another California company heading to Austin

- Austin 22, 2014, *BioNews Texas*, CPRIT grants \$107M to cancer research, prevention and product development projects in Texas

IDENTITY AND MESSAGING

Brand Identity: 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 were developed. Templates for memos, letters, presentation slide decks and report layouts have been created within the new brand standards and are now being used by CPRIT staff. The website was also updated to reflect the new brand identity.

Messaging: Key messages to align all communications and effectively share CPRIT's purpose and impact with key audiences are being finalized and incorporated into all materials.

Slide Bank: To assist CPRIT staff, Oversight Committee members and partners when giving formal or informal presentations about the agency, the communications team developed a bank of PowerPoint slides highlighting key facts and information about CPRIT and its work. The slide bank will be updated regularly.

RFA RELEASES

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

PROGRAM PRIORITIES PROJECT

After the Oversight Committee's September 3 discussion on proposed priorities, a draft Program Priorities Report was developed. To solicit public feedback on the priorities, we developed and administered a brief survey and summarized the feedback from that survey for the Oversight Committee.

ANNUAL REPORT AND ACHIEVEMENTS REPORT

A timeline for the development of the FY 2014 Annual Report was circulated to CPRIT Executive staff responsible for drafting portions of the content. The report will follow the format and structure of last year's report.

In addition to the required annual report, a companion Achievements Report will be developed this year. It will highlight the achievements and important progress of CPRIT grantees.

GRANTEE TRAINING VIDEOS

To support CPRIT grantee education, the communications team is helping produce a series of training videos covering key compliance topics. The first video addresses administrative rule changes and will be shared with grantees as well as posted to CPRIT's website and YouTube channel.

CPRIT 2015 CONFERENCE

After receiving proposals in response to a venue RFP sent to Austin area hotels, I revised and prepared a 2015 Conference budget and proposal for the Audit subcommittee to consider. A recommendation from the Audit Subcommittee will be presented to the Oversight Committee.

PBS CANCER DOCUMENTARY OPPORTUNITY

I have been in discussions with Texas Public Broadcasting Association to explore options to participate in the premiere of Ken Burns' new documentary on the *Emperor of all Maladies: A biography of cancer*.

Austin American-Statesman

Saturday, October 25, 2014

Breaking news at statesman.com

STATESMAN IN-DEPTH CANCER INSTITUTE

Agency may shift its focus to rare cancers

State-funded agency has enough money for about 1 in 10 proposals.

By Laylan Copellin
lcopellin@statesman.com

The state's cancer-fighting agency is tweaking its funding priorities, suggesting a greater emphasis on rare and hard-to-treat cancers, including ju-

venile and adolescent cancers.

"We really have to find ways to leverage our \$300 million a year," said Wayne Roberts, chief executive officer of the Cancer Prevention and Research Institute of Texas. "We really have to make sure we're not just mimicking what is going on elsewhere."

In 2007, Texans authorized \$3 billion in bonds over



Wayne Roberts, CPRIT CEO, said the agency must leverage the \$300 million it spends yearly.

10 years to finance cancer research, prevention and commercialization programs. The agency, commonly called

CPRIT, is limited to spending \$300 million a year.

Roberts said \$300 million is a lot of money, but it's a small amount compared with the billions spent annually by the federal government, foundations and health care industry.

"The private sector has a tendency to focus on can-

Cancer continued on A10

Cancer

continued from A1

cers where they can produce a product or pharmaceutical that will address a very large number of people in order to maximize profits," Roberts said. "Juvenile and adolescent cancers are relatively rare to begin with, and some people feel these kind of cancers haven't gotten their fair share from other research entities."

CPRIT only has enough money to fund about 1 in 10 of the proposals it receives.

The Legislature mandated that the agency's oversight committee review its funding priorities after lawmakers replaced the agency's leadership for mismanaging \$56 million in grants. One administrator, Gerald "Jerry" Cobbs, was indicted on a first-degree felony. Cobbs is accused of misleading his bosses about a grant that never got the required scientific review.

"The board had priorities, but it had never articulated them in a public setting where the media, the general public, the research and prevention community would understand what's important to them," Roberts said.

The agency is asking the public to review its draft proposal and answer an online survey at www.cprit.state.tx.us by no later than Oct. 28.

"I'm real interested in the general public's perspective," Roberts said. "I'm sure that will influence the final document."

According to the proposal, CPRIT will seek to emphasize underfunded areas of cancers research, including prevention and early detection research; computational biology and analytic methods; rare cancers; and intractable cancers, including lung, liver, pancreatic and brain cancers.

There are "serious limitations" to current research focused on finding cures for advanced cancers, according to the document.

"Thus far, attempts to control cancer by chemotherapy, radiation and even targeted therapy have been thwarted by the ability of cancer cells to develop resistance to these treatment modalities," the proposal reads. "Detecting cancer early in its development is a more desirable approach to cancer control."

The new guidelines could affect funding decisions.

"As a general rule, we didn't try to steer the research into particular cancers" in the past, Roberts said.

Rebecca Garcia, the agency's chief prevention officer, said no research area is being excluded.

However, "if all things are equal, and we have to choose between meritorious projects because we don't have enough funding, we will use these priorities to help make those decisions," she said.

The proposal also calls

TEXAS' ANNUAL CANCER FUNDING IN PERSPECTIVE

Industry: \$9.2 billion

National Cancer Institute: \$5 billion

Other federal: \$3 billion

Foundations/nonprofits: \$700 million

Cancer Prevention and Research Institute of Texas: \$300 million

— SOURCE: NATIONAL CANCER ADVISORY BOARD

for more funding directed to so-called translational research — the link between basic research

and development of new products and treatments.

Roberts said the agency also will continue to

recruit cancer researchers to Texas.

As of September, the agency had relocated 71 researchers to Texas institutions.

"Anytime you bring in a researcher, particularly a young researcher, that's going to give you 25 to 30 years of research," Roberts said. "By the time we're done, I imagine we will have created in Texas the finest cluster of cancer knowledge in the world."

Contact Laylan Copellin at 512-445-3617.

THE CANCER LETTER

Inside information on cancer research and drug development

Published September 8, 2014

CPRIT Awards Round of Grants

The Cancer Prevention and Research Institute of Texas last month awarded 101 new grants: 84 for research, 15 for prevention and two for product development.

CPRIT received nearly 600 grant applications, and after review, awarded grants to cancer researchers, prevention initiatives and product development projects from institutions and organizations across the state.

- The research grants added up to \$76.2 million, supporting 76 research projects and the recruitment of eight cancer scientists and clinicians to academic institutions in Texas.
- The prevention awards added up to \$17.5 million. The projects will support prevention services for underserved populations, focusing on HPV vaccination rates, tobacco cessation in young adult smokers and increasing access to colorectal cancer screening.
- The \$13.5 million of two product development grants will support cancer research and development conducted by a Texas-based company and the relocation of an existing cancer-focused company to Texas. The grants will fund projects to develop novel brain cancer treatments and advanced imaging and diagnostic techniques.

With this \$107.2 million in grants, CPRIT has given out a total of \$970 million in Texas taxpayers' money. Altogether, the state institution was authorized to spend \$3 billion over a decade.


Following a series of scandals in 2012, Texas officials imposed a moratorium on CPRIT's grant-making. That moratorium was lifted in October 2013, after new members were appointed to the CPRIT oversight committee.

CPRIT, which pays as much in cancer research grants as the federal government within the state, reactivated grant-making in November 2013. The organization has reconstituted its scientific review mechanism after many reviewers resigned in protest over the decision to award of a "commercialization" grant to MD Anderson Cancer Center.

The most recent round of grants is the second since the moratorium. A list of these awards is posted [on CPRIT's website](#).

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UT Southwestern Lands \$26 Million In CPRIT Grants

09/2/2014 | by Matt Goodman |  Share Post

The state's cancer research agency awarded 19 grants to UT Southwestern faculty worth \$26 million, which will go toward, among other things, bolstering the telemedicine program and research into cancer treatments.

The Cancer Prevention and Research Institute of Texas announced the grants last week. Here's where the money will go, via the school:

- \$10.1 million total for 12 Individual Investigator Research Awards involving treatments and strategies targeting lung, breast, prostate, and head and neck cancers, as well as basic science research into cancer biology;
- \$8 million for recruitment of faculty from Brandeis University, Massachusetts Institute of Technology, and the University of California, San Francisco;
- \$6 million in Product Development Grants for OncoNano Medicine, LLC to commercialize technology invented by UT Southwestern faculty members for oncology surgery;
- \$1.5 million in Competitive Expansion Grants to expand a unique telemedicine program to provide genetic cancer screenings for underserved and rural areas; and
- \$400,000 in High-Impact/High-Risk Research Awards involving cellular pathways that could help disrupt the spread of cancer cells.

"We are extremely appreciative and gratified to receive this additional support from CPRIT and the people of Texas. The grants will provide funding for the critical cancer research carried out by the talented faculty of UT Southwestern who are pursuing many innovative approaches to ultimately improve treatment and prevention of the scourge of cancer," said Dr. Daniel K. Podolsky, president of UTSW.

The grants were among 101 issued to state agencies, totaling more than \$107 million. More than 600 proposals were submitted.

CPRIT hands out \$107M for anti-cancer projects; Another California company heading to Austin

Aug 21, 2014, 11:24am CDT



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Chad Swiatecki
Staff Writer-
Austin Business Journal
[Email](#) | [Twitter](#)



The Cancer Prevention and Research Institute of Texas has announced \$107 million in grants to 101 recipients throughout the state, including \$9.6 million for research and business relocation efforts in Austin.

The largest single grant given this round by the state anti-cancer agency will go to Curtana Pharmaceuticals, which is relocating to Austin from San Diego. It will receive \$7.5 million over three years to develop treatments for adult and pediatric brain cancer tumors. The rest of the \$1.9 million headed to Austin is divided into five research projects at the [University of Texas](#).

Get the full list of [101 grant recipients here](#).

See Also

- [CPRIT names executive to head product development funding](#)

Curtana is a preclinical drug development company started last year with licensed medical technology and expects to relocate its 12 employees to Austin in October. In addition to the CPRIT money, the company is nearing completion of an equity round of funding for at least \$3.8 million, which it expects to close by the time it opens shop in Austin.

CPRIT is a state agency created with \$3 billion in bond money to fund cancer research and prevention efforts and to stimulate private business interests around the development of commercial cancer therapies. The agency drew controversy and was [forced to stop its grant processes](#) amid allegations of improperly awarded grants shortly after it was created, but a [change in management](#) and a more strenuous review process has allowed it to resume its application and award process.

Chad Swiatecki covers Austin's creative industries, health care and education.

CPRIT Grants \$107M to Cancer Research, Prevention and Product Development Projects in Texas

Posted by: [Leonor Mateus Ferreira](#) | August 21, 2014 | 26 Views



The **Cancer Prevention and Research Institute of Texas** (CPRIT) recently granted 101 awards totaling upwards of \$107 million in funding to support cancer-related projects. Two grants were earmarked for product development programs, 15 grants to prevention programs, and 84 grants to research programs. After reviewing 600 grant applications, CPRIT announced the winners from institutions and organizations across the state.

"CPRIT funds provide needed support for individuals and organizations working to reduce the burden of cancer," said Wayne Roberts, CPRIT's chief executive officer. "Through our merit-based peer review, we identify a wide range of high-quality, innovative projects that positively impact the lives of Texans, both now and into the future. These new grants, plus the more than \$970 million CPRIT has already invested in research, prevention and product development projects, will make new discoveries to cure and prevent cancer a reality."

Highly qualified cancer researchers, prevention initiatives, and product development projects are the target of the grants from CPRIT, as outlined by the organization's Oversight Committee. The first set of grants, totaling approximately \$76.2 million, was given to eight cancer scientists and clinicians working at academic institutions in Texas. The scientists were chosen for being "promising 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 press release.

76 other research grants will support innovative research projects that are thought to significantly advance knowledge of the causes, prevention, and treatment of cancer. The prevention awards, on the other hand, will grant \$17.5 million to novel research projects working on preventing cancer for underserved populations in Texas.

"The projects receiving evidence-based grants will address increasing HPV vaccination rates, tobacco cessation in young adult smokers and increasing access to colorectal cancer screening. The projects receiving competitive continuation grants will provide screening, diagnostic and vaccination services for breast, cervical, colorectal and other cancers. Additional competitive continuation grants support public and professional education projects," according to the press release.

In the area of product development, CPRIT will assign about \$13.5 million to a Texas-based company and the relocation of an existing cancer-focused company to Texas, which are working on projects that are expected to offer breakthroughs in the treatment of brain cancer treatments, as well as in the improvement of imaging and diagnostic techniques.





CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	CPRIT OVERSIGHT COMMITTEE MEMBERS
FROM:	REBECCA GARCIA, PH.D. CHIEF PREVENTION AND COMMUNICATIONS OFFICER
SUBJECT:	PROGRAM PRIORITIES REPORT AND RECOMMENDATION
DATE:	NOVEMBER 19, 2014

Recommendation:

That the Oversight Committee adopt the program priorities as revised by the respective Program Subcommittees.

Background:

The Program Priorities Project activities since the September 3 Oversight Committee meeting include:

- A draft Program Priorities report was developed after the Oversight Committee's September 3 discussion on proposed priorities.
- Public input on the draft report was solicited via a survey posted online October 3. After the comment period ended October 28, the feedback from the survey was summarized for the Oversight Committee.
- The Oversight Committee's Research, Prevention and Product Development Subcommittees met via teleconference on Nov 12, 13, and 14 and reviewed the survey comments as well as information submitted after the September 3 meeting from LIVESTRONG and the CPRIT Advisory Committee on Childhood Cancers. Revisions recommended by the Program Subcommittees are presented for the Oversight Committee's consideration.

The entire project plan and timeline are outlined in the table below.

Project Plan for CPRIT Oversight Committee Priority-Setting Process

Task	Purpose	Dates
Oversight Committee Meeting	Discussion and overview of the priority-setting process. Introduction of Robert Mittman, facilitator for the project.	May 21
Calls with Subcommittee Chairs	Facilitator calls with OC Program Chairs and Program Officers to discuss objectives and overall process; discuss initial thinking about guidelines/priorities for their Subcommittee (1-hour calls)	July 1-11
Subcommittee Meetings	Program Subcommittees meetings in Austin to develop draft guidelines to inform program priorities (3-4 hour meetings)	July 16-17
Conference Call with Subcommittee Chairs	Program Subcommittee Chairs conference call to discuss guidelines/priorities; discuss approaches to balancing priorities among the programs (2-3 hour conference call)	August 15
Oversight Committee Working Session (1-day working session)	OC meeting to discuss and revise draft guidelines/priorities for each Program; discuss and revise guidelines/priorities for Program Integration Committee to balance priorities across programs; solicit public input.	September 3
Public Input period	Draft report and survey soliciting public input posted on CPRIT's website. Listserv message and news article announced the opportunity for input.	October 3-28
Subcommittee meetings	Program Subcommittee meetings to review input; revise draft report	November 11-13
Oversight Committee Review and Action	Review and approve/revise draft report	November 19
Final Report	Staff to prepare final report specifying guidelines/priorities pursuant to OC charge	By December 31

The attached DRAFT Report is the version posted for public input on October 3.

A revised report with the Program Subcommittee's recommendations will be handed out at the November 19 meeting.



**CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
PROGRAM PRIORITIES PROJECT REPORT**

Draft – October 3, 2014

CONTENTS:

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- Process to Develop Program Priorities Page 3
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 - Prevention Program Page 6
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- Priorities Across CPRIT's Three Programs Page 8



ABOUT CPRIT PROGRAM PRIORITIES PROJECT

CPRIT is governed by Health and Safety Code: Chapter 102. Legislation from the 83rd Texas Legislature modified that code to include enhancements to CPRIT's governance and operations. One of the specific enhancements requires CPRIT's Oversight Committee to establish program priorities on an annual basis. The priorities are intended to provide transparency in how the Oversight Committee directs the orientation of the agency's funding portfolio between and within its three programs as well as guide CPRIT staff and Review Councils on the development and issuance of program-specific Requests for Applications (RFAs) and the evaluation of applications submitted in response to those RFAs.

The Oversight Committee priorities are to be reviewed and adjusted annually as circumstances change and new information is found concerning cancer-related advances in prevention, scientific research and product development.

CPRIT Purpose

Health and Safety Code: Chapter 102

Sec. 102.002. PURPOSES. The Cancer Prevention and Research Institute of Texas is established to:

- (1) 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 cancer and cures for cancer;
- (2) 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
- (3) develop and implement the Texas Cancer Plan.

Program Priorities Legislative Mandate

Health and Safety Code: Chapter 102

Sec. 102.107. POWERS AND DUTIES. The oversight committee shall:

- (1) hire a chief executive officer;
- (2) annually set priorities as prescribed by the legislature for each grant program that receives money under this chapter; and
- (3) consider the priorities set under Subdivision (2) in awarding grants under this chapter.



PROCESS TO DEVELOP PROGRAM PRIORITIES

At the May 2014 meeting the Oversight Committee discussed the objectives and process for establishing the first annual program priorities. Between June and August, the Oversight Committee program subcommittees discussed guidelines and priorities. Each subcommittee developed draft program priorities for its respective program and provided input on priorities across the three programs. Draft priorities were presented to the full Oversight Committee at a working session on September 3 where the public was invited to provide input.

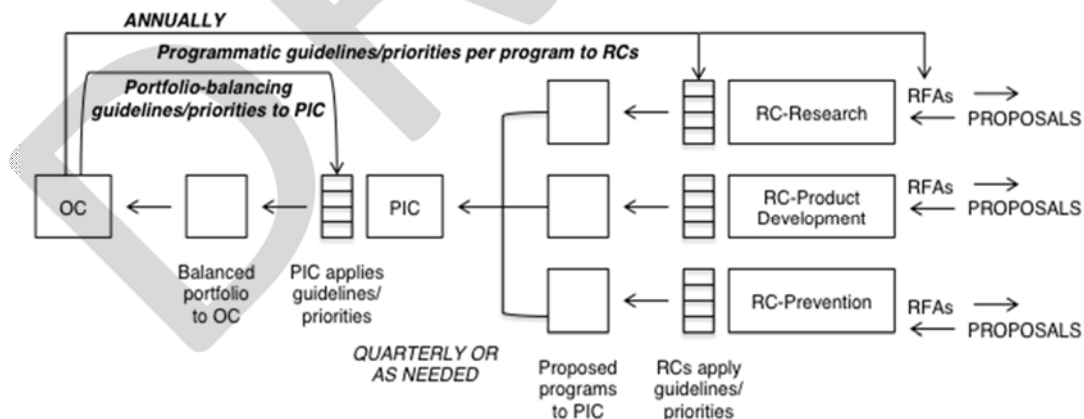
This draft report is the result of the Oversight Committee's process and is being presented for additional public input.

SCOPE OF PROGRAM PRIORITIES PROJECT

The Program Priorities Project establishes priorities at two levels of CPRIT's grant making process:

- **Priorities Within Each of CPRIT's Programs** – priorities to inform staff and respective Peer Review Councils (RCs) on the development and issuance of program-specific Requests for Applications (RFAs) and evaluation of applications submitted in response to those RFAs.
- **Priorities Across CPRIT's Three Programs** – priorities to inform the Program Integration Committee (PIC) on balancing the portfolio across the research, prevention and product development programs.

Priorities and CPRIT's Grant Making Process





CPRIT'S LONG-TERM VISION

As the Oversight Committee set out to establish program priorities, it began by defining the long-term vision for the agency and each of the three programs in alignment with CPRIT's mandated purpose.

Innovative projects funded by CPRIT will result in:

- A decrease in the burden of cancer in Texas through preventive measures, new diagnostics and treatments, and effective translation of discoveries into products;
- A recognition of and focus on disparities in cancer incidence, mortality and access to care;
- Significant advancements in the scientific understanding of cancer; and
- An enhanced and expanded life sciences infrastructure in the state as a result of recruiting researchers, training health care/science professionals, attracting companies and supporting investigator startups.

PRIORITIES WITHIN EACH OF CPRIT'S PROGRAMS

Priorities within each of CPRIT's programs – research, prevention and product development – will inform staff and respective Peer Review Councils on the development and issuance of program-specific Requests for Applications (RFAs) and evaluation of applications to those RFAs.

CPRIT's three programs are currently guided by established key principles essential to executing CPRIT's purpose. The main principle underlying all three programs is that they will continue to ensure only applications with scientific merit will move forward in CPRIT's peer review grant process. In addition, the programs have established principles that are unique to each program. The new program priorities will supplement these principles to guide the selection of meritorious applications to address CPRIT's strategic priorities as set annually by the Oversight Committee.

*It is important to note that these priorities **do not** exclude funding in areas outside of the identified priorities.*

Research Program

Background: The goal of CPRIT's research program is to discover new information about cancer that can lead to prevention, early detection, and more effective treatments; translate new and existing discoveries into practical advances in cancer diagnosis, treatment, and survivorship; and increase the prominence and stature of Texas in the fight against cancer. Until now, CPRIT's strategy has been to support the most creative ideas and the most meritorious projects brought forward by the cancer research community in Texas. Going forward, the overarching principles for awarding CPRIT funds will continue to be scientific excellence and impact on



reducing the burden of cancer. However, more strategic deployment of funds is intended to accelerate progress in cancer research beyond what can be achieved by simply adding incrementally to the types of cancer research funded by other agencies.

Therefore, CPRIT's research program will seek to fund projects in critical, but underfunded areas of cancer research, in addition to funding investigator-initiated, untargeted proposals. Areas of opportunity for strategic deployment of funds include prevention and early detection research; computational biology and analytic methods; rare cancers, particularly pediatric tumors, and intractable cancers, including lung, liver, pancreatic and brain cancers, with particular emphasis on cancers of significance in Texas; and early stage applied research leading to development of new approaches and products for cancer prevention, detection, diagnosis, and cures.

Finally, it is critically important to add to the life sciences infrastructure in the State of Texas. This will enable CPRIT's impact on cancer research to extend for years beyond the lifetime of the program. Most important to increasing infrastructure is the recruitment of preeminent researchers. Such individuals bring additional resources to the State, including research funding and new expertise, as well as help build the critical mass of science needed to attract investments in the development of products for cancer prevention, diagnosis, and treatment.

Established Principles:

- Scientific excellence and impact on cancer
- Targeting underfunded areas
- Increasing the life sciences infrastructure

Proposed Research Program Priorities

- A broad range of innovative, investigator-initiated research projects
- Prevention and early detection
- Computational biology and analytic methods
- Rare and intractable cancers, including childhood cancers
- Cancers of importance in Texas
- Research to move basic science toward its application
- Recruit outstanding cancer researchers to Texas



Prevention Program

Background: The following principles have guided the prevention program since its inception in 2009. These principles have informed the development of the requests for applications (RFAs) and the evaluation of applications submitted in response to the RFAs.

Through the prevention program, CPRIT seeks to fund projects that:

- Are evidence based – offering effective prevention interventions based on the existing body of knowledge about and evidence for cancer prevention.
- Deliver primary, secondary, or tertiary prevention interventions – providing state of the art preventive clinical services and tailored, culturally appropriate, and accurate information to the public and health professionals.

In addition, the program has focused on providing access to underserved populations and serving the populations in most need including underinsured and uninsured individuals and those disproportionately affected by cancer.

In order to achieve some degree of balance to the prevention program portfolio, the Prevention Review Council (PRC) conducts a programmatic review of applications under consideration. During programmatic review, the Prevention Review Council (PRC) evaluates applications judged to be meritorious by prevention review panels. Programmatic considerations include:

- Potential for impact
- Geographic distribution
- Cancer type
- Type of program or service

While these principles provide guidance for the program, identifying priorities based on areas where significant cancer incidence and mortality disparities exist focuses the program further on areas of greatest need and greatest potential for impact.

Data on cancer incidence, mortality and disparities (geographic, ethnic, etc.) are reviewed annually to identify priorities and identify areas of emphasis. This information informs the development of RFAs and informs programmatic decisions during the PRC level of review.



Established Principles:

- Fund evidence-based interventions and their dissemination
- Support the prevention continuum of primary, secondary and tertiary prevention interventions

Proposed Prevention Program Priorities

- Prioritize areas of greatest need, greatest potential for impact
- Focus on underserved populations
- Increase targeting of preventive efforts to areas where significant disparities in cancer incidence or mortality in the state exist

Product Development

Background: CPRIT's product development program should:

- **Identify private sector entities to develop products that will benefit cancer patients –**
Gaps exist in the market's ability to translate research insights and product visions into FDA approved and commercially available products. These gaps may delay, or even deny, cancer patient access to important scientific advances. CPRIT should work to bridge these gaps, leveraging its funds with matching funds from other sources.
- **Selectively deploy its resources where they are most needed and can do the most good –** There are more scientifically and commercially sound product development opportunities than CPRIT is capable of funding. Thus, CPRIT should:
 - Fund commercial projects that might be “game changing” or disruptive;
 - Attract and support cancer-related life sciences companies that will create jobs in Texas;
 - Attract matching funds and additional investments from other sources; and
 - Act in conjunction, but not in competition, with private funding sources or other governmental funding sources.



Established Principles:

- Moving forward the development of commercial products to diagnose and treat cancer and improve the lives of cancer patients
- Creation of good, high-paying jobs for Texans
- Sound financial return on the monies invested
- Development of the Texas high tech life sciences business environment

Proposed Product Development Program Priorities

- Funding projects at Texas companies and relocating companies that are most likely to bring important products to the market
- Providing funding that promotes the translation of research at Texas institutions into new companies able to compete in the marketplace
- Identifying and funding projects to develop tools and technologies of special relevance to cancer research, treatment, and prevention

PRIORITIES ACROSS CPRIT'S THREE PROGRAMS

Establishing priorities across CPRIT's research, prevention and product development programs will inform the Program Integration Committee (PIC) on balancing the portfolio across the three programs.

CPRIT's structure, which includes programs in research, prevention and product development, presents a unique opportunity for funding projects that span the continuum from discovery to delivery to the public and creating synergy across the spectrum. While CPRIT programs would continue to fund a broad range of programs and cancer types, selecting areas of emphasis where CPRIT could have an impact and distinguish it from other funding sources provides a basis for focusing resources and guiding decisions when resources are limited. The recommended areas of emphasis outlined below also correspond to unmet needs – places in the cancer research and care continuum where existing institutions have not provided strong programs or results.

It is important to note that these priorities serve as strategic areas of emphasis and do not exclude funding in areas outside of the identified priorities.



Prevention and Early Detection Initiatives

Rationale: Nowhere is there greater potential to reduce the burden of cancer than by reducing its incidence. This spares people and families from the psychological and emotional trauma of a cancer diagnosis, the often devastating physical consequences of cancer therapies, and the financial burden associated with cancer treatment. In addition, the current emphasis in cancer research on finding cures for advanced cancers has serious limitations. Thus far, attempts to control cancer by chemotherapy, radiation, and even targeted therapy have been thwarted by the ability of cancer cells to develop resistance to these treatment modalities. Detecting cancer early in its development is a more desirable approach to cancer control. In spite of the potential impact of prevention and early detection on reducing the cancer burden, these areas of cancer research receive little funding relative to funding devoted to curing advanced cancer.

Emphasis: Ideally, research would create the evidence base for new approaches to prevention and early detection, product development would provide new methods, diagnostics, imaging or devices for early cancer detection, and the prevention program would implement interventions to put these new approaches into practice once a solid evidence base of effectiveness exists. Strategies would include each program issuing either a targeted RFA or listing prevention and early detection as an area of emphasis (among others) within current RFAs. In addition, the programs can explore RFAs that could span programs, e.g. RFAs that would support a research component to a prevention project.

Early Translational Research

Rationale: One well-documented impediment to bringing the results of basic research to bear on cancer is the shortage of funding to translate new discoveries into practical advances for cancer patients. Research and development are needed between the stages of discovery science, traditionally funded by grants from federal sources and foundations, and late term development and commercialization of drugs, devices, diagnostic tests, and biologicals traditionally funded by private sector industries. Data indicate that such translational research is underfunded and would benefit from additional investment. Funding such research and development by CPRIT could have the added benefit of stimulating public-private partnerships and bringing new commercial investments to Texas.

Emphasis: Funding translational research that bridges the gap between basic research and product development, and between research on preventive measures and new technologies for early detection represents opportunities for inter-program strategic investment by CPRIT. The time needed to move some projects from research to products is often lengthy and may limit the role of the prevention program in this area of emphasis.



Enhance Texas' Research Capacity and Life Science Infrastructure

Rationale: CPRIT's statute emphasizes enhancing research superiority, increasing applied science and technology research capabilities and increasing high-quality jobs in the state. All three programs contribute to enhancing the research, life science and cancer control workforce and infrastructure in the state.

Emphasis: Establishing a critical mass of cancer researchers in Texas is possible by supporting the recruitment of cancer scientists and clinicians, at all career levels, to academic institutions in Texas and through training programs in which pre- and post-doctoral fellows are educated to become cancer researchers. The recruitment program has been successful in enhancing Texas' cancer research efforts and increasing the external visibility of the state in the medical and scientific communities.

CPRIT's investments in product development help to build Texas' life-science industry. While bringing a product to market can take time, jobs and economic activity are generated throughout the process. Every CPRIT award includes intellectual property requirements that specify a revenue return to Texas through the successful development of CPRIT-funded drugs, devices, diagnostics or services.

The prevention program supports the education and training of health care professionals and community workers, thereby increasing the state's capacity for cancer prevention and control activities. By requiring collaborative partnerships, the program also creates incentives for organizations and individuals to collaborate to tackle community problems through networks that can mobilize resources and avoid duplication of efforts. Implementing system changes (such as reducing wait times between screening and diagnostics, implementing patient reminder systems) by CPRIT funded programs also improves the infrastructure for the delivery of preventive interventions.



Summary: Priorities Across CPRIT's Three Programs

Below is a table summarizing how each of CPRIT's three programs would implement the recommended areas of emphasis outlined above.

	Prevention and Early Detection Initiatives	Early Translational Research	Enhance Texas' Research Capacity and Life Science Infrastructure
Research Program Implementation	Create the evidence base for new approaches to prevention and early detection.	Identify CPRIT funded basic research that could translate new discoveries into practical advances.	Increase workforce and infrastructure: researcher recruitment, training grants and core facilities.
Prevention Program Implementation	Implement programs to put these new approaches into practice and continue to fund what is known to work (evidence based).	Due to long lead-time to product development, there may be limited role for prevention to implement programs resulting from this research.	Implementing systems change, developing partnerships and collaborations, training of community and healthcare providers, and creating new jobs.
Product Development Program Implementation	Fund new tools, technologies, methods and devices for early cancer detection and prevention.	Fund translational research that bridges the gap between basic research and product development.	Build up life sciences infrastructure and industry in Texas and create new high paying jobs.



**CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
PROGRAM PRIORITIES PROJECT REPORT**

Draft – October 3, 2014

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ABOUT CPRIT PROGRAM PRIORITIES PROJECT

CPRIT is governed by Health and Safety Code: Chapter 102. Legislation from the 83rd Texas Legislature modified that code to include enhancements to CPRIT's governance and operations. One of the specific enhancements requires CPRIT's Oversight Committee to establish program priorities on an annual basis. The priorities are intended to provide transparency in how the Oversight Committee directs the orientation of the agency's funding portfolio between and within its three programs as well as guide CPRIT staff and Review Councils on the development and issuance of program-specific Requests for Applications (RFAs) and the evaluation of applications submitted in response to those RFAs.

The Oversight Committee priorities are to be reviewed and adjusted annually as circumstances change and new information is found concerning cancer-related advances in prevention, scientific research and product development.

CPRIT Purpose

Health and Safety Code: Chapter 102

Sec. 102.002. PURPOSES. The Cancer Prevention and Research Institute of Texas is established to:

- (1) 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 cancer and cures for cancer;
- (2) 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
- (3) develop and implement the Texas Cancer Plan.

Program Priorities Legislative Mandate

Health and Safety Code: Chapter 102

Sec. 102.107. POWERS AND DUTIES. The oversight committee shall:

- (1) hire a chief executive officer;
- (2) annually set priorities as prescribed by the legislature for each grant program that receives money under this chapter; and
- (3) consider the priorities set under Subdivision (2) in awarding grants under this chapter.



PROCESS TO DEVELOP PROGRAM PRIORITIES

At the May 2014 meeting the Oversight Committee discussed the objectives and process for establishing the first annual program priorities. Between June and August, the Oversight Committee program subcommittees discussed guidelines and priorities. Each subcommittee developed draft program priorities for its respective program and provided input on priorities across the three programs. Draft priorities were presented to the full Oversight Committee at a working session on September 3 where the public was invited to provide input.

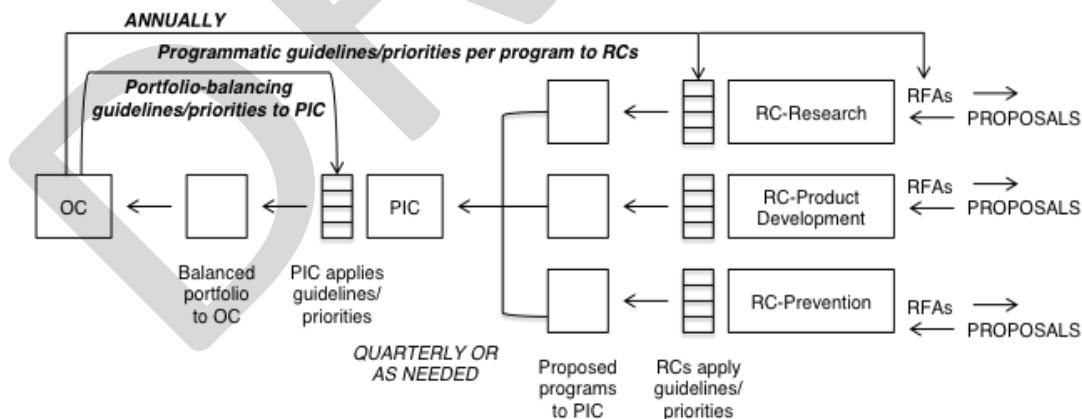
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- Significant advancements in the scientific understanding of cancer; and
- An enhanced and expanded life sciences infrastructure in the state as a result of recruiting researchers, training health care/science professionals, attracting companies and supporting investigator startups.

PRIORITIES WITHIN EACH OF CPRIT'S PROGRAMS

Priorities within each of CPRIT's programs – research, prevention and product development – will inform staff and respective Peer Review Councils on the development and issuance of program-specific Requests for Applications (RFAs) and evaluation of applications to those RFAs.

CPRIT's three programs are currently guided by established key principles essential to executing CPRIT's purpose. The main principle underlying all three programs is that they will continue to ensure only applications with scientific merit will move forward in CPRIT's peer review grant process. In addition, the programs have established principles that are unique to each program. The new program priorities will supplement these principles to guide the selection of meritorious applications to address CPRIT's strategic priorities as set annually by the Oversight Committee.

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Research Program

Background: The goal of CPRIT's research program is to discover new information about cancer that can lead to prevention, early detection, and more effective treatments; translate new and existing discoveries into practical advances in cancer diagnosis, treatment, and survivorship; and increase the prominence and stature of Texas in the fight against cancer. Until now, CPRIT's strategy has been to support the most creative ideas and the most meritorious projects brought forward by the cancer research community in Texas. Going forward, the overarching principles for awarding CPRIT funds will continue to be scientific excellence and impact on reducing the burden of cancer. However, more strategic deployment of funds is intended to



accelerate progress in cancer research beyond what can be achieved by simply adding incrementally to the types of cancer research funded by other agencies.

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Finally, it is critically important to add to the life sciences infrastructure in the State of Texas. This will enable CPRIT's impact on cancer research to extend for years beyond the lifetime of the program. Most important to increasing infrastructure is the recruitment of preeminent researchers. Such individuals bring additional resources to the State, including research funding and new expertise, as well as help build the critical mass of science needed to attract investments in the development of products for cancer prevention, diagnosis, and treatment. Also critical are the training programs that aim to produce the next generation of cancer researchers and increase the diversity of the cancer research workforce.

Established Principles:

- Scientific excellence and impact on cancer
- Targeting underfunded areas
- Increasing the life sciences infrastructure

Proposed Research Program Priorities

- A broad range of innovative, investigator-initiated research projects
- Prevention and early detection
- Computational biology and analytic methods
- Rare and intractable cancers, including childhood cancers
- Population disparities and cancers of importance in Texas
- ~~• Research to move basic science toward its application~~
- Recruit outstanding cancer researchers to Texas



Prevention Program

Background: The following principles have guided the prevention program since its inception in 2009. These principles have informed the development of the requests for applications (RFAs) and the evaluation of applications submitted in response to the RFAs.

Through the prevention program, CPRIT seeks to fund projects that:

- Are evidence based – offering effective prevention interventions based on the existing body of knowledge about and evidence for cancer prevention.
- Deliver primary, secondary, or tertiary (includes survivorship) prevention interventions – providing state of the art preventive clinical services and tailored, culturally appropriate, and accurate information to the public and health professionals.

In addition, the program has focused on providing access to underserved populations and serving the populations in most need including underinsured and uninsured individuals and those disproportionately affected by cancer.

In order to achieve some degree of balance to the prevention program portfolio, the Prevention Review Council (PRC) conducts a programmatic review of applications under consideration. During programmatic review, the Prevention Review Council (PRC) evaluates applications judged to be meritorious by prevention review panels. Programmatic considerations include:

- Potential for impact
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- Cancer type
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While these principles provide guidance for the program, identifying priorities based on areas where significant cancer incidence and mortality disparities exist focuses the program further on areas of greatest need and greatest potential for impact.

Data on cancer incidence, mortality and disparities (geographic, ethnic, etc.) are reviewed annually to identify priorities and identify areas of emphasis. This information informs the development of RFAs and informs programmatic decisions during the PRC level of review.



Established Principles:

- Fund evidence-based interventions and their dissemination
- Support the prevention continuum of primary, secondary and tertiary (includes survivorship) prevention interventions

Proposed Prevention Program Priorities

- Prioritize populations and areas of greatest need, greatest potential for impact
- Focus on underserved populations
- Increase targeting of preventive efforts to areas where significant disparities in cancer incidence or mortality in the state exist

Product Development

Background: CPRIT's product development program should:

- **Identify private sector entities to develop products that will benefit cancer patients –**
Gaps exist in the market's ability to translate research insights and product visions into FDA approved and commercially available products. These gaps may delay, or even deny, cancer patient access to important scientific advances. CPRIT should work to bridge these gaps, leveraging its funds with matching funds from other sources.
- **Selectively deploy its resources where they are most needed and can do the most good –** There are more scientifically and commercially sound product development opportunities than CPRIT is capable of funding. Thus, CPRIT should:
 - Fund commercial projects that might be “game changing” or disruptive;
 - Attract and support cancer-related life sciences companies that will create jobs in Texas;
 - Attract matching funds and additional investments from other sources; and
 - Act in conjunction, but not in competition, with private funding sources or other governmental funding sources.



Established Principles:

- Moving forward the development of commercial products to diagnose and treat cancer and improve the lives of cancer patients
- Creation of good, high-paying jobs for Texans
- Sound financial return on the monies invested
- Development of the Texas high tech life sciences business environment

Proposed Product Development Program Priorities

- Funding projects at Texas companies and relocating companies that are most likely to bring important products to the market
- Providing funding that promotes the translation of research at Texas institutions into new companies able to compete in the marketplace
- Identifying and funding projects to develop tools and technologies of special relevance to cancer research, treatment, and prevention

PRIORITIES ACROSS CPRIT'S THREE PROGRAMS

Establishing priorities across CPRIT's research, prevention and product development programs will inform the Program Integration Committee (PIC) on balancing the portfolio across the three programs.

CPRIT's structure, which includes programs in research, prevention and product development, presents a unique opportunity for funding projects that span the continuum from discovery to delivery to the public and creating synergy across the spectrum. While CPRIT programs would continue to fund a broad range of programs and cancer types, selecting areas of emphasis where CPRIT could have an impact and distinguish it from other funding sources provides a basis for focusing resources and guiding decisions when resources are limited. The recommended areas of emphasis outlined below also correspond to unmet needs – places in the cancer research and care continuum where existing institutions have not provided strong programs or results.

It is important to note that these priorities serve as strategic areas of emphasis and do not exclude funding in areas outside of the identified priorities.



Prevention and Early Detection Initiatives

Rationale: Nowhere is there greater potential to reduce the burden of cancer than by reducing its incidence. This spares people and families from the psychological and emotional trauma of a cancer diagnosis, the often devastating physical consequences of cancer therapies, and the financial burden associated with cancer treatment. In addition, the current emphasis in cancer research on finding cures for advanced cancers has serious limitations. Thus far, attempts to control cancer by chemotherapy, radiation, and even targeted therapy have been thwarted by the ability of cancer cells to develop resistance to these treatment modalities. Detecting cancer early in its development is a more desirable approach to cancer control. In spite of the potential impact of prevention and early detection on reducing the cancer burden, these areas of cancer research receive little funding relative to funding devoted to curing advanced cancer.

Emphasis: Ideally, research would create the evidence base for new approaches to prevention and early detection, product development would provide new methods, diagnostics, imaging or devices for early cancer detection, and the prevention program would implement interventions to put these new approaches into practice once a solid evidence base of effectiveness exists. Strategies would include each program issuing either a targeted RFA or listing prevention and early detection as an area of emphasis (among others) within current RFAs. In addition, the programs can explore RFAs that could span programs, e.g. RFAs that would support a research component to a prevention project.

Early Translational Research

Rationale: One well-documented impediment to bringing the results of basic research to bear on cancer is the shortage of funding to translate new discoveries into practical advances for cancer patients. Research and development are needed between the stages of discovery science, traditionally funded by grants from federal sources and foundations, and late term development and commercialization of drugs, devices, diagnostic tests, and biologicals traditionally funded by private sector industries. Data indicate that such translational research is underfunded and would benefit from additional investment. Funding such research and development by CPRIT could have the added benefit of stimulating public-private partnerships and bringing new commercial investments to Texas.

Emphasis: Funding translational research that bridges the gap between basic research and product development, and between research on preventive measures and new technologies for early detection and on adaptation of tested interventions represents opportunities for inter-program strategic investment by CPRIT. The time needed to move some projects from research to products is often lengthy and may limit the role of the prevention program in this area of emphasis.



Enhance Texas' Research Capacity and Life Science Infrastructure

Rationale: CPRIT's statute emphasizes enhancing research superiority, increasing applied science and technology research capabilities and increasing high-quality jobs in the state. All three programs contribute to enhancing the research, life science and cancer control workforce and infrastructure in the state.

Emphasis: Establishing a critical mass of cancer researchers in Texas is possible by supporting the recruitment of cancer scientists and clinicians, at all career levels, to academic institutions in Texas and through training programs in which pre- and post-doctoral fellows are educated to become cancer researchers. The recruitment program has been successful in enhancing Texas' cancer research efforts and increasing the external visibility of the state in the medical and scientific communities.

CPRIT's investments in product development help to build Texas' life-science industry. While bringing a product to market can take time, jobs and economic activity are generated throughout the process. Every CPRIT award includes intellectual property requirements that specify a revenue return to Texas through the successful development of CPRIT-funded drugs, devices, diagnostics or services.

The prevention program supports the education and training of health care professionals and community workers, thereby increasing the state's capacity for cancer prevention and control activities. By requiring collaborative partnerships, the program also creates incentives for organizations and individuals to collaborate to tackle community problems through networks that can mobilize resources and avoid duplication of efforts. Implementing system changes (such as reducing wait times between screening and diagnostics, implementing patient reminder systems) by CPRIT funded programs also improves the infrastructure for the delivery of preventive interventions.



Summary: Priorities Across CPRIT's Three Programs

Below is a table summarizing how each of CPRIT's three programs would implement the recommended areas of emphasis outlined above.

	Prevention and Early Detection Initiatives	Early Translational Research	Enhance Texas' Research Capacity and Life Science Infrastructure
Research Program Implementation	Create the evidence base for new approaches to prevention and early detection.	Identify CPRIT funded basic research that could translate new discoveries into practical advances.	Increase workforce and infrastructure: researcher recruitment, training grants and core facilities.
Prevention Program Implementation	Implement programs to put these new approaches into practice and continue to fund what is known to work (evidence based).	Due to long lead-time to product development, there may be limited role for prevention to implement programs resulting from this research.	Implementing systems change, developing partnerships and collaborations, training of community and healthcare providers, and creating new jobs.
Product Development Program Implementation	Fund new tools, technologies, methods and devices for early cancer detection and prevention.	Fund translational research that bridges the gap between basic research and product development.	Build up life sciences infrastructure and industry in Texas and create new high paying jobs.



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

November 5, 2014

Dear Oversight Committee Members:

I am pleased to present the Program Integration Committee's (PIC) unanimous recommendations for funding 33 grant applications totaling \$71,128,208 in grants. The PIC recommendations for 8 scientific research grant awards, 5 prevention awards and 20 product development awards are attached.

Dr. Margaret Kripke, CPRIT's Chief Scientific Officer, Dr. Becky Garcia, CPRIT's Chief Prevention Officer, and Dr. Tom Goodman, CPRIT's Chief Product Development Officer, have prepared overviews of the scientific research, prevention, and product development program slates to assist your evaluation of the recommended awards. The overviews are intended to provide a comprehensive summary of the recommended proposals with enough detail that you should be able to understand the substance of the proposal and the reasons endorsing grant funding.

In addition to the comprehensive overviews, all of the information reviewed by the Review Councils is available by clicking on the appropriate link in the portal. This information includes the full application, peer reviewer critiques, and the CEO affidavit for each proposal.

The approval of these grant recommendations is governed by a statutory process that requires two-thirds of the members present and voting to approve each recommendation. David Reisman, CPRIT's Chief Compliance Officer, will certify that the review process for the recommended grants followed CPRIT's award process prior to any Oversight Committee action.

The award recommendations will not be considered final until the Oversight Committee meeting on Wednesday, November 19, 2014. Consistent with the non-disclosure agreement that all Oversight Committee members have signed, the recommendations should be kept confidential and not be disclosed to anyone until the award list is publicly announced at the Oversight Committee meeting. I request that Oversight Committee members not print, email or save to your computer's hard drive any material on the portal. I appreciate your assistance in taking all necessary precautions to protect this information.

If you have any questions or would like more information on the review process or any of the projects recommended for an award, CPRIT's staff, including myself, Dr. Kripke, Dr. Garcia, and Dr. Goodman, are always available. Please feel free to contact us directly should you have any questions. The programs that will be supported by the CPRIT awards are an important step in our efforts to mitigate the effects of cancer in Texas. Thank you for being part of this endeavor.

Sincerely,
Wayne R. Roberts
Chief Executive Officer

Academic Research Award Recommendations –

The PIC unanimously recommends approval of eight academic grant proposals totaling \$30 million. The recommended grant proposals were submitted in response to one of three grant mechanisms: Recruitment of Established Investigators, Recruitment of Rising Stars, and Recruitment of First-Time Tenure-Track Faculty Members. The PIC followed the recommendations made by the Scientific Review Council (SRC). The SRC provided the prioritized list of recommendations for the Recruitment awards to the presiding officers on October 8, 2014.

The PIC is required to give funding priority, to the extent possible, to applications that meet one or more criteria set forth in V.T.C.A., TEX. HEALTH & SAFETY CODE § 102.251(a)(2)(C). The PIC determined that these academic research proposals met the following CPRIT funding priorities:

- could lead to immediate or long-term medical and scientific breakthroughs in the area of cancer prevention or cures for cancer;
- strengthen and enhance fundamental science in cancer research;
- ensure a comprehensive coordinated approach to cancer research and cancer prevention;
- address federal or other major research sponsors' priorities in emerging scientific or technology fields in the area of cancer prevention or cures for cancer;
- are matched with funds available by a private or nonprofit entity and institution or institutions of higher education;
- have a demonstrable economic development benefit to this state;
- enhance research superiority at institutions of higher education in this state by creating new research superiority, attracting existing research superiority from institutions not located in this state and other research entities, or enhancing existing research superiority by attracting from outside this state additional researchers and resources;
- expedite innovation and commercialization, attract, create, or expand private sector entities that will drive a substantial increase in high-quality jobs, and increase higher education applied science or technology research capabilities; and
- address the goals of the Texas Cancer Plan.

Recruitment Grant Award Recommendations

Application ID	Nominator Organization	Candidate	Mechanism*	Budget Requested
RR150013	The University of Texas M. D. Anderson Cancer Center	Dr. Marcin Imielinski	RFT	\$2,000,000
RR150009	Baylor College of Medicine	Dr. Xi Chen	RFT	\$2,000,000
RR150005	Baylor College of Medicine	Dr. Melanie Samuel	RFT	\$2,000,000
RR150010	The University of Texas Southwestern Medical Center	Dr. Robert Mattrey	REI	\$6,000,000
RR150012	The University of Texas M. D. Anderson Cancer Center	Dr. J. Silvio Gutkind	REI	\$6,000,000
RR150015	The University of Texas Southwestern Medical Center	Dr. Samara Peck-Peterson	RRS	\$4,000,000
RR150016	The University of Texas Southwestern Medical Center	Dr. Andres Leschziner	RRS	\$4,000,000
RR150017	The University of Texas Southwestern Medical Center	Dr. Issam El Naqa	RRS	\$4,000,000

*RRS = Recruitment of Rising Star, RFT = Recruitment of First Time Tenure Track, REI = Recruitment of Established Investigator

Prevention Award Recommendations -

The PIC unanimously recommends approval of five prevention grant proposals totaling \$7,271,233. The recommended grant proposals were submitted in response to one of two grant mechanisms: Evidence-Based Cancer Prevention Services and Competitive Continuation/Expansion Grants. The PIC followed the recommendations made by the Prevention Review Council (PRC). The PRC provided the prioritized list of recommendations for the Recruitment awards to the presiding officers on October 28, 2014.

The PIC is required to give funding priority, to the extent possible, to applications that meet one or more criteria set forth in V.T.C.A., TEX. HEALTH & SAFETY CODE § 102.251(a)(2)(C). The PIC determined that these prevention proposals met the following CPRIT funding priorities:

- ensure a comprehensive coordinated approach to cancer research and cancer prevention;
- are interdisciplinary or interinstitutional;
- address federal or other major research sponsors' priorities in emerging scientific or technology fields in the area of cancer prevention or cures for cancer;
- are collaborative between any combination of private and nonprofit entities, public or private agencies or institutions in this state, and public or private institutions outside this state [Evidence-Based Cancer Prevention Services];
- have a demonstrable economic development benefit to this state; and
- address the goals of the Texas Cancer Plan.

Evidence-Based Cancer Prevention Services and Competitive Continuation/Expansion Grant Award Recommendations

App ID	Mechanism	Application Title	Organization	Score	Recommended Funding
PP150025	CCE-EBP	Continuation and Expansion of Texas A&M's Colon Cancer Screening, Training, Education and Prevention Program	Texas A&M University System Health Science Center	2.3	\$1,500,000
PP150031	EBP	Get FIT to Stay Fit. Stepping Up to Fight Colorectal Cancer in the Panhandle	Texas Tech University Health Sciences Center	2.4	\$1,455,409
PP150004	EBP	A multi-pronged approach to increase HPV vaccination rates among adolescents 9–17 years of age from Galveston and Brazoria Counties	The University of Texas Medical Branch at Galveston	2.6	\$1,406,919
PP150009	EBP	ACCION for Rural West Texas	Texas Tech University Health Sciences Center	3.1	\$1,467,820

PP150012	EBP	Improving Cervical Cancer Screening and Prevention in the Lower Rio Grande Valley Through Public Outreach, Patient Navigation, and Telementoring	The University of Texas M. D. Anderson Cancer Center	3.2	\$1,441,085
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Product Development Award Recommendations –

The PIC unanimously recommends approval of 20 product development grant proposals totaling \$33,856,975. The recommended grant proposals were submitted in response to the Early Translational Research Award Request for Applications. The PIC followed the recommendations made by the Product Development Review Council (PDRC). The PDRC provided the prioritized list of recommendations for the Recruitment awards to the presiding officers on October 28, 2014.

The PIC is required to give funding priority, to the extent possible, to applications that meet one or more criteria set forth in V.T.C.A., TEX. HEALTH & SAFETY CODE § 102.251(a)(2)(C). The PIC determined that these product development proposals met the following CPRIT funding priorities:

- could lead to immediate or long-term medical and scientific breakthroughs in the area of cancer prevention or cures for cancer ;
- strengthen and enhance fundamental science in cancer research;
- ensure a comprehensive coordinated approach to cancer research and cancer prevention;
- are interdisciplinary or interinstitutional;
- address federal or other major research sponsors' priorities in emerging scientific or technology fields in the area of cancer prevention or cures for cancer;
- are matched with funds available by a private or nonprofit entity and institution or institutions of higher education;
- have a demonstrable economic development benefit to this state;
- enhance research superiority at institutions of higher education in this state by creating new research superiority, attracting existing research superiority from institutions not located in this state and other research entities, or enhancing existing research superiority by attracting from outside this state additional researchers and resources
- expedite innovation and product development, attract, create, or expand private sector entities that will drive a substantial increase in high-quality jobs, and increase higher education applied science or technology research capabilities; and
- address the goals of the Texas Cancer Plan.

Product Development Grant Award Recommendations

App. ID	Applicant	Organization	Recommended Funding	FINAL SCORE
DP150083	Metelitsa	Baylor College of Medicine	\$1,928,220	2.3
DP150069	Tweardy	Baylor College of Medicine	\$1,999,569	2.3
DP150052	Hung	The University of Texas M. D. Anderson Cancer Center	\$1,359,649	2.3
DP150102	Milner	The University of Texas at Austin	\$1,694,460	2.4
DP150093	Gorfe	The University of Texas Health Science Center at Houston	\$1,969,826	2.4
DP150064	Pati	Baylor College of Medicine	\$2,000,000	2.5
DP150086	Walker	Texas A&M University System Health Science Center	\$1,999,979	2.6
DP150056	Zhang	The University of Texas Southwestern Medical Center	\$2,000,000	2.7

DP150094	Cooper	The University of Texas M. D. Anderson Cancer Center	\$1,992,245	2.9
DP150055	Li	The University of Texas Health Science Center at San Antonio	\$1,998,444	2.9
DP150096	Vadlamudi	The University of Texas Health Science Center at San Antonio	\$1,992,460	3.1
DP150051	Ariizumi	The University of Texas Southwestern Medical Center	\$1,163,655	3.1
DP150061	Georgiou	The University of Texas at Austin	\$1,790,486	3.2
DP150065	Hancock	The University of Texas Health Science Center at Houston	\$1,511,840	3.3
DP150059	Bresalier	The University of Texas M. D. Anderson Cancer Center	\$1,693,599	3.3
DP150074	Hellmich	The University of Texas Medical Branch at Galveston	\$1,605,119	3.6
DP150077	Zhu	The University of Texas Southwestern Medical Center	\$1,357,880	3.6
DP150091	Lacko	University of North Texas Health Science Center at Fort Worth	\$742,048	3.6
DP150087	Sessler	The University of Texas at Austin	\$1,464,504	3.8
DP150099	Wang	The Methodist Hospital Research Institute	\$1,592,992	3.8



CANCER PREVENTION & RESEARCH
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**Conflict of Interest Disclosure – Oversight Committee Members
For Applications Recommended for Consideration at November 19, 2014 Open Meeting**

Conflict of Interest Disclosure - Amy Mitchell

Prevention (5)

PP150025, PP150031, PP150004, PP150009, PP150012

Scientific Research (8)

RR150013, RR150009, RR150005, RR150010, RR150012, RR150015, RR150016, RR150017

Product Development (20)

DP150083, DP150069, DP150052, DP150102, DP150093, DP150064, DP150086, DP150056,
DP150094, DP150055, DP150096, DP150051, DP150061, DP150065, DP150059, DP150074,
DP150077, DP150091, DP150087, DP150099

By my signature, this list of reported conflicts of interest shall be included as the official record of conflicts of interest reported by Oversight Committee members for grant award recommendations considered at the November 19, 2014, Oversight Committee meeting.

Dr. William Rice, Presiding Officer, Oversight Committee

Date

Amy Mitchell, Secretary, Oversight Committee

Date



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: CPRIT OVERSIGHT COMMITTEE MEMBERS
FROM: REBECCA GARCIA, PHD, CHIEF PREVENTION AND COMMUNICATIONS OFFICER
SUBJECT: PREVENTION PROGRAM UPDATE
DATE: NOVEMBER 10, 2014

In late September and October, the Prevention Program peer review panels continued reviewing applications submitted for the first round of FY 2015 grant awards, and Requests for Applications (RFAs) for the second round of FY 2015 grant awards were released.

FY2015 Review Cycle 1: CPRIT received 16 applications in response to two RFAs, Evidence-Based Cancer Prevention Services and Competitive Continuation/Expansion. On October 24, 2014, the Prevention Review Council completed their review of the applications forwarded by the Prevention review panels and submitted their recommendations to the Program Integration Committee. Five projects are being recommended for approval by the Oversight Committee at the November 19, 2014 meeting.

FY2015 Review Cycle 2: We released four prevention RFAs on September 25, 2014, two of which are new. Applications are due December 4, 2014.

- Competitive Continuation/Expansion - Evidence-Based Cancer Prevention Services
Supports the continuation or expansion of previously funded cancer prevention and control clinical services that have demonstrated exemplary success.
- Evidence-Based Cancer Prevention Services
Supports the delivery of evidence-based cancer prevention and control clinical services.
- New: Evidence-Based Cancer Prevention Services – Colorectal Cancer Prevention Coalition
Supports the delivery of colorectal cancer prevention and control services through simultaneous implementation in multiple clinical sites.
- New : Cancer Prevention Promotion and Navigation to Clinical Services
Supports public education, outreach and navigation to cancer screening and preventive services.

One hundred seven people signed up for a webinar presented by Dr. Garcia and Ramona Magid on October 22. The webinar allowed potential applicants to ask questions regarding the four award mechanisms and the online CPRIT Application Receipt System (CARS).

Timeline for FY15 Prevention Grants Cycles

Steps	Cycle 15.1	Cycle 15.2
RFA Release	March 31, 2014	September 29, 2014
Applications Due	July 10, 2014	December 4, 2014
Peer review	October 1-2, 2014	February, 2015
PRC Review	October 24, 2014	February, 2015
PIC meeting	November 4, 2014	May 5, 2015
OC meeting	November 19, 2014	May 20, 2015

Meetings were held October 27-29 with five Prevention program grantees in the Dallas/Fort Worth area. The purpose of these meetings was to review the projects' status and explore components of projects that may be candidates for replication by others.

In other activities, we had a meeting with the American Cancer Society (ACS) on October 20 to discuss possible collaboration on colorectal cancer initiatives. They will inform the clinics and partners they work with in the state about CPRIT's new colorectal cancer RFA. CPRIT and ACS will also explore other partnership opportunities. We also continued our discussions with the College of American Pathologists about partnering to expand their *See, Test, and Treat Program* on breast and cervical cancer in Texas. Ramona and I met with the Foundation's Executive Director and Foundation Chair on September 27 to observe a program that was held in Austin.

On November 5, I presented an overview of CPRIT at the **LeadTexas** regional event hosted by the Texas Healthcare and Bioscience Institute. **LeadTexas** is a project to join corporations, communities, economic development entities, foundations, academic institutions, and individuals to create jobs in the bioscience industry.



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: PROGRAM INTEGRATION COMMITTEE
FROM: REBECCA GARCIA, PH.D., CHIEF PREVENTION AND COMMUNICATIONS OFFICER
SUBJECT: PREVENTION GRANT RECOMMENDATIONS
DATE: OCTOBER 27, 2014

Summary and Recommendation:

The CPRIT Prevention Review Council has reviewed and recommends awarding five prevention projects totaling \$7,271,233. The grant recommendations are presented in two slates corresponding to the following grant mechanisms:

1. **Evidence-Based Cancer Prevention Services**—4 projects, totaling \$ 5,771,233
2. **Competitive Continuation/Expansion Grants**—1 project, totaling \$ 1,500,000

Background:

Sixteen prevention grant applications were submitted in response to the following CPRIT RFAs:

- ***Evidence-Based Cancer Prevention Services*** – For projects that provide the delivery of evidence-based prevention services (e.g., screening, survivorship services). The maximum grant award is up to \$1.5 million for up to three years.
- ***Competitive Continuation/Expansion Grants*** – For projects that propose to continue or expand highly successful projects previously or currently funded by CPRIT. The award amount ranges from \$150,000 to \$1.5 million depending on the type of project proposed.

The RFAs were released March 31 and applications were due July 10, 2014. Peer review of the applications was conducted in October 2014.

By statute the Prevention Program funding is limited to no more than 10% of available funding which is approximately \$30 million per fiscal year.

Evidence-Based Cancer Prevention Services Slate

Recommended projects (4): \$5,771,233

There are four new evidence based prevention services projects in the proposed slate. Of the four, three focus on increasing HPV vaccination rates and screening for cervical cancer and the fourth project addresses colorectal cancer education and screening.

The **University of Texas Medical Branch at Galveston** will use a multi-pronged approach to increase HPV vaccination rates in Galveston and Brazoria Counties. The project will educate health care providers as well as hire and train Patient Navigators (PNs) to assist adolescents with initiating and completing the series. PNs will identify families who present to a UTMB pediatric clinic and have a child 9–17 years old who has not initiated or completed the HPV vaccine. If the family is agreeable, the PN will educate them in private about the vaccine in a culturally appropriate manner. The PN will also make appointments, set up text and phone reminders, and reschedule missed appointments.

FP150004



Geographic region: Brazoria, Galveston

UT M.D. Anderson Cancer Center will implement two innovative, evidence-based, complementary interventions in the Lower Rio Grande Valley (LRGV) to increase participation in cervical cancer screening and expand the professional capacity for accurate diagnosis and treatment of precancerous lesions. The first is Cultivando La Salud (Cultivating Health, CLS), an educational outreach and navigation program designed for promotoras to teach low-income Hispanic women about cervical cancer screening and connect them with the cervical cancer screening services offered at participating sites. The second intervention, Project Extension for Community Healthcare Outcomes (ECHO) will increase the number of community providers in the LRGV trained to manage abnormal cervical cancer screening tests including performing the recommended diagnostic and treatment procedures. ECHO is a well-established telementoring model proven to expand access to specialty medical care for underserved areas using videoconferencing, case-based learning and patient co-management.

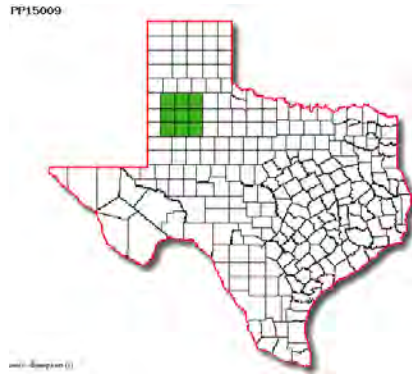
FP150012



Geographic region: Cameron, Starr, Willacy, Hidalgo

Texas Tech University Health Sciences Center will take the successful El Paso based ACCION project and work with local communities to modify the program for rural West Texas. The program will include outreach through community organizations and Federally Qualified Health Centers, education about colorectal cancer delivered by community health workers, FIT testing and colonoscopy as needed, and navigation to assist participants in completing testing and finding health care coverage and treatment for cancer as needed.

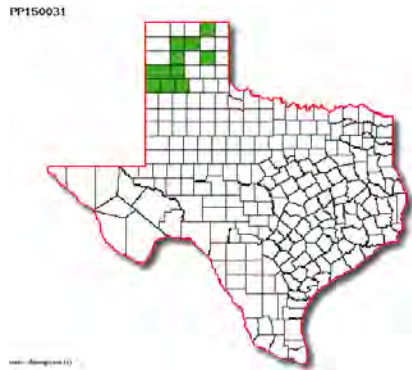
PP15009



Geographic region: Lubbock, Lynn, Floyd, Crosby, Hockley, Hale, Terry, Garza, Lamb

This **Texas Tech University Health Sciences Center** project will target low income, undereducated, and minority populations including refugees. Components of the project include educating the community via community health workers (CHWs) and distributing stool (FIT) collection kits. Positive tests will be managed by the referral system in place. Other goals include reducing structural barriers, increasing provider recommendation for CRC screening and building a sustainable screening, diagnosis and treatment network.

PP150031



Geographic region: Potter, Randall, Gray, Hutchinson, Moore, Deaf Smith, Parmer, Ochiltree, Castro, Swisher

Competitive Continuation/Expansion Grants

Recommended projects (1): \$1,500,000

This mechanism is intended to fund the continuation or expansion of currently or previously funded projects that have demonstrated exemplary success as evidenced by progress reports and project evaluations. Of the five applications submitted, one is being recommend for funding.

The Texas A&M University System Health Science Center project proposes a continuation of services to the 7-county Brazos Valley area, while expanding access to C-STEP services in 10 additional Texas counties. The goals of this application are to increase the number of underserved and rural Texans who receive colorectal cancer (CRC) screening, improve access to CRC prevention education, screening and follow-up care through use of community health workers and increase the number of family medicine physicians receiving colonoscopy training.

PP150025



Geographic region: Brazos, Burleson, Falls, Freestone, Grimes, Houston, Lee, Leon, Limestone, Madison, Milam, Montgomery, Robertson, Trinity, Walker, Waller, Washington



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: DAVID REISMAN, CHIEF COMPLIANCE OFFICER
SUBJECT: COMPLIANCE CERTIFICATION – PREVENTION AWARDS SLATES
DATE: NOVEMBER 6, 2014

Summary and Recommendation:

As CPRIT's Chief Compliance Officer, I am responsible for reporting to the Oversight Committee regarding the agency's compliance with applicable statutory and administrative rule requirements during the grant review process. I have reviewed the compliance pedigrees for the grant applications submitted to CPRIT for the:

- Evidence-Based Cancer Prevention Award Slate
- Competitive Continuation/Expansion Grants Award Slate

With regard to the Evidence-Based Cancer Prevention Award Slate, I have conferred with staff at CPRIT and SRA International (SRA), CPRIT's contracted third-party grant administrator, and studied the supporting grant review documentation, including third-party observer reports for the peer review meetings. I am satisfied that the application review process that resulted in the four Evidence-Based Cancer Prevention grants, recommended by the Chief Executive Officer, followed applicable laws and agency administrative rules. I certify this award slate for the Oversight Committee's consideration.

With regard to the Competitive Continuation/Expansion Grants Award Slate, I have conferred with staff at CPRIT and SRA International (SRA), CPRIT's contracted third-party grant administrator, and studied the supporting grant review documentation, including third-party observer reports for the peer review meetings. I am satisfied that the application review process that resulted in the one Competitive Continuation/Expansion grants, recommended by the Chief Executive Officer, followed applicable laws and agency administrative rules. I certify this award slate for the Oversight Committee's consideration.

Background:

CPRIT is statutorily required to employ a Chief Compliance Officer to report to the Oversight Committee regarding compliance with the statute and the agency's administrative rules. Among the Chief Compliance Officer's responsibilities is the obligation "to ensure that all grant proposals comply with this chapter and rules adopted under this chapter before the proposals are submitted to the oversight committee for approval." TEX HEALTH & SAFETY CODE §102.051(c) and (d).

CPRIT uses a compliance pedigree process to formally document compliance for the grant awards. The compliance pedigree tracks the grant application as it moves through the review process and documents compliance with applicable laws and administrative rules. A compliance pedigree is created for each application; the information related to the procedural steps listed on the pedigree is entered and attested to by SRA employees and CPRIT employees. To the greatest extent possible, information reported in the compliance pedigree is imported directly from data contained in CPRIT's Application Receipt System (CARS), the grant application database managed by SRA. This is done to minimize the opportunity for error caused by manual data entry.

Pre-Receipt Compliance:

The activities listed in pre-receipt stage cover the period beginning with CPRIT's issuance of the Request for Application (RFA) through the submission of grant applications. CPRIT's administrative rules require that RFAs be publicly posted in the *Texas Register*. The RFA specifies a deadline and mandates that only those applications submitted electronically through CARS are eligible for consideration. CARS blocks an application from being submitted once the deadline passes. Occasionally, an applicant may have technical difficulties that prevent the applicant from completing the application submission. When this occurs, the applicant may appeal to CPRIT (through the CPRIT Helpdesk that is managed by SRA) to allow for a submission after the deadline. The program officer considers any appeals and may approve a late filing for good cause. When a late filing request is approved, the appellee is notified and CARS is reopened for a brief period – usually two to three hours – the next business day.

For each of the sixteen prevention grant applicants, I reviewed the application pedigrees. All of the RFA's were posted in the Texas Register. All of the applicants registered through CARS. One applicant did not submit the application within the receipt period. The appeal for an extension not accepted.

Receipt, Referral, and Assignment Compliance:

Once applications have been submitted through CARS, SRA staff reviews the applications for compliance with RFA directions. If an applicant does not comply with the directions, SRA notifies the program officer and the program officer makes the final decision to administratively withdraw the application. The program officer and the Review Council Chair assign applications to peer review panels and primary reviewers. Prior to distribution of the applications, reviewers are given summary information about the applicant, including the Project Director and collaborators. Reviewers must sign a conflict of interest agreement and confirm that they do not have a conflict of interest with the application before they are provided with the full application.

The pedigrees attest that a conflict of interest statement was signed by each primary reviewer for each Grant Application.

Peer Review:

Primary reviewers (typically three) must submit written critiques for each of their assigned applications prior to the peer review meeting. After the peer review meetings, a final score report from the review committee is delivered to the Review Council for additional review. Following the peer review meetings, each participating peer reviewer must sign a post-review peer review statement certifying that the reviewer knew of and understood CPRIT's conflict of interest policy and followed the policy for this review process.

I reviewed the peer reviewer critiques and supporting documentation, such as the sign-out sheets from the peer review panel meetings and post-review peer reviewer statements. Sign out sheets are used to document when a peer review panel member with a conflict of interest associated with a particular application leaves the room (or disengages from the conference call) during the discussion and scoring of the application. With regard to the Evidence-Based Cancer Prevention applications there was two noted conflicts of interest involving two applications. With regard to the Competitive Continuation/Expansion Grant applications, there were no noted conflicts of interest. I also reviewed and confirmed that the post review conflict of interest statements were signed by the peer reviewers.

Programmatic Review:

Programmatic review is conducted by the Prevention Review Council (PRC). The PRC creates the final list of grant applications it will recommend to the Program Integration Committee (PIC) for grant award slates.

For these two slates before the Oversight Committee, I reviewed that the slates correspond to RFAs that have been released and that the pedigree reflects the date of the PRC meetings and that the applications were included on the slates of award recommendations.

I also reviewed the third party observer reports for these meetings. The third party observer reports document that the PRC members who indicated a conflict with an application recused themselves from the peer review meeting and left the discussion. The pedigrees for these applications, note that all PRC members participated in the final ranking of applications after the peer review meeting since the discussion did not influence scoring.

Program Integration Committee Review:

CPRIT rules require that, at the time the Program Integration Committee's final Grant Award recommendations are formally submitted to the Oversight Committee, the Chief Executive Officer shall prepare a written affidavit for each Grant Application recommended by the PIC containing relevant information related to the Grant Application recommendations. A review of the affidavits confirms that such affidavits were executed and provided for each Grant Application recommendation.

In this cycle, I reviewed the written notification submitted by Stephen W. Wyatt, Chair, Prevention Review Council, to Wayne Roberts recommending five of the applications for grant awards. I compared

the list of grant applications submitted to the Oversight Committee by Mr. Roberts with the list of applications the PRC recommended for awards and confirmed that the recommendations are the same on both lists

Other Information Reviewed:

Third-Party Observer Reports - In May 2012, CPRIT implemented the use of an independent third-party observer at peer review meetings to ensure that panel discussions are limited to the merits of the application and adhere to established evaluation criteria. In addition, the third-party observer reports whether CPRIT staff attending the peer review meeting participates in the discussion, scoring or vote on the grant application. CPRIT staff may attend peer review meetings, but may not participate in the review process other than to answer technical questions. The third-party reviewer is the agency's internal auditor, Grant Thornton. I have reviewed the third-party observer reports for the peer review meetings for this cycle. Nothing unusual was reported. The reports are attached.

Conflicts of Interest for Prevention Cycle 15.1 Applications
(Prevention Cycle 15.1 Awards Announced at November 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.

Application ID	Applicant	Institution	Conflict Noted
Applications Considered by the PIC and Oversight Committee			
PP150025	McClellan, David	Texas A&M University System Health Science Center	Mitchell, Amy
PP150031	Misra, Subhasis	Texas Tech University Health Science Center	Mitchell, Amy
PP150004	Berenson, Abbey	The University of Texas Medical Branch at Galveston	Mitchell, Amy
PP150012	Schmeler, Kathleen	The University of Texas M.D. Anderson Cancer Center	Mitchell, Amy
PP150009	Byrd, Theresa	Texas Tech University Health Sciences Center	Brandt, Heather; Mitchell, Amy
Applications Not Recommended for PIC or Oversight Committee Consideration			
PP150003	Foxhall, Lewis	The University of Texas MD Anderson Cancer Center	Mahoney, Martin
PP150019	Parra-Medina, Deborah	The University of Texas Health Science Center at San Antonio	Brandt, Heather; Green, Lawrence



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO Affidavit Supporting Information

FY 2015—Cycle 1
Competitive Continuation/Expansion Projects

Request for Applications



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS RFA P-15-CCE-1

Competitive Continuation/Expansion

**Please also refer to the “Instructions for Applicants” document, which will be
posted April 29, 2014**

Application Receipt Opening Date: April 29, 2014

Application Receipt Closing Date: July 10, 2014

FY 2015

Fiscal Year Award Period

September 1, 2014–August 31, 2015

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RFA VERSION HISTORY

Rev 3/31/14 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 primary, secondary, and/or tertiary cancer prevention and control. Project activities include, but are not

limited to, public education, professional education, and clinical service delivery and include systems/policy change.

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://cpritrants.org/Previous_Funding_Opportunities).

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;
 - Offer systems and/or policy changes that are sustainable over time;
 - 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 that have the potential to create demonstrable and sustainable change in behaviors that can prevent or reduce cancer by:
 - Leveraging existing resources;
 - Navigating participants to prevention services; and
 - Demonstrating impact on public health behaviors by individuals taking preventive measures and/or changes in provider practice.

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, and desire to further enhance their impact on target populations. Detailed descriptions of **results, barriers, outcomes, and impact of the currently or previously funded project are required** (see outline of Project Plan, [Section 4.2.4](#)).

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. Established infrastructure/processes and fully described prior project results are required. 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 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 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 already been established and that continued improvement over baseline is 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. 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.

CPRIT requires applicants to deliver evidence-based interventions in at least one of the following cancer prevention and control areas (see [Section 2.3.2](#) for areas of emphasis):

Clinical Services

- Delivery of vaccines that reduce the risk of cancer
- Evidence-based assessment and counseling services for behaviors established as increasing cancer risk
- Screening and early detection services
- Survivorship 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. This mechanism **will fund** case management/patient navigation if it is paired with the actual delivery of a clinical service.

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 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 and have a process for tracking participants to document actions taken.

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

- **Projects focusing on case management/patient navigation services through the treatment phase of cancer**
- **Projects utilizing State Quitline services.** 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 the Texas Department of State Health Services (DSHS)
- **Resources for the treatment of cancer**
- **Prevention/intervention research.** Applicants interested in prevention research should review CPRIT's research RFAs (available at <http://www.cprit.state.tx.us>.)

2.3.1. Priority Areas

Types of Cancer: Applications addressing any cancer type(s) for which there is strong evidence of effectiveness and that are responsive to this RFA will be considered for funding.

Target Populations: 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).

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 never before screened or who are significantly out of compliance with nationally recommended screening guidelines (more than 5 years for breast/cervical cancers).

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 (see [Section 5.1](#)), 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 (see <http://www.cprit.state.tx.us/prevention/resources-for-cancer-prevention-and-control> and <http://www.cprit.state.tx.us/funded-grants>).

2.3.2. Specific Areas of Emphasis

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** 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}

C. Survivorship Services

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 in one or more of the following areas:

- Preventing secondary cancers and recurrence of cancer
- Managing the after effects of cancer and treatment to maximize quality of life and number of years of healthy life
- Minimizing preventable pain, disability, and psychosocial distress

2.3.3. 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. Interim measures that are associated with the final outcome measures 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
- Percentage of people reporting sustained behavior change
- Estimates of cancers prevented as a result of primary preventive 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, if such an instrument is applicable to the project
- Percentage of people reporting sustained behavior change
- 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 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 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 evaluation outcome measures for an example of an evaluation framework and definition of provider performance change⁴):
 - Increase over baseline in the number of healthcare providers who screen and counsel their at-risk patients on preventive measures and available prevention services
 - 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

- The applicant must be a Texas-based entity 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 is submitted.
- An applicant is not eligible to receive a CPRIT grant award if the applicant PD, 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 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. Applicants may submit a continuation application before the end of the currently funded project but should time their submission to ensure minimal overlap of funding. Unexpended funds from the original project will not carry forward to the continuation/expansion project.
- If the applicant or a partner is an existing DSHS contractor, 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.

- 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 6](#). 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).

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 EBP mechanism, the following estimates may be used as a general guide:

- Primary prevention services only: \$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 only: \$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). Requests for funds to support construction, renovation, or any other infrastructure needs or requests to support lobbying will not be approved under this mechanism. 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.

3. KEY DATES

RFA

RFA release	March 31, 2014
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Application

Online application opens	April 29, 2014, 7 a.m. Central Time
Application due	July 10, 2014, 3 p.m. Central Time
Application review	September 2014

Award

Award notification	November 2014
Anticipated start date	December 2014

Applicants will be notified of peer review panel assignment prior to the peer review meeting dates.

4. 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 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 (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 April 29, 2014, and must be submitted by 3 p.m. Central Time on July 10, 2014. Detailed instructions for submitting an application are in the *Instructions for Applicants* document, posted on CARS. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

4.1. 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.

4.2. 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 will be administratively withdrawn without review.

4.2.1. Abstract and Significance (5,000 characters)

Clearly explain the problem(s) to be addressed and the approach(es) to the solution and 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 of incidence, 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, including the services to be provided and the process/system for delivery of services and outreach to the targeted population.
- **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.

4.2.2. 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. Applicants must explain plans to establish baseline in cases where it has not been defined.

4.2.3. Project Timeline

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

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

The required Project Plan format follows. Applicants must include the components in the order presented below: Introduction, Project Components, Sustainability, Dissemination (Table 2). The project plan must include information for both the initial funded project and the proposed continuation/expansion project.

The format of the Project Plan does not have to be a table. Information may be presented by project: The format may be initial funded project (describe the four components) followed by proposed continuation/expansion project (describe the four components). Alternatively, information may be presented by component: The format may be component 1 (describe the initial project, describe the proposed continuation/expansion project, etc.). 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 Provide the anticipated end date of the initial project. 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 4.2.2). 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 4.2.2). 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
<p>SECTION III: Sustainability</p> <p>Describe ongoing efforts toward sustainability. Elements contributing to organizational project sustainability may include some or all of the following:</p> <ul style="list-style-type: none"> • 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) 	<p>SECTION III: Organizational Capacity and Sustainability</p> <p>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. Elements contributing to organizational project sustainability may include some or all of the following:</p> <ul style="list-style-type: none"> • 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)
<p>SECTION IV: Dissemination</p> <p>Describe any dissemination of project results to date. Describe how the project lends itself to further dissemination to other communities.</p>	<p>SECTION IV: Dissemination</p> <p>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.</p>

4.2.5. 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 the [Appendix](#) for definitions of people/professionals reached and people/professionals served.

4.2.6. References

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

4.2.7. CPRIT Grants Summary (download template)

Provide a description of the progress or final results of any CPRIT-funded projects of the PD or Co-PD, 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 4.2.2](#)) and need not be repeated here. 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.

4.2.8. 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, services delivery, and other expenses. CPRIT funds will be distributed on a reimbursement basis.

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 the [Appendix](#)).
- **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 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. Justification must be provided for why funding for this equipment cannot be found elsewhere; CPRIT funding should not supplant existing funds. 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).

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

Describe the funding source and duration of all current and pending support for the proposed project, including a capitalization table that reflects private investors, if any. Information for the initial funded project need not be included.

4.2.10. 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 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.

4.2.11. 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.).

4.2.12. 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. **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 withdrawn without review.**

5. APPLICATION REVIEW

5.1. 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 scores are only one factor considered during programmatic review. 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.

Applications approved by the Prevention 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.

Each stage of application review is conducted confidentially, and all CPRIT Peer Review Panel members, Review Council members, PIC 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 Peer Review Panel members and 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 PIC Member, a Review Panel member, or a Review Council member. Applicants should note that the CPRIT PIC 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 preapplications 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.

5.2. 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 and advocates will evaluate and score each primary criterion and subsequently assign an overall score that reflects an overall assessment of the application. The overall evaluation score 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.

5.2.1. Primary Evaluation Criteria

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?
- 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?

Project Strategy and Feasibility

- Does the proposed project provide prevention interventions or services specified in the RFA?
- Are the overall program approach, strategy, and design 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?
- 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? If applicable, does the application demonstrate the availability of resources and expertise to provide case management, including follow-up for abnormal results and access to treatment?
- Does the program leverage partners and resources to maximize the reach of the services proposed? 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 is committed to working 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

- 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?

5.2.2. Secondary Evaluation Criteria

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)

- Are plans for dissemination of the project's results and outcomes, including barriers encountered and successes achieved, clearly described?
- 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?

6. 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.

7. CONTACT INFORMATION

7.1. 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 April 29, 2014), which provides a step-by-step guide to using CARS.

Dates of operation: April 29, 2014, to July 10, 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

7.2. 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

8. RESOURCES

- The Texas Cancer Registry: <http://www.dshs.state.tx.us/tcr>
 - [Breast Cancer in Texas: A Closer Look \(1/4/10\)](http://www.cprit.state.tx.us/images/uploads/report_breastc_a_closer_look.pdf)
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)
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)
http://www.cprit.state.tx.us/images/uploads/colorectal_cancer_in_texas_tcr_2010_low.pdf
- The Community Guide <http://www.thecommunityguide.org/index.html>
- Cancer Control P.L.A.N.E.T. <http://cancercontrolplanet.cancer.gov>

- Guide to Clinical Preventive Services: Recommendations of the U.S. Preventive Services Task Force. <http://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/guide/>
- Centers for Disease Control and Prevention: The Program Sustainability Assessment Tool: A New Instrument for Public Health Programs
http://www.cdc.gov/pcd/issues/2014/13_0184.htm
- Centers for Disease Control and Prevention: Using the Program Sustainability Tool to Assess and Plan for Sustainability http://www.cdc.gov/pcd/issues/2014/13_0185.htm

9. 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. 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.
5. 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>.

10. APPENDIX: KEY TERMS

- **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>.

- **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.
- **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).

Third Party Observer Report

CPRIT Prevention Peer Review Panel Observation Report

Report #2014-29

Panel Name: Prevention Peer Review Panel

Panel Date: October 1 – October 2, 2014

Report Date: October 2, 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 chaired by Larry Green and Nancy Lee. The meetings were held by teleconference on October 1 – October 2, 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 by teleconference and chaired by Lawrence Green and Nancy Lee on October 1 – October 2, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Sixteen prevention program applications were presented, discussed, and evaluated by the Prevention Review Panel.
- Eleven peer review panel members, two advocate reviewers, two CPRIT staff members, and nine SRA employees were present for the telephonic panel meeting.

- Four conflict of interest were identified prior to or during the meeting. The reviewers with the conflicts of interest 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.

CPRIT Prevention Review Council Observation Report

Report #2015-206

Panel Name: Prevention Review Council

Panel Date: October 24, 2014

Report Date: October 24, 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's finalization of recommended prevention program applications. The meeting was chaired by Stephen Wyatt and held via teleconference on October 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 Council discussion is focused on the established scoring criteria.

Observation Results Summary

Internal Audit participated in the Prevention Review Council meeting held by teleconference and chaired by Stephen Wyatt on October 24, 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 prevention applications were included within the application listing submitted to the Prevention Review Council for their review and approval.
- Three Council members, two CPRIT staff members and one SRA employee were present for the meetings by teleconference.
- 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 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.

Noted Conflicts of Interest

Conflicts of Interest for Prevention Cycle 15.1 Applications
(Prevention Cycle 15.1 Awards Announced at November 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.

Application ID	Applicant	Institution	Conflict Noted
Application Considered by the PIC			
PP150009	Byrd, Theresa	Texas Tech University Health Sciences Center	Brandt, Heather
Applications Not Recommended for PIC or Oversight Committee Consideration			
PP150003	Foxhall, Lewis	The University of Texas MD Anderson Cancer Center	Mahoney, Martin
PP150019	Parra-Medina, Deborah	The University of Texas Health Science Center at San Antonio	Brandt, Heather; Green, Lawrence

De-Identified Overall Evaluation Scores

Competitive Continuation/Expansion

Application ID	Final Overall Score
PP150025*	2.3
K1	4.0
K2	4.1
K3	4.7
K4	4.9

*=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 FY2015. These recommendations reflect 50+ hours of work by individual reviewers and include panel discussion of the applicants' proposals in addition to 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 has \$29,006,567 in available funding for the fiscal year. The PRC is recommending awards totaling \$7,271,233.

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

**FY15.1 Application Working Spreadsheet
(sorted by applications ID #)**

App ID	Mechanism	Application Title	PD	Organization	Total Requested Funding	Score	Changes recommended from Peer Review	Rank Order Score	Total Recommended Funding	Comments
PP150025	CCE-EBP	Continuation and Expansion of Texas A&M's Colon Cancer Screening, Training, Education and Prevention Program	McClellan, David A	Texas A&M University System Health Science Center	\$1,500,000	2.3		1	\$1,500,000	
PP150031	EBP	Get FIT to Stay Fit. Stepping Up to Fight Colorectal Cancer in the Panhandle	Misra, Subhasis	Texas Tech University Health Sciences Center	\$1,455,409	2.4		2	\$1,455,409	
PP150004	EBP	A multi-pronged approach to increase HPV vaccination rates among adolescents 9–17 years of age from Galveston and Brazoria Counties	Berenson, Abbey B	The University of Texas Medical Branch at Galveston	\$1,406,919	2.6	The percent effort by the PI should be reduced by half to 20%.	3	\$1,406,919	The PRC reviewed and discussed the recommendations from Peer Reviewers (at least one) for both proposals. Both recommendations were budget focused. The PRC REJECTED the very specific recommendations on percent effort; for PP150004, reducing proposed effort from 40% to 20% AND for PP150012 to increase percent effort for PD and all key personnel except the biostatistician. However, the PRC requested that CPRIT staff obtain additional information from the proposed grantees on percent effort as part of the budget negotiations/discussions process.

**FY15.1 Application Working Spreadsheet
(sorted by applications ID #)**

PP150009	EBP	ACCION for Rural West Texas	Byrd, Theresa L	Texas Tech University Health Sciences Center	\$1,467,820	3.1		4	\$1,467,820	
PP150012	EBP	Improving Cervical Cancer Screening and Prevention in the Lower Rio Grande Valley Through Public Outreach, Patient Navigation, and Telementoring	Schmeler, Kathleen M	The University of Texas M. D. Anderson Cancer Center	\$1,441,085	3.2	Increase percent effort of Program Director and all key personnel, except the biostatistician, to 20%.	5	\$1,441,085	The PRC reviewed and discussed the recommendations from Peer Reviewers (at least one) for both proposals. Both recommendations were budget focused. The PRC REJECTED the very specific recommendations on percent effort; for PP150004, reducing proposed effort from 40% to 20% AND for PP150012 to increase percent effort for PD and all key personnel except the
					\$7,271,233				\$7,271,233	



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO Affidavit Supporting Information

FY 2015—Cycle 1
Evidence-Based Cancer Prevention Services

Request for Applications



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS RFA P-15-EBP-1

Evidence-Based Cancer Prevention Services

**Please also refer to the “Instructions for Applicants” document, which will be
posted April 29, 2014**

Application Receipt Opening Date: April 29, 2014

Application Receipt Closing Date: July 10, 2014

FY 2015

Fiscal Year Award Period

September 1, 2014–August 31, 2015

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RFA VERSION HISTORY

Rev 3/31/14 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;
- Offer systems and/or policy changes that are sustainable over time;
- 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**:

- 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

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.

This mechanism will fund case management/patient navigation if it is paired with the 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.

CPRIT's service grants are intended to fund prevention interventions that have a demonstrated evidence base and are culturally appropriate for the target population.

CPRIT recognizes that evidence-based services have been developed but not implemented or tested 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 required. Comprehensive projects include a continuum of services and systems and/or policy changes and 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.

This RFA encourages traditional and nontraditional partnerships as well as leveraging of existing resources and dollars from other sources. 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 the following:

- **Projects focusing solely on systems and/or policy change or solely on education and/or outreach** that do not include the delivery of services
- **Projects focusing solely on case management/patient navigation services.** Case management/patient navigation services must be paired with the delivery of a clinical service. 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 for continuation/expansion of a currently or previously funded project.** Applications for continuation/expansion should be submitted in response to the Competitive Continuation/Expansion RFA.
- **Projects utilizing State Quitline services.** 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 the Texas Department of State Health Services (DSHS).
- **Projects focusing on computerized tomography (CT) screening for lung cancer**
- **Projects involving prevention/intervention research.** Applicants interested in prevention research should review CPRIT's research RFAs (available at <http://www.cprit.state.tx.us>).

2.3.1. Priority Areas

Types of Cancer: Applications addressing any cancer type(s) that are responsive to this RFA will be considered for funding.

Target Populations: 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).

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 never before screened or who are significantly out of compliance with nationally recommended screening guidelines (more than 5 years for breast/cervical cancers).

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 5.1](#)), 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 (see <http://www.cprit.state.tx.us/prevention/resources-for-cancer-prevention-and-control/> and <http://www.cprit.state.tx.us/funded-grants/>)

2.3.2. Specific Areas of Emphasis

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** 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.^{[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](#)}

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.^{[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](#)}

C. Survivorship Services

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 in one or more of the following areas:

- Preventing secondary cancers and recurrence of cancer
- Managing the after effects of cancer and treatment to maximize quality of life and number of years of healthy life
- Minimizing preventable pain, disability, and psychosocial distress.

2.3.3. Outcome Metrics

The applicant is required to describe final outcome measures for the project. Interim measures that are associated with the final outcome measures 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 include an explanation and describe clear plans to collect the data necessary to establish a baseline.

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

2.4. Eligibility

- 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.
- An applicant is not eligible to receive a CPRIT grant award if the applicant PD, 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 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, 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.
- 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](#). All statutory provisions and relevant administrative rules can be found at <http://www.cprit.state.tx.us>.

2.4.1. Resubmission Policy

More than one resubmission is not permitted. An application is considered a resubmission if the proposed project is the same project as presented in the original submission. A change in the identity of the PD for a project, or a change of title for a project that was previously submitted to CPRIT does not constitute a new application; the application would be considered a resubmission.

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. 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). Requests for funds to support construction, renovation, or any other infrastructure needs or requests to support lobbying will not be approved under this mechanism. 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.

3. KEY DATES

RFA

RFA release	March 31, 2014
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Application

Online application opens	April 29, 2014, 7 a.m. Central Time
Application due	July 10, 2014, 3 p.m. Central Time
Application review	September 2014

Award

Award notification	November 2014
Anticipated start date	December 2014

Applicants will be notified of peer review panel assignment prior to the peer review meeting dates.

4. 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 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 (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 April 29, 2014, and must be submitted by 3 p.m. Central Time on July 10, 2014. Detailed instructions for submitting an application are in the *Instructions for Applicants* document, posted on CARS. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

4.1. 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.

4.2. 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 will be administratively withdrawn without review.

4.2.1. Abstract and Significance (5,000 characters)

Clearly explain the problem(s) to be addressed, the approach(es) to the solution, and 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 of incidence, 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, including the services to be provided and the process/system for delivery of services and outreach to the targeted population.
- **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 and how it differs from current programs 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.

4.2.2. Goals and Objectives

List specific goals and **measurable** objectives for each year of the project. Provide baseline and method(s) of measurement. Applicants must explain plans to establish baseline in cases where it has not been defined.

4.2.3. Project Timeline

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

4.2.4. 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 implemented or tested for the specific population or service setting proposed, provide evidence that the proposed service is appropriate for the population and has a high likelihood of success. Baseline data for the target population and target service area are required where applicable. Reviewers will be aware of national and State statistics, and these should be used only to compare rates for the proposed service area. 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, creative or unique. Clearly demonstrate the ability to provide the proposed service, describe how results will be improved over baseline and the ability to reach the target population. Applicants must also clearly describe plans to ensure access to treatment services should cancer be detected.

Evaluation Strategy: Describe the impact on ultimate outcome measures and interim outcome measures as outlined in [Section 2.3.3](#). Describe the plan for outcome measurements, including data collection and management methods, statistical analyses, and anticipated results. Evaluation and reporting of outcomes 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 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.

4.2.5. 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 the [Appendix](#) for definitions of people/professionals reached and people/professionals served.

4.2.6. References

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

4.2.7. Resubmission Summary (if applicable; download template)

Describe the approach to the resubmission and how reviewers' comments were addressed. 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.

4.2.8. CPRIT Grants Summary (download template)

Provide a description of the progress or final results of **all** CPRIT-funded projects of the PD or Co-PD, regardless of their connection to this application. Indicate how the current application builds on the previous work or addresses new areas of cancer prevention and control services. 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.

4.2.9. 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. 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 [Appendix](#)). 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 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. Justification must be provided for why funding for this equipment cannot be found elsewhere; CPRIT funding

should not supplant existing funds. 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).

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

Describe the funding source and duration of all current and pending support for the proposed project, including a capitalization table that reflects private investors, if any. Information for the initial funded project need not be included.

4.2.11. 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 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.

4.2.12. 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.).

4.2.13. 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.

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 withdrawn without review.

5. APPLICATION REVIEW

5.1. 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 scores are only one factor considered during programmatic review. 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.

Applications approved by 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.

Each stage of application review is conducted confidentially, and all CPRIT Peer Review Panel members, Review Council members, PIC 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 Peer Review Panel members and 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 PIC Member, a Review Panel member, or a 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. The prohibition on communication does not apply to the time period when preapplications 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.

5.2. 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 and advocates will evaluate and score each primary criterion and subsequently assign an overall score that reflects an overall assessment of the application. The overall evaluation score 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.

5.2.1. Primary Evaluation Criteria

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? Does the proposed project demonstrate creativity, ingenuity, resourcefulness, or imagination? Does it take evidence-based interventions and apply them in innovative ways 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 the applicant 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, strategy, and design 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?
- 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?
- 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?
- Does the program leverage partners and resources to maximize the reach of the services proposed? 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 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?
- If an evidence-based intervention is being adapted in a population where it has not been implemented or 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 is committed to working together to implement the project?

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

Sustainability

- 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?

5.2.2. Secondary Evaluation Criteria

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

- Are plans for dissemination of the project's results and outcomes, including barriers encountered and successes achieved, clearly described?
- Does the project or do some components of the project lend themselves to scalability/expansion by others in the State? If so, does the application describe a plan for doing so?

6. 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 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. 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.

7. CONTACT INFORMATION

7.1. 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 April 29, 2014), which provides a step-by-step guide to using CARS.

Dates of operation: April 29, 2014 to July 10, 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

7.2. 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

8. RESOURCES

- The Texas Cancer Registry: <http://www.dshs.state.tx.us/tcr>
 - [Breast Cancer in Texas: A Closer Look \(1/4/10\)](http://www.cprit.state.tx.us/images/uploads/report_breastc_a_closer_look.pdf)
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)
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)
http://www.cprit.state.tx.us/images/uploads/colorectal_cancer_in_texas_tcr_2010_low.pdf
- The Community Guide <http://www.thecommunityguide.org/index.html>
- Cancer Control P.L.A.N.E.T. <http://cancercontrolplanet.cancer.gov>
- Guide to Clinical Preventive Services: Recommendations of the U.S. Preventive Services Task Force. <http://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/guide/>

- Centers for Disease Control and Prevention: The Program Sustainability Assessment Tool: A New Instrument for Public Health Programs
http://www.cdc.gov/pcd/issues/2014/13_0184.htm
- Centers for Disease Control and Prevention: Using the Program Sustainability Tool to Assess and Plan for Sustainability http://www.cdc.gov/pcd/issues/2014/13_0185.htm

9. 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>

10. APPENDIX: KEY TERMS

- **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.cpritis.state.tx.us/prevention/resources-for-cancer-prevention-and-control>.
- **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.
- **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).

Third Party Observer Report

CPRIT Prevention Peer Review Panel Observation Report

Report #2014-29

Panel Name: Prevention Peer Review Panel

Panel Date: October 1 – October 2, 2014

Report Date: October 2, 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 chaired by Larry Green and Nancy Lee. The meetings were held by teleconference on October 1 – October 2, 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 by teleconference and chaired by Lawrence Green and Nancy Lee on October 1 – October 2, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Sixteen prevention program applications were presented, discussed, and evaluated by the Prevention Review Panel.
- Eleven peer review panel members, two advocate reviewers, two CPRIT staff members, and nine SRA employees were present for the telephonic panel meeting.

- Four conflict of interest were identified prior to or during the meeting. The reviewers with the conflicts of interest 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.

CPRIT Prevention Review Council Observation Report

Report #2015-206

Panel Name: Prevention Review Council

Panel Date: October 24, 2014

Report Date: October 24, 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's finalization of recommended prevention program applications. The meeting was chaired by Stephen Wyatt and held via teleconference on October 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 Council discussion is focused on the established scoring criteria.

Observation Results Summary

Internal Audit participated in the Prevention Review Council meeting held by teleconference and chaired by Stephen Wyatt on October 24, 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 prevention applications were included within the application listing submitted to the Prevention Review Council for their review and approval.
- Three Council members, two CPRIT staff members and one SRA employee were present for the meetings by teleconference.
- 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 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.

Noted Conflicts of Interest

Conflicts of Interest for Prevention Cycle 15.1 Applications
(Prevention Cycle 15.1 Awards Announced at November 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.

Application ID	Applicant	Institution	Conflict Noted
Application Considered by the PIC			
PP150009	Byrd, Theresa	Texas Tech University Health Sciences Center	Brandt, Heather
Applications Not Recommended for PIC or Oversight Committee Consideration			
PP150003	Foxhall, Lewis	The University of Texas MD Anderson Cancer Center	Mahoney, Martin
PP150019	Parra-Medina, Deborah	The University of Texas Health Science Center at San Antonio	Brandt, Heather; Green, Lawrence

De-Identified Overall Evaluation Scores

Evidence-Based Cancer Prevention Services

Application ID	Final Overall Score
PP150031*	2.4
PP150004*	2.6
PP150009*	3.1
PP150012*	3.2
L1	4.1
L2	4.7
L3	4.7
L4	5.3
L5	6.3
L6	6.5
L7	7.3

*=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 FY2015. These recommendations reflect 50+ hours of work by individual reviewers and include panel discussion of the applicants' proposals in addition to 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 has \$29,006,567 in available funding for the fiscal year. The PRC is recommending awards totaling \$7,271,233.

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

**FY15.1 Application Working Spreadsheet
(sorted by applications ID #)**

App ID	Mechanism	Application Title	PD	Organization	Total Requested Funding	Score	Changes recommended from Peer Review	Rank Order Score	Total Recommended Funding	Comments
PP150025	CCE-EBP	Continuation and Expansion of Texas A&M's Colon Cancer Screening, Training, Education and Prevention Program	McClellan, David A	Texas A&M University System Health Science Center	\$1,500,000	2.3		1	\$1,500,000	
PP150031	EBP	Get FIT to Stay Fit. Stepping Up to Fight Colorectal Cancer in the Panhandle	Misra, Subhasis	Texas Tech University Health Sciences Center	\$1,455,409	2.4		2	\$1,455,409	
PP150004	EBP	A multi-pronged approach to increase HPV vaccination rates among adolescents 9–17 years of age from Galveston and Brazoria Counties	Berenson, Abbey B	The University of Texas Medical Branch at Galveston	\$1,406,919	2.6	The percent effort by the PI should be reduced by half to 20%.	3	\$1,406,919	The PRC reviewed and discussed the recommendations from Peer Reviewers (at least one) for both proposals. Both recommendations were budget focused. The PRC REJECTED the very specific recommendations on percent effort; for PP150004, reducing proposed effort from 40% to 20% AND for PP150012 to increase percent effort for PD and all key personnel except the biostatistician. However, the PRC requested that CPRIT staff obtain additional information from the proposed grantees on percent effort as part of the budget negotiations/discussions process.

**FY15.1 Application Working Spreadsheet
(sorted by applications ID #)**

PP150009	EBP	ACCION for Rural West Texas	Byrd, Theresa L	Texas Tech University Health Sciences Center	\$1,467,820	3.1		4	\$1,467,820	
PP150012	EBP	Improving Cervical Cancer Screening and Prevention in the Lower Rio Grande Valley Through Public Outreach, Patient Navigation, and Telementoring	Schmeler, Kathleen M	The University of Texas M. D. Anderson Cancer Center	\$1,441,085	3.2	Increase percent effort of Program Director and all key personnel, except the biostatistician, to 20%.	5	\$1,441,085	The PRC reviewed and discussed the recommendations from Peer Reviewers (at least one) for both proposals. Both recommendations were budget focused. The PRC REJECTED the very specific recommendations on percent effort; for PP150004, reducing proposed effort from 40% to 20% AND for PP150012 to increase percent effort for PD and all key personnel except the
					\$7,271,233				\$7,271,233	



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application PP150025
Competitive Continuation/Expansion

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 the *Competitive Continuation/Expansion* Request for Applications (RFA). CPRIT received five applications for this RFA. The application was assigned to the Prevention 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:

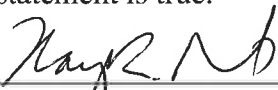
- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT’s grant review processes were followed by the review panel evaluating 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

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 FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

Dr. Lakey was called away on important state business that conflicted with the meeting of the PIC. The remaining members of the PIC unanimously approved a motion to excuse his absence.

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 November, 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 2015
CYCLE 1
PROGRAM Prevention
AWARD MECHANISM Competitive Continuation/Expansion (CCE)
APPLICATION ID PP150025
APPLICATION TITLE Continuation and Expansion of Texas A&M's Colon Cancer Screening, Training, Education and Prevention Program
APPLICANT NAME McClellan, David
ORGANIZATION Texas A&M University System Health Science Center
PANEL NAME Panel A 15.1 (A 15.1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	05/23/14	10/14/14
	CPRIT Application Receipt System (CARS) opened	04/29/14	10/14/14
	CPRIT Application Receipt System (CARS) closed	07/10/14	10/14/14
	Date application submitted	07/07/14	10/14/14
	Method of submission	CARS	10/14/14
	Within receipt period	YES	10/14/14
	Appeal to submit application after CARS closed	N/A	10/14/14
	Appeal for late application submission accepted	N/A	10/14/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	10/14/14
	Donation(s) made to CPRIT/foundation	NO	10/14/14
	Assigned to primary reviewers	08/08/14	10/14/14
	Applicant notified of review panel assignment	09/17/14	10/14/14
	Primary Reviewer 1 COI signed	08/01/14	10/14/14
	Primary (Advocate) Reviewer 2 COI signed	08/02/14	10/14/14
	Primary Reviewer 3 COI signed	08/01/14	10/14/14
3. Peer Review Meeting	Primary Reviewer 4 COI signed	08/05/14	10/14/14
	Primary Reviewer 1 critique submitted	09/15/14	10/14/14
	Primary (Advocate) Reviewer 2 critique submitted	09/15/14	10/14/14
	Primary Reviewer 3 critique submitted	08/22/14	10/14/14
	Primary Reviewer 4 critique submitted	09/15/14	10/14/14
	COI indicated by non-primary reviewer	NONE	10/14/14
	COI recused from participation	N/A	10/14/14
	Discussed at Peer Review Meeting	YES	10/14/14
	Peer Review Meeting	10/01/14-10/02/14	10/14/14
	Post review statements signed	10/08/14	10/14/14
	Third Party Observer Report	10/02/14	10/15/14
	Score report delivered to CPO	10/07/14	10/14/14
4. Final PRC Recommendation	Recommended for PRC Review	YES	10/14/14
	COI indicated by PRC member	NONE	10/29/14
	COI recused from participation	N/A	10/29/14
	PRC Meeting	10/24/14	10/14/14
	Third Party Observer Report	10/24/14	10/30/14
	Recommended for grant award	YES	10/29/14
5. PIC Review	PRC Chair Notification to PIC and OC	10/28/14	10/29/14
	COI indicated by PIC member	NONE	11/04/14
	COI recused from participation	N/A	11/04/14
	PIC review meeting	11/04/14	11/04/14
6. Oversight Committee Approval	Recommended for grant award	YES	11/04/14
	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

CEO AFFIDAVIT
Application PP150004
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 the *Evidence-Based Cancer Prevention Services* Request for Applications (RFA). CPRIT received 11 applications for this RFA. The application was assigned to the Prevention 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

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 FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

Dr. Lakey was called away on important state business that conflicted with the meeting of the PIC. The remaining members of the PIC unanimously approved a motion to excuse his absence.

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."



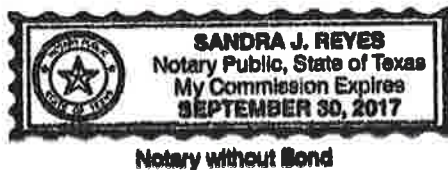
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 4th day of November, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2015
CYCLE 1
PROGRAM Prevention
AWARD MECHANISM Evidence-Based Cancer Prevention Services (EBP)
APPLICATION ID PP150004
APPLICATION TITLE A Multi-Pronged Approach to Increase HPV Vaccination Rates Among Adolescents 9–17 Years of Age from Galveston and Brazoria Counties
APPLICANT NAME Berenson, Abbey
ORGANIZATION The University of Texas Medical Branch at Galveston
PANEL NAME Panel A 15.1 (A 15.1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	05/23/14	10/14/14
	CPRIT Application Receipt System (CARS) opened	04/29/14	10/14/14
	CPRIT Application Receipt System (CARS) closed	07/10/14	10/14/14
	Date application submitted	07/01/14	10/14/14
	Method of submission	CARS	10/14/14
	Within receipt period	YES	10/14/14
	Appeal to submit application after CARS closed	N/A	10/14/14
	Appeal for late application submission accepted	N/A	10/14/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	10/14/14
	Donation(s) made to CPRIT/foundation	NO	10/14/14
	Assigned to primary reviewers	08/08/14	10/14/14
	Applicant notified of review panel assignment	09/17/14	10/14/14
	Primary Reviewer 1 COI signed	08/04/14	10/14/14
	Primary (Advocate) Reviewer 2 COI signed	08/05/14	10/14/14
	Primary Reviewer 3 COI signed	08/05/14	10/14/14
	Primary Reviewer 4 COI signed	08/01/14	10/14/14
3. Peer Review Meeting	Primary Reviewer 1 critique submitted	09/03/14	10/14/14
	Primary (Advocate) Reviewer 2 critique submitted	09/11/14	10/14/14
	Primary Reviewer 3 critique submitted	09/15/14	10/14/14
	Primary Reviewer 4 critique submitted	09/07/14	10/14/14
	COI indicated by non-primary reviewer	NONE	10/14/14
	COI recused from participation	N/A	10/14/14
	Discussed at Peer Review Meeting	YES	10/14/14
	Peer Review Meeting	10/01/14-10/02/14	10/14/14
	Post review statements signed	10/08/14	10/14/14
	Third Party Observer Report	10/02/14	10/15/14
	Score report delivered to CPO	10/07/14	10/14/14
	Recommended for PRC Review	YES	10/14/14
4. Final PRC Recommendation	COI indicated by PRC member	NONE	10/29/14
	COI recused from participation	N/A	10/29/14
	PRC Meeting	10/24/14	10/14/14
	Third Party Observer Report	10/24/14	10/30/14
	Recommended for grant award	YES	10/29/14
	PRC Chair Notification to PIC and OC	10/28/14	10/29/14
5. PIC Review	COI indicated by PIC member	NONE	11/04/14
	COI recused from participation	N/A	11/04/14
	PIC review meeting	11/04/14	11/04/14
	Recommended for grant award	YES	11/04/14
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 & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application PP150009
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 the *Evidence Based Cancer Prevention Services Request for Applications (RFA)*. CPRIT received 11 applications for this RFA. The application was assigned to the Prevention 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

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 FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

Dr. Lakey was called away on important state business that conflicted with the meeting of the PIC. The remaining members of the PIC unanimously approved a motion to excuse his absence.

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."



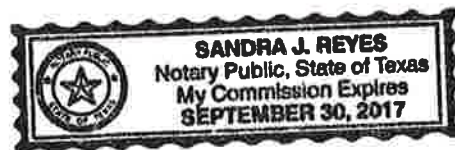
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 4th day of November, 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 2015
 CYCLE 1
 PROGRAM Prevention
 AWARD MECHANISM Evidence-Based Cancer Prevention Services (EBP)
 APPLICATION ID PP150009
 APPLICATION TITLE ACCION for Rural West Texas
 APPLICANT NAME Byrd, Theresa
 ORGANIZATION Texas Tech University Health Sciences Center
 PANEL NAME Panel A 15.1 (A 15.1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	05/23/14	10/14/14
	CPRIT Application Receipt System (CARS) opened	04/29/14	10/14/14
	CPRIT Application Receipt System (CARS) closed	07/10/14	10/14/14
	Date application submitted	07/10/14	10/14/14
	Method of submission	CARS	10/14/14
	Within receipt period	YES	10/14/14
	Appeal to submit application after CARS closed	N/A	10/14/14
	Appeal for late application submission accepted	N/A	10/14/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	10/14/14
	Donation(s) made to CPRIT/foundation	NO	10/14/14
	Assigned to primary reviewers	08/08/14	10/14/14
	Applicant notified of review panel assignment	09/17/14	10/14/14
	Primary Reviewer 1 COI signed	08/04/14	10/14/14
	Primary (Advocate) Reviewer 2 COI signed	08/02/14	10/14/14
	Primary Reviewer 3 COI signed	08/04/14	10/14/14
	Primary Reviewer 4 COI signed	08/05/14	10/14/14
3. Peer Review Meeting	Primary Reviewer 1 critique submitted	09/15/14	10/14/14
	Primary (Advocate) Reviewer 2 critique submitted	09/08/14	10/14/14
	Primary Reviewer 3 critique submitted	09/10/14	10/14/14
	Primary Reviewer 4 critique submitted	09/15/14	10/14/14
	COI indicated by non-primary reviewer	Brandt, Heather	10/14/14
	COI recused from participation	YES	10/14/14
	Discussed at Peer Review Meeting	YES	10/14/14
	Peer Review Meeting	10/01/14-10/02/14	10/14/14
	Post review statements signed	10/08/14	10/14/14
	Third Party Observer Report	10/02/14	10/15/14
	Score report delivered to CPO	10/07/14	10/14/14
	Recommended for PRC Review	YES	10/14/14
4. Final PRC Recommendation	COI indicated by PRC member	NONE	10/29/14
	COI recused from participation	N/A	10/29/14
	PRC Meeting	10/24/14	10/14/14
	Third Party Observer Report	10/24/14	10/30/14
	Recommended for grant award	YES	10/29/14
	PRC Chair Notification to PIC and OC	10/28/14	10/29/14
5. PIC Review	COI indicated by PIC member	NONE	11/04/14
	COI recused from participation	N/A	11/04/14
	PIC review meeting	11/04/14	11/04/14
	Recommended for grant award	YES	11/04/14
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 & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application PP150012
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 the *Evidence-Based Cancer Prevention Services* Request for Applications (RFA). CPRIT received 11 applications for this RFA. The application was assigned to the Prevention 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

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 FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). As required by the terms of the FY2015 waiver, Dr. Kripke abstained from voting on this application during the PIC meeting. At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

Dr. Lakey was called away on important state business that conflicted with the meeting of the PIC. The remaining members of the PIC unanimously approved a motion to excuse his absence.


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."



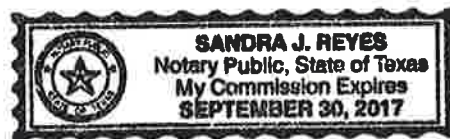
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 4th day of November, 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 2015
CYCLE 1
PROGRAM Prevention
AWARD MECHANISM Evidence-Based Cancer Prevention Services (EBP)
APPLICATION ID PP150012
APPLICATION TITLE Improving Cervical Cancer Screening and Prevention in the Lower Rio Grande Valley Through Public Outreach, Patient Navigation, and Telementoring
APPLICANT NAME Schmeler, Kathleen
ORGANIZATION The University of Texas M. D. Anderson Cancer Center
PANEL NAME Panel A 15.1 (A 15.1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	05/23/14	10/14/14
	CPRIT Application Receipt System (CARS) opened	04/29/14	10/14/14
	CPRIT Application Receipt System (CARS) closed	07/10/14	10/14/14
	Date application submitted	07/10/14	10/14/14
	Method of submission	CARS	10/14/14
	Within receipt period	YES	10/14/14
	Appeal to submit application after CARS closed	N/A	10/14/14
	Appeal for late application submission accepted	N/A	10/14/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	10/14/14
	Donation(s) made to CPRIT/foundation	NO	10/14/14
	Assigned to primary reviewers	08/08/14	10/14/14
	Applicant notified of review panel assignment	09/17/14	10/14/14
	Primary Reviewer 1 COI signed	08/05/14	10/14/14
	Primary (Advocate) Reviewer 2 COI signed	08/05/14	10/14/14
	Primary Reviewer 3 COI signed	08/05/14	10/14/14
	Primary Reviewer 4 COI signed	08/04/14	10/14/14
3. Peer Review Meeting	Primary Reviewer 1 critique submitted	09/15/14	10/14/14
	Primary (Advocate) Reviewer 2 critique submitted	09/11/14	10/14/14
	Primary Reviewer 3 critique submitted	09/15/14	10/14/14
	Primary Reviewer 4 critique submitted	09/11/14	10/14/14
	COI indicated by non-primary reviewer	NONE	10/14/14
	COI recused from participation	N/A	10/14/14
	Discussed at Peer Review Meeting	YES	10/14/14
	Peer Review Meeting	10/01/14-10/02/14	10/14/14
	Post review statements signed	10/08/14	10/14/14
	Third Party Observer Report	10/02/14	10/15/14
	Score report delivered to CPO	10/07/14	10/14/14
	Recommended for PRC Review	YES	10/14/14
4. Final PRC Recommendation	COI indicated by PRC member	NONE	10/29/14
	COI recused from participation	N/A	10/29/14
	PRC Meeting	10/24/14	10/14/14
	Third Party Observer Report	10/24/14	10/30/14
	Recommended for grant award	YES	10/29/14
	PRC Chair Notification to PIC and OC	10/28/14	10/29/14
5. PIC Review	COI indicated by PIC member	NONE	11/04/14
	COI recused from participation*	M. Kripke	11/04/14
	PIC review meeting	11/04/14	11/04/14
	Recommended for grant award	YES	11/04/14
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	

*Dr. Margaret Kripke abstained from voting. Dr. Kripke has an approved COI waiver on file for FY2015 regarding M.D. Anderson applications. The COI is waived; however, the terms of Dr. Kripke's FY2015 waiver require her to abstain from voting on M.D. Anderson applications.

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application PP150031
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 the *Evidence-Based Cancer Prevention Services Request for Applications* (RFA). CPRIT received 11 applications for this RFA. The application was assigned to the Prevention 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

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 FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

Dr. Lakey was called away on important state business that conflicted with the meeting of the PIC. The remaining members of the PIC unanimously approved a motion to excuse his absence.

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."



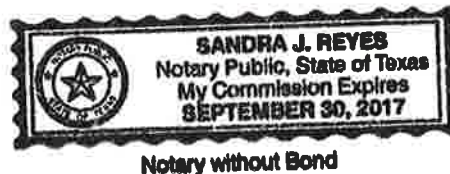
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 4th day of November, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2015
CYCLE 1
PROGRAM Prevention
AWARD MECHANISM Evidence-Based Cancer Prevention Services (EBP)
APPLICATION ID PP150031
APPLICATION TITLE Get FIT to Stay Fit. Stepping Up to Fight Colorectal Cancer in the Panhandle.
APPLICANT NAME Misra, Subhasis
ORGANIZATION Texas Tech University Health Sciences Center
PANEL NAME Panel A 15.1 (A 15.1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	05/23/14	10/14/14
	CPRIT Application Receipt System (CARS) opened	04/29/14	10/14/14
	CPRIT Application Receipt System (CARS) closed	07/10/14	10/14/14
	Date application submitted	07/08/14	10/14/14
	Method of submission	CARS	10/14/14
	Within receipt period	YES	10/14/14
	Appeal to submit application after CARS closed	N/A	10/14/14
	Appeal for late application submission accepted	N/A	10/14/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	10/14/14
	Donation(s) made to CPRIT/foundation	NO	10/14/14
	Assigned to primary reviewers	08/08/14	10/14/14
	Applicant notified of review panel assignment	09/17/14	10/14/14
	Primary Reviewer 1 COI signed	08/04/14	10/14/14
	Primary (Advocate) Reviewer 2 COI signed	08/02/14	10/14/14
	Primary Reviewer 3 COI signed	08/06/14	10/14/14
	Primary Reviewer 4 COI signed	08/05/14	10/14/14
3. Peer Review Meeting	Primary Reviewer 1 critique submitted	09/11/14	10/14/14
	Primary (Advocate) Reviewer 2 critique submitted	09/15/14	10/14/14
	Primary Reviewer 3 critique submitted	09/15/14	10/14/14
	Primary Reviewer 4 critique submitted	09/15/14	10/14/14
	COI indicated by non-primary reviewer	NONE	10/14/14
	COI recused from participation	N/A	10/14/14
	Discussed at Peer Review Meeting	YES	10/14/14
	Peer Review Meeting	10/01/14-10/02/14	10/14/14
	Post review statements signed	10/08/14	10/14/14
	Third Party Observer Report	10/02/14	10/15/14
	Score report delivered to CPO	10/07/14	10/14/14
	Recommended for PRC Review	YES	10/14/14
4. Final PRC Recommendation	COI indicated by PRC member	NONE	10/29/14
	COI recused from participation	N/A	10/29/14
	PRC Meeting	10/24/14	10/14/14
	Third Party Observer Report	10/24/14	10/30/14
	Recommended for grant award	YES	10/29/14
	PRC Chair Notification to PIC and OC	10/28/14	10/29/14
5. PIC Review	COI indicated by PIC member	NONE	11/04/14
	COI recused from participation	N/A	11/04/14
	PIC review meeting	11/04/14	11/04/14
	Recommended for grant award	YES	11/04/14
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 & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: MARGARET KRIPKE, PH.D., CHIEF SCIENTIFIC OFFICER
SUBJECT: UPDATE OF RESEARCH ACTIVITIES
DATE: NOVEMBER 19, 2014

Research Grants

The Scientific Review Council (SRC) evaluated responses to RFAs for the Recruitment of Established Investigators, Rising Stars, and First-Time, Tenure-Track Faculty (REC 14.1) on September 30, 2014, and its recommendation was forwarded to the Program Integration Committee and the Oversight Committee for approval. Ten applications were reviewed by the SRC, and eight were recommended for funding for a total of \$30M. The Oversight Committee will vote on these recommendations later in this meeting.

The scientific research peer review panels met from October 27 to November 11 to discuss the applications that were submitted in response to three RFAs on June 26th. 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. Applications recommended by the seven peer review panels will be discussed by the Scientific Review Council (SRC) in January. The SRC will present their recommendation to the Program Integration Committee (PIC) to be discussed on February 3, 2015 and the Oversight Committee will vote on these recommendations at the February meeting.

RFAs for Multi-Investigator Research Awards, Core Facility Support Awards, and another round of High Impact/High Risk Awards (RP15.2) opened in mid-July. The closing date for these RFAs is November 17, 2014 with application review from December to March. Additionally, RFAs for the recruitment mechanisms remain open and will be reviewed by the SRC monthly.

Research Subcommittee

The Oversight Committee's Research Subcommittee met on November 12, 2014 to discuss the research awards mentioned above, the restoration of funding for two Core Facility Support Awards grant programs, update on the peer review meetings held to discuss three individual investigator grant programs, Advisory Committee on Childhood Cancer charter and whitepaper, a potential CPRIT partnership with NCI, and the program priorities project.

Meeting of the Advisory Committee Childhood Cancers

The Advisory Committee Childhood Cancers met on September 2, 2014 in Austin to discuss the CPRIT program priorities project. The committee worked diligently to produce a whitepaper with recommendations to the Oversight Committee and also to approve the ACCC charter which is before you today. The ACCC recommendations were captured in a document titled, "Program Priorities for CPRIT: A Perspective on Childhood Cancer" that was submitted to the Scientific Review Office on October 30, 2014.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: MARGARET KRIPKE, PH.D.
SUBJECT: FY15, CYCLE 2 RECRUITMENT AWARDS
DATE: OCTOBER 29, 2014

The applications recommended for funding by the CPRIT Scientific Review Council (SRC) have been reviewed and approved by the Program Integration Committee. Applications were submitted in response to three scientific research recruitment award mechanism Request for Applications (RFAs): Recruitment of Established Investigators (RFA R-15-REI-2), Recruitment of Rising Stars (RFA R-15-RRS-2), and Recruitment of First-Time, Tenure-Track Faculty Members (RFA R-15-RFT-2). Ten applications were received in total for all three award mechanisms. All applications were reviewed. Eight applications are being recommended for funding, for a combined amount of \$30,000,000.

Recruitment of Established Investigators (RFA R-15-REI-2)

Applications Reviewed: 3
Applications Recommended: 2
Total Funding Request: \$12,000,000

The aim of this RFA is to recruit outstanding senior research faculty with distinguished professional careers and established cancer research programs to academic institutions in Texas. Award: Up to \$6M over a period of five years.

The applications were evaluated and scored by the SRC to determine the candidates' potential to make a significant contribution to the cancer research program of the nominating institution. Review criteria focused on the overall impression of the candidate and his/her potential for continued superb performance as a cancer researcher, his/her scientific merit of the proposed research program, his/her long-term contribution to and impact on the field of cancer research, and strength of the institutional commitment to the candidate.

Questions that were considered by reviewers include: 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?

Established Investigator candidates recommended by the Scientific Review Council include:

Robert Mattrey, M.D., is being recruited to the University of Texas Southwestern Medical Center from the University of California, San Diego. Dr. Mattrey is an internationally recognized expert in ultrasound and a distinctively qualified clinician-scientist with the ability to innovate and implement the full spectrum of this technology's potential for the benefit of cancer care. His skills span the disciplines of clinical imaging, ultrasound technology and nanotechnology, enabled by his rigorous training and experiences in engineering and medicine.

J. Silvio Gutkind, Ph.D. is being recruited to the University of Texas M.D. Anderson Cancer from the National Institute of Health, National Institute of Dental and Craniofacial Research-Oral and Pharyngeal Cancer Branch. Dr. Gutkind brings significant expertise in the fields of chemoprevention and cell signaling in head and neck cancers. In particular, he pioneered work investigating the role of G-protein coupled receptors in tumorigenesis, as well as studying mTOR signaling and PI3kinase targeting in head and neck squamous carcinomas.

Recruitment of Rising Stars (RFA R-15-RRS-2)

Applications Reviewed:	3
Applications Recommended:	3
Total Funding Request:	\$12,000,000

The aim of this RFA is to recruit outstanding early-stage investigators to Texas, who have demonstrated the promise for continued and enhanced contributions to the field of cancer research. Award: Up to \$4 million over a period of 5 years.

The application was evaluated and scored by the SRC to determine the candidate's potential to make a significant contribution to the cancer research program of the nominating institution. Review criteria focused on the overall impression of the candidate and his/her potential for continued superb performance as a cancer researcher, his/her scientific merit of the proposed research program, his/her long-term contribution to and impact on the field of cancer research, and strength of the institutional commitment to the candidate.

Questions that were considered by reviewers include: 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?

Rising Star candidates recommended by the Scientific Review Council:

Samara L. Reck-Peterson, Ph.D., is being recruited to The University of Texas Southwestern Medical Center Department of Cell Biology from Harvard Medical School. Her recruitment is highly complementary to the department's vision of understanding how dynamic processes are integrated in the living cell to create complex cellular behaviors in health and disease. Dr. Reck-Peterson was the first to isolate recombinant dynein and to characterize the molecule's step-wise behavior during binding and tracking along microtubules. She has remained a leader in this field and continues to study microtubule-based transport across all scales, including single-molecule biophysics and structure, the complex regulation of dynein activity by multiple co-factors and interactions with cargo, and the high-precision tracking of motor activities within living cells.

Andres E. Leschziner, Ph.D., is being recruited to The University of Texas Southwestern Medical Center from Harvard University. Dr. Leschziner has a unique combination of skills in biochemistry and single-particle cryo-electron microscopy and is a rising star in the use of these technologies to understand chromatin remodeling machineries. CPRIT funding will allow Dr. Leschziner to expand his research program to study a broad range of chromatin remodeling complexes and how defects in these systems lead to cancer. His recruitment will bring new expertise that fills a crucial need at UT Southwestern to bridge existing strengths in structural biology with those of light-microscopy, thus fulfilling a joint vision of imaging biological processes across length and time scales.

Issam El Naqa, Ph.D., DABR, is being recruited to The University of Texas Southwestern Medical Center from McGill University Health Center. Dr. El Naqa is at the forefront of oncology bioinformatics, multimodality image analysis, and treatment outcome modeling. He has obtained numerous honors, the most recent include a New Investigator Salary Award from the Canadian Institutes of Health Research, and obtaining a number of grants from Fonds de la Recherche en Santé du Quebec (FRSQ). He is an active member of academic and professional societies within the field such as IEEE, AAPM, and ASTRO. Dr. El Naqa currently heads a lab in the Medical Physics unit of McGill University. His primary research goals are to develop novel approaches to unravel cancer patient responses to chemoradiotherapy treatment by integrating physical, biological, and imaging information into advanced mathematical models.

Recruitment of First-Time, Tenure-Track Faculty Members (RFA R-15-RFT-2)

Applications Reviewed:	4
Applications Recommended:	3
Total Funding Request:	\$6,000,000

The aim of this RFA is to recruit and support very promising emerging investigators, pursuing their first faculty appointment in Texas, who have the ability to make outstanding contributions to the field of cancer research. Award: Up to \$2 million over a period of 4 years.

The applications were evaluated and scored by the SRC to determine the candidates' potential to make a significant contribution to the cancer research program of the nominating institution. Review criteria focused on the overall impression of the candidate and his/her potential for continued superb performance as a cancer researcher, his/her scientific merit of the proposed research program, his/her

long-term contribution to and impact on the field of cancer research, and strength of the institutional commitment to the candidate.

Questions that were considered by reviewers include: 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?

Three candidates are being recommended for First-time Tenure-Track Faculty Awards, 2 at Baylor College of Medicine and 1 at University of Texas M.D. Anderson Cancer Center. Below is a listing of these candidates with their associated expertise. All have outstanding training and records of achievement and a strong commitment to cancer research.

- **Xi Chen, Ph.D.** (BCM) - Unfolded Protein Response, Endoplasmic reticulum stress, Breast cancer, Mouse genetics, Genomics, Biochemistry, Transcription factor, Epigenetics, Immunology, Stem cells
- **Marcin Imielinski, M.D., Ph.D.** (UTMDA) - Lung adenocarcinoma, whole genome and whole exome sequencing, pan-cancer somatic genetic analysis, algorithms for structural variant analysis in whole genome sequence data
- **Melanie Samuel, Ph.D.** (BCM) - nervous system cancers, energy homeostasis, cell specification, glia, aging, retina



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: DAVID REISMAN, CHIEF COMPLIANCE OFFICER
SUBJECT: COMPLIANCE CERTIFICATION – RESEARCH AWARDS SLATES
DATE: NOVEMBER 6, 2014

Summary and Recommendation:

As CPRIT's Chief Compliance Officer, I am responsible for reporting to the Oversight Committee regarding the agency's compliance with applicable statutory and administrative rule requirements during the grant review process. I have reviewed the compliance pedigrees for the grant applications submitted to CPRIT for the:

- Recruitment of First-Time, Tenure-Track Faculty Members Award Slate
- Recruitment of Rising Stars Award Slate
- Recruitment of Established Investigators Award Slate

With regard to the Recruitment of First-Time, Tenure-Track Faculty Members Award Slate, I have conferred with staff at CPRIT and SRA International (SRA), CPRIT's contracted third-party grant administrator, and studied the supporting grant review documentation, including third-party observer reports for the peer review meetings. I am satisfied that the application review process that resulted in the three Recruitment of First-Time, Tenure-Track Faculty Members grants, recommended by the Chief Executive Officer, followed applicable laws and agency administrative rules. I certify this award slate for the Oversight Committee's consideration.

With regard to the Recruitment of Rising Stars Award Slate, I have conferred with staff at CPRIT and SRA International (SRA), CPRIT's contracted third-party grant administrator, and studied the supporting grant review documentation, including third-party observer reports for the peer review meetings. I am satisfied that the application review process that resulted in the three Recruitment of Rising Stars grants, recommended by the Chief Executive Officer, followed applicable laws and agency administrative rules. I certify this award slate for the Oversight Committee's consideration.

With regard to the Recruitment of Established Investigators Award Slate, I have conferred with staff at CPRIT and SRA International (SRA), CPRIT's contracted third-party grant administrator, and studied the supporting grant review documentation, including third-party observer reports for the peer review meetings. I am satisfied that the application review process that resulted in the two Recruitment of

Established Investigators grants, recommended by the Chief Executive Officer, followed applicable laws and agency administrative rules. I certify this award slate for the Oversight Committee's consideration.

Background:

CPRIT is statutorily required to employ a Chief Compliance Officer to report to the Oversight Committee regarding compliance with the statute and the agency's administrative rules. Among the Chief Compliance Officer's responsibilities is the obligation "to ensure that all grant proposals comply with this chapter and rules adopted under this chapter before the proposals are submitted to the oversight committee for approval." TEX HEALTH & SAFETY CODE §102.051(c) and (d).

CPRIT uses a compliance pedigree process to formally document compliance for the grant awards. The compliance pedigree tracks the grant application as it moves through the review process and documents compliance with applicable laws and administrative rules. A compliance pedigree is created for each application; the information related to the procedural steps listed on the pedigree is entered and attested to by SRA employees and CPRIT employees. To the greatest extent possible, information reported in the compliance pedigree is imported directly from data contained in CPRIT's Application Receipt System (CARS), the grant application database managed by SRA. This is done to minimize the opportunity for error caused by manual data entry.

Pre-Receipt Compliance:

The activities listed in pre-receipt stage cover the period beginning with CPRIT's issuance of the Request for Application (RFA) through the submission of grant applications. CPRIT's administrative rules require that RFAs be publicly posted in the *Texas Register*. The RFA specifies a deadline and mandates that only those applications submitted electronically through CARS are eligible for consideration. CARS blocks an application from being submitted once the deadline passes. Occasionally, an applicant may have technical difficulties that prevent the applicant from completing the application submission. When this occurs, the applicant may appeal to CPRIT (through the CPRIT Helpdesk that is managed by SRA) to allow for a submission after the deadline. The program officer considers any appeals and may approve a late filing for good cause. When a late filing request is approved, the appellee is notified and CARS is reopened for a brief period – usually two to three hours – the next business day.

For each of the ten research grant applicants, I reviewed the application pedigrees. All of the RFA's were posted in the Texas Register. All of the applicants registered through CARS and none of the applicants requested an extension.

Receipt, Referral, and Assignment Compliance:

Once research applications have been submitted through CARS, SRA staff reviews the applications for compliance with RFA directions. If an applicant does not comply with the directions, SRA notifies the program officer and the program officer makes the final decision to administratively withdraw the

application. The program officer and the Review Council Chair assign applications to peer review panels and primary reviewers. Prior to distribution of the applications, reviewers are given summary information about the applicant, including the Project Director and collaborators. Reviewers must sign a conflict of interest agreement and confirm that they do not have a conflict of interest with the application before they are provided with the full application.

The pedigrees attest that a conflict of interest statement was signed by each primary reviewer for each Grant Application.

Peer Review:

Primary reviewers (typically three) must submit written critiques for each of their assigned applications prior to the peer review meeting. After the peer review meetings, a final score report from the review committee is delivered to the Review Council for additional review. Following the peer review meetings, each participating peer reviewer must sign a post-review peer review statement certifying that the reviewer knew of and understood CPRIT's conflict of interest policy and followed the policy for this review process.

For Recruitment Awards, there is no Peer Review stage for the applications. The applications go straight to Scientific Review Council (SRC) for consideration.

Programmatic Review:

Programmatic review is conducted by the Scientific Review Council (SRC). The SRC creates the final list of grant applications it will recommend to the Program Integration Committee (PIC) for grant award slates.

For these three slates before the Oversight Committee, I reviewed that the slates correspond to RFAs that have been released and that the pedigrees reflect the date of the SRC meeting and that the applications were included on the slates of award recommendations.

I also reviewed the third party observer reports for these meetings. The third party observer reports document that if an SRC member indicated a conflict with an application, the member recused themselves from the peer review meeting and left the discussion. There were no conflicts noted for these three slates.

Program Integration Committee Review:

CPRIT rules require that, at the time the Program Integration Committee's final Grant Award recommendations are formally submitted to the Oversight Committee, the Chief Executive Officer shall prepare a written affidavit for each Grant Application recommended by the PIC containing relevant information related to the Grant Application recommendations. A review of the affidavits confirms that such affidavits were executed and provided for each Grant Application recommendation.

In this cycle, I reviewed the written notification submitted by Richard D. Kolodner, Chair, Scientific Review Council, to Wayne Roberts recommending eight of the applications for grant awards. I compared the list of grant applications submitted to the Oversight Committee by Mr. Roberts with the list of applications the SRC recommended for awards and confirmed that the recommendations are the same on both lists.

Other Information Reviewed:

Third-Party Observer Reports - In May 2012, CPRIT implemented the use of an independent third-party observer at peer review meetings to ensure that panel discussions are limited to the merits of the application and adhere to established evaluation criteria. In addition, the third-party observer reports whether CPRIT staff attending the peer review meeting participates in the discussion, scoring or vote on the grant application. CPRIT staff may attend peer review meetings, but may not participate in the review process other than to answer technical questions. The third-party reviewer is the agency's internal auditor, Grant Thornton. I have reviewed the third-party observer reports for the peer review meetings for this cycle. Nothing unusual was reported. The reports are attached.

**Conflicts of Interest for Scientific Research Cycle 15.1 Recruitment Applications
(Scientific Research Cycle 15.1 Recruitment Awards Announced at November 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.

Application ID	Applicant	Institution	Conflict Noted
Applications considered by the PIC and Oversight Committee			
RR150005	Kuspa, Adam	Baylor College of Medicine	Mitchell, Amy
RR150009	Kuspa, Adam	Baylor College of Medicine	Mitchell, Amy
RR150010	Fitz, John	The University of Texas Southwestern Medical Center	Mitchell, Amy
RR150013	Dmitrovsky, Ethan	The University of Texas M.D. Anderson Cancer Center	Mitchell, Amy
RR150015	Fitz, John	The University of Texas Southwestern Medical Center	Mitchell, Amy
RR150016	Fitz, John	The University of Texas Southwestern Medical Center	Mitchell, Amy
RR150017	Fitz, John	The University of Texas Southwestern Medical Center	Mitchell, Amy



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO Affidavit Supporting Information

FY 2015—Cycle 1
Recruitment of Established Investigators

Request for Applications



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA R-15-REI-2

**Recruitment of
Established Investigators**

**Please also refer to the Instructions for Applicants document, which will be
posted on September 2, 2014**

Application Receipt Dates:

September 2, 2014-August 31, 2015

Fiscal Year Award Period

September 1, 2014-August 31, 2015 (FY 2015)

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RFA VERSION HISTORY

Rev 9/2/14 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 do the following:

- 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. 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 to secure 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 strongly encouraged 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% of the total award amount (5.263% 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% 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, vice president for research, 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 1 institution. If more than 1 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 MD, PhD, DDS, DMD, DrPH, DO, DVM, or equivalent, and reside in Texas for the duration of the appointment. The candidate must devote at least 70% 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, or any officer or director of the grant applicant's institution or organization (or any person related to 1 or more of these individuals within the second degree of consanguinity or affinity), has 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, or 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 10](#) and [Section 11](#). All statutory provisions and relevant administrative rules can be found at www.cprit.state.tx.us.

6. RESUBMISSION POLICY

Resubmissions will not be accepted for the Recruitment of Established Investigators award mechanism. Any nomination for the Recruitment of Established Investigators that was previously submitted to CPRIT and reviewed but was not recommended for funding may not be resubmitted. If a nomination was administratively rejected prior to review, it can be resubmitted in the following cycles.

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 is submitted.

Candidates must be nominated by the institution's president, provost, vice president for research, 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 monthly. To manage the timely review of nominations for each evaluation period, the application submitted by the 20th day of each month will be reviewed by the 15th day of the following month. For the most immediate submission period, nominations will be accepted beginning at 7 AM central time on September 2, 2014, and must be submitted by 3 PM central time on September 20, 2014, to be reviewed by October 15, 2014. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

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 1 or more components or do not meet the eligibility requirements listed in [Section 5](#) will be administratively withdrawn without review.

7.2.1. 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.

7.2.2. Institutional Commitment (2 pages)

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.

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 (ie, “rent”) is not a permitted institutional commitment item.

7.2.3. Letter of Support from Department Chair (1 page)

Provide the letter of support from and signed by the chair of the department that the candidate is being recruited to. The following information should be included in the letter:

Recruitment Activities: The letter should provide a description of the recruitment activities, strategies, and priorities that have led to the nomination of this candidate.

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 of 70% Time Commitment to Research.

While scholars may engage in direct patient care activities and/or have some administrative or teaching duties, at least 70% of the candidate’s time must be available for research. Breach of this requirement will constitute grounds for discontinuation of funding. The certification that 70% time will be spent on research must be included.

7.2.4. Curriculum Vitae (CV)

Provide a complete CV and list of publications for the candidate.

7.2.5. 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.**

7.2.6. Research (4 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 1 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."

7.2.7. Publications

Provide the 5 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.

7.2.8. Timeline (1 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.

7.2.9. 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.

7.2.10. Research Environment (1 page)

Briefly describe the research environment available to support the candidate's research program, including core facilities, training programs, and collaborative opportunities.

7.2.11. Descriptive Biography (Up to 2 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 website.

Candidates are advised not to include information that they consider confidential or proprietary when preparing this section.

Applications that are missing 1 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.

8. APPLICATION REVIEW

8.1. 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 monthly 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.

8.2. 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 comprises 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.

8.3. 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 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?

9. KEY DATES

RFA

RFA Release

September 2, 2014

Application Receipt and Review Timeline

Application Receipt System opens, 7 AM CT	Application Receipt	Anticipated Application Review
September 2, 2014	Continuous	Monthly by the 15 th day of the month

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. 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.

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 members are not in a position to answer questions regarding scientific aspects of applications.

Dates of operation: September 2, 2014, onward (excluding public holidays)

Hours of operation: Monday, Tuesday, Thursday, Friday, 7 AM to 4 PM central time
Wednesday, 8 AM to 4 PM 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 other funding opportunities, should be directed to the CPRIT Senior Program Manager for Research.

Tel: 512-305-8491

E-mail: Help@CPRITGrants.org

Website: www.cprit.state.tx.us

Third Party Observer Report

CPRIT Scientific Review Council Observation Report

Report #2014-28

Panel Name: FY15 Scientific Review Council Meeting – Tenure Track Recruitment Applications

Panel Date: September 30, 2014

Report Date: October 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 Scientific Review Council review of tenure track recruitment applications. The meeting was chaired by Richard Kolodner held by teleconference on September 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 Council 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 September 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:

- Ten recruitment applications were discussed and evaluated by the Scientific Review Council to determine which grants would receive CPRIT funding.
- Seven council members, two CPRIT staff members, and three SRA employees were present for the Council meeting over the 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 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

Recruitment of Established Investigators

Application ID	Final Overall Score
RR150010*	2.0
RR150012*	2.0
B	3.7

*=Recommended for Funding

Final Overall Evaluation Scores and Rank Order Scores

Ludwig Institute for
Cancer Research Ltd

October 8, 2014

Richard D. Kolodner
Ph.D.

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Cancer Genetics
San Diego Branch

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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 Tuesday, September 30th 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 Council

Attachment

Rank	Application ID	Nominator Organization	Candidate	Mechanism	Budget Requested	Meeting Score
1	RR150013	The University of Texas M. D. Anderson Cancer Center	Dr. Marcin Imielinski	RFT	\$2,000,000	1.0
2	RR150009	Baylor College of Medicine	Dr. Xi Chen	RFT	\$2,000,000	1.5
3	RR150005	Baylor College of Medicine	Dr. Melanie Samuel	RFT	\$2,000,000	2.0
4	RR150010	The University of Texas Southwestern Medical Center	Dr. Robert Mattrey	REI	\$6,000,000	2.0
5	RR150012	The University of Texas M. D. Anderson Cancer Center	Dr. J. Silvio Gutkind	REI	\$6,000,000	2.0
6	RR150015	The University of Texas Southwestern Medical Center	Dr. Samara Reck-Peterson	RRS	\$4,000,000	2.2
7	RR150016	The University of Texas Southwestern Medical Center	Dr. Andres Leschziner	RRS	\$4,000,000	2.7
8	RR150017	The University of Texas Southwestern Medical Center	Dr. Issam El Naqa	RRS	\$4,000,000	2.7

RFT = Recruitment of First-Time, Tenure-Track Faculty Members

RRS = Recruitment of Rising Stars

REI = Recruitment of Established Investigators



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO Affidavit Supporting Information

FY 2015—Cycle 1
*Recruitment of First-Time, Tenure-Track Faculty
Members*

Request for Applications



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA R-15-RFT-2

**Recruitment of First-Time
Tenure-Track Faculty Members**

Please also refer to the Instructions for Applicants document, which will be
posted on September 2, 2014

Application Receipt Dates:

September 2, 2014-Aug 31, 2015

Fiscal Year Award Period

September 1, 2014-August 31, 2015 (FY 2015)

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RFA VERSION HISTORY

Rev 9/2/14 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 do the following:

- 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. 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 strongly encouraged 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% of the total award amount (5.263% 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% 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, vice president for research, 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 1 institution. If more than 1 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 MD, PhD, DDS, DMD, DrPH, DO, DVM, or equivalent, and reside in Texas for the duration of the appointment. The

candidate must devote at least 70% 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, or any officer or director of the grant applicant's institution or organization (or any person related to 1 or more of these individuals within the second degree of consanguinity or affinity), has 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, or 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 10](#) and [Section 11](#). All statutory provisions and relevant administrative rules can be found at www.cprit.state.tx.us.

6. RESUBMISSION POLICY

Resubmissions will not be accepted for the Recruitment of First-Time, Tenure-Track Faculty Members award mechanism. Any nomination for the Recruitment of First-Time, Tenure-Track Faculty Members that was previously submitted to CPRIT and reviewed but was not recommended for funding may not be resubmitted. If a nomination was administratively rejected prior to review, it can be resubmitted in the following cycles.

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 is submitted. Candidates must be nominated by the institution's president, provost, vice president for research, 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 monthly. To manage the timely review of nominations for each evaluation period, the application submitted by the 20th day of each month will be reviewed by the 15th day of the following month. For the most immediate submission period, nominations will be accepted beginning at 7 AM central time on September 2, 2014, and must be submitted by 3 PM central time on September 20, 2014, to be reviewed by October 15, 2014. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

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 1 or more components or do not meet the eligibility requirements listed in [Section 5](#) will be administratively withdrawn without review.

7.2.1. 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.

7.2.2. Institutional Commitment (3 pages)

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. 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 (ie, “rent”) is not a permitted institutional commitment item.

7.2.3. Letter of Support from Department Chair (1 page)

Provide the letter of support from and signed by the chair of the department that the candidate is being recruited to. The following information should be included in the letter:

Recruitment Activities: The letter should provide a description of the recruitment activities, strategies, and priorities that have led to the nomination of this candidate.

Caliber of Candidate: The letter should include a description of the caliber of the candidate and justification of the nomination of the candidate by the institution.

Description of Candidate Duties and Certification of 70% Time Commitment to Research.

While scholars may engage in direct patient care activities and/or have some administrative or teaching duties, at least 70% of the candidate’s time must be available for research. Breach of this requirement will constitute grounds for discontinuation of funding. The certification that 70% time will be spent on research must be included.

The letter of support from the department chair must also do the following:

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.

7.2.4. Curriculum Vitae (CV)

Provide a complete CV and list of publications for the candidate.

7.2.5. 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.**

7.2.6. Research (4 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 1 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."

7.2.7. Publications

Provide the 3 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.

7.2.8. Timeline (1 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.

7.2.9. 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.

7.2.10. Letters of Recommendation

Provide 3 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.

7.2.11. Research Environment (1 page)

Briefly describe the research environment available to support the candidate's research program, including core facilities, training programs, and collaborative opportunities.

7.2.12. Descriptive Biography (Up to 2 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 website.

Candidates are advised not to include information that they consider confidential or proprietary when preparing this section.

Applications that are missing 1 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.

8. APPLICATION REVIEW

8.1. 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 monthly 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.

8.1.1. 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 comprises 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.

8.2. 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 for 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?

9. KEY DATES

RFA

RFA Release September 2, 2014

Application Receipt and Review Timeline

Application Receipt System opens, 7 AM CT	Application Receipt	Anticipated Application Review
September 2, 2014	Continuous	Monthly by the 15 th day of the month

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. 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.cpr.it.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.

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 members are not in a position to answer questions regarding scientific aspects of applications.

Dates of operation: September 2, 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

12.2. Scientific and Programmatic Questions

Questions regarding the CPRIT Program, including questions regarding this or other funding opportunities, should be directed to the CPRIT Senior Program Manager for Research.

Tel: 512-305-8491

E-mail: Help@CPRITGrants.org

Website: www.cprit.state.tx.us

Third Party Observer Report

CPRIT Scientific Review Council Observation Report

Report #2014-28

Panel Name: FY15 Scientific Review Council Meeting –
Tenure Track Recruitment Applications

Panel Date: September 30, 2014

Report Date: October 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 Scientific Review Council review of tenure track recruitment applications. The meeting was chaired by Richard Kolodner held by teleconference on September 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 Council 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 September 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:

- Ten recruitment applications were discussed and evaluated by the Scientific Review Council to determine which grants would receive CPRIT funding.
- Seven council members, two CPRIT staff members, and three SRA employees were present for the Council meeting over the 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 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

Recruitment of First-Time Tenure-Track Faculty Members

Application ID	Final Overall Score
RR150013*	1.0
RR150009*	1.5
RR150005*	2.0
A	3.3

*=Recommended for Funding

Final Overall Evaluation Scores and Rank Order Scores

Ludwig Institute for
Cancer Research Ltd

October 8, 2014

Richard D. Kolodner
Ph.D.

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San Diego Branch

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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 Tuesday, September 30th 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 Council

Attachment

Rank	Application ID	Nominator Organization	Candidate	Mechanism	Budget Requested	Meeting Score
1	RR150013	The University of Texas M. D. Anderson Cancer Center	Dr. Marcin Imielinski	RFT	\$2,000,000	1.0
2	RR150009	Baylor College of Medicine	Dr. Xi Chen	RFT	\$2,000,000	1.5
3	RR150005	Baylor College of Medicine	Dr. Melanie Samuel	RFT	\$2,000,000	2.0
4	RR150010	The University of Texas Southwestern Medical Center	Dr. Robert Mattrey	REI	\$6,000,000	2.0
5	RR150012	The University of Texas M. D. Anderson Cancer Center	Dr. J. Silvio Gutkind	REI	\$6,000,000	2.0
6	RR150015	The University of Texas Southwestern Medical Center	Dr. Samara Reck-Peterson	RRS	\$4,000,000	2.2
7	RR150016	The University of Texas Southwestern Medical Center	Dr. Andres Leschziner	RRS	\$4,000,000	2.7
8	RR150017	The University of Texas Southwestern Medical Center	Dr. Issam El Naqa	RRS	\$4,000,000	2.7

RFT = Recruitment of First-Time, Tenure-Track Faculty Members

RRS = Recruitment of Rising Stars

REI = Recruitment of Established Investigators



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO Affidavit Supporting Information

FY 2015—Cycle 1
Recruitment of Rising Stars

Request for Applications



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS

RFA R-15-RRS-2

Recruitment of Rising Stars

**Please also refer to the Instructions for Applicants document, which will be
posted on September 2, 2014**

Application Receipt Dates:

September 2, 2014-August 31, 2015

Fiscal Year Award Period

September 1, 2014-August 31, 2015 (FY 2015)

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RFA VERSION HISTORY

Rev 9/2/14 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 do the following:

- 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. 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 strongly encouraged 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% of the total award amount (5.263% 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% 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, vice president for research, 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 1 institution. If more than 1 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 MD, PhD, DDS, DMD, DrPH, DO, DVM, or equivalent, and reside in Texas for the duration of the appointment. The

candidate must devote at least 70% 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, or any officer or director of the grant applicant's institution or organization (or any person related to 1 or more of these individuals within the second degree of consanguinity or affinity), has 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, or 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 10](#) and [Section 11](#). All statutory provisions and relevant administrative rules can be found at www.cprit.state.tx.us.

6. RESUBMISSION POLICY

Resubmissions will not be accepted for the Recruitment of Rising Stars award mechanism. Any nomination for the Recruitment of Rising Stars that was previously submitted to CPRIT and reviewed but was not recommended for funding may not be resubmitted. If a nomination was administratively rejected prior to review, it can be resubmitted in the following cycles.

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 is submitted. Candidates must be nominated by the institution's president, provost, vice president for research, 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 monthly. To manage the timely review of nominations for each evaluation period, the application submitted by 20th day of each month will be reviewed by 15th day of the following month. For the most immediate submission period, nominations will be accepted beginning at 7 AM central time on September 2, 2014 and must be submitted by 3 PM central time on September 20, 2014 to be reviewed by October 15, 2014. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

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 1 or more components or do not meet the eligibility requirements listed in [Section 5](#) will be administratively withdrawn without review.

7.2.1. 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.

7.2.2. Institutional Commitment (2 pages)

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.

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 (ie, "rent") is not a permitted institutional commitment item.

7.2.3. Letter of Support from Department Chair (1 page)

Provide the letter of support from and signed by the chair of the department that the candidate is being recruited to. The following information should be included in the letter:

Recruitment Activities: The letter should provide a description of the recruitment activities, strategies, and priorities that have led to the nomination of this candidate.

Caliber of Candidate: The letter should include a description of the caliber of the candidate and justification of the nomination of the candidate by the institution.

Description of Candidate Duties and Certification of 70% Time Commitment to Research.

While scholars may engage in direct patient care activities and/or have some administrative or teaching duties, at least 70% of the candidate's time must be available for research. Breach of this requirement will constitute grounds for discontinuation of funding. The certification that 70% time will be spent on research must be included.

7.2.4. Curriculum Vitae (CV)

Provide a complete CV, and list of publications for the candidate.

7.2.5. 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.**

7.2.6. Research (4 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 1 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.”

7.2.7. Publications

Provide the 5 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.

7.2.8. Timeline (1 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.

7.2.9. 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.

7.2.10. Research Environment (1 page)

Briefly describe the research environment available to support the candidate’s research program, including core facilities and training programs, and collaborative opportunities.

7.2.11. Descriptive Biography (Up to 2 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 website.

Candidates are advised not to include information that they consider confidential or proprietary when preparing this section.

Applications that are missing 1 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.

8. APPLICATION REVIEW

8.1. 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 monthly 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.

8.1.1. 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 comprises 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.

8.2. 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 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?

9. KEY DATES

RFA

RFA Release September 2, 2014

Application Receipt and Review Timeline

Application Receipt System opens, 7 AM CT	Application Receipt System closes, 3 PM CT	Anticipated Application Review
September 2, 2014	Continuous	Monthly by the 15 th day of the month

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. 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.cpr.it.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.cpr.it.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 members are not in a position to answer questions regarding scientific aspects of applications.

Dates of operation: September 2, 2014 onward (excluding public holidays)

Hours of operation: Monday, Tuesday, Thursday, Friday, 7 AM to 4 PM central time
Wednesday, 8 AM to 4 PM 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 other funding opportunities, should be directed to the CPRIT Senior Program Manager for Research.

Tel: 512-305-8491

E-mail: Help@CPRITGrants.org

Website: www.cprit.state.tx.us

Third Party Observer Report

CPRIT Scientific Review Council Observation Report

Report #2014-28

Panel Name: FY15 Scientific Review Council Meeting – Tenure Track Recruitment Applications

Panel Date: September 30, 2014

Report Date: October 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 Scientific Review Council review of tenure track recruitment applications. The meeting was chaired by Richard Kolodner held by teleconference on September 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 Council 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 September 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:

- Ten recruitment applications were discussed and evaluated by the Scientific Review Council to determine which grants would receive CPRIT funding.
- Seven council members, two CPRIT staff members, and three SRA employees were present for the Council meeting over the 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 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

Recruitment of Rising Stars

Application ID	Final Overall Score
RR150015*	2.2
RR150016*	2.7
RR150017*	2.7

*=Recommended for Funding

Final Overall Evaluation Scores and Rank Order Scores

Ludwig Institute for
Cancer Research Ltd

October 8, 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
Cellular & Molecular
Medicine, University of
California San Diego

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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 Tuesday, September 30th 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 Council

Attachment

Rank	Application ID	Nominator Organization	Candidate	Mechanism	Budget Requested	Meeting Score
1	RR150013	The University of Texas M. D. Anderson Cancer Center	Dr. Marcin Imielinski	RFT	\$2,000,000	1.0
2	RR150009	Baylor College of Medicine	Dr. Xi Chen	RFT	\$2,000,000	1.5
3	RR150005	Baylor College of Medicine	Dr. Melanie Samuel	RFT	\$2,000,000	2.0
4	RR150010	The University of Texas Southwestern Medical Center	Dr. Robert Mattrey	REI	\$6,000,000	2.0
5	RR150012	The University of Texas M. D. Anderson Cancer Center	Dr. J. Silvio Gutkind	REI	\$6,000,000	2.0
6	RR150015	The University of Texas Southwestern Medical Center	Dr. Samara Reck-Peterson	RRS	\$4,000,000	2.2
7	RR150016	The University of Texas Southwestern Medical Center	Dr. Andres Leschziner	RRS	\$4,000,000	2.7
8	RR150017	The University of Texas Southwestern Medical Center	Dr. Issam El Naqa	RRS	\$4,000,000	2.7

RFT = Recruitment of First-Time, Tenure-Track Faculty Members

RRS = Recruitment of Rising Stars

REI = Recruitment of Established Investigators



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RR150010
Recruitment of Established Investigators
Nomination of Dr. Robert Mattrey

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:

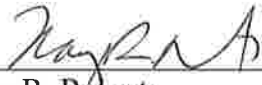
- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT’s grant review processes were followed by the review panel evaluating 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 FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

Dr. Lakey was called away on important state business that conflicted with the meeting of the PIC. The remaining members of the PIC unanimously approved a motion to excuse his absence.

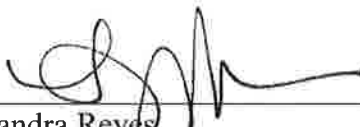
I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.

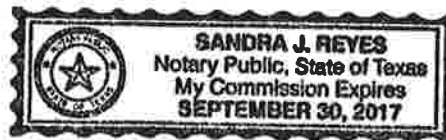
This statement is true."


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 November, 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 2015
CYCLE 1
PROGRAM Research
AWARD MECHANISM Recruitment of Established Investigators (REI)
APPLICATION ID RR150010
APPLICATION TITLE Developing and Translating Ultrasound and Nanotechnology to Enhance Cancer Imaging and Targeted Therapy
APPLICANT NAME Fitz, John
ORGANIZATION The University of Texas Southwestern Medical Center
PANEL NAME 15_Recruitment Review Panel – 1 (15_RRP-1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	06/27/14	10/13/14
	CPRIT Application Receipt Cycle opened	06/12/14	10/13/14
	CPRIT Application Receipt Cycle closed	08/29/14	10/13/14
	Date application submitted	08/25/14	10/13/14
	Method of submission	CARS	10/13/14
	Within receipt period	YES	10/13/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	10/13/14
	Donation(s) made to CPRIT/foundation	NO	10/13/14
	Assigned to primary reviewers	09/15/14	10/13/14
	Applicant notified of review panel assignment	N/A	10/13/14
	Primary Reviewer 1 COI signed	09/11/14	10/13/14
	Primary Reviewer 2 COI signed	09/11/14	10/13/14
3. Peer Review Meeting	Primary Reviewer 1 critique submitted	09/29/14	10/13/14
	Primary Reviewer 2 critique submitted	09/29/14	10/13/14
	COI indicated by non-primary reviewer	NONE	10/13/14
	COI recused from participation	N/A	10/13/14
	Discussed at Peer Review Meeting	YES	10/13/14
	Peer Review Meeting	09/30/14	10/13/14
	Post review statements signed	10/07/14	10/13/14
	Third Party Observer Report	10/01/14	10/15/14
	Score report delivered to CSO	10/03/14	10/13/14
	Recommended for SRC Review	YES	10/13/14
4. Final SRC Recommendation	COI indicated by SRC member	NONE	10/13/14
	COI recused from participation	N/A	10/13/14
	SRC Meeting	09/30/14	10/13/14
	Third Party Observer Report	10/01/14	10/15/14
	Recommended for grant award	YES	10/13/14
	SRC Chair Notification to PIC and OC	10/08/14	10/14/14
5. PIC Review	COI indicated by PIC member	NONE	11/04/14
	COI recused from participation	N/A	11/04/14
	PIC review meeting	11/04/14	11/04/14
	Recommended for grant award	YES	11/04/14
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 & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RR150005
Recruitment of First-Time, Tenure-Track Faculty Members
Nomination of Dr. Melanie Samuel

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 Members* Request for Applications (RFA). CPRIT received four 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.

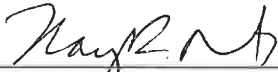
CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and 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 FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

Dr. Lakey was called away on important state business that conflicted with the meeting of the PIC. The remaining members of the PIC unanimously approved a motion to excuse his absence.

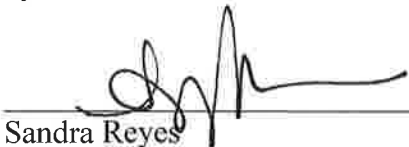
I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.
This statement is true."



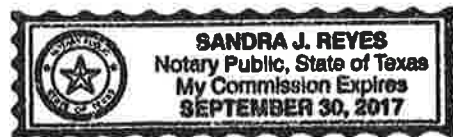
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 4th day of November, 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 2015
CYCLE 1
PROGRAM Research
AWARD MECHANISM Recruitment of First-Time Faculty Members (RFT)
APPLICATION ID RR150005
APPLICATION TITLE Melanie Samuel-First Time Tenure Track Recruit
APPLICANT NAME Kuspa, Adam
ORGANIZATION Baylor College of Medicine
PANEL NAME 15_Recruitment Review Panel – 1 (15_RRP-1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	06/27/14	10/13/14
	CPRIT Application Receipt Cycle opened	06/12/14	10/13/14
	CPRIT Application Receipt Cycle closed	08/29/14	10/13/14
	Date application submitted	08/21/14	10/13/14
	Method of submission	CARS	10/13/14
	Within receipt period	YES	10/13/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	10/13/14
	Donation(s) made to CPRIT/foundation	NO	10/13/14
	Assigned to primary reviewers	09/15/14	10/13/14
	Applicant notified of review panel assignment	N/A	10/13/14
	Primary Reviewer 1 COI signed	09/08/14	10/13/14
	Primary Reviewer 2 COI signed	09/09/14	10/13/14
3. Peer Review Meeting	Primary Reviewer 1 critique submitted	09/16/14	10/13/14
	Primary Reviewer 2 critique submitted	09/26/14	10/13/14
	COI indicated by non-primary reviewer	NONE	10/13/14
	COI recused from participation	N/A	10/13/14
	Discussed at Peer Review Meeting	YES	10/13/14
	Peer Review Meeting	09/30/14	10/13/14
	Post review statements signed	10/07/14	10/13/14
	Third Party Observer Report	10/01/14	10/15/14
	Score report delivered to CSO	10/03/14	10/13/14
	Recommended for SRC Review	YES	10/13/14
4. Final SRC Recommendation	COI indicated by SRC member	NONE	10/13/14
	COI recused from participation	N/A	10/13/14
	SRC Meeting	09/30/14	10/13/14
	Third Party Observer Report	10/01/14	10/15/14
	Recommended for grant award	YES	10/13/14
	SRC Chair Notification to PIC and OC	10/08/14	10/14/14
5. PIC Review	COI indicated by PIC member	NONE	11/04/14
	COI recused from participation	N/A	11/04/14
	PIC review meeting	11/04/14	11/04/14
	Recommended for grant award	YES	11/04/14
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 & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RR150009
Recruitment of First-Time, Tenure-Track Faculty Members
Nomination of Dr. Xi 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 Members* Request for Applications (RFA). CPRIT received four 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:

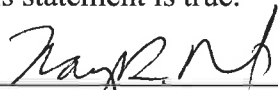
- The applicable Request for Applications (RFA) for this grant cycle
- An overview of the conflict of interest process, including any conflict of interest waivers granted
- The third party observer report(s) documenting that CPRIT’s grant review processes were followed by the review panel evaluating the applications in this grant cycle
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Dr. Lakey was called away on important state business that conflicted with the meeting of the PIC. The remaining members of the PIC unanimously approved a motion to excuse his absence.

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."



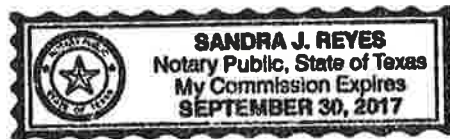
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 4th day of November, 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 2015
CYCLE 1
PROGRAM Research
AWARD MECHANISM Recruitment of First-Time Faculty Members (RFT)
APPLICATION ID RR150009
APPLICATION TITLE Xi_Chen_FTTT
APPLICANT NAME Kuspa, Adam
ORGANIZATION Baylor College of Medicine
PANEL NAME 15_Recruitment Review Panel – 1 (15_RRP-1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	06/27/14	10/13/14
	CPRIT Application Receipt Cycle opened	06/12/14	10/13/14
	CPRIT Application Receipt Cycle closed	08/29/14	10/13/14
	Date application submitted	08/26/14	10/13/14
	Method of submission	CARS	10/13/14
	Within receipt period	YES	10/13/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	10/13/14
	Donation(s) made to CPRIT/foundation	NO	10/13/14
	Assigned to primary reviewers	09/15/14	10/13/14
	Applicant notified of review panel assignment	N/A	10/13/14
	Primary Reviewer 1 COI signed	09/09/14	10/13/14
	Primary Reviewer 2 COI signed	09/08/14	10/13/14
3. Peer Review Meeting	Primary Reviewer 1 critique submitted	09/26/14	10/13/14
	Primary Reviewer 2 critique submitted	09/20/14	10/13/14
	COI indicated by non-primary reviewer	NONE	10/13/14
	COI recused from participation	N/A	10/13/14
	Discussed at Peer Review Meeting	YES	10/13/14
	Peer Review Meeting	09/30/14	10/13/14
	Post review statements signed	10/07/14	10/13/14
	Third Party Observer Report	10/01/14	10/15/14
	Score report delivered to CSO	10/03/14	10/13/14
	Recommended for SRC Review	YES	10/13/14
4. Final SRC Recommendation	COI indicated by SRC member	NONE	10/13/14
	COI recused from participation	N/A	10/13/14
	SRC Meeting	09/30/14	10/13/14
	Third Party Observer Report	10/01/14	10/15/14
	Recommended for grant award	YES	10/13/14
	SRC Chair Notification to PIC and OC	10/08/14	10/14/14
5. PIC Review	COI indicated by PIC member	NONE	11/04/14
	COI recused from participation	N/A	11/04/14
	PIC review meeting	11/04/14	11/04/14
	Recommended for grant award	YES	11/04/14
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 & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RR150013
Recruitment of First-Time, Tenure-Track Faculty Members
Nomination of Dr. Marcin Imielinski

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 Members* Request for Applications (RFA). CPRIT received four 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 FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). As required by the terms of the FY2015 waiver, Dr. Kripke abstained from voting on this application during the PIC meeting. At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).


Dr. Lakey was called away on important state business that conflicted with the meeting of the PIC. The remaining members of the PIC unanimously approved a motion to excuse his absence.

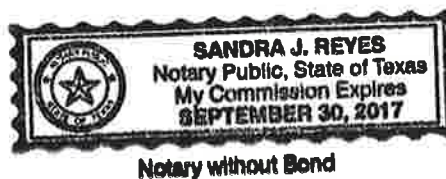
I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process 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 November, 2014,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2015
CYCLE 1
PROGRAM Research
AWARD MECHANISM Recruitment of First-Time Faculty Members (RFT)
APPLICATION ID RR150013
APPLICATION TITLE Recruitment of Marcin Imielinski MD, PhD for First-Time, Tenure-Track Faculty
APPLICANT NAME Dmitrovsky, Ethan
ORGANIZATION The University of Texas M. D. Anderson Cancer Center
PANEL NAME 15_Recruitment Review Panel – 1 (15_RRP-1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	06/27/14	10/13/14
	CPRIT Application Receipt Cycle opened	06/12/14	10/13/14
	CPRIT Application Receipt Cycle closed	08/29/14	10/13/14
	Date application submitted	08/29/14	10/13/14
	Method of submission	CARS	10/13/14
	Within receipt period	YES	10/13/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	10/13/14
	Donation(s) made to CPRIT/foundation	NO	10/13/14
	Assigned to primary reviewers	09/15/14	10/13/14
	Applicant notified of review panel assignment	N/A	10/13/14
	Primary Reviewer 1 COI signed	09/08/14	10/13/14
	Primary Reviewer 2 COI signed	09/15/14	10/13/14
3. Peer Review Meeting	Primary Reviewer 1 critique submitted	09/21/14	10/13/14
	Primary Reviewer 2 critique submitted	09/24/14	10/13/14
	COI indicated by non-primary reviewer	NONE	10/13/14
	COI recused from participation	N/A	10/13/14
	Discussed at Peer Review Meeting	YES	10/13/14
	Peer Review Meeting	09/30/14	10/13/14
	Post review statements signed	10/07/14	10/13/14
	Third Party Observer Report	10/01/14	10/15/14
	Score report delivered to CSO	10/03/14	10/13/14
	Recommended for SRC Review	YES	10/13/14
4. Final SRC Recommendation	COI indicated by SRC member	NONE	10/13/14
	COI recused from participation	N/A	10/13/14
	SRC Meeting	09/30/14	10/13/14
	Third Party Observer Report	10/01/14	10/15/14
	Recommended for grant award	YES	10/13/14
	SRC Chair Notification to PIC and OC	10/08/14	10/14/14
5. PIC Review	COI indicated by PIC member	NONE	11/04/14
	COI recused from participation*	M. Kripke	11/04/14
	PIC review meeting	11/04/14	11/04/14
	Recommended for grant award	YES	11/04/14
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	

*Dr. Margaret Kripke abstained from voting. Dr. Kripke has an approved COI waiver on file for FY2015 regarding M.D. Anderson applications. The COI is waived; however, the terms of Dr. Kripke's FY2015 waiver require her to abstain from voting on M.D. Anderson applications.

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RR150015
Recruitment of Rising Stars
Nomination of Dr. Samara Reck-Peterson

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 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.

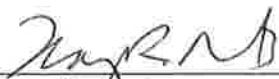
CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and 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 FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

Dr. Lakey was called away on important state business that conflicted with the meeting of the PIC. The remaining members of the PIC unanimously approved a motion to excuse his absence.


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."



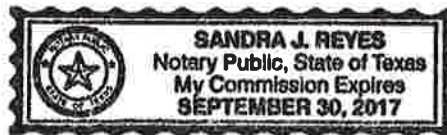
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 4th day of November, 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 2015
CYCLE 1
PROGRAM Research
AWARD MECHANISM Recruitment of Rising Stars (RRS)
APPLICATION ID RR150015
APPLICATION TITLE Molecular Motors and Oncogenesis: Characterization of Cargo-Specific Transport in Cancer Cells
APPLICANT NAME Fitz, John
ORGANIZATION The University of Texas Southwestern Medical Center
PANEL NAME 15_Recruitment Review Panel – 1 (15_RRP-1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	06/27/14	10/13/14
	CPRIT Application Receipt Cycle opened	06/12/14	10/13/14
	CPRIT Application Receipt Cycle closed	08/29/14	10/13/14
	Date application submitted	08/25/14	10/13/14
	Method of submission	CARS	10/13/14
	Within receipt period	YES	10/13/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	10/13/14
	Donation(s) made to CPRIT/foundation	NO	10/13/14
	Assigned to primary reviewers	09/15/14	10/13/14
	Applicant notified of review panel assignment	N/A	10/13/14
	Primary Reviewer 1 COI signed	09/08/14	10/13/14
	Primary Reviewer 2 COI signed	09/11/14	10/13/14
3. Peer Review Meeting	Primary Reviewer 1 critique submitted	09/20/14	10/13/14
	Primary Reviewer 2 critique submitted	09/29/14	10/13/14
	COI indicated by non-primary reviewer	NONE	10/13/14
	COI recused from participation	N/A	10/13/14
	Discussed at Peer Review Meeting	YES	10/13/14
	Peer Review Meeting	09/30/14	10/13/14
	Post review statements signed	10/07/14	10/13/14
	Third Party Observer Report	10/01/14	10/15/14
	Score report delivered to CSO	10/03/14	10/13/14
	Recommended for SRC Review	YES	10/13/14
4. Final SRC Recommendation	COI indicated by SRC member	NONE	10/13/14
	COI recused from participation	N/A	10/13/14
	SRC Meeting	09/30/14	10/13/14
	Third Party Observer Report	10/01/14	10/15/14
	Recommended for grant award	YES	10/13/14
	SRC Chair Notification to PIC and OC	10/08/14	10/14/14
5. PIC Review	COI indicated by PIC member	NONE	11/04/14
	COI recused from participation	N/A	11/04/14
	PIC review meeting	11/04/14	11/04/14
	Recommended for grant award	YES	11/04/14
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 & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RR150016
Recruitment of Rising Stars
Nomination of Dr. Andres Leschziner

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 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 FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

Dr. Lakey was called away on important state business that conflicted with the meeting of the PIC. The remaining members of the PIC unanimously approved a motion to excuse his absence.

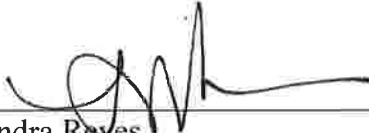
I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process described in the statute and CPRIT's administrative rules.
This statement is true."



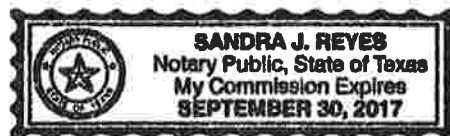
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 4th day of November, 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 2015
CYCLE 1
PROGRAM Research
AWARD MECHANISM Recruitment of Rising Stars (RRS)
APPLICATION ID RR150016
APPLICATION TITLE The Role of ATP-Dependent Chromatin Remodeling Complexes as Tumor Suppressors: A Structural and Mechanistic Analysis
APPLICANT NAME Fitz, John
ORGANIZATION The University of Texas Southwestern Medical Center
PANEL NAME 15_Recruitment Review Panel – 1 (15_RRP-1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	06/27/14	10/13/14
	CPRIT Application Receipt Cycle opened	06/12/14	10/13/14
	CPRIT Application Receipt Cycle closed	08/29/14	10/13/14
	Date application submitted	08/26/14	10/13/14
	Method of submission	CARS	10/13/14
	Within receipt period	YES	10/13/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	10/13/14
	Donation(s) made to CPRIT/foundation	NO	10/13/14
	Assigned to primary reviewers	09/15/14	10/13/14
	Applicant notified of review panel assignment	N/A	10/13/14
	Primary Reviewer 1 COI signed	09/09/14	10/13/14
	Primary Reviewer 2 COI signed	09/15/14	10/13/14
3. Peer Review Meeting	Primary Reviewer 1 critique submitted	09/26/14	10/13/14
	Primary Reviewer 2 critique submitted	09/24/14	10/13/14
	COI indicated by non-primary reviewer	NONE	10/13/14
	COI recused from participation	N/A	10/13/14
	Discussed at Peer Review Meeting	YES	10/13/14
	Peer Review Meeting	09/30/14	10/13/14
	Post review statements signed	10/07/14	10/13/14
	Third Party Observer Report	10/01/14	10/15/14
	Score report delivered to CSO	10/03/14	10/13/14
	Recommended for SRC Review	YES	10/13/14
4. Final SRC Recommendation	COI indicated by SRC member	NONE	10/13/14
	COI recused from participation	N/A	10/13/14
	SRC Meeting	09/30/14	10/13/14
	Third Party Observer Report	10/01/14	10/15/14
	Recommended for grant award	YES	10/13/14
	SRC Chair Notification to PIC and OC	10/08/14	10/14/14
5. PIC Review	COI indicated by PIC member	NONE	11/04/14
	COI recused from participation	N/A	11/04/14
	PIC review meeting	11/04/14	11/04/14
	Recommended for grant award	YES	11/04/14
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 & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application RR150017
Recruitment of Rising Stars
Nomination of Dr. Issam El Naqa

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:

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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:

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Dr. Lakey was called away on important state business that conflicted with the meeting of the PIC. The remaining members of the PIC unanimously approved a motion to excuse his absence.


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This statement is true."



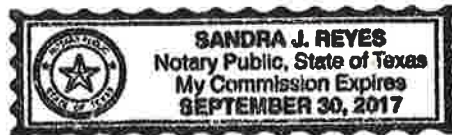
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 4th day of November, 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 2015
CYCLE 1
PROGRAM Research
AWARD MECHANISM Recruitment of Rising Stars (RRS)
APPLICATION ID RR150017
APPLICATION TITLE A Platform for Bioinformatics and Outcomes Research in Radiotherapy
APPLICANT NAME Fitz, John
ORGANIZATION The University of Texas Southwestern Medical Center
PANEL NAME 15_Recruitment Review Panel – 1 (15_RRP-1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	06/27/14	10/13/14
	CPRIT Application Receipt Cycle opened	06/12/14	10/13/14
	CPRIT Application Receipt Cycle closed	08/29/14	10/13/14
	Date application submitted	08/28/14	10/13/14
	Method of submission	CARS	10/13/14
	Within receipt period	YES	10/13/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	10/13/14
	Donation(s) made to CPRIT/foundation	NO	10/13/14
	Assigned to primary reviewers	09/15/14	10/13/14
	Applicant notified of review panel assignment	N/A	10/13/14
	Primary Reviewer 1 COI signed	09/08/14	10/13/14
	Primary Reviewer 2 COI signed	09/11/14	10/13/14
3. Peer Review Meeting	Primary Reviewer 1 critique submitted	09/23/14	10/13/14
	Primary Reviewer 2 critique submitted	09/29/14	10/13/14
	COI indicated by non-primary reviewer	NONE	10/13/14
	COI recused from participation	N/A	10/13/14
	Discussed at Peer Review Meeting	YES	10/13/14
	Peer Review Meeting	09/30/14	10/13/14
	Post review statements signed	10/07/14	10/13/14
	Third Party Observer Report	10/01/14	10/15/14
	Score report delivered to CSO	10/03/14	10/13/14
	Recommended for SRC Review	YES	10/13/14
4. Final SRC Recommendation	COI indicated by SRC member	NONE	10/13/14
	COI recused from participation	N/A	10/13/14
	SRC Meeting	09/30/14	10/13/14
	Third Party Observer Report	10/01/14	10/15/14
	Recommended for grant award	YES	10/13/14
	SRC Chair Notification to PIC and OC	10/08/14	10/14/14
5. PIC Review	COI indicated by PIC member	NONE	11/04/14
	COI recused from participation	N/A	11/04/14
	PIC review meeting	11/04/14	11/04/14
	Recommended for grant award	YES	11/04/14
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.

**Ludwig Institute for
Cancer Research Ltd**

**Richard D. Kolodner
Ph.D.**

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Cancer Genetics
San Diego Branch

Head, Academic Affairs
New York Office

Distinguished Professor of
Medicine, University of
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November 14, 2014

William Rice, M.D.
Oversight Committee Chair
Cancer Prevention and Research Institute of Texas

Wayne R. Roberts
Chief Executive Officer
Cancer Prevention and Research Institute of Texas

Dear Dr. Rice and Mr. Roberts,

The Scientific Review Council (SRC) has reviewed two requests for the restoration of Core Facility Support Award funding that were submitted in response to a notification from the CPRIT Oversight Committee and Chief Compliance Officer that there may have been irregularities when the proposals were originally approved at a reduced amount. After a careful review of the memo explaining the background for the request, requests from each institution for funds to be restored, the Year 1 progress reports and evaluations, original application materials, and the reviewer comments, it is the recommendation of the SRC that the award amount for Baylor College of Medicine be increased from \$3,650,000 (amount awarded) to \$5,300,000 (amount originally requested) and the award amount for The University of Texas M.D. Anderson Cancer Center to be increased from \$1,698,169 (amount awarded) to \$4,500,000 (partial funding). The recommended award amounts represent a total dollar amount, not an addition to the originally approved amount.

The SRC found that, based on the original application, grantee request for increased funds, and the progress report, only partial funding should be restored for the MDACC grant, and therefore the new award amount will be \$4,500,000 instead of the \$6,000,000 originally requested. Additionally, the SRC recommends that the grant period for MDACC be increased from three years to five years as requested in the original proposal. Of the six SRC members that reviewed that requests for restoration of funds, one member recommended full funding, four members recommended partial funding, and one member recommended not to restore funding. Five of the six members recommended to extend the grant period to the full five years initially requested.

This review was done in compliance with CPRIT conflict of interest policies and no reviewer reported a conflict.

Sincerely yours,



Richard D. Kolodner, Ph.D
Chair, CPRIT Scientific Review Council



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: CPRIT OVERSIGHT COMMITTEE MEMBERS
FROM: KRISTEN DOYLE, GENERAL COUNSEL
SUBJECT: ADDITIONAL FUNDING CONSIDERATION – RP130256 AND RP130397
DATE: NOVEMBER 12, 2014

Summary and Recommendation:

Two Core Facility Support projects ratified for grant awards at the December 5, 2012, Oversight Committee meeting require additional review and consideration prior to additional funding. CPRIT Project Nos. RP130256 at Baylor College of Medicine (BCM) and RP130397 at University of Texas M.D. Anderson Cancer Center (MD Anderson) were approved for award amounts that were less than the amounts originally requested in the proposals submitted to CPRIT. In addition, the term of the RP130397 award was two years less than the term requested in the application. These were due to irregularities in the review process that may have impacted the review panels' decision on the recommended award amount for these two awards. As a result, the Oversight Committee voted to allow the grantees to seek later consideration for the full amount of funding and term originally requested after the first annual progress report was submitted to CPRIT. The Scientific Review Council (SRC) has reviewed the requests for full funding and term; the SRC's recommendations will be presented to the Oversight Committee for consideration on November 19, 2014. Any additional funding, if approved by the Oversight Committee, will come from FY2015 appropriations.

Background:

BCM and MD Anderson applied for Core Facility Support grants pursuant to RFA 13-CFSA-1, requesting \$5,300,000 and \$6,000,000 in funding, respectively, over five years. After considering the proposals, the review panels recommended grants totaling \$3,650,000 for BCM and \$1,698,169 for MD Anderson. In addition, the review panel cut the grant term for RP130397 to three years. The SRC included both proposals on its list of award recommendations, albeit with the decreased amounts and shorter term recommended by the review panels.

The Core Facilities award recommendations were presented for Oversight Committee ratification at the December 5, 2012, meeting. As part of the Compliance Officer's certification of the Core Facilities Award slate, Patricia Vojack reported that the third party grant observer noted irregularities in the review panel discussion for two proposals, RP130256 and RP130397.

According to Ms. Vojack, “CPRIT staff is limited to answering questions of policy and procedure during the peer review process. Upon review of RP130256, Baylor College of Medicine Core Facility grant application, during the budget discussion, CPRIT staff deviated from CPRIT procedure which could have impacted the grant application.” Ms. Vojack reported the same irregularity for the panel’s discussion of the RP130397 proposal.

In order to resolve any possible budget impact, Ms. Vojack recommended that BCM and MD Anderson be permitted to request restoration of the full funding amount and term requested in the original grant application. The request and consideration would take place as part of the annual progress report submission process. The Oversight Committee voted to approve the recommendation for both proposals at the time that it ratified the award recommendations.

Process for Consideration of Full Funding Amount and Term:

BCM and MD Anderson recently submitted progress reports for the Core Facility grant awards announced at the December 5, 2012, meeting. Both grantees seek reconsideration of the full funding and term amount requested in its application.

CPRIT contracts with SRA International, Inc. to conduct the review of annual progress reported by the scientific research award grantees. In addition to the SRA review, I suggested that a scientific research peer review panel evaluate the grantees’ requests seeking restoration of the original budgets proposed in the applications submitted to CPRIT. Consistent with this recommendation, the SRC met on November 12, 2014, to conduct the assessment of the requests for full funding.

Dr. Kripke will present the SRC’s recommendation related to increasing the award amount for one or both grants for Oversight Committee approval on November 19, 2014. Chief Operating Officer Heidi McConnell reports that CPRIT no longer has appropriations authority over unspent funding from FY2013. Accordingly, should the Oversight Committee approve increased funding, the additional money will come from FY2015 appropriations.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: CPRIT OVERSIGHT COMMITTEE MEMBERS
FROM: THOMAS C. GOODMAN, PhD, CHIEF PRODUCT DEVELOPMENT OFFICER
SUBJECT: PRODUCT DEVELOPMENT PROGRAM OVERVIEW
DATE: NOVEMBER 10, 2014

Product Development Program activities since the last Oversight Committee meeting have focused on completion of a slate of recommended grant awards from the Early Translational Grant Applications for Oversight Committee approval, conclusion of the Program Priorities Project, the creation of a new Product Development Advisory Committee, and discussions of standardized CPRIT contract terms with this committee and the Oversight Committee Subcommittee on Economic Terms.

- Early Translational Grant Award Recommendations. After scientific review, twenty Early Translational Grants were recommended by the Product Development Review Council and Program Integration Committee for approval by Oversight Committee. These applications are described in a separate memorandum. The total amount recommended is \$33,856,975.
- Program Priorities Project. After public comment was received, some relatively small changes were made to the draft Program Priorities Project Report. The public comment and changes to the draft were earlier conveyed to the Product Development Subcommittee for their consideration and review.
- CPRIT's Standard Revenue Sharing Contract Terms. A Product Development Advisory Committee was created and has begun advising the Oversight Committee Subcommittee on Economic Terms. A CPRIT Revenue Sharing Policy Briefing Document was communicated to both these Committees. As of this writing, a timeframe to complete the Subcommittee's task has not been established.
- Applications for FY2015 Product Development Awards. From among 30 grant applications requesting in aggregate over \$280 million, seventeen companies were chosen for in-person presentations to the full product development review panels, and nine of these were recommended by those panels and the PDRC for advancement into business and patent due diligence. Due diligence was delayed by the renewal of the ICON contract. Any Product Development Award recommendations from this cycle are expected to be presented for approval at the February Oversight Committee meeting.
- New Nomination to the Review Panel. The approval of the Oversight Committee will be sought for the appointment of Robert A. Kramer, PhD to the Product Development Review Panel.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: CPRIT OVERSIGHT COMMITTEE MEMBERS
FROM: DR. WILLIAM RICE, NOMINATIONS SUBCOMMITTEE ACTING CHAIR
SUBJECT: INTENTION TO RECOMMEND APPROVAL OF APPOINTMENTS TO THE SCIENTIFIC RESEARCH AND PREVENTION PROGRAMS COMMITTEE AND ADVISORY COMMITTEE ON PRODUCT DEVELOPMENT
DATE: NOVEMBER 14, 2014

Summary and Recommendation:

The Chief Executive Officer has appointed two experts to the CPRIT's Scientific Research and Prevention Programs Committee; one appointment is to the Product Development review panel and the other appointment is to the Prevention Review Council. In addition, CPRIT has proposed appointees to the Advisory Committee on Product Development (ACPD). CPRIT's statute requires the appointments be approved by the Oversight Committee. The Nominations Subcommittee discussed the appointments at its meeting on November 14 and recommends that the Oversight Committee vote to approve the appointments.

Discussion:

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. Peer reviewers perform an important role for the state; all CPRIT grant awards must first be recommended by a Scientific Research and Prevention Programs committee. Therefore, the individuals appointed to serve as CPRIT's Scientific Research and Prevention Programs committee members must be exceptionally qualified, highly respected, well-established members of the cancer research, product development, and prevention communities.

Texas Health and Safety Code Section 102.151(a) directs the Chief Executive Officer to appoint members to the Scientific Research and Prevention Programs committees. The CEO's appointments are final once approved by a simple majority of the Oversight Committee. The Nominations Subcommittee charter assigns the subcommittee with the responsibility "to circulate to Oversight Committee members in advance of a public meeting written notification of the committee's intent to make the nomination, along with such information about the nominee as may be relevant."

Texas Health and Safety Code Section 102.155 authorizes the Oversight Committee to create an ad hoc committee of experts to advise the Oversight Committee on issues related to cancer. The provisional members of the ACPD met on November 6, 2014. The nine individuals proposed for appointments to the ACPD are experts in the field of venture capital, technology transfer, start-up companies, and life sciences technology development.

The Nominations Subcommittee considered the pending peer reviewer and ACPD appointments and recommends Oversight Committee approval.

Robert A Kramer, Ph.D.

Summary

- Proven Oncology Pharmaceutical Research Leader with 23 years Pharmaceutical experience
- Initiated projects and/or provided direct management oversight for >35 development candidates that advanced into clinical development, resulting in several approved cancer drugs (*eg.*, Sprycel, Ixempra)
- Extensive experience in the Discovery and Early Development of both small molecule and biologic based cancer agents and all aspects of drug discovery from target identification to proof of clinical concept
- Initiated and championed the Immune Oncology approach at Bristol Myers Squibb leading to the partnering with, and subsequent acquisition of Medarex and their portfolio of Immune checkpoint agents (Yervoy, Nivolumab).
- Respected Team and Division leader, built, developed and managed teams of >100 scientists across different continents
- Extensive expertise in conceptualizing, championing and managing research alliances
- Extensive network of contacts and experts
- Outstanding communicator and invited speaker at multiple venues, with a proven publication record (>45 publications)

Experience

RAKramer Consulting

2014-

Independent Consultant to the Pharmaceutical Industry

- Board of Directors, Meditope BioSciences (2014-present)
- Board of Directors, PHussis Therapeutics (2014-present)
- Scientific Advisory Board, NovAliX SAS, France (2014-present)

Janssen Pharmaceuticals Companies of Johnson & Johnson

2011-2014

Vice President, Global Head Oncology Drug Discovery

- Leader of a team of 110+ Scientists (Biologists and Medicinal Chemists) across three sites in Springhouse, PA; Val de Reuil, France and Beerse, Belgium plus an additional 50 contract scientists around the globe (China, UK, Spain).
- Direct responsibility for all Oncology Drug Discovery activities from Target Identification through Clinical Candidate selection. Responsible for securing alignment between Discovery and Development in support of Janssen's corporate priority to focus on Heme malignancies (Myeloma, AML); and Lung, Prostate and Colon cancer. Generated a portfolio of high priority Discovery programs that is leading to the sustained advancement of 3-4 clinical candidates per year.
- Initiated Janssens' entry into the field of Immune Oncology and championed Janssen's first external partnership for Immune Oncology (ImmuNext) for a first in class immune checkpoint target, VISTA. Built a large portfolio of Immune checkpoint programs (4 compounds will enter clinical development between now and 2016).
- Championed and established a bi-functional antibody T cell redirection (CD3) research platform, which includes a collaboration with Genmab, an international biotechnology company.
- Research focus also includes key driver pathways in priority tumor types, (e.g., Androgen, KRas and B cell receptor signaling pathways).

- Core member of Oncology Senior Leadership Team, which provides overall oversight and strategy from target discovery through life cycle management for global oncology business.

Bristol-Myers Squibb

1995-2010

Vice President, Oncology and Immunology Drug Discovery and Princeton Research Site Head

- Leader of 170 cancer and immunology biologists (50+ PhDs; molecular biology, biochemistry, pharmacology, and cell biology). Matrix management of an additional >250 scientists that include medicinal and protein-chemists, assay and screen designers, structural biologists, pharmacokinetic and drug safety scientists, clinical pharmacologists, medical oncologists, rheumatologists and bioinformatics and genomics experts.
- Leadership and strategic oversight for >40 preclinical Oncology and Immunology programs/projects. Responsible for defining strategy and securing alignment with the various BMS functions required to support the development of compounds from Phase I to proof of concept (Phase IIa). Over 30 compounds successfully approved for clinical development, resulting in 2 approved agents (Sprycel and Ixempra), and numerous agents that are progressing through phase II including Urelumab, an immune checkpoint agonistic antibody.
- Championed multiple strategic business opportunities designed to secure Bristol Myers Squibb' long-term leadership position in Oncology and build a Biologics technology platform. These activities included the identification and partnering/acquisition of numerous opportunities, and served as the internal champion responsible for driving the management decision for these partnerships. Examples included a long-term oncology alliance with Exelixis, a biologics partnership with Domantis for the discovery of T-cell co-stimulatory domain antibodies and the acquisitions of Adnexus and Medarex. Responsible for leading the integration of Medarex and Adnexus into the BMS R&D organization and oversight for these acquired biotech divisions. The acquisition of Medarex led to the establishment of an Immune Oncology franchise at BMS.
- Core member of the cross functional Oncology Disease Strategy Team responsible for identifying areas of medical need and designing development strategy across the range of tumors in which the BMS Oncology portfolio is placed. Team was responsible for long term strategic planning for Oncology Franchise, including regions of commercialization and tumor focus.
- Core member of the BMS Discovery and Exploratory Clinical Research Management Team, responsible for setting R & D priorities across all therapeutic areas and continuous improvement of the drug discovery/development process.
- Co-Chair, Lead Discovery Operating Committee, oversight for entire BMS Discovery portfolio (2001-2003)
- Chair, BMS Unrestricted Cancer Grant Program, responsible for funding >\$1M/year, was the longest running Pharmaceutical grant for cancer research (started in 1977).

Lederle-Wyeth**1991-1995*****Director, Oncology and Immunology Research***

- Led Pharmacology efforts for all Oncology projects as well as initiated and led drug discovery projects directed against farnesyl transferase, EGFr, multidrug resistant transporters and mTOR

Harvard Medical School**1986-1991*****Assistant Professor, Department of Radiation Therapy***

- Research focus was on mechanisms of resistance to cancer drugs and radiation therapy, with the goal to design pharmacologic modifiers of resistance.
- Research led to the publication of a manuscript in Science, 241:694-698, 1988 (Kramer RA, et al: Role of the Glutathione Redox Cycle in Acquired and de novo Multidrug Resistance) and an NIH Grant (NCI) R29-CA50473.

Education**National Institutes of Health****1982-1986**

NIH Postdoctoral Fellow, Laboratory of Pharmacology & Experimental Therapeutics, Developmental Therapeutics Program, Division of Cancer Treatment, NCI

University of Vermont, Department of Pharmacology**1976-1982*****PhD in Pharmacology*****SUNY at Stonybrook, B.S. Biology****1970-1974****Professional Activities, Awards**

1982-1984	National Research Service Award, US Public Health Service Grant 5F32 CA06793
1988-1989	Milton Fund Award, Harvard Medical School
1990-1994	FIRST Award, National Cancer Institute, Grant CA50473
2002	Chair, Gordon Conference, Cancer Chemotherapy
2007-current	VP and Founding member of the non-profit, Cancer Molecular Therapeutics Research Association which holds an annual Scientific Conference
2005-current	Pharmacology Basic Science Committee of the Pharmaceutical Manufacturers Association (2005-current)
2006-2011	AACR Industry Round Table

**CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS**

MEMORANDUM

TO: MEMBERS OF THE OVERSIGHT COMMITTEE
FROM: THOMAS C. GOODMAN, PH.D., M.B.A., CHIEF PRODUCT DEVELOPMENT OFFICER
SUBJECT: PRODUCT DEVELOPMENT GRANT RECOMMENDATIONS
DATE: NOVEMBER 5, 2014

Summary and Recommendation:

The CPRIT Product Development Review Council reviewed and recommended awarding 20 Early Translational Research Award (ETRA) grants totaling \$33,856,975. The slate is described below. The Program Integration Committee has voted to advance these awards for the consideration of the Oversight Committee.

Background:

ETRA grants support projects that "bridge the gap" between promising new discoveries achieved in the research laboratory and commercial development for a therapeutic, device, or diagnostic assay through activities up to and including preclinical proof-of-principle data that demonstrate applicability to the planned clinical scenario. The work funded by an ETRA grant must be deemed sufficiently robust such that successful completion would result in identification of a "lead" compound, assay, or device that, as a next stage, could be taken into full commercial development in compliance with FDA regulations. Applicants must identify a clear path of development consistent with the Target Product Profile outlined in the application.

Grant funding may be provided for intermediate steps according to established milestones (often referred to as "stage gates") consistent with those utilized by pharmaceutical/biotechnology therapeutic, diagnostic, and/or device companies for "target identification to lead" development (i.e., achievement of planned Target Product Profile) prior to full development activities.

Any not-for-profit institution that conducts research is eligible to receive an ETRA grant; companies are not eligible. The ETRA grant mechanism was recently transferred from the Academic Research program to Product Development program. This was done to focus attention on its goal of catalyzing new business formation based on research results emanating from academic laboratories. A new feature is the requirement that the grantee prepare a business plan in the first year of the award.

Applications for these awards were submitted pursuant to the RFA released May 23, 2014. All applications were submitted by August 7, 2014, and peer review took place October 7-8, 2014.

Summary of Product Development Slate

Applications were submitted in response to the following CPRIT RFA:

❖ ***Bridging the Gap: Early Translational Research Awards – RFA C15-ETRA-1***

The ETRA grants fund innovative cancer research from target identification to “lead candidate” stage, according to a defined target product profile that projects a clear path to full commercial development. Applicants may request up to \$2 million in funding for projects that are one to three years in duration.

Applications Submitted: 46
Recommended Projects: 20
Total Recommended: \$33,856,975

Early Translational Research Awards Slate

Recommended projects (20):

DP150051

Targeting the DC-HIL Receptor for Anti-Cancer Immunotherapy

(University of Texas Southwestern Medical Center, Kiyoshi Ariizumi, \$1,163,655 requested)

The goal is to create an antibody that will be used to treat patients with advanced melanoma and other cancers. A blood marker that signals the presence of the target for this antibody can identify patients who might best respond to this treatment.

DP150052

High-Throughput Flow-Proteometric System in Screening Functional Complexes as Cancer Biomarkers

(M.D. Anderson Cancer Center, Mien-Chie Hung, \$1,359,649 requested)

Biomarkers are important for cancer patients because they can predict their responsiveness to various forms of chemotherapy and allow them to avoid unhelpful treatments. The microchannel device to be developed in this proposal will allow the identification of functional biomarkers in a high-throughput manner to predict cancer treatment response.

DP150055**Druggable Targets That Regulate the Antitumor Activity of ER-beta**

(University of Texas Health Science Center at San Antonio, Rong Li, \$1,998,444 requested)

The goal is to develop ER-beta agonist drugs for the treatment of triple-negative breast cancer.

DP150056**New Antibody Therapy for Treating Leukemia**

(University of Texas Southwestern Medical Center, Chengcheng Zhang, \$2,000,000 requested)

Leukemia cells are believed to be derived from leukemia stem cells. These stem cells depend on the expression on their surface of a molecule called leukocyte Immunoglobulin-like receptor (LILRB).

Blockade of LILRB signaling may prove to be an effective strategy for elimination of leukemia stem cells and lead to complete remission of this cancer in patients.

DP150059**Blood-Based Markers for Screening and Early Detection of Colorectal Neoplasia**

(M.D. Anderson Cancer Center, Robert Bresalier, \$1,693,599 requested)

The goal is to develop a blood-based screening tests for colorectal cancer based on detection of a molecule in blood called galectin-3 ligand and another called MAPRE1.

DP150061**Preclinical Development of a Therapeutic Enzyme for Immune Checkpoint Inhibition in Cancer**

(University of Texas at Austin, George Georgiou, \$1,790,486 requested)

The goal is to develop an enzyme (Kynureninase) that degrades Kyn into safe byproducts and restores normal immune cell functions. This is expected to result in dramatic growth retardation of melanoma tumors.

DP150064**Novel Separase Inhibitors to Treat Refractory Breast Cancer**

(Baylor College of Medicine, Debananda Pati, \$2,000,000 requested)

Triple-negative breast cancer (TNBC) is difficult to treat. Such tumors frequently express the molecule Separase. The goal of this project is to develop a novel small molecular inhibitor of Separase, Sepin-1. Sepin-1 is well tolerated in animals and highly effective in inhibiting the growth of Separase-over-expressing human TNBC xenografts in mice.

DP150065**Development of a Novel K-Ras Therapeutic**

(University of Texas Health Science Center at Houston, John Hancock, \$1,511,840 requested)

Fendiline is a small molecule that blocks calcium channels in the body. It is known to inhibit a tumor promoter gene called K-Ras. The goal of this project is to improve the K-Ras inhibitor function of fendiline by modifying the molecule and synthesizing new chemical derivatives.

DP150069**Oral Stat3 Inhibitor as Targeted Treatment for Triple-Negative Breast Cancer**

(Baylor College of Medicine, David, Tweardy, \$1,999,569 requested)

Stat3 is essential for tumor cell survival and growth. An agent that targets Stat3 may overcome chemotherapy resistance and dramatically reduce relapses in patients with TNBC.

DP150074**Inhibitors of Hydrogen Sulfide Biosynthesis: Preclinical Development of Novel Colorectal Cancer Therapies**

(University of Texas Medical Branch at Galveston, Mark Hellmich, \$1,605,119 requested)

Cystathionine-beta-synthase (CBS) produces hydrogen sulfide (H₂S) and is expressed at higher levels in colorectal cancer than normal tissue. CBS-produced H₂S stimulates the metabolism and growth of colon cancers. The goal is to make drugs that reduce CBS levels in tumor cells or block the production of H₂S slowing tumor cell metabolism and growth.

DP150077**Targeting the SWI/SNF Chromatin-Remodeling Complex in Liver Cirrhosis and Hepatocellular Carcinoma**

(University of Texas Southwestern Medical Center, Hao Zhu, \$1,357,880 requested)

The project will validate the SWI/SNF pathway as a target in chronic liver disease and hepatocellular carcinoma. It seeks also to develop compounds for the simultaneous treatment of cirrhosis and cancer of the liver.

DP150083**NKT Cell Platform for Cancer Immunotherapy**

(Baylor College of Medicine, Leonid Metelitsa, \$1,928,220 requested)

Natural Killer T-cells (NKTs) are capable of destroying tumor cells. The proposed project will develop banked or "off-the-shelf" NKTs engineered to express the cytokine IL-15, which is a survival factor for both NKTs and T cells.

DP150086**Therapeutic Targeting of Skp2/Ck1 to Restore Nuclear p27**

(Texas A&M University System Health Science Center, Cheryl Walker, \$1,999,979 requested)

p27 is a protein that suppresses tumor growth. It is frequently inactivated in cancers. The goal is to identify drugs that can restore p27 activity specifically in the nucleus of cells, where it acts as a tumor suppressor to inhibit cell growth in endometrial cancer.

DP150087**Pre-IND Development of OxaliTex**

(University of Texas at Austin, Jonathan Sessler, \$1,464,504 requested)

The platinum containing drugs are a class of compounds that are very effective in treating cancer. Unfortunately, cancer cells develop resistance to these agents. This project will develop a texaphyrin-platinum hybrid, termed oxaliTEX, which overcomes the two dominant modes of platinum resistance seen in ovarian cancer.

DP150091**Selective Tumor Delivery of Anti-cancer Agents in Ovarian Cancer Therapy**

(University of North Texas Health Science Center at Fort Worth, Andras Lacko, \$742,048 requested)

The proposed drug delivery strategy involves the encapsulation of small interfering RNA (Stat-3 targeted siRNA) into biocompatible nanoparticles as a novel therapeutic approach to target ovarian cancer cells and tumors.

DP150093**Targeting an Elusive Foe: Development of K-Ras Inhibitors**

(University of Texas Health Science Center at Houston, Alemayehu Gorfe, \$1,969,826 requested)
The goal is to rationally design and develop compounds that directly attack misbehaving mutant K-Ras in cancer cells and kill them.

DP150094

Genetic Engineering of T Cells as an “Off-the-Shelf” Therapy for Leukemias and Lymphomas

(M.D. Anderson Cancer Center, Laurence Cooper, \$1,992,245 requested)

The goal is to develop a method whereby gene therapy can be used to manipulate T cells for cancer therapy before a patient needs them.

DP150096

ESR1 Coregulator Binding Site Inhibitors (ECBIs) as Novel Therapeutics to Target Hormone Therapy Resistant Metastatic Breast Cancer

(University of Texas Health Science Center at San Antonio, Ratna Vadlamudi, \$1,992,460 requested)

The goal is to develop a small organic molecule that can bind to a specific structure in a receptor inside of the nucleus of a cancer cell. The receptor is called ESR1. Accomplishing this may shut down the growth of breast cancer cells.

DP150099

Immunotherapy Targeting Triple Negative Breast Cancer Using NY-ESO-1-Specific TCRs and Blockade of Immune

(Methodist Hospital Research Institute, Rongfu Wang, \$1,592,992 requested)

The goal of this project is to develop a novel therapy for triple-negative breast cancer (TNBC). This will be done by targeting NY-ESO-1 for development of immunotherapy of TNBC patients using NY-ESO-1 T cell receptor (TCR).

DP150102

Image-Guided Smart Laser Knife for Cancer Surgery

(University of Texas at Austin, Thomas Milner, \$1,694,460 requested)

The goal is to develop an image-guided smart laser knife incorporating three laser beams for imaging, prevention of bleeding and tissue cutting. It will be used to remove neural tumors inside the body.



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: DAVID A. REISMAN, CHIEF COMPLIANCE OFFICER
SUBJECT: COMPLIANCE CERTIFICATION:
PRODUCT DEVELOPMENT AWARD SLATES
DATE: NOVEMBER 6, 2014

Summary and Recommendation:

As CPRIT's Chief Compliance Officer, I am responsible for reporting to the Oversight Committee regarding the agency's compliance with applicable statutory and administrative rule requirements during the grant review process. I have reviewed the compliance pedigrees for the grant applications for Product Development awards. I have conferred with staff at CPRIT and SRA International (SRA), CPRIT's contracted third-party grant administrator, and studied the supporting grant review documentation, including third-party observer reports for the peer review meetings. I am satisfied that the application review process that resulted in the Early Translational Research Product Development Award Slate recommended by the Chief Executive Officer followed applicable laws and agency administrative rules. I certify this award slate for the Oversight Committee's consideration.

Background:

Texas law requires that CPRIT employ a Chief Compliance Officer to report to the Oversight Committee regarding compliance with the statute and the agency's administrative rules. Among the Chief Compliance Officer's responsibilities is the obligation "to ensure that all grant proposals comply with this chapter and rules adopted under this chapter before the proposals are submitted to the oversight committee for approval." TEX HEALTH & SAFETY CODE §102.051(c) and (d).

A compliance pedigree is created for each application, which tracks the grant application as it moves through the review process and documents compliance with applicable laws and administrative rules. The information related to the procedural steps listed on the pedigree is entered and attested to by SRA employees and CPRIT employees. To the greatest extent possible, information reported in the compliance pedigree is imported directly from data contained in CPRIT's Application Receipt System (CARS), the grant application database managed by SRA. This is done to minimize the opportunity for error caused by manual data entry. The compliance pedigree for product development grants is divided into eight categories that reflect the seven stages of review. A brief description of each category and information tracked in the category is provided below.

Pre-Receipt Compliance:

The activities listed in pre-receipt stage cover the period beginning with CPRIT's issuance of the Request for Application (RFA) through the submission of grant applications. CPRIT's administrative rules require that RFAs be publicly posted in the *Texas Register*. The RFA specifies a deadline and mandates that only those applications submitted electronically through CARS are eligible for consideration. CARS blocks an application from being submitted once the deadline passes. Occasionally an applicant may have technical difficulties that prevent the applicant from completing the application submission. When this occurs, the applicant may appeal to CPRIT (through the CPRIT Helpdesk that is managed by SRA) to allow for a submission after the deadline. The program officer considers any appeals and may approve a late filing for good cause. When a late filing request is approved, the appellee is notified and CARS is reopened for a brief period – usually two to three hours – the next business day.

In this cycle, all forty six applicants submitted their applications by the deadline. No extensions were requested.

Receipt, Referral, and Assignment Compliance:

Once product development applications have been submitted through CARS, SRA staff reviews the applications for compliance with RFA directions. If an applicant does not comply with the directions, SRA notifies the program officer and the program officer makes the final decision to administratively withdraw the application. The program officer and the Review Council Chair assign applications to peer review panels and primary reviewers. Prior to distribution of the applications, reviewers are given summary information about the applicant, including the Project Director and collaborators. Reviewers must sign a conflict of interest agreement and confirm that they do not have a conflict of interest with the application before they are provided with the full application.

In this cycle, the application pedigrees indicate that a conflict of interest agreement was signed by each reviewer for each of the applications.

Peer Review Screening Conference:

At this stage, the entire review panel meets to discuss the preliminary reviews and scores. The review panel determines which applicants should be invited to proceed to the next stage of the review. For applicants that are not invited to the in-person presentation, the application process ends here.

The application pedigrees were reviewed and showed that a non-primary reviewer in eight of the applicant peer reviews indicated a conflict of interest and were recused from participation. This was cross-checked and verified with the sign-out sheets with those perspective teleconferences. The application pedigrees reflect that twenty of the applicants were invited to proceed to the next stage of the process.

Final Product Development Review Council (PDRC) Recommendation:

The PDRC considers the intellectual property and due diligence reports and creates a final list of applications that it recommends to CPRIT for funding. The Review Council's written recommendations include specific reasons for selecting applications, which are provided to both the Chief Executive Officer and the Oversight Committee. Once the awards are announced, the written recommendation is made public on CPRIT's website. The pedigree reflects the date of the PDRC meeting and whether the application was included on the slate of award recommendations.

The pedigrees reflect that no PDRC members indicated a conflict of interest in the applications. This was cross-checked with the sign out sheets for the teleconference. The pedigrees note that twenty applications were recommended for the slate.

Program Integration Committee Review:

The Product Development Review Council submits their grant award recommendations to the Program Integrations Committee (PIC) which considers the list of Grant Applications. The PIC approves by majority vote a final list of Grant Applications recommended for Grant Awards to be provided to the Oversight Committee. The pedigree reflects the date that the Executive Director was notified of the grant award slates and whether the award was presented to the Oversight Committee.

In this cycle, I reviewed the written notification submitted by Jack Geltsky, Chair, Product Development Review Council, to Wayne Roberts recommending twenty applications for grant awards. I compared the list of grant applications submitted to the Oversight Committee by Mr. Roberts with the list of applications the PDRC recommended for awards and confirmed that the recommendations are the same on both lists.

Other Information Reviewed:

Oversight Committee Conflict of Interest Policy Statements - Prior to receiving grant applicant information, the Oversight Committee members reviewed, signed, and returned CPRIT's conflict of interest policy statement to CPRIT. In addition, prior to viewing grant applicant information, the Oversight Committee members confirmed that they did not have a conflict of interest requiring recusal with any of the applications recommended for grant awards

Third-Party Observer Reports - In May 2012, CPRIT implemented the use of an independent third-party observer at peer review meetings to ensure that panel discussions are limited to the merits of the application and adhere to established evaluation criteria. In addition, the third-party observer reports whether CPRIT staff attending the peer review meeting participates in the discussion, scoring or vote on the grant application. CPRIT staff may attend peer review meetings, but may not participate in the review process other than to answer technical questions. The third-party reviewer is the agency's internal auditor, Grant Thornton. I have reviewed the third-party observer reports for the peer review meetings for this cycle. Nothing unusual was reported. The reports are attached.

**Conflicts of Interest for Product Development Cycle 15.2 Applications
(Product Development Cycle 15.2 Awards Announced at November 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.

Application ID	Applicant	Institution	Conflict Noted
Applications Considered by the PIC and Oversight Committee			
DP150051	Ariizumi, Kiyoshi	The University of Texas Southwestern Medical Center	Mitchell, Amy
DP150052	Hung, Mien-Chie	The University of Texas M.D. Anderson Cancer Center	Mitchell, Amy
DP150056	Zhang, Chengcheng	The University of Texas Southwestern Medical Center	Mitchell, Amy
DP150059	Bresalier, Robert	The University of Texas M.D. Anderson Cancer Center	Mitchell, Amy
DP150061	Georgiou, George	The University of Texas at Austin	Mitchell, Amy
DP150064	Pati, Debananda	Baylor College of Medicine	Mitchell, Amy
DP150065	Hancock, John	The University of Texas Health Science Center at Houston	Mitchell, Amy
DP150069	Tweardy, David	Baylor College of Medicine	Mitchell, Amy; Rosenfeld, Craig
DP150077	Zhu, Hao	The University of Texas Southwestern Medical Center	Mitchell, Amy
DP150083	Metelista, Leonid	Baylor College of Medicine	Mitchell, Amy
DP150086	Walker, Cheryl	Texas A&M University System	Mitchell, Amy

* = Not discussed

		Health Science Center	
DP150087	Sessler, Jonathan	The University of Texas at Austin	Mitchell, Amy
DP150091	Lacko, Andras	University of North Texas Health Science Center at Fort Worth	Mitchell, Amy
DP150093	Gorfe, Alemayehu	The University of Texas Health Science Center at Houston	Mitchell, Amy
DP150096	Vadlamudi, Ratna	The University of Texas Health Science Center at San Antonio	Mitchell, Amy
DP150099	Wang, Rongfu	The Methodist Hospital Research Institute	Mitchell, Amy
DP150102	Milner, Thomas	The University of Texas at Austin	Mitchell, Amy
DP150094	Cooper, Laurence	The University of Texas MD Anderson Cancer Center	DuBois, Ray; Mitchell, Amy
DP150055	Li, Rong	The University of Texas Health Science Center at San Antonio	Jones, Elaine; Mitchell, Amy
DP150074	Hellmich, Mark	The University of Texas Medical Branch at Galveston	Jones, Eliane; Mitchell, Amy
Applications Not Recommended for PIC or Oversight Committee Consideration			
DP150060*	Ciu, Zhengrong	The University of Texas at Austin	Jones, Elaine
DP150062*	Bittner, Michael	Texas A&M University	Sarisky, Robert
DP150071*	Sun, Luzhe	The University of Texas Health Science Center at San Antonio	Jones, Elaine
DP150079	Chen, Changyi	Baylor College of Medicine	Wong, David
DP150092	Huang, Peng	The University of Texas MD Anderson Cancer Center	DuBois, Ray

* = Not discussed



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO Affidavit Supporting Information

FY 2015—Cycle 2
Early Translational Research Awards

Request for Applications



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

REQUEST FOR APPLICATIONS RFA C-15-ETRA-2

Bridging the Gap: Early Translational Research Awards

**Please also refer to the Instructions for Applicants document, which will be
posted June 26, 2014**

FY 2015

Fiscal Year Award Period

September 1, 2014 — August 31, 2015

Applications for this award are subject to institutional caps. Applicants are advised to consult their institution's Office of Research and Sponsored Programs (or equivalent).

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RFA VERSION HISTORY

Rev 05/23/14 RFA release

1. ABOUT CPRIT

The State of Texas 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, 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. EXECUTIVE SUMMARY

CPRIT fosters 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 research projects addressing critically important needs related to the diagnosis, prevention, and/or treatment of cancer. The objective of this award is to “bridge the gap” between promising new discoveries achieved in the research laboratory and commercial development by funding advancement toward investigational new drug (IND) clearance or investigational device exemption (IDE) approval (See Section 3, Mechanism of Support) for the therapeutic, device, or

diagnostic assay through activities up to and including preclinical proof-of-principle data that demonstrate applicability to the planned clinical scenario. The work funded under this RFA must be deemed sufficiently robust such that successful completion would result in identification of a “lead” compound, assay, or device that, as a next stage, could be taken into full development in compliance with International Conference on Harmonization (ICH) Guidelines and U.S. regulatory guidance documents and regulations. Applicants must identify a clear path of development consistent with the Target Product Profile outlined in the application. **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.**

3. MECHANISM OF SUPPORT

The goal of awards made in response to this RFA is to fund innovative cancer research from target identification to “lead candidate” stage, according to a defined Target Product Profile, that projects a clear path to full commercial development. This award allows the opportunity to develop proof-of-principle data necessary to bring promising cancer research projects to lead stage in preparation for full commercial development according to Food and Drug Administration (FDA) regulations. Funding may be provided for intermediate steps according to established milestones (often referred to as “stage gates”) consistent with those utilized by pharmaceutical/biotechnology therapeutic, diagnostic, and/or device companies for “target identification to lead” development (i.e., achievement of planned Target Product Profile [Draft Package Insert]) prior to full development activities. The Target Product Profile should include the parameters below; the questions are intended to guide the thinking process and may include, but are not limited to, the examples provided.

- 1. Identification of a target that is applicable to human cancer treatment.** Is intervention with this target likely to lead to a therapeutic, diagnostic, or medical device that could be useful in the treatment of cancer?
- 2. Selection of a lead compound, assay, or device technology based on the target.** Is the identification of potential developmental candidates based on a set of *in vitro* tests followed by selection of a lead candidate based on considerations (as appropriate for the candidate) of

pharmacodynamic parameters and the results of preclinical, *in vivo*, proof-of-principle studies in relevant animal models of disease?

- 3. Description of a high-level clinical development plan detailing each of the clinical studies the preclinical work is meant to support.** Designing the preclinical program requires an understanding of the duration of the clinical studies required by regulatory authorities. Consequently, a brief outline of each of the Phase I, Phase II, and Phase III studies necessary to obtain regulatory approval and reimbursement funding must be sketched out prior to deciding which toxicology studies would be required.

Additionally, for therapeutics the following apply:

Intended route of administration and dosing regimen. Is the intended route of administration and dosing regimen consistent with accepted convention and medical need for the therapeutic, or will the use of this new agent require a paradigm shift (more frequent or less frequent dosing, new route of administration), and if so, what impact will it have on current standard of care?

Optimization of the lead to ensure desired characteristics, including, but not limited to, the following studies:

- 1. Absorption, distribution, metabolism, excretion (ADME),** including, but not limited to, relevant studies based on route of administration.
- 2. Safety (studies as mandated by ICH Guidelines).**
- 3. Biomarkers (assays) that potentially target specific patient populations** for clinical trials.
- 4. Biomarkers (assays) that can serve as potential pharmacodynamic markers** of clinical activity during early clinical trials designed to demonstrate proof-of-concept.
- 5. Proposed current Good Manufacturing Practice (cGMP)** (including estimated costs) that can be scalable from Phase I through Phase III. Include information if there are possible plans for formulation.

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.

4. RESEARCH OBJECTIVES

Areas of interest include translational preclinical studies that establish proof-of-concept. A detailed preclinical development plan that demonstrates the translation of the preclinical work to the eventual clinical studies will be required.

The current trend strongly favors programs with a strong proof-of-concept that can be undertaken at an acceptable level of risk. Increasingly, this is taken as a clear preclinical indication of a population subset or biomarker approach allowing selection of an enhanced patient population more likely to respond to the therapy.

Examples of fundable projects include those that incorporate the study of potential biomarkers of use for the clinic, such as biomarkers for selection of patients (e.g., tumors with mutations in EGFR, DDR2, BRAF) and/or biomarkers that can be utilized as pharmacodynamic end points (e.g., measurement of bone degradation products in preclinical animal studies and early clinical studies of treatment of bone metastases), tissue distribution, preliminary stability or other “drugability” criteria or safety pharmacology studies conducted in compliance with ICH Guidelines and, thus, usable in a formal FDA regulatory submission.

5. FUNDING INFORMATION

Applicants may request a maximum of \$2,000,000 in total costs over a period of 1 to 3 years. Exceptions to these limits may be requested if extremely well justified (See [Section 10.4.9](#)). Applications funded under this mechanism will not be eligible for competitive renewal. Funds may be used for salary and fringe benefits, research supplies, equipment, *in vitro* and *in vivo* studies, and travel to scientific/technical meetings or collaborating institutions. Funding is also available to support Good Laboratory Practice (GLP), cGMP, Good Clinical Practice (GCP), and regulatory expertise; to provide access to specialized technical infrastructure; and to develop a level of oversight and management that may be beyond the reach and experience of those conducting the research.

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.

6. KEY DATES

RFA

RFA release May 23, 2014

Application

Online application opens June 26, 2014, 7 a.m., Central Time
Application due August 7, 2014, 3 p.m. Central Time
Application review October 2014

Award

Award notification November 2014
Anticipated start date December 2014

7. 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; these entities must use the appropriate award mechanism(s) under CPRIT's Commercialization 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 application under this RFA during this funding cycle.
- A PI may resubmit an application that was previously not funded (See Section 8). However, such a submission will consume the institution's quota.
- Because this award mechanism is intended to support research directed by a single investigator, only one Co-Principal Investigator (Co-PI) may be included. Collaborators should have specific and well-defined roles.
- 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.

- **This award mechanism should not be used for clinical-stage development programs.**

In such instances, the Individual Investigator Research Award, Multi-Investigator Research Award, or Product Development Program award mechanisms are more suitable alternatives to this Early Translational Research Award mechanism.

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.

8. RESUBMISSION POLICY

Since the Early Translational Research Awards is a new award mechanism in the Product Development Program, resubmissions are not available under this RFA. Any previously unfunded application may be submitted as a new application under this mechanism.

9. APPLICATION REVIEW

9.1. Review Process Overview

All eligible applications will be reviewed using a two-stage peer review process: (1) Full peer review and (2) prioritization of grant applications by the CPRIT Product Development Review Council. In the first stage, applications will be evaluated by an independent review panel consisting of scientific reviewers who have extensive experience with the business and entrepreneurial aspects of the pharmaceutical and biotechnology industries as well as advocate reviewers. Applications will be assessed for both scientific merit and commercial potential, including underlying intellectual property, perceived developmental path to market, and regulatory and market assessments. Committees will pay particular attention to the approach

being proposed and the likelihood that the project will be positioned to attract other funding at program completion. 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 Product Development Review Council based on comparisons with applications from all of the peer review panels and programmatic priorities. Applications approved 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. 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.

9.1.1. Confidentiality of Review

Each stage of application review is conducted confidentially, and all CPRIT Product Development Panel members, Product Development Review Council members, PIC 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 grant applicant's behalf) and the following individuals: An Oversight Committee member, a PIC member, a Product Development Review Panel member, or a Product Development Review Council member. Applicants should note that the CPRIT PIC comprises 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.

9.2. 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 and commercial merit of each application is within the sole discretion of the peer reviewers.**

9.2.1. Primary Criteria

Primary criteria will evaluate the scientific and commercial merit of the proposed work and the ability of this work to translate to the intended clinical scenario 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.

Impact and Responsiveness to RFA: Does the applicant's research support a feasible approach to an unmet cancer need? Is the application innovative? Does the project develop or capitalize on state-of-the-art technologies, methods, tools, or resources for cancer treatment or address important underexplored or unexplored areas that have application to the clinic? If the research project is successful, will it lead to truly substantial advances in the field rather than add modest

increments of insight? Will the results of this research, if successful, position the lead of interest such that it can compete successfully for private sector funding?

Research and Development Plan: Is the proposed work presented as a self-contained research project? Does the proposed research have a clearly defined plan for acquiring proof-of-principle data that can be translated to the clinic? Are the methods appropriate, and are potential experimental obstacles and unexpected results discussed?

Competitive Landscape/Intellectual Property: Are you aware of the competitive landscape related to your project? Has the regulatory pathway been adequately described? Have intellectual property issues been addressed?

Applicant Investigator: Does the applicant demonstrate the required creativity, expertise, experience, and accomplishments to make a significant contribution to cancer 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 treatment and application to the clinic? This will be an important criterion for evaluation of projects for CPRIT support.

9.2.2. 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 the following:

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, is certification of approval in place by the institutional IACUC and/or IRB, as appropriate? This certification will be required before funding can occur.

Budget: Is the budget appropriate and reasonable for the proposed work?

Duration: Is the stated duration appropriate for the proposed work?

10. SUBMISSION GUIDELINES

10.1. Institutional Limit

Because a large number of submissions is anticipated and to ensure timely and high-quality review of the most innovative and cutting-edge early translational research, CPRIT is imposing a limit on the number of applications that may be submitted by an institution during this review cycle. CPRIT expects institutions to **initiate an internal review process** and authorize submission of only those applications that have been rigorously judged to be responsive to this RFA. Institutional limits are as follows: University of Texas M. D. Anderson Cancer Center, six; Baylor College of Medicine, six; University of Texas Southwestern Medical Center, six; University of Texas Health Science Center at San Antonio, four; University of Texas Health Science Center at Houston, 4; University of Texas at Austin, four; University of Texas Medical Branch, four; Texas A&M University, four; Texas A&M University Health Science Center, four; Texas Tech University, four; Texas Tech University Health Sciences Center (combined campuses), four; all others, two each.

10.2. Online Application Receipt System

Applications must be submitted via the CPRIT Application Receipt System (<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. Applications will be accepted beginning at 7 a.m. Central Time on June 26, 2014, and must be submitted by 3 p.m. Central Time on August 7, 2014. **Submission of an application is considered an acceptance of the terms and conditions of the RFA.**

10.3. 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.

10.4. 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 or 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 7 will be administratively withdrawn without review.

10.4.1. Application Signing Official (ASO)

The ASO is an individual authorized to submit an application on behalf of an organization. An ASO must be identified and assigned to the application by the PI. An application may not be submitted without ASO approval. Only the ASO is authorized to officially submit the application to CPRIT. The ASO must also create a user account in the online application receipt system.

10.4.2. Grants Contract/Office of Sponsored Projects Official

The Grants Contract/Office of Sponsored Projects official is the individual who will manage the grant if an award is made. This individual must be identified and assigned to the application either by the PI or by the ASO. The Grants Contract/Office of Sponsored Projects official must also create an ASO-type user account in the online application receipt system.

10.4.3. 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 care of patients with cancer. Explain how this application provides a clear path for acquiring proof-of-principle data necessary for next-stage commercial development.

10.4.4. Layperson's Summary (2,000 characters)

Provide a layperson's summary of the proposed work. Describe in very 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 improving the treatment of cancer. 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 9.1](#)) in evaluating the significance and impact of the proposed work.

10.4.5. Goals and Objectives (1,200 characters each)

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 if the award is made.

10.4.6. 10.4.6 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.

10.4.7. Research and Development 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.

10.4.8. Vertebrate Animals and/or Human Biological Samples (One page)

If vertebrate animals will be used, provide an outline of the appropriate protocols that will be followed. If human biological samples will be used, provide a plan for acquisition of samples that will meet the time constraints of this award mechanism. Human/clinical trials are not permitted under this award mechanism.

10.4.9. Competitive Landscape/Intellectual Property (Five pages)

Complete the Competitive Landscape/Intellectual Property Plan using the template provided on the CPRIT Application Receipt System. Provide a clear discussion of the competitive landscape related to your project, including any companies/university laboratories working on similar projects; indicate which of these projects constitutes the greatest competitive threat. Describe the regulatory pathway for this project and any issues that may arise. Provide a concise discussion of the intellectual property issues related to your project and list any relevant issued patents and patent applications, along with their titles and dates they were issued/filed/published.

10.4.10. Publications/References

Provide a concise and relevant list of publications/references cited for the application.

10.4.11. 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. Also state and justify if funds are requested to support expertise in regulatory issues, to provide access to specialized technical infrastructure, and/or to develop a level of oversight and management that may be beyond the reach and experience of those conducting the research. Applicants are advised NOT to interpret the maximum allowable request under this award as an invitation to expand the 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 \$2,000,000 (total funds), applicants should include a special and clearly labeled section in the budget justification that explains the request. Poorly justified requests of this type will 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.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) may not be requested. Applications that include such budgetary items will be rejected administratively and returned without review.
- The maximum annual salary (also referred to as direct salary or institutional base salary) that an individual may receive under a CPRIT award for FY 2015 is \$200,000; CPRIT FY 2015 is from September 1, 2014, through August 31, 2015. Salary does not include fringe benefits and/or facilities and administrative 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.

10.4.12. 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 2 pages.

10.4.13. Current and Pending Support

State 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.

10.4.14. 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.

11. 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.cprit.state.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 associated with the requirement to demonstrate available funds.

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: June 26, 2014, to August 7, 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 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 Peer Review Panel Observation Report

Report #2014-30

Panel Name: Product Development Review Panel – 1 (ETRA)

Panel Date: October 7, 2014

Report Date: October 10, 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 1 chaired by Jack Geltosky held October 7, 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 Product Development Panel meeting held by teleconference and chaired by Jack Geltosky on October 7, 2014. The meeting was facilitated by SRA International, CPRIT's contracted third-party grant application administrator.

Internal Audit noted the following during our observation:

- Fifteen 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.
- Fourteen peer review panel members, three advocate reviewers, four CPRIT staff members and three SRA employees were present for the meetings by teleconference.

- Four conflicts of interest were identified prior to or during the meeting. The council member with the conflict of interests 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.

CPRIT Product Development Peer Review Panel Report

Report #2014-31

Panel Name: Product Development Review Panel - 2

Panel Date: October 8, 2014

Report Date: October 9, 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 2 chaired by David Shoemaker and held October 8, 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 telephonic meeting held October 8, 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 the conference call, 14 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 was determined by the panel as to which applications will move on further for due diligence.
- Thirteen peer review panel members, three advocate reviewers, three CPRIT staff members, and two SRA employees were present for the telephonic panel meeting.

- No conflicts of interest were identified prior 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 Product Development Review Council Report

Report #2015-05

Panel Name: FY 15.2 Product Development Review Council

Panel Date: October 20, 2014

Report Date: October 21, 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 of applications for FY15 funding. The meeting was chaired by David Shoemaker. The teleconference meeting was held October 20, 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 final scoring of applications held October 20, 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 the call, a review of the applications was done to ensure that they would in fact be recommended for funding. A score cut-off was reinforced by the panel as to which applications will move on further for due diligence.
- Four council members, two CPRIT staff members, and one SRA employee was present for the Council meeting.

- No conflicts of interest were identified prior 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 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.

Noted Conflicts of Interest

**Conflicts of Interest for Product Development Cycle 15.2 Applications
(Product Development Cycle 15.2 Awards Announced at November 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.

Application ID	Applicant	Institution	Conflict Noted
Applications considered by the PIC			
DP150094	Cooper, Laurence	The University of Texas MD Anderson Cancer Center	DuBois, Ray
DP150055	Li, Rong	The University of Texas Health Science Center at San Antonio	Jones, Elaine
DP150074	Hellmich, Mark	The University of Texas Medical Branch at Galveston	Jones, Eliane
Applications Not Recommended for PIC or Oversight Committee Consideration			
DP150060*	Ciu, Zhengrong	The University of Texas at Austin	Jones, Elaine
DP150062*	Bittner, Michael	Texas A&M University	Sarisky, Robert
DP150071*	Sun, Luzhe	The University of Texas Health Science Center at San Antonio	Jones, Elaine
DP150079	Chen, Changyi	Baylor College of Medicine	Wong, David
DP150092	Huang, Peng	The University of Texas MD Anderson Cancer Center	DuBois, Ray

* = Not discussed

High Level Summary of Due Diligence

Early Translational Awards (ETRAAs) do not go through due diligence. Therefore, there is no high level summary of due diligence.

De-Identified Overall Evaluation Scores

Early Translational Research Awards

Application ID	Final Overall Score
DP150083*	2.3
DP150069*	2.3
DP150052*	2.3
DP150102*	2.4
DP150093*	2.4
DP150064*	2.5
DP150086*	2.6
DP150056*	2.7
DP150094*	2.9
DP150055*	2.9
DP150096*	3.1
DP150051*	3.1
DP150061*	3.2
DP150065*	3.3
DP150059*	3.3
DP150074*	3.6
DP150077*	3.6
DP150091*	3.6
DP150087*	3.8
DP150099*	3.8
a1	4.0
a2	4.0
a3	4.1
a4	4.2
a5	4.3
a6	4.4
a7	4.5
a8	4.5
a9	4.8
b1	4.8
b2	4.8
b3	4.8
b4	5.3
b5	5.3
b6	5.3
b7	5.5

*=Recommended for Funding

b8	5.5
b9	5.6
c1	5.8
c2	6.3
c3	6.5
c4	6.5
c5	6.8
c6	7.0
c7	7.0
c8	8.0

*=Recommended for Funding

Final Overall Evaluation Scores and Rank Order Scores

October 28, 2014

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 the Early Translational Research Awards. The entities on the attached list submitted proposals in response to CPRIT's request for applications (RFA) released for the first review Product Development cycle of FY2015. Each recommendation reflects 20+ hours of individual review and panel discussion of the applicant's proposal.

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 review panel recommended a change to the scope of work and budget for one proposal (DP150094). However, after discussion, the PDRC does not recommend changes to the funding amount, goals, timelines, or project objectives requested by DP150094 or any of the applicants recommended for grant awards.

The review panel also pointed out issues to be addressed by the Program Officer during contract negotiation, should the proposal DP150056 be approved for funding. With regard to the question about DP150056's similarity with another funded research award, the PDRC asked SRA International to contact the applicant about the similarities and provide a response. The PDRC is satisfied with the applicant's response (see attached). The PDRC does recommend that the Program Officer address the issues identified for DP150056 in contract negotiation.

Our recommendations met the PDRC's standards for grant award

funding. These standards include the applicants' 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,

/s/

Jack Geltosky, PhD
Chair, Product Development Review Council

Early Translational Research Awards, FY15 Cycle 2
Product Development Review Council Recommendations

Rank Order	App. ID	Applicant	Organization	Requested Funding	FINAL SCORE
1	DP150083	Metelitsa	Baylor College of Medicine	\$1,928,220	2.3
1	DP150069	Tweardy	Baylor College of Medicine	\$1,999,569	2.3
1	DP150052	Hung	The University of Texas M. D. Anderson Cancer Center	\$1,359,649	2.3
4	DP150102	Milner	The University of Texas at Austin	\$1,694,460	2.4
4	DP150093	Gorfe	The University of Texas Health Science Center at Houston	\$1,969,826	2.4
6	DP150064	Pati	Baylor College of Medicine	\$2,000,000	2.5
7	DP150086	Walker	Texas A&M University System Health Science Center	\$1,999,979	2.6
8	DP150056	Zhang	The University of Texas Southwestern Medical Center	\$2,000,000	2.7
9	DP150094	Cooper	The University of Texas M. D. Anderson Cancer Center	\$1,992,245	2.9
9	DP150055	Li	The University of Texas Health Science Center at San Antonio	\$1,998,444	2.9
11	DP150096	Vadlamudi	The University of Texas Health Science Center at San Antonio	\$1,992,460	3.1
11	DP150051	Ariizumi	The University of Texas Southwestern Medical Center	\$1,163,655	3.1
13	DP150061	Georgiou	The University of Texas at Austin	\$1,790,486	3.2
14	DP150065	Hancock	The University of Texas Health Science Center at Houston	\$1,511,840	3.3
14	DP150059	Bresalier	The University of Texas M. D. Anderson Cancer Center	\$1,693,599	3.3
16	DP150074	Hellmich	The University of Texas Medical Branch at Galveston	\$1,605,119	3.6
16	DP150077	Zhu	The University of Texas Southwestern Medical Center	\$1,357,880	3.6
16	DP150091	Lacko	University of North Texas Health Science Center at Fort Worth	\$742,048	3.6
19	DP150087	Sessler	The University of Texas at Austin	\$1,464,504	3.8
19	DP150099	Wang	The Methodist Hospital Research Institute	\$1,592,992	3.8

*Applications with the same score were given the same rank order number by the PDRC



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application DP150051
Early Translational Research Awards

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 the *Early Translational Research Awards* Request for Applications (RFA). CPRIT received 46 applications for this RFA. 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 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 FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

Dr. Lakey was called away on important state business that conflicted with the meeting of the PIC. The remaining members of the PIC unanimously approved a motion to excuse his absence.

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."



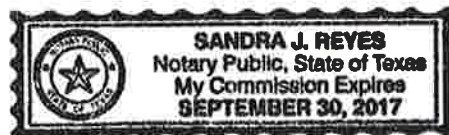
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 4th day of November, 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 2015
CYCLE 2
PROGRAM Product Development
AWARD MECHANISM Bridging the Gap: Early Translational Research Awards (ETRA)
APPLICATION ID DP150051
APPLICATION TITLE Targeting the DC-HIL Receptor for Anti-Cancer Immunotherapy
APPLICANT NAME Ariizumi, Kiyoshi
ORGANIZATION The University of Texas Southwestern Medical Center
PANEL NAME 15.2 Product Development Panel-2 (15.2 PDP-2)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	06/27/14	10/14/14
	CPRIT Application Receipt System (CARS) opened	06/26/14	10/14/14
	CPRIT Application Receipt System (CARS) closed	08/07/14	10/14/14
	Date application submitted	08/07/14	10/14/14
	Method of submission	CARS	10/14/14
	Within receipt period	YES	10/14/14
	Appeal to submit application after CARS closed	N/A	10/14/14
	Appeal for late application submission accepted	N/A	10/14/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	10/14/14
	Donation(s) made to CPRIT/foundation	NO	10/14/14
	Assigned to primary reviewers	08/31/14	10/14/14
	Applicant notified of review panel assignment	09/30/14	10/14/14
	Primary Reviewer 1 COI signed	08/27/14	10/14/14
	Primary (Advocate) Reviewer 2 COI signed	08/20/14	10/14/14
	Primary Reviewer 3 COI signed	08/28/14	10/14/14
	Primary Reviewer 4 COI signed	08/23/14	10/14/14
3. Peer Review Meeting	Primary Reviewer 1 critique submitted	10/05/14	10/14/14
	Primary (Advocate) Reviewer 2 critique submitted	09/27/14	10/14/14
	Primary Reviewer 3 critique submitted	10/06/14	10/14/14
	Primary Reviewer 4 critique submitted	09/09/14	10/14/14
	COI indicated by non-primary reviewer	NONE	10/14/14
	COI recused from participation	N/A	10/14/14
	Peer Review Meeting	10/08/14	10/14/14
	Discussed at Peer Review Meeting	YES	10/14/14
	Post review statements signed	10/13/14	10/28/14
	Third Party Observer Report	10/09/14	10/15/14
	Score report delivered to CPDO	10/28/14	10/28/14
	Recommended for PDRC Review	YES	10/14/14
4. Final PDRC Recommendation	COI indicated by PDRC member	NONE	10/28/14
	COI recused from participation	N/A	10/28/14
	PDRC Meeting	10/20/14	10/14/14
	Third Party Observer Report	10/21/14	10/28/14
	Recommended for grant award	YES	10/28/14
	PDRC Chair Notification to PIC and OC	10/28/14	10/28/14
5. PIC Review	COI indicated by PIC member	NONE	11/04/14
	COI recused from participation	N/A	11/04/14
	PIC review meeting	11/04/14	11/04/14
	Recommended for grant award	YES	11/04/14
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 & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application DP150052
Early Translational Research Awards

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 the *Early Translational Research Awards* Request for Applications (RFA). CPRIT received 46 applications for this RFA. 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.

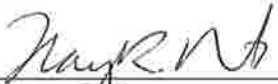
CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and 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 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 FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). As required by the terms of the FY2015 waiver, Dr. Kripke abstained from voting on this application during the PIC meeting. At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

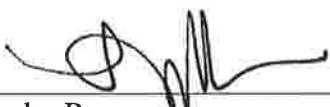
Dr. Lakey was called away on important state business that conflicted with the meeting of the PIC. The remaining members of the PIC unanimously approved a motion to excuse his absence.

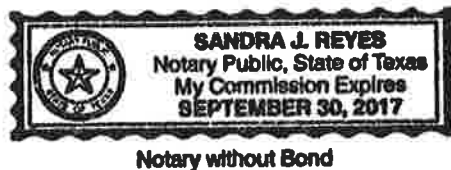
I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process 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 November, 2014,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2015
CYCLE 2
PROGRAM Product Development
AWARD MECHANISM Bridging the Gap: Early Translational Research Awards (ETRA)
APPLICATION ID DP150052
APPLICATION TITLE High-throughput Flow-proteomic System in Screening Functional Complexes as Cancer Biomarkers
APPLICANT NAME Hung, Mien-Chie
ORGANIZATION The University of Texas M. D. Anderson Cancer Center
PANEL NAME 15.2 Product Development Panel-1 (15.2 PDP-1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	06/27/14	10/14/14
	CPRIT Application Receipt System (CARS) opened	06/26/14	10/14/14
	CPRIT Application Receipt System (CARS) closed	08/07/14	10/14/14
	Date application submitted	08/07/14	10/14/14
	Method of submission	CARS	10/14/14
	Within receipt period	YES	10/14/14
	Appeal to submit application after CARS closed	N/A	10/14/14
	Appeal for late application submission accepted	N/A	10/14/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	10/14/14
	Donation(s) made to CPRIT/foundation	NO	10/14/14
	Assigned to primary reviewers	08/31/14	10/14/14
	Applicant notified of review panel assignment	9/30/2014	10/14/14
	Primary Reviewer 1 COI signed	08/27/14	10/14/14
	Primary (Advocate) Reviewer 2 COI signed	08/20/14	10/14/14
	Primary Reviewer 3 COI signed	08/26/14	10/14/14
	Primary Reviewer 4 COI signed	08/27/14	10/14/14
3. Peer Review Meeting	Primary Reviewer 1 critique submitted	10/03/14	10/14/14
	Primary (Advocate) Reviewer 2 critique submitted	10/01/14	10/14/14
	Primary Reviewer 3 critique submitted	10/05/14	10/14/14
	Primary Reviewer 4 critique submitted	09/28/14	10/14/14
	COI indicated by non-primary reviewer	NONE	10/14/14
	COI recused from participation	N/A	10/14/14
	Peer Review Meeting	10/07/14	10/14/14
	Discussed at Peer Review Meeting	YES	10/14/14
	Post review statements signed	10/22/14	10/28/14
	Third Party Observer Report	10/10/14	10/15/14
	Score report delivered to CPDO	10/28/14	10/28/14
	Recommended for PDRC Review	YES	10/14/14
4. Final PDRC Recommendation	COI indicated by PDRC member	NONE	10/28/14
	COI recused from participation	N/A	10/28/14
	PDRC Meeting	10/20/14	10/14/14
	Third Party Observer Report	10/21/14	10/28/14
	Recommended for grant award	YES	10/28/14
	PDRC Chair Notification to PIC and OC	10/28/14	10/28/14
5. PIC Review	COI indicated by PIC member	NONE	11/04/14
	COI recused from participation*	M. Kripke	11/04/14
	PIC review meeting	11/04/14	11/04/14
	Recommended for grant award	YES	11/04/14
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	

*Dr. Margaret Kripke abstained from voting. Dr. Kripke has an approved COI waiver on file for FY2015 regarding M.D. Anderson applications. The COI is waived; however, the terms of Dr. Kripke's FY2015 waiver require her to abstain from voting on M.D. Anderson applications.

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application DP150055
Early Translational Research Awards

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 the *Early Translational Research Awards* Request for Applications (RFA). CPRIT received 46 applications for this RFA. 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 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 FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

Dr. Lakey was called away on important state business that conflicted with the meeting of the PIC. The remaining members of the PIC unanimously approved a motion to excuse his absence.

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."



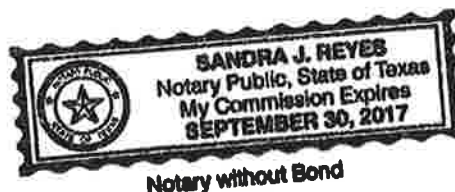
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 4th day of November, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2015
CYCLE 2
PROGRAM Product Development
AWARD MECHANISM Bridging the Gap: Early Translational Research Awards (ETRA)
APPLICATION ID DP150055
APPLICATION TITLE Druggable Targets that Regulate the Antitumor Activity of ER-beta
APPLICANT NAME Li, Rong
ORGANIZATION The University of Texas Health Science Center at San Antonio
PANEL NAME 15.2 Product Development Panel-1 (15.2 PDP-1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	06/27/14	10/14/14
	CPRIT Application Receipt System (CARS) opened	06/26/14	10/14/14
	CPRIT Application Receipt System (CARS) closed	08/07/14	10/14/14
	Date application submitted	08/07/14	10/14/14
	Method of submission	CARS	10/14/14
	Within receipt period	YES	10/14/14
	Appeal to submit application after CARS closed	N/A	10/14/14
	Appeal for late application submission accepted	N/A	10/14/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	10/14/14
	Donation(s) made to CPRIT/foundation	NO	10/14/14
	Assigned to primary reviewers	08/31/14	10/14/14
	Applicant notified of review panel assignment	09/30/14	10/14/14
	Primary Reviewer 1 COI signed	08/27/14	10/14/14
	Primary (Advocate) Reviewer 2 COI signed	08/20/14	10/14/14
	Primary Reviewer 3 COI signed	08/27/14	10/14/14
	Primary Reviewer 4 COI signed	08/24/14	10/14/14
3. Peer Review Meeting	Primary Reviewer 1 critique submitted	09/28/14	10/14/14
	Primary (Advocate) Reviewer 2 critique submitted	10/01/14	10/14/14
	Primary Reviewer 3 critique submitted	10/03/14	10/14/14
	Primary Reviewer 4 critique submitted	10/04/14	10/14/14
	COI indicated by non-primary reviewer	Jones, Elaine	10/14/14
	COI recused from participation	YES	10/14/14
	Peer Review Meeting	10/07/14	10/14/14
	Discussed at Peer Review Meeting	YES	10/14/14
	Post review statements signed	10/22/14	10/28/14
	Third Party Observer Report	10/10/14	10/15/14
	Score report delivered to CPDO	10/28/14	10/28/14
	Recommended for PDRC Review	YES	10/14/14
4. Final PDRC Recommendation	COI indicated by PDRC member	NONE	10/28/14
	COI recused from participation	N/A	10/28/14
	PDRC Meeting	10/20/14	10/14/14
	Third Party Observer Report	10/21/14	10/28/14
	Recommended for grant award	YES	10/28/14
	PDRC Chair Notification to PIC and OC	10/28/14	10/28/14
5. PIC Review	COI indicated by PIC member	NONE	11/04/14
	COI recused from participation	N/A	11/04/14
	PIC review meeting	11/04/14	11/04/14
	Recommended for grant award	YES	11/04/14
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 & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application DP150056
Early Translational Research Awards

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).

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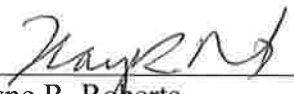
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Dr. Lakey was called away on important state business that conflicted with the meeting of the PIC. The remaining members of the PIC unanimously approved a motion to excuse his absence.

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 November, 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 2015
CYCLE 2
PROGRAM Product Development
AWARD MECHANISM Bridging the Gap: Early Translational Research Awards (ETRA)
APPLICATION ID DP150056
APPLICATION TITLE New Antibody Therapy for Treating Leukemia
APPLICANT NAME Zhang, Chengcheng
ORGANIZATION The University of Texas Southwestern Medical Center
PANEL NAME 15.2 Product Development Panel-2 (15.2 PDP-2)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	06/27/14	10/14/14
	CPRIT Application Receipt System (CARS) opened	06/26/14	10/14/14
	CPRIT Application Receipt System (CARS) closed	08/07/14	10/14/14
	Date application submitted	08/07/14	10/14/14
	Method of submission	CARS	10/14/14
	Within receipt period	YES	10/14/14
	Appeal to submit application after CARS closed	N/A	10/14/14
	Appeal for late application submission accepted	N/A	10/14/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	10/14/14
	Donation(s) made to CPRIT/foundation	NO	10/14/14
	Assigned to primary reviewers	08/31/14	10/14/14
	Applicant notified of review panel assignment	09/30/14	10/14/14
	Primary Reviewer 1 COI signed	08/21/14	10/14/14
	Primary (Advocate) Reviewer 2 COI signed	09/12/14	10/14/14
	Primary Reviewer 3 COI signed	08/27/14	10/14/14
	Primary Reviewer 4 COI signed	08/26/14	10/14/14
3. Peer Review Meeting	Primary Reviewer 1 critique submitted	10/03/14	10/14/14
	Primary (Advocate) Reviewer 2 critique submitted	10/05/14	10/14/14
	Primary Reviewer 3 critique submitted	10/05/14	10/14/14
	Primary Reviewer 4 critique submitted	10/05/14	10/14/14
	COI indicated by non-primary reviewer	NONE	10/14/14
	COI recused from participation	N/A	10/14/14
	Peer Review Meeting	10/08/14	10/14/14
	Discussed at Peer Review Meeting	YES	10/14/14
	Post review statements signed	10/13/14	10/28/14
	Third Party Observer Report	10/09/14	10/15/14
	Score report delivered to CPDO	10/28/14	10/28/14
	Recommended for PDRC Review	YES	10/14/14
4. Final PDRC Recommendation	COI indicated by PDRC member	NONE	10/28/14
	COI recused from participation	N/A	10/28/14
	PDRC Meeting	10/20/14	10/14/14
	Third Party Observer Report	10/21/14	10/28/14
	Recommended for grant award	YES	10/28/14
	PDRC Chair Notification to PIC and OC	10/28/14	10/28/14
5. PIC Review	COI indicated by PIC member	NONE	11/04/14
	COI recused from participation	N/A	11/04/14
	PIC review meeting	11/04/14	11/04/14
	Recommended for grant award	YES	11/04/14
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 & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application DP150059
Early Translational Research Awards

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).

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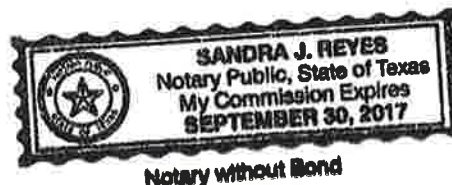
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State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 4th day of November, 2014,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

FY 2015
 CYCLE 2
 PROGRAM Product Development
 AWARD MECHANISM Bridging the Gap: Early Translational Research Awards (ETRA)
 APPLICATION ID DP150059
 APPLICATION TITLE Blood-Based Markers for Screening and Early Detection of Colorectal Neoplasia
 APPLICANT NAME Bresalier, Robert
 ORGANIZATION The University of Texas M. D. Anderson Cancer Center
 PANEL NAME 15.2 Product Development Panel-2 (15.2 PDP-2)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	06/27/14	10/14/14
	CPRIT Application Receipt System (CARS) opened	06/26/14	10/14/14
	CPRIT Application Receipt System (CARS) closed	08/07/14	10/14/14
	Date application submitted	08/07/14	10/14/14
	Method of submission	CARS	10/14/14
	Within receipt period	YES	10/14/14
	Appeal to submit application after CARS closed	N/A	10/14/14
	Appeal for late application submission accepted	N/A	10/14/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	10/14/14
	Donation(s) made to CPRIT/foundation	NO	10/14/14
	Assigned to primary reviewers	08/31/14	10/14/14
	Applicant notified of review panel assignment	09/30/14	10/14/14
	Primary Reviewer 1 COI signed	08/26/14	10/14/14
	Primary (Advocate) Reviewer 2 COI signed	08/20/14	10/14/14
	Primary Reviewer 3 COI signed	08/21/14	10/14/14
	Primary Reviewer 4 COI signed	08/20/14	10/14/14
3. Peer Review Meeting	Primary Reviewer 1 critique submitted	10/05/14	10/14/14
	Primary (Advocate) Reviewer 2 critique submitted	09/27/14	10/14/14
	Primary Reviewer 3 critique submitted	10/04/14	10/14/14
	Primary Reviewer 4 critique submitted	10/04/14	10/14/14
	COI indicated by non-primary reviewer	NONE	10/14/14
	COI recused from participation	N/A	10/14/14
	Peer Review Meeting	10/08/14	10/14/14
	Discussed at Peer Review Meeting	YES	10/14/14
	Post review statements signed	10/13/14	10/28/14
	Third Party Observer Report	10/09/14	10/15/14
	Score report delivered to CPDO	10/28/14	10/28/14
	Recommended for PDRC Review	YES	10/14/14
4. Final PDRC Recommendation	COI indicated by PDRC member	NONE	10/28/14
	COI recused from participation	N/A	10/28/14
	PDRC Meeting	10/20/14	10/14/14
	Third Party Observer Report	10/21/14	10/28/14
	Recommended for grant award	YES	10/28/14
	PDRC Chair Notification to PIC and OC	10/28/14	10/28/14
5. PIC Review	COI indicated by PIC member	NONE	11/04/14
	COI recused from participation*	M. Kripke	11/04/14
	PIC review meeting	11/04/14	11/04/14
	Recommended for grant award	YES	11/04/14
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	

*Dr. Margaret Kripke abstained from voting. Dr. Kripke has an approved COI waiver on file for FY2015 regarding M.D. Anderson applications. The COI is waived; however, the terms of Dr. Kripke's FY2015 wavier require her to abstain from voting on M.D. Anderson applications.

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application DP150061
Early Translational Research Awards

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 the *Early Translational Research Awards* Request for Applications (RFA). CPRIT received 46 applications for this RFA. 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.

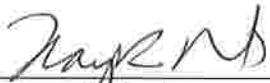
CPRIT staff and CPRIT’s third-party grants management vendor have recorded information and prepared documents during the course of their employment that are related to CPRIT’s grant review process described by Health & Safety Code Chapter 102. I have reviewed the information prepared by CPRIT staff and 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 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 FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

Dr. Lakey was called away on important state business that conflicted with the meeting of the PIC. The remaining members of the PIC unanimously approved a motion to excuse his absence.


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."



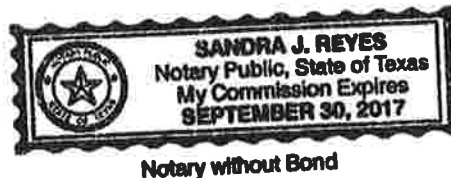
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 4th day of November, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2015
CYCLE 2
PROGRAM Product Development
AWARD MECHANISM Bridging the Gap: Early Translational Research Awards (ETRA)
APPLICATION ID DP150061
APPLICATION TITLE Preclinical Development of a Therapeutic Enzyme for Immune Checkpoint Inhibition in Cancer
APPLICANT NAME Georgiou, George
ORGANIZATION The University of Texas at Austin
PANEL NAME 15.2 Product Development Panel-2 (15.2 PDP-2)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	06/27/14	10/14/14
	CPRIT Application Receipt System (CARS) opened	06/26/14	10/14/14
	CPRIT Application Receipt System (CARS) closed	08/07/14	10/14/14
	Date application submitted	08/07/14	10/14/14
	Method of submission	CARS	10/14/14
	Within receipt period	YES	10/14/14
	Appeal to submit application after CARS closed	N/A	10/14/14
	Appeal for late application submission accepted	N/A	10/14/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	10/14/14
	Donation(s) made to CPRIT/foundation	NO	10/14/14
	Assigned to primary reviewers	08/31/14	10/14/14
	Applicant notified of review panel assignment	09/30/14	10/14/14
	Primary Reviewer 1 COI signed	08/21/14	10/14/14
	Primary (Advocate) Reviewer 2 COI signed	08/20/14	10/14/14
	Primary Reviewer 3 COI signed	08/25/14	10/14/14
	Primary Reviewer 4 COI signed	08/21/14	10/14/14
3. Peer Review Meeting	Primary Reviewer 1 critique submitted	10/01/14	10/14/14
	Primary (Advocate) Reviewer 2 critique submitted	09/30/14	10/14/14
	Primary Reviewer 3 critique submitted	10/05/14	10/14/14
	Primary Reviewer 4 critique submitted	10/05/14	10/14/14
	COI indicated by non-primary reviewer	NONE	10/14/14
	COI recused from participation	N/A	10/14/14
	Peer Review Meeting	10/08/14	10/14/14
	Discussed at Peer Review Meeting	YES	10/14/14
	Post review statements signed	10/13/14	10/28/14
	Third Party Observer Report	10/09/14	10/15/14
	Score report delivered to CPDO	10/28/14	10/28/14
	Recommended for PDRC Review	YES	10/14/14
4. Final PDRC Recommendation	COI indicated by PDRC member	NONE	10/28/14
	COI recused from participation	N/A	10/28/14
	PDRC Meeting	10/20/14	10/14/14
	Third Party Observer Report	10/21/14	10/28/14
	Recommended for grant award	YES	10/28/14
	PDRC Chair Notification to PIC and OC	10/28/14	10/28/14
5. PIC Review	COI indicated by PIC member	NONE	11/04/14
	COI recused from participation	N/A	11/04/14
	PIC review meeting	11/04/14	11/04/14
	Recommended for grant award	YES	11/04/14
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 & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application DP150064
Early Translational Research Awards

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 the *Early Translational Research Awards* Request for Applications (RFA). CPRIT received 46 applications for this RFA. 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 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 FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

Dr. Lakey was called away on important state business that conflicted with the meeting of the PIC. The remaining members of the PIC unanimously approved a motion to excuse his absence.


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."



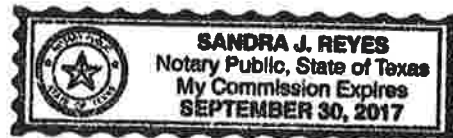
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 4th day of November, 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 2015
CYCLE 2
PROGRAM Product Development
AWARD MECHANISM Bridging the Gap: Early Translational Research Awards (ETRA)
APPLICATION ID DP150064
APPLICATION TITLE Novel Separate Inhibitors to Treat Refractory Breast Cancer
APPLICANT NAME Pati, Debananda
ORGANIZATION Baylor College of Medicine
PANEL NAME 15.2 Product Development Panel-1 (15.2 PDP-1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	06/27/14	10/14/14
	CPRIT Application Receipt System (CARS) opened	06/26/14	10/14/14
	CPRIT Application Receipt System (CARS) closed	08/07/14	10/14/14
	Date application submitted	08/05/14	10/14/14
	Method of submission	CARS	10/14/14
	Within receipt period	YES	10/14/14
	Appeal to submit application after CARS closed	N/A	10/14/14
	Appeal for late application submission accepted	N/A	10/14/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	10/14/14
	Donation(s) made to CPRIT/foundation	NO	10/14/14
	Assigned to primary reviewers	08/31/14	10/14/14
	Applicant notified of review panel assignment	09/30/14	10/14/14
	Primary Reviewer 1 COI signed	08/24/14	10/14/14
	Primary (Advocate) Reviewer 2 COI signed	08/22/14	10/14/14
	Primary Reviewer 3 COI signed	08/27/14	10/14/14
	Primary Reviewer 4 COI signed	08/27/14	10/14/14
3. Peer Review Meeting	Primary Reviewer 1 critique submitted	10/05/14	10/14/14
	Primary (Advocate) Reviewer 2 critique submitted	10/05/14	10/14/14
	Primary Reviewer 3 critique submitted	10/04/14	10/14/14
	Primary Reviewer 4 critique submitted	10/04/14	10/14/14
	COI indicated by non-primary reviewer	NONE	10/14/14
	COI recused from participation	N/A	10/14/14
	Peer Review Meeting	10/07/14	10/14/14
	Discussed at Peer Review Meeting	YES	10/14/14
	Post review statements signed	10/22/14	10/28/14
	Third Party Observer Report	10/10/14	10/15/14
	Score report delivered to CPDO	10/28/14	10/28/14
	Recommended for PDRC Review	YES	10/14/14
4. Final PDRC Recommendation	COI indicated by PDRC member	NONE	10/28/14
	COI recused from participation	N/A	10/28/14
	PDRC Meeting	10/20/14	10/14/14
	Third Party Observer Report	10/21/14	10/28/14
	Recommended for grant award	YES	10/28/14
	PDRC Chair Notification to PIC and OC	10/28/14	10/28/14
5. PIC Review	COI indicated by PIC member	NONE	11/04/14
	COI recused from participation	N/A	11/04/14
	PIC review meeting	11/04/14	11/04/14
	Recommended for grant award	YES	11/04/14
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 & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application DP150065
Early Translational Research Awards

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 the *Early Translational Research Awards* Request for Applications (RFA). CPRIT received 46 applications for this RFA. 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 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 FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

Dr. Lakey was called away on important state business that conflicted with the meeting of the PIC. The remaining members of the PIC unanimously approved a motion to excuse his absence.

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 November, 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 2015
CYCLE 2
PROGRAM Product Development
AWARD MECHANISM Bridging the Gap: Early Translational Research Awards (ETRA)
APPLICATION ID DP150065
APPLICATION TITLE Development of a Novel K-Ras Therapeutic
APPLICANT NAME Hancock, John
ORGANIZATION The University of Texas Health Science Center at Houston
PANEL NAME 15.2 Product Development Panel-2 (15.2 PDP-2)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	06/27/14	10/14/14
	CPRIT Application Receipt System (CARS) opened	06/26/14	10/14/14
	CPRIT Application Receipt System (CARS) closed	08/07/14	10/14/14
	Date application submitted	08/06/14	10/14/14
	Method of submission	CARS	10/14/14
	Within receipt period	YES	10/14/14
	Appeal to submit application after CARS closed	N/A	10/14/14
	Appeal for late application submission accepted	N/A	10/14/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	10/14/14
	Donation(s) made to CPRIT/foundation	NO	10/14/14
	Assigned to primary reviewers	08/31/14	10/14/14
	Applicant notified of review panel assignment	09/30/14	10/14/14
	Primary Reviewer 1 COI signed	09/08/14	10/14/14
	Primary (Advocate) Reviewer 2 COI signed	08/20/14	10/14/14
	Primary Reviewer 3 COI signed	08/26/14	10/14/14
	Primary Reviewer 4 COI signed	08/23/14	10/14/14
3. Peer Review Meeting	Primary Reviewer 1 critique submitted	09/27/14	10/14/14
	Primary (Advocate) Reviewer 2 critique submitted	09/27/14	10/14/14
	Primary Reviewer 3 critique submitted	10/01/14	10/14/14
	Primary Reviewer 4 critique submitted	10/01/14	10/14/14
	COI indicated by non-primary reviewer	NONE	10/14/14
	COI recused from participation	N/A	10/14/14
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	Third Party Observer Report	10/21/14	10/28/14
	Recommended for grant award	YES	10/28/14
	PDRC Chair Notification to PIC and OC	10/28/14	10/28/14
5. PIC Review	COI indicated by PIC member	NONE	11/04/14
	COI recused from participation	N/A	11/04/14
	PIC review meeting	11/04/14	11/04/14
	Recommended for grant award	YES	11/04/14
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 & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application DP150069
Early Translational Research Awards

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 the *Early Translational Research Awards* Request for Applications (RFA). CPRIT received 46 applications for this RFA. 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:

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- A de-identified list of the overall evaluation scores for applications submitted pursuant to the applicable RFA for this grant cycle
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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 FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).


Dr. Lakey was called away on important state business that conflicted with the meeting of the PIC. The remaining members of the PIC unanimously approved a motion to excuse his absence.

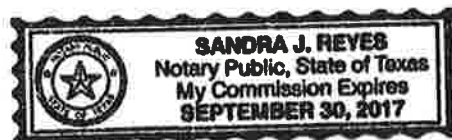
I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process 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 November, 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 2015
CYCLE 2
PROGRAM Product Development
AWARD MECHANISM Bridging the Gap: Early Translational Research Awards (ETRA)
APPLICATION ID DP150069
APPLICATION TITLE Oral Stat3 Inhibitor as Targeted Treatment for Triple-Negative Breast Cancer
APPLICANT NAME Tweardy, David
ORGANIZATION Baylor College of Medicine
PANEL NAME 15.2 Product Development Panel-1 (15.2 PDP-1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	06/27/14	10/14/14
	CPRIT Application Receipt System (CARS) opened	06/26/14	10/14/14
	CPRIT Application Receipt System (CARS) closed	08/07/14	10/14/14
	Date application submitted	08/06/14	10/14/14
	Method of submission	CARS	10/14/14
	Within receipt period	YES	10/14/14
	Appeal to submit application after CARS closed	N/A	10/14/14
	Appeal for late application submission accepted	N/A	10/14/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	10/14/14
	Donation(s) made to CPRIT/foundation	NO	10/14/14
	Assigned to primary reviewers	08/31/14	10/14/14
	Applicant notified of review panel assignment	09/30/14	10/14/14
	Primary Reviewer 1 COI signed	08/28/14	10/14/14
	Primary (Advocate) Reviewer 2 COI signed	08/20/14	10/14/14
	Primary Reviewer 3 COI signed	08/26/14	10/14/14
	Primary Reviewer 4 COI signed	08/23/14	10/14/14
3. Peer Review Meeting	Primary Reviewer 1 critique submitted	10/05/14	10/14/14
	Primary (Advocate) Reviewer 2 critique submitted	10/01/14	10/14/14
	Primary Reviewer 3 critique submitted	10/05/14	10/14/14
	Primary Reviewer 4 critique submitted	10/02/14	10/14/14
	COI indicated by non-primary reviewer	NONE	10/14/14
	COI recused from participation	N/A	10/14/14
	Peer Review Meeting	10/07/14	10/14/14
	Discussed at Peer Review Meeting	YES	10/14/14
	Post review statements signed	10/22/14	10/28/14
	Third Party Observer Report	10/10/14	10/15/14
	Score report delivered to CPDO	10/28/14	10/28/14
	Recommended for PDRC Review	YES	10/14/14
4. Final PDRC Recommendation	COI indicated by PDRC member	NONE	10/28/14
	COI recused from participation	N/A	10/28/14
	PDRC Meeting	10/20/14	10/14/14
	Third Party Observer Report	10/21/14	10/28/14
	Recommended for grant award	YES	10/28/14
	PDRC Chair Notification to PIC and OC	10/28/14	10/28/14
5. PIC Review	COI indicated by PIC member	NONE	11/04/14
	COI recused from participation	N/A	11/04/14
	PIC review meeting	11/04/14	11/04/14
	Recommended for grant award	YES	11/04/14
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 & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application DP150074
Early Translational Research Awards

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 the *Early Translational Research Awards* Request for Applications (RFA). CPRIT received 46 applications for this RFA. 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 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 FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

Dr. Lakey was called away on important state business that conflicted with the meeting of the PIC. The remaining members of the PIC unanimously approved a motion to excuse his absence.

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."



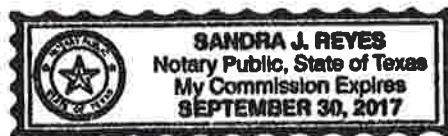
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 1st day of November, 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 2015
CYCLE 2
PROGRAM Product Development
AWARD MECHANISM Bridging the Gap: Early Translational Research Awards (ETRA)
APPLICATION ID DP150074
APPLICATION TITLE Inhibitors of Hydrogen Sulfide Biosynthesis: Preclinical Development of Novel Colorectal Cancer Therapies
APPLICANT NAME Hellmich, Mark
ORGANIZATION The University of Texas Medical Branch at Galveston
PANEL NAME 15.2 Product Development Panel-1 (15.2 PDP-1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	06/27/14	10/14/14
	CPRIT Application Receipt System (CARS) opened	06/26/14	10/14/14
	CPRIT Application Receipt System (CARS) closed	08/07/14	10/14/14
	Date application submitted	08/06/14	10/14/14
	Method of submission	CARS	10/14/14
	Within receipt period	YES	10/14/14
	Appeal to submit application after CARS closed	N/A	10/14/14
	Appeal for late application submission accepted	N/A	10/14/14
2. Receipt, Referral, and Assignment	Administrative review notification	09/02/14	10/14/14
	Donation(s) made to CPRIT/foundation	NO	10/14/14
	Assigned to primary reviewers	08/31/14	10/14/14
	Applicant notified of review panel assignment	09/30/14	10/14/14
	Primary Reviewer 1 COI signed	08/23/14	10/14/14
	Primary (Advocate) Reviewer 2 COI signed	08/26/14	10/14/14
	Primary Reviewer 3 COI signed	08/27/14	10/14/14
	Primary Reviewer 4 COI signed	08/28/14	10/14/14
3. Peer Review Meeting	Primary Reviewer 1 critique submitted	10/05/14	10/14/14
	Primary (Advocate) Reviewer 2 critique submitted	10/05/14	10/14/14
	Primary Reviewer 3 critique submitted	10/05/14	10/14/14
	Primary Reviewer 4 critique submitted	10/05/14	10/14/14
	COI indicated by non-primary reviewer	Jones, Elaine	10/14/14
	COI recused from participation	YES	10/14/14
	Peer Review Meeting	10/07/14	10/14/14
	Discussed at Peer Review Meeting	YES	10/14/14
	Post review statements signed	10/22/14	10/28/14
	Third Party Observer Report	10/10/14	10/15/14
	Score report delivered to CPDO	10/28/14	10/28/14
4. Final PDRC Recommendation	Recommended for PDRC Review	YES	10/14/14
	COI indicated by PDRC member	NONE	10/28/14
	COI recused from participation	N/A	10/28/14
	PDRC Meeting	10/20/14	10/14/14
	Third Party Observer Report	10/21/14	10/28/14
	Recommended for grant award	YES	10/28/14
5. PIC Review	PDRC Chair Notification to PIC and OC	10/28/14	10/28/14
	COI indicated by PIC member	NONE	11/04/14
	COI recused from participation	N/A	11/04/14
	PIC review meeting	11/04/14	11/04/14
6. Oversight Committee Approval	Recommended for grant award	YES	11/04/14
	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

CEO AFFIDAVIT
Application DP150077
Early Translational Research Awards

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 the *Early Translational Research Awards* Request for Applications (RFA). CPRIT received 46 applications for this RFA. 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 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 FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

Dr. Lakey was called away on important state business that conflicted with the meeting of the PIC. The remaining members of the PIC unanimously approved a motion to excuse his absence.

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."



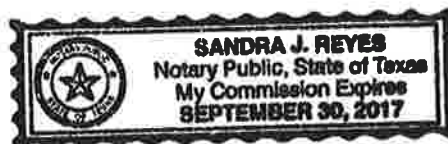
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 4th day of November, 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 2015
 CYCLE 2
 PROGRAM Product Development
 AWARD MECHANISM Bridging the Gap: Early Translational Research Awards (ETRA)
 APPLICATION ID DP150077
 APPLICATION TITLE Targeting the SWI/SNF Chromatin-Remodeling Complex in Liver Cirrhosis and Hepatocellular Carcinoma
 APPLICANT NAME Zhu, Hao
 ORGANIZATION The University of Texas Southwestern Medical Center
 PANEL NAME 15.2 Product Development Panel-1 (15.2 PDP-1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	06/27/14	10/14/14
	CPRIT Application Receipt System (CARS) opened	06/26/14	10/14/14
	CPRIT Application Receipt System (CARS) closed	08/07/14	10/14/14
	Date application submitted	08/07/14	10/14/14
	Method of submission	CARS	10/14/14
	Within receipt period	YES	10/14/14
	Appeal to submit application after CARS closed	N/A	10/14/14
	Appeal for late application submission accepted	N/A	10/14/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	10/14/14
	Donation(s) made to CPRIT/foundation	NO	10/14/14
	Assigned to primary reviewers	08/31/14	10/14/14
	Applicant notified of review panel assignment	09/30/14	10/14/14
	Primary Reviewer 1 COI signed	08/20/14	10/14/14
	Primary (Advocate) Reviewer 2 COI signed	08/20/14	10/14/14
	Primary Reviewer 3 COI signed	08/27/14	10/14/14
3. Peer Review Meeting	Primary Reviewer 4 COI signed	08/24/14	10/14/14
	Primary Reviewer 1 critique submitted	09/29/14	10/14/14
	Primary (Advocate) Reviewer 2 critique submitted	10/01/14	10/14/14
	Primary Reviewer 3 critique submitted	10/04/14	10/14/14
	Primary Reviewer 4 critique submitted	10/04/14	10/14/14
	COI indicated by non-primary reviewer	NONE	10/14/14
	COI recused from participation	N/A	10/14/14
	Peer Review Meeting	10/07/14	10/14/14
	Discussed at Peer Review Meeting	YES	10/14/14
	Post review statements signed	10/22/14	10/28/14
	Third Party Observer Report	10/10/14	10/15/14
	Score report delivered to CPDO	10/28/14	10/28/14
4. Final PDRC Recommendation	Recommended for PDRC Review	YES	10/14/14
	COI indicated by PDRC member	NONE	10/28/14
	COI recused from participation	N/A	10/28/14
	PDRC Meeting	10/20/14	10/14/14
	Third Party Observer Report	10/21/14	10/28/14
	Recommended for grant award	YES	10/28/14
5. PIC Review	PDRC Chair Notification to PIC and OC	10/28/14	10/28/14
	COI indicated by PIC member	NONE	11/04/14
	COI recused from participation	N/A	11/04/14
	PIC review meeting	11/04/14	11/04/14
6. Oversight Committee Approval	Recommended for grant award	YES	11/04/14
	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

CEO AFFIDAVIT
Application DP150083
Early Translational Research Awards

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 the *Early Translational Research Awards* Request for Applications (RFA). CPRIT received 46 applications for this RFA. 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 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 FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).


Dr. Lakey was called away on important state business that conflicted with the meeting of the PIC. The remaining members of the PIC unanimously approved a motion to excuse his absence.

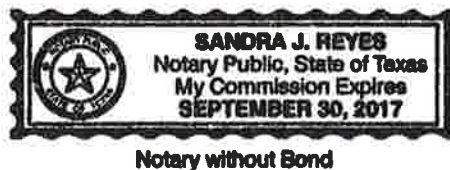
I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process 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 November, 2014,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2015
CYCLE 2
PROGRAM Product Development
AWARD MECHANISM Bridging the Gap: Early Translational Research Awards (ETRA)
APPLICATION ID DP150083
APPLICATION TITLE NKT Cell Platform for Cancer Immunotherapy
APPLICANT NAME Metelitsa, Leonid
ORGANIZATION Baylor College of Medicine
PANEL NAME 15.2 Product Development Panel-1 (15.2 PDP-1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	06/27/14	10/14/14
	CPRIT Application Receipt System (CARS) opened	06/26/14	10/14/14
	CPRIT Application Receipt System (CARS) closed	08/07/14	10/14/14
	Date application submitted	08/01/14	10/14/14
	Method of submission	CARS	10/14/14
	Within receipt period	YES	10/14/14
	Appeal to submit application after CARS closed	N/A	10/14/14
	Appeal for late application submission accepted	N/A	10/14/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	10/14/14
	Donation(s) made to CPRIT/foundation	NO	10/14/14
	Assigned to primary reviewers	08/31/14	10/14/14
	Applicant notified of review panel assignment	09/30/14	10/14/14
	Primary Reviewer 1 COI signed	08/27/14	10/14/14
	Primary (Advocate) Reviewer 2 COI signed	08/26/14	10/14/14
	Primary Reviewer 3 COI signed	08/20/14	10/14/14
	Primary Reviewer 4 COI signed	08/24/14	10/14/14
3. Peer Review Meeting	Primary Reviewer 1 critique submitted	09/20/14	10/14/14
	Primary (Advocate) Reviewer 2 critique submitted	10/05/14	10/14/14
	Primary Reviewer 3 critique submitted	09/29/14	10/14/14
	Primary Reviewer 4 critique submitted	10/05/14	10/14/14
	COI indicated by non-primary reviewer	NONE	10/14/14
	COI recused from participation	N/A	10/14/14
	Peer Review Meeting	10/07/14	10/14/14
	Discussed at Peer Review Meeting	YES	10/14/14
	Post review statements signed	10/22/14	10/28/14
	Third Party Observer Report	10/10/14	10/15/14
	Score report delivered to CPDO	10/28/14	10/28/14
	Recommended for PDRC Review	YES	10/14/14
4. Final PDRC Recommendation	COI indicated by PDRC member	NONE	10/28/14
	COI recused from participation	N/A	10/28/14
	PDRC Meeting	10/20/14	10/14/14
	Third Party Observer Report	10/21/14	10/28/14
	Recommended for grant award	YES	10/28/14
	PDRC Chair Notification to PIC and OC	10/28/14	10/28/14
5. PIC Review	COI indicated by PIC member	NONE	11/04/14
	COI recused from participation	N/A	11/04/14
	PIC review meeting	11/04/14	11/04/14
	Recommended for grant award	YES	11/04/14
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 & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application DP150086
Early Translational Research Awards

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 the *Early Translational Research Awards* Request for Applications (RFA). CPRIT received 46 applications for this RFA. 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 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 FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).


Dr. Lakey was called away on important state business that conflicted with the meeting of the PIC. The remaining members of the PIC unanimously approved a motion to excuse his absence.

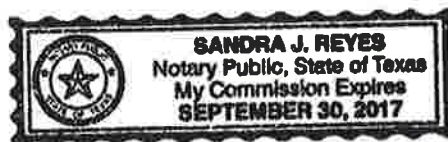
I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process 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 November, 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 2015
CYCLE 2
PROGRAM Product Development
AWARD MECHANISM Bridging the Gap: Early Translational Research Awards (ETRA)
APPLICATION ID DP150086
APPLICATION TITLE Therapeutic Targeting of Skp2/Ck1 to Restore Nuclear p27
APPLICANT NAME Walker, Cheryl
ORGANIZATION Texas A&M University System Health Science Center
PANEL NAME 15.2 Product Development Panel-2 (15.2 PDP-2)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	06/27/14	10/14/14
	CPRIT Application Receipt System (CARS) opened	06/26/14	10/14/14
	CPRIT Application Receipt System (CARS) closed	08/07/14	10/14/14
	Date application submitted	08/07/14	10/14/14
	Method of submission	CARS	10/14/14
	Within receipt period	YES	10/14/14
	Appeal to submit application after CARS closed	N/A	10/14/14
	Appeal for late application submission accepted	N/A	10/14/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	10/14/14
	Donation(s) made to CPRIT/foundation	NO	10/14/14
	Assigned to primary reviewers	08/31/14	10/14/14
	Applicant notified of review panel assignment	09/30/14	10/14/14
	Primary Reviewer 1 COI signed	08/23/14	10/14/14
	Primary (Advocate) Reviewer 2 COI signed	09/12/14	10/14/14
	Primary Reviewer 3 COI signed	08/25/14	10/14/14
	Primary Reviewer 4 COI signed	08/20/14	10/14/14
3. Peer Review Meeting	Primary Reviewer 1 critique submitted	09/10/14	10/14/14
	Primary (Advocate) Reviewer 2 critique submitted	10/05/14	10/14/14
	Primary Reviewer 3 critique submitted	10/05/14	10/14/14
	Primary Reviewer 4 critique submitted	09/26/14	10/14/14
	COI indicated by non-primary reviewer	NONE	10/14/14
	COI recused from participation	N/A	10/14/14
	Peer Review Meeting	10/08/14	10/14/14
	Discussed at Peer Review Meeting	YES	10/14/14
	Post review statements signed	10/13/14	10/28/14
	Third Party Observer Report	10/09/14	10/15/14
	Score report delivered to CPDO	10/28/14	10/28/14
	Recommended for PDRC Review	YES	10/14/14
4. Final PDRC Recommendation	COI indicated by PDRC member	NONE	10/28/14
	COI recused from participation	N/A	10/28/14
	PDRC Meeting	10/20/14	10/14/14
	Third Party Observer Report	10/21/14	10/28/14
	Recommended for grant award	YES	10/28/14
	PDRC Chair Notification to PIC and OC	10/28/14	10/28/14
5. PIC Review	COI indicated by PIC member	NONE	11/04/14
	COI recused from participation	N/A	11/04/14
	PIC review meeting	11/04/14	11/04/14
	Recommended for grant award	YES	11/04/14
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 & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application DP150087
Early Translational Research Awards

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 the *Early Translational Research Awards* Request for Applications (RFA). CPRIT received 46 applications for this RFA. 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 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 FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

Dr. Lakey was called away on important state business that conflicted with the meeting of the PIC. The remaining members of the PIC unanimously approved a motion to excuse his absence.

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."



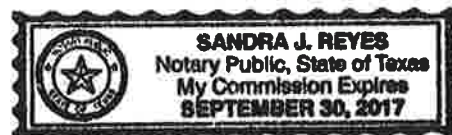
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 4th day of November, 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 2015
CYCLE 2
PROGRAM Product Development
AWARD MECHANISM Bridging the Gap: Early Translational Research Awards (ETRA)
APPLICATION ID DP150087
APPLICATION TITLE Pre-IND Development of OxaliTex
APPLICANT NAME Sessler, Jonathan
ORGANIZATION The University of Texas at Austin
PANEL NAME 15.2 Product Development Panel-1 (15.2 PDP-1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	06/27/14	10/14/14
	CPRIT Application Receipt System (CARS) opened	06/26/14	10/14/14
	CPRIT Application Receipt System (CARS) closed	08/07/14	10/14/14
	Date application submitted	08/07/14	10/14/14
	Method of submission	CARS	10/14/14
	Within receipt period	YES	10/14/14
	Appeal to submit application after CARS closed	N/A	10/14/14
	Appeal for late application submission accepted	N/A	10/14/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	10/14/14
	Donation(s) made to CPRIT/foundation	NO	10/14/14
	Assigned to primary reviewers	08/31/14	10/14/14
	Applicant notified of review panel assignment	09/30/14	10/14/14
	Primary Reviewer 1 COI signed	08/27/14	10/14/14
	Primary (Advocate) Reviewer 2 COI signed	08/22/14	10/14/14
	Primary Reviewer 3 COI signed	08/24/14	10/14/14
	Primary Reviewer 4 COI signed	08/20/14	10/14/14
3. Peer Review Meeting	Primary Reviewer 1 critique submitted	10/02/14	10/14/14
	Primary (Advocate) Reviewer 2 critique submitted	10/06/14	10/14/14
	Primary Reviewer 3 critique submitted	10/06/14	10/14/14
	Primary Reviewer 4 critique submitted	09/24/14	10/14/14
	COI indicated by non-primary reviewer	NONE	10/14/14
	COI recused from participation	N/A	10/14/14
	Peer Review Meeting	10/07/14	10/14/14
	Discussed at Peer Review Meeting	YES	10/14/14
	Post review statements signed	10/22/14	10/28/14
	Third Party Observer Report	10/10/14	10/15/14
	Score report delivered to CPDO	10/28/14	10/28/14
	Recommended for PDRC Review	YES	10/14/14
4. Final PDRC Recommendation	COI indicated by PDRC member	NONE	10/28/14
	COI recused from participation	N/A	10/28/14
	PDRC Meeting	10/20/14	10/14/14
	Third Party Observer Report	10/21/14	10/28/14
	Recommended for grant award	YES	10/28/14
	PDRC Chair Notification to PIC and OC	10/28/14	10/28/14
5. PIC Review	COI indicated by PIC member	NONE	11/04/14
	COI recused from participation	N/A	11/04/14
	PIC review meeting	11/04/14	11/04/14
	Recommended for grant award	YES	11/04/14
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 & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application DP150091
Early Translational Research Awards

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 the *Early Translational Research Awards* Request for Applications (RFA). CPRIT received 46 applications for this RFA. 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:

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- 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 FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

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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

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the 4th day of November, 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 2015
CYCLE 2
PROGRAM Product Development
AWARD MECHANISM Bridging the Gap: Early Translational Research Awards (ETRA)
APPLICATION ID DP150091
APPLICATION TITLE Selective Tumor Delivery of Anti-Cancer Agents in Ovarian Cancer Therapy
APPLICANT NAME Lacko, Andras
ORGANIZATION University of North Texas Health Science Center at Fort Worth
PANEL NAME 15.2 Product Development Panel-2 (15.2 PDP-2)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	06/27/14	10/14/14
	CPRIT Application Receipt System (CARS) opened	06/26/14	10/14/14
	CPRIT Application Receipt System (CARS) closed	08/07/14	10/14/14
	Date application submitted	08/06/14	10/14/14
	Method of submission	CARS	10/14/14
	Within receipt period	YES	10/14/14
	Appeal to submit application after CARS closed	N/A	10/14/14
	Appeal for late application submission accepted	N/A	10/14/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	10/14/14
	Donation(s) made to CPRIT/foundation	NO	10/14/14
	Assigned to primary reviewers	08/31/14	10/14/14
	Applicant notified of review panel assignment	09/30/14	10/14/14
	Primary Reviewer 1 COI signed	08/21/14	10/14/14
	Primary (Advocate) Reviewer 2 COI signed	08/20/14	10/14/14
	Primary Reviewer 3 COI signed	08/21/14	10/14/14
	Primary Reviewer 4 COI signed	08/21/14	10/14/14
3. Peer Review Meeting	Primary Reviewer 1 critique submitted	10/05/14	10/14/14
	Primary (Advocate) Reviewer 2 critique submitted	09/30/14	10/14/14
	Primary Reviewer 3 critique submitted	10/03/14	10/14/14
	Primary Reviewer 4 critique submitted	10/01/14	10/14/14
	COI indicated by non-primary reviewer	NONE	10/14/14
	COI recused from participation	N/A	10/14/14
	Peer Review Meeting	10/08/14	10/14/14
	Discussed at Peer Review Meeting	YES	10/14/14
	Post review statements signed	10/13/14	10/28/14
	Third Party Observer Report	10/09/14	10/15/14
	Score report delivered to CPDO	10/28/14	10/28/14
	Recommended for PDRC Review	YES	10/14/14
4. Final PDRC Recommendation	COI indicated by PDRC member	NONE	10/28/14
	COI recused from participation	N/A	10/28/14
	PDRC Meeting	10/20/14	10/14/14
	Third Party Observer Report	10/21/14	10/28/14
	Recommended for grant award	YES	10/28/14
	PDRC Chair Notification to PIC and OC	10/28/14	10/28/14
5. PIC Review	COI indicated by PIC member	NONE	11/04/14
	COI recused from participation	N/A	11/04/14
	PIC review meeting	11/04/14	11/04/14
	Recommended for grant award	YES	11/04/14
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 & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application DP150093
Early Translational Research Awards

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:

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State of Texas
County of Travis

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Sandra Reyes
Notary Public, State of Texas



Notary without Bond

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2015
CYCLE 2
PROGRAM Product Development
AWARD MECHANISM Bridging the Gap: Early Translational Research Awards (ETRA)
APPLICATION ID DP150093
APPLICATION TITLE Targeting an Elusive Foe: Development of K-Ras Inhibitors
APPLICANT NAME Gorfe, Alemayehu
ORGANIZATION The University of Texas Health Science Center at Houston
PANEL NAME 15.2 Product Development Panel-2 (15.2 PDP-2)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	06/27/14	10/14/14
	CPRIT Application Receipt System (CARS) opened	06/26/14	10/14/14
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	Method of submission	CARS	10/14/14
	Within receipt period	YES	10/14/14
	Appeal to submit application after CARS closed	N/A	10/14/14
	Appeal for late application submission accepted	N/A	10/14/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	10/14/14
	Donation(s) made to CPRIT/foundation	NO	10/14/14
	Assigned to primary reviewers	08/31/14	10/14/14
	Applicant notified of review panel assignment	09/30/14	10/14/14
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	Primary Reviewer 3 critique submitted	09/26/14	10/14/14
	Primary Reviewer 4 critique submitted	10/05/14	10/14/14
	COI indicated by non-primary reviewer	NONE	10/14/14
	COI recused from participation	N/A	10/14/14
	Peer Review Meeting	10/08/14	10/14/14
	Discussed at Peer Review Meeting	YES	10/14/14
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	Third Party Observer Report	10/09/14	10/15/14
	Score report delivered to CPDO	10/28/14	10/28/14
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	COI recused from participation	N/A	10/28/14
	PDRC Meeting	10/20/14	10/14/14
	Third Party Observer Report	10/21/14	10/28/14
	Recommended for grant award	YES	10/28/14
5. PIC Review	PDRC Chair Notification to PIC and OC	10/28/14	10/28/14
	COI indicated by PIC member	NONE	11/04/14
	COI recused from participation	N/A	11/04/14
	PIC review meeting	11/04/14	11/04/14
6. Oversight Committee Approval	Recommended for grant award	YES	11/04/14
	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

CEO AFFIDAVIT
Application DP150094
Early Translational Research Awards

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 the *Early Translational Research Awards* Request for Applications (RFA). CPRIT received 46 applications for this RFA. 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 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 FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). As required by the terms of the FY2015 waiver, Dr. Kripke abstained from voting on this application during the PIC meeting. At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).


Dr. Lakey was called away on important state business that conflicted with the meeting of the PIC. The remaining members of the PIC unanimously approved a motion to excuse his absence.

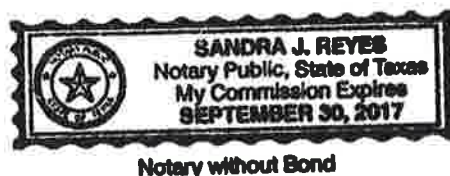
I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process 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 November, 2014,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2015
CYCLE 2
PROGRAM Product Development
AWARD MECHANISM Bridging the Gap: Early Translational Research Awards (ETRA)
APPLICATION ID DP150094
APPLICATION TITLE Genetic Engineering of T Cells as an "Off-the-Shelf" Therapy for Leukemias and Lymphomas
APPLICANT NAME Cooper, Laurence
ORGANIZATION The University of Texas M. D. Anderson Cancer Center
PANEL NAME 15.2 Product Development Panel-1 (15.2 PDP-1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	06/27/14	10/14/14
	CPRIT Application Receipt System (CARS) opened	06/26/14	10/14/14
	CPRIT Application Receipt System (CARS) closed	08/07/14	10/14/14
	Date application submitted	08/07/14	10/14/14
	Method of submission	CARS	10/14/14
	Within receipt period	YES	10/14/14
	Appeal to submit application after CARS closed	N/A	10/14/14
	Appeal for late application submission accepted	N/A	10/14/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	10/14/14
	Donation(s) made to CPRIT/foundation	NO	10/14/14
	Assigned to primary reviewers	08/31/14	10/14/14
	Applicant notified of review panel assignment	09/30/14	10/14/14
	Primary Reviewer 1 COI signed	08/20/14	10/14/14
	Primary (Advocate) Reviewer 2 COI signed	08/22/14	10/14/14
	Primary Reviewer 3 COI signed	08/27/14	10/14/14
	Primary Reviewer 4 COI signed	08/26/14	10/14/14
3. Peer Review Meeting	Primary Reviewer 1 critique submitted	09/29/14	10/14/14
	Primary (Advocate) Reviewer 2 critique submitted	10/06/14	10/14/14
	Primary Reviewer 3 critique submitted	10/03/14	10/14/14
	Primary Reviewer 4 critique submitted	10/05/14	10/14/14
	COI indicated by non-primary reviewer	DuBois, Ray	10/14/14
	COI recused from participation	YES	10/14/14
	Peer Review Meeting	10/07/14	10/14/14
	Discussed at Peer Review Meeting	YES	10/14/14
	Post review statements signed	10/22/14	10/28/14
	Third Party Observer Report	10/10/14	10/15/14
	Score report delivered to CPDO	10/28/14	10/28/14
	Recommended for PDRC Review	YES	10/14/14
4. Final PDRC Recommendation	COI indicated by PDRC member	NONE	10/28/14
	COI recused from participation	N/A	10/28/14
	PDRC Meeting	10/20/14	10/14/14
	Third Party Observer Report	10/21/14	10/28/14
	Recommended for grant award	YES	10/28/14
	PDRC Chair Notification to PIC and OC	10/28/14	10/28/14
5. PIC Review	COI indicated by PIC member	NONE	11/04/14
	COI recused from participation*	M. Kripke	11/04/14
	PIC review meeting	11/04/14	11/04/14
	Recommended for grant award	YES	11/04/14
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	

*Dr. Margaret Kripke abstained from voting. Dr. Kripke has an approved COI waiver on file for FY2015 regarding M.D. Anderson applications. The COI is waived; however, the terms of Dr. Kripke's FY2015 waiver require her to abstain from voting on M.D. Anderson applications.

The identity of the attesting party is retained by CPRIT.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application DP150096
Early Translational Research Awards

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 the *Early Translational Research Awards* Request for Applications (RFA). CPRIT received 46 applications for this RFA. 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 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 FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

Dr. Lakey was called away on important state business that conflicted with the meeting of the PIC. The remaining members of the PIC unanimously approved a motion to excuse his absence.

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 November, 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 2015
CYCLE 2
PROGRAM Product Development
AWARD MECHANISM Bridging the Gap: Early Translational Research Awards (ETRA)
APPLICATION ID DP150096
APPLICATION TITLE ESR1 Coregulator Binding Site Inhibitors (ECBIs) as Novel Therapeutics to Target Hormone Therapy Resistant Metastatic Breast Cancer
APPLICANT NAME Vadlamudi, Ratna
ORGANIZATION The University of Texas Health Science Center at San Antonio
PANEL NAME 15.2 Product Development Panel-1 (15.2 PDP-1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	06/27/14	10/14/14
	CPRIT Application Receipt System (CARS) opened	06/26/14	10/14/14
	CPRIT Application Receipt System (CARS) closed	08/07/14	10/14/14
	Date application submitted	08/07/14	10/14/14
	Method of submission	CARS	10/14/14
	Within receipt period	YES	10/14/14
	Appeal to submit application after CARS closed	N/A	10/14/14
	Appeal for late application submission accepted	N/A	10/14/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	10/14/14
	Donation(s) made to CPRIT/foundation	NO	10/14/14
	Assigned to primary reviewers	08/31/14	10/14/14
	Applicant notified of review panel assignment	09/30/14	10/14/14
	Primary Reviewer 1 COI signed	08/27/14	10/14/14
	Primary (Advocate) Reviewer 2 COI signed	08/26/14	10/14/14
	Primary Reviewer 3 COI signed	08/27/14	10/14/14
3. Peer Review Meeting	Primary Reviewer 4 COI signed	08/27/14	10/14/14
	Primary Reviewer 1 critique submitted	10/05/14	10/14/14
	Primary (Advocate) Reviewer 2 critique submitted	10/05/14	10/14/14
	Primary Reviewer 3 critique submitted	10/06/14	10/14/14
	Primary Reviewer 4 critique submitted	10/04/14	10/14/14
	COI indicated by non-primary reviewer	NONE	10/14/14
	COI recused from participation	N/A	10/14/14
	Peer Review Meeting	10/07/14	10/14/14
	Discussed at Peer Review Meeting	YES	10/14/14
	Post review statements signed	10/22/14	10/28/14
	Third Party Observer Report	10/10/14	10/15/14
	Score report delivered to CPDO	10/28/14	10/28/14
4. Final PDRC Recommendation	Recommended for PDRC Review	YES	10/14/14
	COI indicated by PDRC member	NONE	10/28/14
	COI recused from participation	N/A	10/28/14
	PDRC Meeting	10/20/14	10/14/14
	Third Party Observer Report	10/21/14	10/28/14
	Recommended for grant award	YES	10/28/14
5. PIC Review	PDRC Chair Notification to PIC and OC	10/28/14	10/28/14
	COI indicated by PIC member	NONE	11/04/14
	COI recused from participation	N/A	11/04/14
	PIC review meeting	11/04/14	11/04/14
6. Oversight Committee Approval	Recommended for grant award	YES	11/04/14
	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

CEO AFFIDAVIT
Application DP150099
Early Translational Research Awards

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 the *Early Translational Research Awards* Request for Applications (RFA). CPRIT received 46 applications for this RFA. 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 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 FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

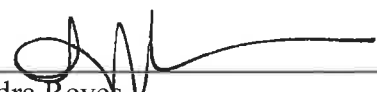
Dr. Lakey was called away on important state business that conflicted with the meeting of the PIC. The remaining members of the PIC unanimously approved a motion to excuse his absence.

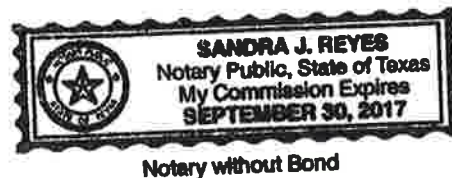
I personally reviewed the information for the grant application listed above and referenced herein. Based upon my review of the information and to the best of my knowledge, I swear or affirm that the peer review process for the grant application was consistent, in all material aspects, with the process 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 November, 2014,
by WAYNE R. ROBERTS.


Sandra Reyes
Notary Public, State of Texas



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
APPLICATION PEDIGREE

FY 2015
CYCLE 2
PROGRAM Product Development
AWARD MECHANISM Bridging the Gap: Early Translational Research Awards (ETRA)
APPLICATION ID DP150099
APPLICATION TITLE Immunotherapy Targeting Triple Negative Breast Cancer Using NY-ESO-1-Specific TCRs and Blockade of Immune Suppression
APPLICANT NAME Wang, Rongfu
ORGANIZATION The Methodist Hospital Research Institute
PANEL NAME 15.2 Product Development Panel-2 (15.2 PDP-2)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	06/27/14	10/14/14
	CPRIT Application Receipt System (CARS) opened	06/26/14	10/14/14
	CPRIT Application Receipt System (CARS) closed	08/07/14	10/14/14
	Date application submitted	08/07/14	10/14/14
	Method of submission	CARS	10/14/14
	Within receipt period	YES	10/14/14
	Appeal to submit application after CARS closed	N/A	10/14/14
	Appeal for late application submission accepted	N/A	10/14/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	10/14/14
	Donation(s) made to CPRIT/foundation	NO	10/14/14
	Assigned to primary reviewers	08/31/14	10/14/14
	Applicant notified of review panel assignment	09/30/14	10/14/14
	Primary Reviewer 1 COI signed	08/28/14	10/14/14
	Primary (Advocate) Reviewer 2 COI signed	09/12/14	10/14/14
	Primary Reviewer 3 COI signed	08/21/14	10/14/14
	Primary Reviewer 4 COI signed	08/27/14	10/14/14
3. Peer Review Meeting	Primary Reviewer 1 critique submitted	10/06/14	10/14/14
	Primary (Advocate) Reviewer 2 critique submitted	10/05/14	10/14/14
	Primary Reviewer 3 critique submitted	10/05/14	10/14/14
	Primary Reviewer 4 critique submitted	10/05/14	10/14/14
	COI indicated by non-primary reviewer	NONE	10/14/14
	COI recused from participation	N/A	10/14/14
	Peer Review Meeting	10/08/14	10/14/14
	Discussed at Peer Review Meeting	YES	10/14/14
	Post review statements signed	10/13/14	10/28/14
	Third Party Observer Report	10/09/14	10/15/14
	Score report delivered to CPDO	10/28/14	10/28/14
	Recommended for PDRC Review	YES	10/14/14
4. Final PDRC Recommendation	COI indicated by PDRC member	NONE	10/28/14
	COI recused from participation	N/A	10/28/14
	PDRC Meeting	10/20/14	10/14/14
	Third Party Observer Report	10/21/14	10/28/14
	Recommended for grant award	YES	10/28/14
	PDRC Chair Notification to PIC and OC	10/28/14	10/28/14
5. PIC Review	COI indicated by PIC member	NONE	11/04/14
	COI recused from participation	N/A	11/04/14
	PIC review meeting	11/04/14	11/04/14
	Recommended for grant award	YES	11/04/14
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 & RESEARCH
INSTITUTE OF TEXAS

CEO AFFIDAVIT
Application DP150102
Early Translational Research Awards

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 the *Early Translational Research Awards* Request for Applications (RFA). CPRIT received 46 applications for this RFA. 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 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 FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(3). At the time of signing this affidavit, the Oversight Committee has not yet reviewed the application; however, I note that member Will Montgomery also has a conflict of interest waiver on file for FY2015 applicable to the conflict of interest specified by V.T.C.A., Health & Safety Code § 102.106(c)(4).

Dr. Lakey was called away on important state business that conflicted with the meeting of the PIC. The remaining members of the PIC unanimously approved a motion to excuse his absence.


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."



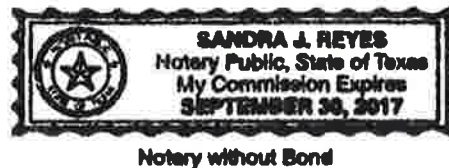
Wayne R. Roberts,
CEO, Cancer Prevention and Research Institute of Texas

State of Texas
County of Travis

SWORN to and SUBSCRIBED before me, the undersigned authority, on
the 4th day of November, 2014,
by WAYNE R. ROBERTS.



Sandra Reyes
Notary Public, State of Texas



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

APPLICATION PEDIGREE

FY 2015
 CYCLE 2
 PROGRAM Product Development
 AWARD MECHANISM Bridging the Gap: Early Translational Research Awards (ETRA)
 APPLICATION ID DP150102
 APPLICATION TITLE Image-Guided Smart Laser Knife for Cancer Surgery
 APPLICANT NAME Milner, Thomas
 ORGANIZATION The University of Texas at Austin
 PANEL NAME 15.2 Product Development Panel-1 (15.2 PDP-1)

Category	Compliance Requirement	Information	Attestation Date
1. Pre-Receipt	RFA published in Texas Register	06/27/14	10/14/14
	CPRIT Application Receipt System (CARS) opened	06/26/14	10/14/14
	CPRIT Application Receipt System (CARS) closed	08/07/14	10/14/14
	Date application submitted	08/07/14	10/14/14
	Method of submission	CARS	10/14/14
	Within receipt period	YES	10/14/14
	Appeal to submit application after CARS closed	N/A	10/14/14
	Appeal for late application submission accepted	N/A	10/14/14
2. Receipt, Referral, and Assignment	Administrative review notification	N/A	10/14/14
	Donation(s) made to CPRIT/foundation	NO	10/14/14
	Assigned to primary reviewers	08/31/14	10/14/14
	Applicant notified of review panel assignment	09/30/14	10/14/14
	Primary Reviewer 1 COI signed	08/26/14	10/14/14
	Primary (Advocate) Reviewer 2 COI signed	08/26/14	10/14/14
	Primary Reviewer 3 COI signed	08/20/14	10/14/14
3. Peer Review Meeting	Primary Reviewer 4 COI signed	08/27/14	10/14/14
	Primary Reviewer 1 critique submitted	10/05/14	10/14/14
	Primary (Advocate) Reviewer 2 critique submitted	10/05/14	10/14/14
	Primary Reviewer 3 critique submitted	10/01/14	10/14/14
	Primary Reviewer 4 critique submitted	09/20/14	10/14/14
	COI indicated by non-primary reviewer	NONE	10/14/14
	COI recused from participation	N/A	10/14/14
	Peer Review Meeting	10/07/14	10/14/14
	Discussed at Peer Review Meeting	YES	10/14/14
	Post review statements signed	10/22/14	10/28/14
	Third Party Observer Report	10/10/14	10/15/14
	Score report delivered to CPDO	10/28/14	10/28/14
4. Final PDRC Recommendation	Recommended for PDRC Review	YES	10/14/14
	COI indicated by PDRC member	NONE	10/28/14
	COI recused from participation	N/A	10/28/14
	PDRC Meeting	10/20/14	10/14/14
	Third Party Observer Report	10/21/14	10/28/14
	Recommended for grant award	YES	10/28/14
5. PIC Review	PDRC Chair Notification to PIC and OC	10/28/14	10/28/14
	COI indicated by PIC member	NONE	11/04/14
	COI recused from participation	N/A	11/04/14
	PIC review meeting	11/04/14	11/04/14
6. Oversight Committee Approval	Recommended for grant award	YES	11/04/14
	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.

Chair Nomination For CPRIT Prevention Review Council



Ross C. Brownson, PhD, is a Professor at Washington University in St. Louis, with appointments in the Brown School and the Alvin J. Siteman Cancer Center. He is involved in numerous community-level studies designed to understand and reduce modifiable risk factors such as physical inactivity, obesity, and tobacco use. In particular, he is interested in the impacts of environmental and policy interventions on health behaviors and he conducts research on dissemination of evidence-based interventions (particularly in policy settings and health departments). His research is supported by the National Institutes of Health, the Centers for Disease Control and Prevention, and the Robert Wood Johnson Foundation. Dr. Brownson is the author of seven books and over 350 peer-reviewed articles. His books include *Chronic Disease Epidemiology and Control*, *Applied Epidemiology*, *Communicating Public Health Information Effectively: A Guide for Practitioners*, *Evidence-Based Public Health*, and *Dissemination and Implementation Research in Health: Translating Science to Practice*. He is associate editor of the *Annual Review of Public Health*, and on the editorial board of five other journals. He is a former and founding member of the 15-person CDC Task Force developing the *Guide to Community Preventive Services*. Dr. Brownson is the recipient of the Award for Excellence in Prevention Research and Research Translation in Chronic Disease (2000, from CDC) and the Abraham Lilienfeld Award for outstanding contributions in teaching and mentoring (2003, from APHA). Prior to joining academe, he was a division director with the Missouri Department of Health. In this capacity he wrote or co-wrote bills on tobacco access to minors, state clean indoor air, and private insurance coverage of screening mammography/Pap testing. Dr. Brownson is active in numerous professional associations, including the American Public Health Association and the Missouri Public Health Association. He is the current President of the American College of Epidemiology.

CURRICULUM VITAE

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Home Address and Phone: 225 Clion Lane
St. Louis, MO 63141
Tel. (314) 275-9497

Date and Place of Birth: September 25, 1957
Grand Junction, Colorado

University Education:

<u>Institution</u>	<u>Degree</u>	<u>Year</u>	<u>Field of Study</u>
University of Montana College of Arts and Sciences Missoula, Montana	B.A. (cum laude)	1979	Cellular Biology/ Chemistry
Colorado State University College of Veterinary Medicine and Biomedical Sciences Fort Collins, Colorado	Ph.D.	1985	Environmental Health/ Epidemiology
Harvard School of Public Health Boston, Massachusetts	--	1998-99	Quantitative Methods

Honors, Awards:

Freshman year: Colorado Scholar's Award (1976)
Junior year: Wallace Scholarship (1978)
Senior year: Watkins Scholarship in conjunction with Senior Honors Program (top university scholarship) (1979)
Graduate school: NIH Biomedical Research Support Grant; Grant from the American Lung Association of Colorado (1981-1983)
Missouri Arthritis Advisory Board: Distinguished Service Award (1991)
Association of State and Territorial Chronic Disease Program Directors: Outstanding Leadership Award (1994)
Association of State and Territorial Chronic Disease Program Directors: Award for Excellence in Chronic Disease Prevention and Control (1994)

Missouri Public Health Association: Publication Award (1994 and 2002)
 Colorado State University Honor Alumnus (1997)
 Inducted, Delta Omega, Alpha Delta Chapter (1998)
 Visiting Professor, Bohan Lecture, University of Kansas Department of Preventive Medicine (1999)
 Award for Excellence in Prevention Research and Research Translation in Chronic Disease, 15th National Conference on Chronic Disease Prevention and Control, CDC and National Prevention Research Centers Program (2000)
 Abraham Lilienfeld Award for excellence in teaching and mentoring, American Public Health Association (2003)
 Visiting Scholar, Faculty of Health Sciences, American University in Beirut (2004)
 Visiting Scholar, DeHaan Lecture, Emory University (2008)
 Langmuir Memorial Lecture, CDC Epidemic Intelligence Service (2008)
 Charles C. Shepard Science Award, the highest CDC award for excellence in science in scientific publication (2009)
 Outstanding Transdisciplinary Scholar, Washington University Institute for Public Health (2011)

University Teaching and Related Experience:

Dates

Faculty and Course Director, Evidence-Based Public Health, Missouri, national, and international versions (5-6 times/annually) (wrote text for course, Oxford Press)	2000-present
Teaching responsibilities in Epidemiology and Public Health, Saint Louis University School of Public Health, Brown School, Washington University (wrote text for applied epidemiology course, Oxford Press)	1994-present
Faculty & national advisory group, Physical Activity and Public Course, University of South Carolina, Hilton Head, SC	1997-present
Co-Coordinator, Tobacco Summer Institute course on surveillance & epidemiology, University of North Carolina, Chapel Hill	1995-1997
Assisting in teaching of Principles of Epidemiology (beginning and advanced courses), University of Missouri School of Medicine	1987-1994
Research Assistant, Department of Environmental Health, Colorado State University	1981-1986
Instructor, Applied Epidemiology and Veterinary Medicine Disease Simulation Courses, Colorado State University	1985-1986
PhD thesis: "The Epidemiology of Lung Cancer in Metropolitan Denver," Colorado State University	1985
Teaching Assistant, Applied Epidemiology, Colorado State University	1982
Senior honors thesis: "The Molecular Basis of Evolution," University of Montana	1978-1979

Professional Experience:

Position

Dates

Professor of Epidemiology (tenured), Brown School,	2008-present
--	--------------

Department of Surgery and Siteman Cancer Center, Washington University School of Medicine, Washington University in St. Louis	
Co-Director, WHO Collaborating Centre for Evidence-Based Chronic Disease Prevention and Control	2005-present
Research Member and Co-Director for Dissemination (-2006), The Siteman Cancer Center at Washington University	1999-present
Professor of Epidemiology (tenured), Department of Community Health, School of Public Health, Saint Louis University	1994-2008
Co-Director, Prevention Research Center in St. Louis	1994-present
Chair, Department of Community Health, School of Public Health Saint Louis University	1994-2006
Director, Division of Epidemiology, School of Public Health, Saint Louis University	1994-2004
Director, Division of Chronic Disease Prevention and Health Promotion, Missouri Department of Health, Columbia	1988-1994
Chief, Bureau of Cancer Epidemiology and Control, Missouri Department of Health	1987-1988
Consultant Epidemiologist, Cancer Epidemiology and Control Program, Missouri Department of Health	1986-1987

Current and Past Professional Service

President, American College of Epidemiology (2013-present)

Member, Dissemination and Implementation Research in Health Review Panel, National Institutes of Health (2010-present); Chair (2011-present)

Associate Editor and Member, Editorial Board, *Translational Behavioral Medicine* (2010-present)

Member, Subcommittee on Action Steps and Evidence for Healthy People 2020 (2010-present)

Chair, Policy Committee, American College of Epidemiology (2009-present)

Fellow and Member, Board of Directors, American College of Epidemiology (2008-present)

Member, National Commission on Prevention Priorities (2007-present)

Member, Awards Committee, American College of Epidemiology (2007-2010)

Member, Review Panel, Centre for Behavioural Research and Program Evaluation, National Cancer Institute of Canada (2007)

Chair, Steering Committee, Prevention Research Centers National Program (CDC) (2007-2008)

Member, ASPH/Pfizer Public Health Academy of Distinguished Teachers (2007-present)

Member, Editorial Board, *Journal of Public Health Management and Practice* (2007-present)

Member, ASPH/Pfizer Public Health Academy of Distinguished Teachers (2006-present)

Member, Editorial Board, *Journal of Physical Activity and Health* (2006-present)

Section Editor, *Maxcy-Rosenau-Last Public Health & Preventive Medicine* (2006-present)

Member, Science Council, Blue Cross and Blue Shield of Minnesota's Prevention Minnesota Science Council (2006-present)

Testimony, US Senate, Committee on Health, Education, Labor, and Pensions (2004)

Member, Institute of Medicine, Food and Nutrition Board, study on "Prevention of Obesity in Children and Youth" and three subsequent studies (2003-present)

Member, Centers for Disease Control and Prevention, Workgroup in Increasing Core Capacity in Chronic Disease Epidemiology (2003-present)

Member, Editorial Board, *Preventing Chronic Disease: Public Health Research, Practice, and Policy* (2002-present)

Member, Provost Search Committee, Saint Louis University (2002-2003)

Member, Protocol Review Committee, Trial of Activity for Adolescent Girls, National Institutes of Health, NHLBI (2002-2004)

Member, Scientific Working Group, International Agency for Research on Cancer, Monographs on tobacco smoke and involuntary smoking (2002)

Member, Executive Committee, PhD Program in Health Care Ethics, Saint Louis University (2001-present)

Co-Chair, Collaborative Evaluation Design Team, *Project DEFINE*: evaluating the national program of Prevention Research Centers (2001-2004)

Associate Editor and Editorial Board, *Annual Review of Public Health* (2001-present)

Member, Editorial Board, *American Journal of Preventive Medicine* (2001-present)

Chair, Epidemiology Study Section, California Cancer Review Program (1999-2003)

Member, Editorial Board, *Health Promotion Practice* (1998-present)

Senior Editor, *Tobacco Control* (1997-2000)

Member, Task Force developing the *Guide to Community Preventive Services* and Chair, Physical Activity Chapter Workgroup, sponsored by the Centers for Disease Control and Prevention (1996-2003)

Member, Review Board, *American Journal of Health Behavior* (1996-present)

Consulting Editor for Methods/Statistics, *Tobacco Control* (1995-1996)

Chair, North Campus Institutional Review Board, Saint Louis University (1995-2001)

Member, California Tobacco Control Evaluation Advisory Committee, California Department of Health Services, evaluating the effects of California's Proposition 99 (1994-2004)

Member, Science and Epidemiology Committee, Chronic Disease Program Directors, Association of State and Territorial Health Officials (1993-1996)

Member, Missouri State Cancer Control Advisory Board, convened by the Missouri Department of Health (1993-2003)

Member, Governing Council for Epidemiology, American Public Health Association (1995-1997)

Member, COMPACT and PROPACT public health teaching and research work groups, sponsored by the Saint Louis University School of Public Health and the Missouri Department of Health (1993-1996)

Chair, Local Health Department Work Group, developing a national survey of chronic disease control activities in local health departments, sponsored by the Centers for Disease Control and Prevention and the Public Health Foundation (1993-1997)

Member, Special Review Groups, Division of Cancer Prevention and Control, National Cancer Institute (1988-present)

Member, Missouri Coalition on Smoking and Health (1988-2004)

Member, Board of Directors, Professional Affairs Committee, Public Issues Committees, and Special Projects Task Force, Missouri Division of the American Cancer Society (1987-2006)

Member, Saint Louis University Strategic Planning Committee (1995-1996)

Member, Prevention Centers Grant Review Committee, Centers for Disease Control and Prevention, appointed by the Secretary of Health and Human Services (1993-1995)

Co-Chair, Breast and Cervical Cancer Evaluation Design Project Advisory Group (Surveillance Subcommittee), convened by the Centers for Disease Control and Prevention (1993-1995)

Co-Chair, School Health Task Force, Department of Health sponsored work group evaluating comprehensive school health programs (1993-1994)

Editor, monthly series on public health for the journal of the Missouri State Medical Association (1990-1994)

Member, *Healthy Missourians 2000* Planning and Oversight Committee, involved in setting and monitoring year 2000 health objectives (1990-1994)

Member, Executive Committee, Missouri American Stop Smoking Intervention Study (ASSIST) Coalition (1990-1994)

Member, Executive Committee, Chronic Disease Program Directors, Association of State and Territorial Health Officials (1989-1994)

Overall administration and direction of research activities for the Division of Chronic Disease Prevention and Health Promotion, Missouri Department of Health (1988-1994)

External representation to the Missouri General Assembly, voluntary health agencies, federal agencies, and health care providers (1988-1994)

Chair, State Agency Smoking Policy Task Force, developed smoking control policies for Missouri governmental agencies (1989-1992)

Ex-officio member, Missouri Cancer Control Advisory Board, statewide panel of experts to recommend priorities and conduct cancer control planning (1987-1992)

President, Chronic Disease Program Directors, Association of State and Territorial Health Officials (1991-1992)

Chair, Legislative and Policy Committee, Chronic Disease Program Directors, Association of State and Territorial Health Officials (1989-1991)

Chair, Model Standards Work Group for tobacco control that published *Healthy Communities 2000*, sponsored by the American Public Health Association (1990-1991)

Member, Special Review Group, Office of Minority Health, National Institutes of Health (1988-1990)

Publications:

Journal Articles

1. Brownson RC, Reif JS, Keefe TJ, Ferguson SW, Pritzl JA. Risk factors for adenocarcinoma of the lung. *American Journal of Epidemiology* 1987;125:25-34.
2. Brownson RC, Chang JC, Davis JR. Occupation, smoking, and alcohol in the epidemiology of bladder cancer. *American Journal of Public Health* 1987;77:1298-1300.
3. Brownson RC, Chang JC. Exposure to alcohol and tobacco and the risk of laryngeal cancer. *Archives of Environmental Health* 1987;42:192-196.
4. Brownson RC, Devier JR, Chang JC, Davis JR. A case-control study of lung cancer in St. Francois County, 1976-1984. *Missouri Medicine* 1987;84:596-598.
5. Brownson RC, Blackwell CW, Pearson DK, Reynolds RD, Richens JW, Papermaster BW. Risk of breast cancer in relation to cigarette smoking. *Archives of Internal Medicine* 1988;148:140-144.
6. Brownson RC, Reif JS. A cancer registry-based study of occupational risk for lymphoma, multiple myeloma, and leukemia. *International Journal of Epidemiology* 1988;17:27-32.
7. Brownson RC, Chang JC, Davis JR, Bagby JR Jr. Occupational risk of prostate cancer: A cancer registry-based study. *Journal of Occupational Medicine* 1988;30:523-526.
8. Brownson RC. Risk of renal cell carcinoma in relation to occupation, smoking and alcohol consumption. *Archives of Environmental Health* 1988;43:238-241.
9. Davis JR, Kern TG, Perry MC, Brownson RC, Harmon RG. Survey of cancer control attitudes among Missouri state legislators. *Missouri Medicine* 1989;86:95-98.
10. Brownson RC, Davis JR, Chang JC, DiLorenzo TM, Keefe TJ, Bagby JR Jr. A study of the accuracy of cancer risk factor information reported to a central registry compared with that obtained by interview. *American Journal of Epidemiology* 1989;129:616-624.

11. Zahm SH, Brownson RC, Chang JC, Davis JR. Study of lung cancer histologic types, occupation, and smoking in Missouri. *American Journal of Industrial Medicine* 1989;15:565-578.
12. Brownson RC, Zahm SH, Chang JC, Blair A. Occupational risk of colon cancer: An analysis by anatomic subsite. *American Journal of Epidemiology* 1989;130:675-687.
13. Licciardone JC, Wilkins JR, Brownson RC, Chang JC. Smoking and alcohol consumption in the etiology of uterine cervical cancer. *International Journal of Epidemiology* 1989;18:533-537.
14. Chang JC, Simms SG, Davis JR, Brownson RC. Breast cancer incidence among women in Missouri: Implications for cancer control. *Missouri Medicine* 1989;86:809-814.
15. Brownson RC, Reif JS, Chang JC, Davis JR. Cancer risks among Missouri farmers. *Cancer* 1989;64:2381-2386.
16. Brownson RC, Chang JC, Davis JR. Lung cancer in Missouri: A cause for concern. *Missouri Medicine* 1990;87:23-25.
17. Brownson RC, Reif JR, Chang JC, Davis JR. An analysis of occupational risks for brain cancer. *American Journal of Public Health* 1990;80:169-172.
18. Davis JR, Brownson RC, Simms SG, Kern TG. Cancer control and public health in Missouri: A time for action. *Missouri Medicine* 1990;87:82-85.
19. Dubbert ML, Sharp GC, Kay DR, Sylvester JL, Brownson RC. Implications of a statewide survey of arthritis in Missouri. *Missouri Medicine* 1990;87:145-148.
20. Brownson RC, Van Tuinen M, Smith CA. Cardiovascular disease in Missouri: Mortality, hospital discharges, and risk factors. *Missouri Medicine* 1990;87:225-227.
21. Devier JR, Brownson RC, Bagby JR Jr, Carlson GM, Crellin JC. A public health response to cancer clusters in Missouri. *American Journal of Epidemiology* 1990;132:S23-S31.
22. Brownson RC, DiLorenzo TM, Van Tuinen M. Smokeless tobacco use among Missouri youth. *Missouri Medicine* 1990;87:351-354.
23. Anger K, Davis JR, Brownson RC, Simms SG, Kern TG. Efforts in primary-care practice to control tobacco use. *Missouri Medicine* 1990;87:681-683.
24. Brownson RC, DiLorenzo TM, Van Tuinen M, Finger WW. Patterns of cigarette and smokeless tobacco use among children and adolescents. *Preventive Medicine* 1990;19:170-180.
25. Brownson RC, Chang JC, Davis JR, Wilkerson JC, Thompson JJ. Breast cancer in Missouri: Staging, survival, and mammography screening patterns. *Missouri Medicine* 1990;87:753-756.
26. Pratt M, Brownson RC. The prevalence of nonpharmacologic measures of blood pressure control in Missouri. *Missouri Medicine* 1990;87:818-821.
27. Licciardone JC, Brownson RC, Chang JC, Wilkins JR. Uterine cervical cancer risk in cigarette smokers: A meta-analytic study. *American Journal of Preventive Medicine* 1990;6:274-281.
28. Davis JR, Eischen MH, Brownson RC. The health and economic burden of smoking in Missouri. *Missouri Medicine* 1990;87:877-880.
29. Neuberger JS, Brownson RC, Morantz RA, Chin TDY. Association of brain cancer with dental x-ray and occupation in Missouri. *Cancer Detection and Prevention* 1991;15:31-34.
30. Brownson RC, Chang JC, Davis JR, Smith CA. Physical activity on the job and cancer in Missouri. *American Journal of Public Health* 1991;81:639-642.
31. Brownson R, Taylor J, Bright F, *et al.* Resources and priorities in chronic disease prevention and control--United States, 1990. *Morbidity and Mortality Weekly Report* 1991;40:697-700.

List shortened by staff. Publications 32- 360 available

Books

1. Brownson RC, Remington PW, Davis JR (Eds). *Chronic Disease Epidemiology and Control*. Washington, DC: American Public Health Association 1993.
2. Brownson RC, Petitti DB (Eds). *Applied Epidemiology: Theory to Practice*. New York: Oxford University Press; 1998
3. Brownson RC, Remington PW, Davis JR (Eds). *Chronic Disease Epidemiology and Control, 2nd Edition*. Washington, DC: American Public Health Association; 1998
4. Brownson RC, Baker EA, Novick LN (Eds). *Community-Based Prevention: Programs that Work*. Gaithersburg, MD: Aspen Publishers; 1999
5. Brownson RC, Baker EA, Leet TL, Gillespie KN. *Evidence-Based Public Health*. New York: Oxford University Press; 2003.
6. Nelson DE, Brownson RC, Remington PL, Parvanta C (Eds.). *Communicating Public Health Information Effectively: A Guide for Practitioners*. Washington, DC: American Public Health Association; 2002.
7. Brownson RC, Petitti DB (Eds). *Applied Epidemiology: Theory to Practice*. 2nd Edition. New York: Oxford University Press; 2006.
8. Kumanyika S, Brownson R (Eds). *Handbook of Obesity Prevention. A Resource for Health Professionals*. New York: Springer; 2007.
9. Remington PW, Brownson RC, Wegner MV (Eds). *Chronic Disease Epidemiology and Control, 3rd Edition*. Washington, DC: American Public Health Association; 2010.
10. Brownson RC, Baker EA, Leet TL, Gillespie KN, True WR. *Evidence-Based Public Health*. 2nd Edition. New York: Oxford University Press; 2011.
11. Brownson RC, Colditz GA, Proctor EK (eds). *Dissemination and Implementation Research in Health: Translating Science to Practice*. New York: Oxford University Press; 2012.

Professional Organizations:

International Epidemiological Association
Society for Epidemiologic Research
American College of Epidemiology
American Public Health Association, Epidemiology Section
Missouri Public Health Association
Chronic Disease Program Directors, Association of State and Territorial Health Officials
Society for Behavioral Medicine

Voluntary Service:

Member, Board of Directors, American College of Epidemiology (2009-present)
Member, Board of Directors, Missouri Institute for Community Health (2007-2012)
Member, Community Advisory Board, Missouri Foundation for Health (2000-2005)
Co-Chair, Advocacy Team, Heartland Division of the American Cancer Society (1996-2001)
Board of Directors, Missouri Division of the American Cancer Society (1991-1996)
Member, Missouri Arthritis Center Advisory Council (1992-1996)
Board of Directors, Alternative Community Training, Columbia, Missouri (1993-1994)

Current Grant Support:

Ongoing Active Research Support

U48DP0011903-01 (Brownson, Ross C.)
HHS/CDC

9/30/09 – 9/29/14

Health Promotion and Disease Prevention Research Center

The major goals of this project are to develop chronic disease prevention interventions that are appropriate for high-risk areas.

U48DP0011903-01SIP 25-01 (Brownson, Ross C.)
CDC

09/30/09 -09/29/14

Applying Evidence-Based Physical Activity Recommendations in Brazil

The overall goal of this project is to adapt evidence-based strategies for promoting physical activity for use in Brazil.

U48DP0011903-01 SIP 9-01 (Eyler, Amy, P.I.)
CDC

09/30/09 – 09/29/14

Physical Activity Policy Research Network –Coordinating Center

The major goal of this project is to maintain, refine and expand a network of experts designed to advance the field of physical activity policy research. As the coordinating center, PRC-StL will lead network activities and help establish community collaboration and the inclusion of transdisciplinary members.

1R25CA171994-01 (Brownson, Ross C.)
06/30/18
NIH

07/01/13-

Mentored Training for Dissemination and Implementation Research in Cancer

The overall goal for the training program is to develop the first of its kind, Mentored Training for Dissemination and Implementation Research in Cancer (MT-DIRC) at Washington University in St. Louis.

1R01CA160327-01A1 (Brownson, Ross C.)
NIH/NCI

05/03/12-03/31/17

Disseminating Evidence-Based Interventions to Control Cancer

The primary goal is to increase the dissemination of interventions to control cancer, focusing on the uptake of effective approaches among state-level practitioners.

1 R18 DK089461-01A1 (Haire-Joshu, Debra, PI)
NIDDK

07/1/2011 -5/31/2016

Translating a Weight Loss Intervention through a National Home Visiting Program

This study will test Healthy Eating & Active Living Taught at Home (HEALTH), which adapts and integrates the Diabetes Prevention Program (DPP) lifestyle intervention within Parents As Teachers (PAT), a national home visiting program. HEALTH will be delivered by parent educators to obese mothers of overweight/obese preschoolers through 36 home visits, 24 group meetings, and 18 booster telephone calls.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: CPRIT OVERSIGHT COMMITTEE MEMBERS
FROM: DR. WILLIAM RICE, OVERSIGHT COMMITTEE CHAIR
SUBJECT: CEO ANNUAL EVALUATION PROCESS
DATE: NOVEMBER 17, 2014

Summary and Recommendation:

It is consistent with the Oversight Committee's statutory obligation and best practices to conduct an annual review of the CEO's performance and to establish expectations for the next year. I recommend that the annual review take place at the February 18, 2015, Oversight Committee meeting. The Board Governance subcommittee has agreed to assume primary responsibility for the review process. The final review will include input from all Oversight Committee members via an individual scoring instrument and during a board discussion with Mr. Roberts to be conducted in closed session.

Discussion:

Pursuant to its statutory responsibility to hire the CPRIT CEO, the Oversight Committee appointed Wayne Roberts as CEO on November 22, 2013. An annual review of the CEO's performance is consistent with best practices for board governance. After consultation with Pete Geren, Vice Chair, we agree that the Board Governance subcommittee should be responsible for overseeing the evaluation process activities, including developing a standard evaluation instrument, compiling the information from individual Oversight Committee members, and proposing performance goals for the coming year. A formal written evaluation will be presented by the full Oversight Committee to Mr. Roberts in closed session at the February Oversight Committee meeting.

The annual review process is an agenda item at the November 19 meeting. To ensure that the Board Governance subcommittee members have the benefit of the Oversight Committee's input, I have set forth a few topics for your consideration and discussion at the meeting.

Evaluation criteria: The annual evaluation should measure competence across several areas the CEO is responsible for managing. I have listed several areas below that the Oversight Committee may want to assess in terms of expected performance. I have also attached the CEO job position posting that was used when hiring Mr. Roberts.

- CPRIT issues (i.e. implementation of State Auditor findings and legislative changes)
- Legislative affairs
- Operational effectiveness
- Agency and fiscal management
- Media relations
- Board liaison

Evaluation instrument: It is fairly common to use a tool for soliciting input from evaluators that relies upon numerical scores (e.g. 1 – 4 scale correlated with “exceeds requirements,” “meets requirements,” “needs improvement,” and “unsatisfactory”) and that provides an opportunity for written comments. The Board Governance subcommittee would be responsible for putting together the evaluation instrument, with major categories representing specific areas of competency, such as administrative, interpersonal, individual, and leadership. Suggestions for categories and subcategories are below, but your input is desired.

Administrative

- Budget Management
- Planning
- Compliance
- Problem Solving/Decision Making
- Risk Management
- Staffing
- Advising Oversight Committee

Individual

- Effort and initiative
- Professional and technical competence
- Innovation
- Objectivity
- Credibility
- Flexibility

Interpersonal

- Communication (oral and written)
- Supervisory Control
- Leadership
- Legislative Affairs
- Media Relations

Leadership

- Team building
- Vision
- Self-development
- Establishing partnerships/coalitions
- Tone from the top (ethics, compliance, mission, etc.)
- Implementation of major agency initiatives (e.g. audit/statutory implementation, program priorities)

CPRIT Governance Internal Audit Report

Report #2014-02

June 19, 2014



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

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Executive Summary

An enterprise risk assessment was performed at the Cancer Prevention and Research Institute of Texas (“CPRIT”) in September 2013. The risk assessment identified the agency’s overall governance structure and stability as a high-priority risk that needed to be addressed.

As part of the audit, Internal Audit reviewed the effectiveness of the governance activities by evaluating the adequacy of existing policies and procedures for the Agency’s governance activities. The audit also focused on the overall duties and responsibilities of the Oversight Committee and subcommittees and how the governance structure fosters monitoring and communication.

The Oversight Committee continues to work towards establishing leading practices to become more efficient and effective in their governing process. However, during the FY2014 Governance internal audit, the following improvement opportunities were noted, in descending priority order:

- Continue to work with CPRIT staff to understand the agency’s strategic plan and help refine the program priority setting process
- Provide information further in advance of the Oversight Committee or subcommittee meetings to allow sufficient review time
- Provide additional guidance around the Open Meetings Act for Committee members
- Provide more robust formal roles and responsibilities training to subcommittees
- Continuously communicate grantee activity and results to Committee members
- Update policies and procedures on the CPRIT website to reflect current rules and processes

Background Information

Background

CPRIT was established by the Texas Legislature in 2007, as authorized by Article 3, Section 67 of the Constitution of the State of Texas. The agency is authorized by 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 almost \$1 billion.

In November 2013, CPRIT's governing board, the Oversight Committee was re-established through the appointment of nine new members by the Texas Governor, the Lieutenant Governor and the Speaker of the House to serve staggered terms. The Oversight Committee members have a range of experience including legal, medical, political, financial, and business development.

The Oversight Committee, led by the Chair William Rice, M.D. and the Vice-Chair Pete Geren, was given the following actions and priorities during FY2014 to help improve the agency's commitment to regulatory and legislative compliance as well as the efficiency and effectiveness of the agency's governance activities:

- Establish roles, responsibilities and terms for Oversight Committee officers
- Authorize general obligation bond issuance
- Develop materials and conduct orientation of new Oversight Committee members as appointed
- Approve publication of proposed administrative rules and adopt final rules after public comment period
- Hire permanent CEO
- Elect Oversight Committee officers
- Develop process for Oversight Committee to affirmatively vote to approve recommendations
- Establish annual priorities for Research, Prevention, and Product Development programs
- Develop and adopt a code of conduct and ethics
- Develop administrative rules and policies consistent with legislative action
- Develop policy prohibiting discussion of grant recommendations between CEO and Oversight Committee members

State leadership imposed a moratorium on new grant awards in December 2012. When the Oversight Committee was re-established at the end of October 2013, state leadership lifted the moratorium that had been imposed almost a year earlier. At its first meeting on November 1, 2013, the new Oversight Committee reinstated agency grant award operations. With that action, the agency finalized grant contracts initially approved in August and December 2012, resumed review of submitted grant applications, released new requests for grant applications, and finalized development of revised administrative rules required by statutory changes made through SB 149.

The Oversight Committee held three meetings in quick succession between November 22, 2013, through February 19, 2014, to organize the Committee by electing officers and organizing their subcommittees and to address the backlog of agency business including the approval of grant awards, approval of major service contracts, and adoption of the changes to the agency's administrative rules. Currently, there are seven subcommittees that have been established to assist the Oversight Committee with its tasks and responsibilities.



The Oversight Committee members must serve on at least one programmatic subcommittee, which is designed to develop a vision, set policies for the Oversight Committee's adoption, and ensure that the agency properly exercises its duty to award grants for prevention, scientific research, and product development. The Oversight Committee members also serve on at least one other subcommittee that focuses on board governance and ethics, audit, nominations, or diversity. See Appendix A for the current subcommittee assignments.

Audit Objectives and Scope

The objectives of the audit were to assess CPRIT's current governance practices. The specific audit objectives were:

- Evaluate the adequacy of existing policies and procedures for the Agency's governance activities
- Assess the responsibilities of the Oversight Committee to verify compliance with laws and regulations and CPRIT policies and procedures
- Review the responsibilities of the Oversight Committee's subcommittees to verify compliance with expectations set forth in CPRIT's policies and procedures related to participation, communication, transparency, and monitoring

In order to assess the governance activities, Internal Audit focused on the following areas:

- CPRIT's policies and procedures
- Code of conduct and ethics policies
- Conflicts of interest, disclosure, and transparency procedures
- Subcommittee structure and assigned responsibilities
- Communication between the Oversight Committee and Subcommittees

Although Texas legislation may potentially change procedural and reporting requirements for CPRIT, the audit performed was designed to evaluate and test compliance with established policies and procedures as of May 2014. Internal Audit interviewed the Oversight Committee members and reviewed documentation for governance activities that were established during Fiscal Year 2014.

Testing Methodology and Approach

Internal Audit reviewed policies and procedures for the agency including the Oversight Committee and its subcommittees. The review included the following:

- Oversight Committee Bylaws
- Charters for Board Governance and Ethics, Audit, and Nominations Subcommittees
- Code of Conduct and Ethics
- Agency Policies and Procedures (as of 2009)
- Updated Draft Administrative Rules
- Health and Safety Code 102 as amended by the 83rd Legislature
- January 2014 Oversight Committee Board Packet

Internal Audit interviewed all nine members of the Oversight Committee telephonically using a board self-assessment questionnaire as a guideline for the discussions. Participants included the following individuals:

Name	Title
William Rice, M.D.	Oversight Committee - Chair
Pete Geren	Oversight Committee - Vice Chair
Amy Mitchell	Oversight Committee - Secretary
Angelos Angelou	Oversight Committee - Member
Gerald Geistweidt	Oversight Committee - Member
Ned Holmes	Oversight Committee - Member
Will Montgomery	Oversight Committee - Member
Cynthia Mulrow, M.D., MSc., MACP	Oversight Committee - Member
Craig Rosenfeld, M.D.	Oversight Committee - Member

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

The Committee of Sponsoring Organizations' (COSO) is an organization that provides thought leadership through the development of comprehensive frameworks and guidance on enterprise risk management, internal control and fraud deterrence designed to improve organizational performance and governance and to reduce the extent of fraud in organizations.¹ The ERM framework (shown below) asserts that a well-designed and effectively operating enterprise risk management function can provide reasonable assurance to management and the board of directors regarding achievement of an entity's objectives.



The enterprise risk management framework show how key elements relate to CPRIT's governance structure:

- The *internal environment* and *objectives setting* components set the “tone at the top” for the agency and set the foundation by providing fundamental discipline and structure.
- The *event identification*, *risk assessment* and *risk response* components identify relevant risks to achieving the agency's predetermined objectives.
- The *control activities* are the policies, procedures, and practices that ensure management objectives are achieved and risk mitigation strategies are carried out.
- The *information and communication* and *monitoring* components are pervasive throughout, affecting all elements of the framework.

Implementing key elements of the framework would contribute to the agency's long-term success by improving organizational performance and governance.

Internal Environment

The internal environment encompasses the tone of an organization, and sets the basis for how risk is viewed and addressed by an entity's people, including risk management philosophy and risk appetite, integrity and ethical values, and the environment in which they operate. Internal Audit examined the agency's overall strategy and mission and also examined the current code of conduct and ethics as well as policies and procedures in place to monitor compliance with the established code, legal requirements, and agency requirements. The following table includes our observations, findings and recommendations, as appropriate.

¹ <http://www.coso.org/aboutus.htm>

Key COSO Principle	Observation	Result / Recommendation
Demonstrates commitment to integrity and ethical values	<ul style="list-style-type: none"> The CPRIT website includes the agency's purpose, powers, and duties. The CPRIT website includes a specific section for "Ethics and Compliance" which has references to agency specific statutes, rules, and policies, and the Code of Conduct and Ethics. The Code of Conduct incorporates the Agency's enforcement policies that state employees are subject to discipline, or termination, for violating the established rules and guidelines within the Code of Conduct. 	No findings noted
Exercises oversight responsibility	<ul style="list-style-type: none"> The Oversight Committee bylaws include the general powers of the Committee and the subcommittees. The bylaws also include guidelines for the Chairperson, Vice Chairperson, and the officers at CPRIT. 	No findings noted
Establishes structure, authority, and responsibility	<ul style="list-style-type: none"> The Board Governance and Ethics Subcommittee reviews and recommends proposed changes for approval to the Oversight Committee with respect to Bylaws, policies and administrative rules of the Institute, legislation regarding or affecting the Institute, and the delegation of authority to the CEO, and reviews the ethics policies of the Institute and their administration. The Board Governance and Ethics Subcommittee also reviews, at least annually, the internal policies and processes of the Oversight Committee. 	No findings noted
Demonstrates commitment to competence	<ul style="list-style-type: none"> The Nominating Subcommittee is responsible for reviewing and reporting to the Oversight Committee regarding the composition and effectiveness of the Institute's advisory committees The Subcommittee also identifies qualified individuals for appointment as members of advisory committees 	No findings noted

Key COSO Principle	Observation	Result / Recommendation
Enforces accountability	<ul style="list-style-type: none"> The agency includes links on their website to the State Auditor's Office Hotline to report fraud, waste, and/or abuse. The Compliance Program, operated under the direction of the Chief Compliance Officer, ensures that Oversight Committee members and all other committee members, Institute employees, grant applicants and recipients, and contract service providers are expected to comply with the laws, regulations, rules, and policies of conduct as well as professional standards and ethics. 	No findings noted

Internal Audit determined that adequate policies, procedures, and processes were in place to verify that a sound internal environment was established and that acceptable governance practices were established at the agency.

Objective Setting

Objectives must exist before management can identify potential events affecting their achievement. Enterprise risk management ensures that management has in place a process to set objectives and that the chosen objectives support and align with the entity's mission and are consistent with its risk appetite. The objectives provide a high level plan for what the organization seeks to achieve, including its overall direction, risk environmental, differentiating capabilities and the infrastructure needed. Strategy is often presented in the form of overall goals, initiatives and tactics. The following table includes our observations, findings and recommendations, as appropriate.

Key COSO Principle	Observation	Result/ Recommendation
Specifies suitable objectives	<ul style="list-style-type: none"> Objectives have been set by the Agency bylaws and state laws. The Oversight Committee members are still familiarizing themselves with the agency rules and requirements due to the short timeframe since their appointments (less than one year at the time of this audit). The Oversight Committee noted that they have additional opportunities to improve CPRIT's strategic direction through the program priority setting process. 	CPRIT staff should work with the Oversight Committee to ensure they understand the agency's strategic plan.

Management Response: Management concurs with the recommendation. Currently, CPRIT relies upon two strategic planning efforts: (1) agency participation in the statewide strategic plan; and (2) program priorities for the agency set by the Oversight Committee. The differences between these two strategic planning efforts and

their relative usefulness have been discussed in public Oversight Committee meetings. Other than these two planning efforts, no agency strategic plan exists or has been discussed.

Statewide Strategic Plan - The agency creates and submits information for the statutorily-mandated statewide strategic plan controlled by the Legislative Budget Board and the Governor's Office. The statewide strategic plan is used to set the appropriations bill format and may be of limited use as an agency planning document for the governing board.

Program Priorities Project - A new provision of Texas Health & Safety Code § 102.107 requires the Oversight Committee to: "annually set priorities as prescribed by the legislature for each grant program that receives money under this chapter." The Oversight Committee initiated the Program Priority Project effort to establish priorities within each program and between the three programs (scientific research, prevention, and product development). The entire Oversight Committee and CPRIT executive staff are involved in this project. Management expects the program priorities determined by the Oversight Committee to be useful to staff in developing Request for Applications, as well as to peer reviewers while examining applications submitted to CPRIT. Program priorities will also inform funding decisions made by the Program Integration Committee and the Oversight Committee.

Much of the Program Priority Project work has taken place during the period of this internal audit. Work completed during this time includes development of the parameters and scope of the project, contracting with a professional facilitator, subcommittee discussions about individual program priorities, and a full Oversight Committee work session to review and further develop the program priorities document. As of this writing, the Program Priority Project is nearing completion, with preliminary approval of program priorities scheduled for the Oversight Committee meeting on November 19, 2014.

Person Responsible: Wayne Roberts

Target Date for Implementation: November 19, 2014

Event Identification, Risk Assessment, and Risk Response

Event identification, as defined by the COSO framework, is made up of the internal and external events affecting achievement of an entity's objectives. Risks associated with these events should be identified and managed taking into consideration risks and opportunities. This process is closely linked to the risk assessment process in which risks are analyzed, considering likelihood and impact, as a basis for determining how they should be managed. Similarly, the risk response is how management decides to avoid, accept, reduce, or share risk. Management should develop a set of actions to align risks with the agency's risk appetite. The following table includes our observations, findings and recommendations, as appropriate.

Key COSO Principle	Observation	Result / Recommendation
Identifies and analyzes risk	<ul style="list-style-type: none">The Audit Subcommittee is tasked to oversee CPRIT's risk management and audit requirements. The subcommittee works to ensure that there are sufficient policies and practices in place to control standard risks in the operations, accounting, and regulatory compliance of CPRIT as a state agency.	No findings noted

Key COSO Principle	Observation	Result / Recommendation
Identifies and analyzes significant change	<ul style="list-style-type: none"> Due to the sweeping changes at the agency, an enterprise risk assessment (ERA) was performed in September 2013 under the direction of CPRIT's Compliance Officer. The ERA identified CPRIT's risk universe and developed a risk action plan for the highest priority enterprise risks. 	No findings noted

As a result of the review, Internal Audit determined that adequate procedures around CPRIT's risk assessment and response are in place to verify that agency objectives could be achieved.

Control Activities

Control activities are the policies, procedures, and practices that ensure management objectives are achieved and risk mitigation strategies are carried out. Control activities are categorized based on the nature of the organization and can add significant value to the organization if they are designed and operating effectively. The following table includes our observations, findings and recommendations, as appropriate.

Key COSO Principle	Observation	Result / Recommendation
Selects and develops control activities	<ul style="list-style-type: none"> CPRIT has established control activities throughout the agency covering the grants management programmatic requirements, the financial reimbursement process, internal fiscal processes, and information technology. These controls are tested on a regular basis by internal audit, external audit, and other state agencies. 	No findings noted
Deploys through policies and procedures	<ul style="list-style-type: none"> CPRIT's Application and Funding Awards Policies and Procedures Guide posted online was last updated in 2009 and have not been updated to reflect the recent changes in the Administrative Code. 	<p>Management should revise the Policies & Procedures Guide to reflect the changes in the Administrative Code.</p> <p>Management should also consider reviewing the guide on an annual basis to verify the latest updates or changes have been incorporated.</p>

Management Response: Management concurs with the recommendation. Management notes that agency statements of general applicability that implement, interpret, or enforce state law or CPRIT policies must follow the requirements of the Texas Administrative Procedure Act (APA). In order for an agency statement to have the force of law and compel compliance through threat of enforcement, the APA requires a formal rulemaking process that includes notice and opportunity for public input. Failure to follow the APA

rulemaking process to set agency policy may result in legal challenges and a finding that the agency engaged in illegal ad hoc rulemaking.

CPRIT initiated a major rulemaking project consistent with the APA in November 2013. This was the first major revision to agency policies since CPRIT adopted administrative rules in 2009. The new rules and rule revisions 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*, and conform agency practices to legislative requirements enacted by the 83rd legislative session. Many of the policy changes implemented through the new rules and rule changes prescribe behavior of agency staff, board members, applicants, peer reviewers, and grant recipients. The changes increased the number of CPRIT's administrative rules from 33 rules to 48 rules. In addition to substantive changes made to 19 existing rules, 18 new rules were adopted. CPRIT has made several additional changes to administrative rules to further clarify agency policies and procedures following the major rulemaking project that concluded earlier this year.

Since the new policies have been adopted via the rulemaking process, CPRIT has provided notice to individuals affected by the new rules and rule changes through training, written communication, and updated forms. Agency rules are available through CPRIT's website. Agency staff is updating the Policies and Procedures Guide as an additional source of guidance about the rule requirements. CPRIT will establish a schedule to annually review and update the Policies and Procedures Guide to reflect any new rules or rule changes.

Person Responsible: Kristen Doyle / Lisa Nelson
Target Date for Implementation: November 1, 2014

Information and Communication

Information and communication support all other control components by communicating control responsibilities to employees and by providing information in a form and timeframe that allows people to carry out their duties. The following table includes our observations, findings and recommendations, as appropriate.

Key COSO Principle	Observation	Result / Recommendation
Uses relevant information	<ul style="list-style-type: none"> The CPRIT staff provides information to the Oversight Committee prior to the meeting, including explanatory memos. 	CPRIT staff should provide information to the Oversight Committee further in advance of the Oversight Committee and subcommittee meetings to give the members enough review time prior to meetings.
Communicates internally	<ul style="list-style-type: none"> The Oversight Committee members requested additional clarification around appropriate communication within the constraints of the Administrative Code and the Open Meetings Act. Some subcommittees are still in development and are working towards setting goals and establishing regular meetings. 	CPRIT legal counsel should provide the Oversight Committee members with guidance around key provisions of the Open Meetings Act.

Key COSO Principle	Observation	Result / Recommendation
Communicates externally	<ul style="list-style-type: none"> The Oversight Committee holds regularly scheduled quarterly meetings and posts agendas and meeting minutes to their website for all employees and stakeholders to view. CPRIT's new Administrative Code Rules mandate that the Compliance Program ensures that agency operations conform to federal and state regulations, and that such operations are undertaken consistent with the Institute's administrative rules, policies, and procedures. The Compliance Program oversees the Institute's activities related to the reporting and investigation of suspected compliance violations. Regular reports are made by the Compliance Officer at each Oversight Committee meeting. 	No findings noted.

Internal Audit determined that adequate processes and procedures were in place to verify that methods for communication of control responsibilities or other matters affecting the functioning of internal control components were established. Additional guidance around key provisions of the Open Meetings Act should be provided to the Oversight Committee.

CPRIT staff's efforts to provide the Oversight Committee with briefing memos and other background materials to ensure they are prepared for meetings has placed a larger burden on the small staff, and in many cases on the same few individuals, to prepare these documents while managing the day-to-day operations of the agency. To compound the staff resource issue, the volume of Committee and subcommittee meeting preparation was high from November 2013 through February 2014 with the organization of subcommittees and the Oversight Committee holding four meetings during that period which coincided with the first four months of their appointments. With the Oversight Committee's adoption of regularly scheduled Oversight Committee and subcommittee meetings once every quarter, CPRIT staff should disburse information further in advance of the meetings.

Management Response:

Management concurs with the recommendation. Since the audit period, CPRIT has added more staff, standardized meeting procedures, and addressed the considerable backlog of action items that confronted the newly constituted Oversight Committee when CPRIT resumed normal operations late last year. These steps should improve the amount of time that Oversight Committee members have to review information prior to regular meetings.

Similarly, since the audit period CPRIT has addressed timing challenges associated with subcommittee meetings by adopting an established schedule for all regular subcommittee meetings through FY2015. The number and

frequency of subcommittee meetings adds significantly to the demand for document production from executive staff. The adoption of a regular subcommittee schedule for meetings taking place prior to quarterly Oversight Committee meetings will help staff's ability to plan and adjust for document production.

Because the Oversight Committee meets four times per year, the number of significant agenda items and award recommendations as well as the volume of supporting documents is not likely to diminish. Management is sensitive to the problems created for the Oversight Committee when members must review a significant amount of material in a short period of time and is committed to addressing this issue by ensuring that members have at least five business days to review written material to be taken up at a regular Oversight Committee meeting or subcommittee meeting.

Person Responsible: Wayne Roberts / CPRIT Executive Staff

Target Date for Implementation: February 2015

Management Response:

Management concurs with the recommendation. Open Meetings Act guidance is a component of new Oversight Committee member training. Since the audit period, General Counsel has provided Oversight Committee members with written guidance regarding common issues arising under the Open Meetings Act. While members are able to seek guidance individually from General Counsel at any time, the entire Oversight Committee was also provided the opportunity to seek legal advice regarding the Open Meetings Act during a recent executive session. The General Counsel will address changes, if any, to the Open Meetings Act following each legislative session via an Oversight Committee briefing.

Person Responsible: Kristen Doyle

Target Date for Implementation: August 14, 2014

Monitoring

Monitoring includes the external oversight of internal controls by management or other parties outside the process; or the application of independent methodologies, like customized procedures or standard checklists, by employees within a process. The following table includes our observations, findings and recommendations, as appropriate.

Key COSO Principle	Observation	Result / Recommendation
Conducts ongoing and/or separate evaluations	<ul style="list-style-type: none">As required by Sec. 102.053 of the Health and Safety Code, CPRIT is required to undergo an independent financial audit of its activities from a certified public accounting firm and provide results to the State Comptroller and the Oversight Committee.As part of the review, Internal Audit performed inquiries of all the Committee members to help self-assess their performance. These self-assessments were used to gather information about the current state of the Committee and determine areas for improvement. Detailed results of these discussions can be found in Appendix B.	No findings noted
Evaluates and communicates deficiencies	<ul style="list-style-type: none">The Audit Subcommittee is tasked to assist the Oversight Committee in fulfilling responsibilities related to monitoring the audit, financial, and compliance functions of the Institute to assure the transparency and integrity of the Institute's operations and use of taxpayer funds.CPRIT must comply with TAC Sec. 701.7 which states that the Compliance Program will ensure that Oversight Committee members and all other committee members, Institute employees, grant applicants and recipients, and contract service providers are in compliance with the laws, regulations, rules, and policies of conduct as well as professional standards and ethics. TAC Sec. 701.7 also states that the Compliance Program should include systems and activities to detect and report instances of conduct that do not conform to the laws and policies, as well as the timely response to non-conforming conduct.	No findings noted

As a result of the review, Internal Audit determined that adequate monitoring procedures were in place.

Conclusion

As part of the audit, Internal Audit reviewed the effectiveness of the governance activities by evaluating the adequacy of existing policies and procedures for the Agency's governance activities. The audit also focused on the overall duties and responsibilities of the Oversight Committee and subcommittees and how their governance structure fosters the necessary monitoring and communication.

The Oversight Committee continues to work towards establishing leading practices to become more efficient and effective in their governing process. However, during the FY2014 Governance review, Internal Audit identified the following potential areas for improvement:

- Offer guidance to Oversight Committee members in understanding the agency's strategic plan
- Provide information, such as agendas, research materials, and memos, at least one week prior to the scheduled meeting to ensure the committee members have sufficient review time
- Provide clarity and guidance around the Open Meetings Act and Administrative Code limitations on Oversight Committee members' communication

In addition, as a result of discussions with the Oversight Committee members, Internal Audit recommends the following:

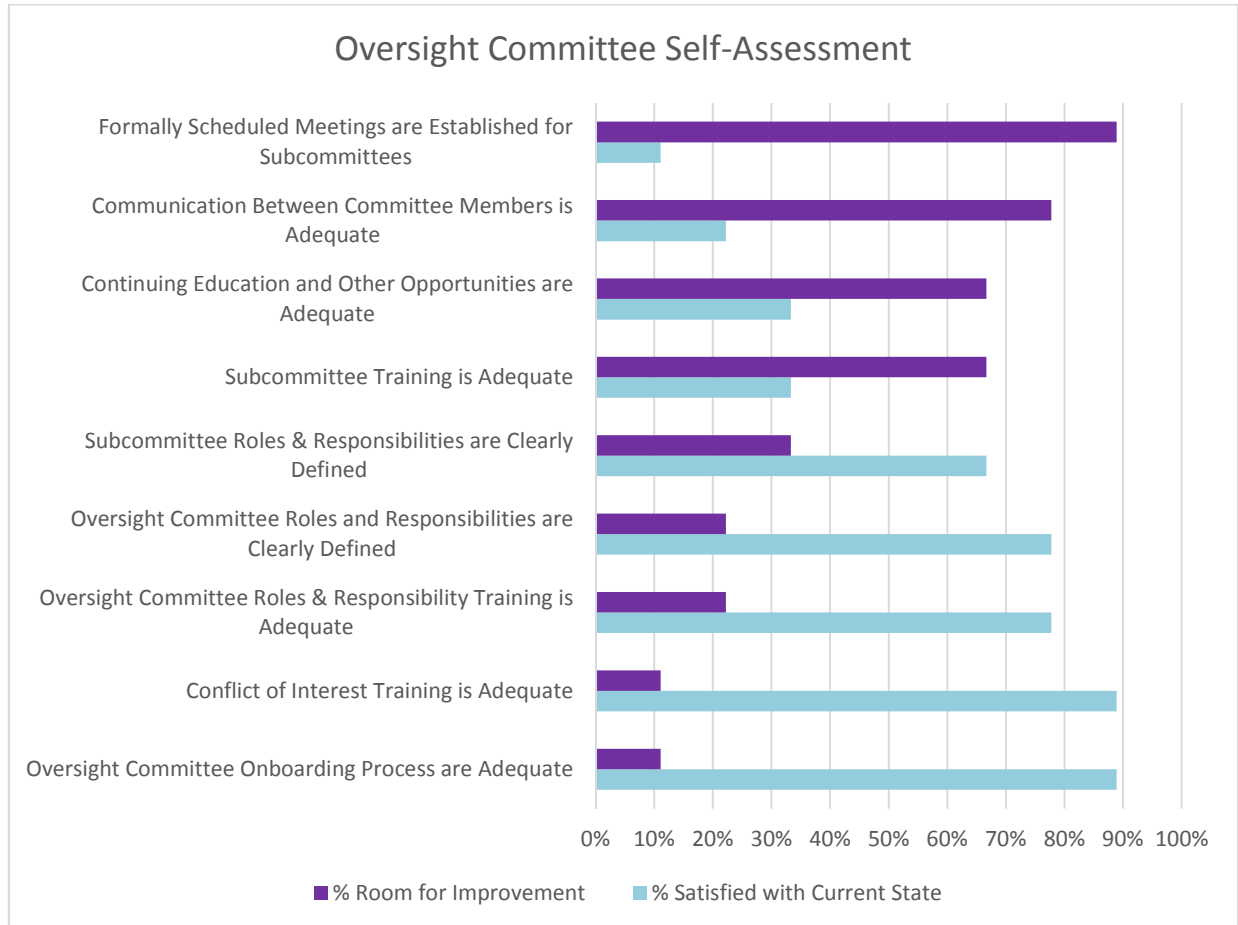
- *Establish formal communication and sufficient advance scheduling of subcommittee meetings:* meeting dates for all the subcommittees should be established at the start of each year to ensure members have sufficient notice to attend
- *Provide more robust formal roles and responsibilities training to subcommittee:* using the responsibilities outlined in the subcommittee charters, ensure that all members understand their roles and expectations
- *Continuously communicate grantee activity and results to committee members:* committee members would like more opportunities for continuing education and training for industry specific topics such as current scientific breakthroughs or methods to reduce the burden of cancer

Appendix A – CPRIT Subcommittee Structure

Board Governance & Ethics	<ul style="list-style-type: none">•Amy Mitchell - Chair•Gerald Geistweidt•Pete Geren•Ned Holmes
Audit	<ul style="list-style-type: none">•Angelos Angelou - Chair•Will Montgomery•William Rice, M.D
Nominations	<ul style="list-style-type: none">•Gerald Geistweidt•Ned Holmes•William Rice, M.D.•Craig Rosenfeld, M.D.
Diversity Workgroup	<ul style="list-style-type: none">•Cynthia Mulrow, M.D., MSc., MACP - Chair•Amy Mitchell
Product Development	<ul style="list-style-type: none">•Craig Rosenfeld, M.D. - Chair•Angelos Angelou•Ned Holmes
Scientific Research	<ul style="list-style-type: none">•William Rice, M.D. - Chair•Gerald Geistweidt•Will Montgomery
Prevention	<ul style="list-style-type: none">•Cynthia Mulrow, M.D., MSc., MACP - Chair•Pete Geren•Amy Mitchell

Appendix B – Oversight Committee Self-Assessment Results

The self-assessment is designed to help CPRIT evaluate the Oversight Committee's performance and identify areas for improvement going forward. The assessment identifies areas in which the Committee is operating strongly but also highlights areas for improvement. The output of the assessment is intended to aid in discussions amongst CPRIT and its Committee members that result in the greatest outcome for the agency. Internal Audit interviewed all nine members of the Oversight Committee using a board self-assessment questionnaire as a basis. The results are as follows:



Overall, the Oversight Committee members stated that the onboarding process was very effective and that CPRIT staff has been very helpful since their appointments.

Grants Management Internal Audit Report

Report #2014-04

July 25, 2014



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

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Executive Summary

In support of the FY2014 Internal Audit Plan, an audit of the grants management process was conducted in June 2014. The objectives of the audit were to assess current practices and identify opportunities to improve efficiency and effectiveness in administering grant funds. The specific audit objectives were:

- Determine if grant application process is compliant with CPRIT policies and procedures
- Determine if subsequent reviews of programmatic and financial grant activities are operating effectively
- Determine if grantee activity is monitored periodically throughout the grant program duration

The CPRIT Finance staff is responsible for maintaining grantee records as well as tracking and reporting detailed grantee budget and expenditure information. The CPRIT Programs staff must also assess the progress of each program's achievement of goals to evaluate program success and sustainability and periodically report this information to the Finance team.

CPRIT continues to work towards establishing leading practices to become more efficient and effective in their grants management process. However, during the FY2013 Grants Management internal audit, the following improvement opportunities were noted, in descending priority:

- **Insufficient Supporting Documentation for Reimbursements** – Supporting documentation accompanying reimbursement claims submitted by grantees do not adhere to CPRIT Policy and Procedures which require the verification of amount and appropriateness. In addition, one reimbursement claim was not evidenced as reviewed by the Grant Accountant.
- **No Desk Reviews performed during the year** – Desk reviews which entail detailed review of expense reimbursement claims were not performed during the audit period.
- **Inadequate enforcement of the rules surrounding the Texas Administrative Code** - Texas law requires that grantees adhere to certain rules around the purchase of at least 50% of goods and services from Texas and utilization of Historically Underutilized Businesses (HUBs) where possible. For three samples selected no disclosure was made for purchases outside the state or from HUBs.
- **Policies and Procedures** – CPRIT's Application and Funding Awards Policies and Procedures Guide posted online was last updated in 2009 and have not been updated to reflect the recent changes in the Administrative Code.

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 544 grants totaling \$1,020,947,235.¹

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.

CPRIT accepts applications and awards grants for a wide variety of cancer-related prevention and research programs and services by public and private entities located within Texas. The grants program staff is divided into three areas: research, prevention, and product development. Each group is led by an executive officer with vast experience in their fields of expertise. Dr. Thomas Goodman was hired as Chief Product Development Officer in April 2014. The programs staff is charged with coordinating efforts with their support staff to establish guidelines for the grant application process, review panel process, and progress reporting criteria.

¹ Figures provided by the CPRIT website. <http://www.cprit.state.tx.us/>

Applications for grants are submitted through an online application receipt system, the CPRIT Application Receipt System (CARS) that is managed by SRA International, Inc. Once applications are approved and move towards the executed contract stage, the CPRIT Grant Management System, (CGMS) which was built as an enhancement to CARS and implemented in September 2013, track the contract, correspondence, and other compliance documentation for each grant. From January 2014, the grant process has been amended with the implementation of a Program Integration Committee and other minor amendments.²

Audit Objectives

The objectives of the audit were to assess current practices and identify opportunities to improve efficiency and effectiveness in administering grant funds. The specific audit objectives were:

- Determine if grant application process is compliant with CPRIT policies and procedures
- Determine if subsequent reviews of programmatic and financial grant activities are operating effectively
- Determine if grantee activity is monitored periodically throughout the grant program duration

In order to assess the grant management activities, Internal Audit reviewed the following:

- Grant Application Process
 - Conflicts of interest
 - Grant applications and contracts
 - Progress reports
 - Procedures around extending, closing, or renewing grants
 - Financial policies and procedures
- Expense Reimbursement Process
 - Grantee Form 269A submissions
 - Grantee reimbursements
 - Desk reviews
 - Financial policies and procedures
- CPRIT's compliance with legislative requirements
 - CPRIT Annual Report and program metrics

Scope and Testing Approach

The audit performed was designed to evaluate and test compliance with established policies and procedures as of June 2014. Internal Audit interviewed staff and completed field work on a sample of grants that were managed during Fiscal Year 2014.

During the grants management audit, Internal Audit reviewed 35 new contracts signed during the period. The review included the following:

- Determine whether awarded grants followed CPRIT's grant application process with respect to approval of the grant and adherence to CPRIT requirements.
 - All contracts were signed by CPRIT and the grantee
 - Grant amounts per contract tied to grant award slate approved by the Oversight Committee based on law in effect prior to passage of SB 149, 83rd Legislature, Regular Session and amount published on CPRIT's website

² Grant process can be found on the CPRIT website <http://www.cprit.state.tx.us/grants-process/>

- Grantees were compliant with reporting requirements
- Grantees were compliant with performance requirements
- Certification of matching funds was provided

Internal Audit reviewed 35 expense reimbursements. The review included the following:

- Determine the sufficiency and effectiveness of overall grantee monitoring with respect to identification of potential fraudulent or inappropriate use of grant funds.
 - All costs incurred are allowable under CPRIT regulations and applicable grant contract
 - Indirect costs incurred were less than or equal to 5% of the requested reimbursement amount
 - Budget transfer notifications were correctly filed and approved where required
 - At a minimum 50% of any goods and services purchased were from Texas suppliers
 - Good faith efforts to purchase from Historically Underutilized Businesses (HUBs) were reported
- Completeness and accuracy of reimbursement
 - Financial Status Reports (FSR) reconciled to supporting documentation provided by grantee
 - Expenses were within budget for all categories in the FSR
 - Proper approval signature on purchase voucher
 - Remaining encumbered funds documented by CPRIT reconciled to remaining budget balance per the FSR

Internal audit also reviewed CPRIT's compliance with legislative requirements for performance measurement during the period and disclosures within the annual report which are required by the Texas Administrative Code.

Statistical sampling was used in order to infer the conclusions of the test work performed. When appropriate, judgmental sampling was used to improve the overall efficiency of the audit.

Our procedures included discussions with the following CPRIT personnel:

Name	Title
Heidi McConnell	Chief Operating Officer
Kristen Doyle	Chief Advisor and General Counsel
Alfonso Royal	Finance Manager
Lisa Nelson	Operations Manager

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 and Findings

Summary of Findings and Related Recommendations
During the audit, the following observation(s) were noted:

Description	Priority	Risk/Observation	Recommendation
1. Reimbursement Claims	High	<p>CPRIT's documented policies and procedures state that the detail provided by the grantees in the reimbursement forms should be sufficient to verify the expenditure amount and appropriateness to the CPRIT award. However, per our review of 35 reimbursements claims, the documentation provided for 21 reimbursements (60% of the sample) mainly for supplies sourced from grantees' central institutional supply stores for research projects was not sufficient to support the expense incurred or identify how the expenditure was appropriate to the award.</p> <p>The Financial Status Report Checklist was not signed off by the Grant Accountant on one of the 35 reimbursement claims sampled.</p> <p>For one reimbursement claim that was not part of our original sample we noted there was no signed payment voucher, however the claim was paid. We identified it while reviewing documentation related to our original sample. Per discussion with Management, this may have been misfiled.</p>	<p>We recommend that grantees should be required to provide supporting invoices and receipts for all expenses incurred, including transactions that are internal to a grantee's entity, and submitted on the Financial Status Report regardless of dollar amount. We also recommend that a detailed description be provided by the grantee to show how the expenditure is appropriate to the award.</p> <p>We further recommend that all Financial Status Reports should be signed off by the Grant Accountant as evidence of review and all relevant documents should be maintained within the correct files.</p>

Description	Priority	Risk/Observation	Recommendation
<p>Management Response: Management concurs with this recommendation. CPRIT Finance has implemented a procedure to require grantees with central institutional supply stores to provide documentation of the internal transaction between the organization's departments as verification of the expense reported on a Financial Status Report. CPRIT Finance will also require documentation of all expenses reflected on the Financial Status Report regardless of the amount with the update of the its Grant Policies & Procedures and education of the grantees, particularly research and prevention grantees, about these more stringent requirements. Grant accountants have always verified all expenditures reported on all product development grant Financial Status Reports since those grants have been awarded.</p> <p>Person Responsible: Heidi McConnell Target Date for Implementation: December 1, 2014</p>			
2. Desk Reviews	High	<p>Desk reviews are in-depth reviews of a sample of the reimbursement claims submitted as part of the Financial Status Reports (FSRs) or Form 269A.</p> <p>The internal audit conducted previously in 2013, included the following observation: Policies and procedures outlining the guidelines and timeline for desk reviews were not included within the CPRIT Policies and Procedures Guide. During the time of the audit, the grantees were in the middle of the reconciliation period to get caught up with their reimbursement submissions. As a result, no desk reviews were performed.</p> <p>The 2014 current year internal audit noted the following: During the time of the audit, no desk reviews had been performed. Per Management, checks performed at the time of reviewing the reimbursement are sufficiently detailed to mitigate associated risks. However, as per our findings in Section 1, we believe that initial reviews may not be sufficiently verifying expenditures to detect errors or omissions.</p>	<p>2013 recommendation: Implement policies and procedures related to desk reviews to ensure the process is consistent and performed in a timely manner.</p> <p>2014 recommendation: A schedule for desk reviews should be developed and implemented for the high risk grantees and on an ad hoc basis for lower risk grantees.</p>

Description	Priority	Risk/Observation	Recommendation
<p>Management Response:</p> <p>Management concurs with the recommendation. CPRIT has worked with an independent consultant and researched other state compliance programs to design a model grant monitoring plan. The grant monitoring plans includes desk reviews as part of a comprehensive compliance program.</p> <p>Knowing that desk reviews are an integral part of a compliance program, in June 2014 the agency hired three grant specialists and redirected an existing staff position to manage the team to monitor grant reporting, including performing desk reviews of the Financial Status Reports. Since the creation of this team, the grant specialists have assessed grant reporting accuracy in the CPRIT Grants Management System and agency physical records for compliance. Some data inconsistencies were identified. These inconsistencies are being used to improve programs operated by CPRIT's third party grants management support vendor. In addition, the grant specialists are also performing secondary reviews of Financial Status Reports following the initial FSR reviews performed by grant accountants to confirm the accuracy of the first reviews of grantee reports.</p> <p>Once the compliance program design and its risk analysis is finalized by the agency and approved by the Oversight Committee, the grant specialists will be assigned to perform individual desk reviews of grantees considered high or moderate risk in that analysis.</p> <p>Person Responsible: David Reisman Target Date for Implementation: December 1, 2014</p> <p>Prior Year (FY 2013) Management's Response: CPRIT has maintained desk reviews for its highest risk grants. Desk reviews for lower risk grantees are being conducted again on an as-needed basis using a judgmental sample based on certain indicators in conjunction with the review of quarterly financial reports. The desk review guidelines, which are included in internal CPRIT Finance procedures, will be incorporated in the CPRIT Policies.</p>			

Description	Priority	Risk/Observation	Recommendation
3. CPRIT Policies and Procedures	Medium	<p>Texas Administrative Code, Section 703.14, 'Grant Termination, Extension and Close Out' was adopted January 24, 2014, by the Oversight Committee but not effective until June 1 and is available on CPRIT's website. Per discussion with Management, CPRIT is following the requirements of this rule; however, CPRIT has yet to incorporate the related process into their policy and procedure documents.</p> <p>The CPRIT policies and procedures stipulate approval for the purchase of equipment greater than \$5,000. However, the policy should be updated to reflect that approval from CPRIT is only required in instances where the purchases were not previously authorized as part of the grant contract. The equipment purchase is considered authorized based on an award of funds for a grant application that included the purchase as an equipment budget item.</p> <p>Similarly, the policies and procedures should be updated to provide guidance around the matching funds requirement for research awards.</p>	<p>Management should revise the Policies & Procedures Guide to reflect the changes in the Administrative Code.</p> <p>Management should also consider reviewing the guide on an annual basis to verify the latest updates or changes have been incorporated.</p>

Description	Priority	Risk/Observation	Recommendation
<p>Management Response:</p> <p>Management concurs with the recommendation. Agency statements of general applicability that implement, interpret, or enforce state law or CPRIT policies must follow the requirements of the Texas Administrative Procedure Act (APA). In order for an agency statement to have the force of law and compel compliance through threat of enforcement, the APA requires a formal rulemaking process that includes notice and opportunity for public input. Failure to follow the APA rulemaking process to set agency policy may result in legal challenges and a finding that the agency engaged in illegal ad hoc rulemaking.</p> <p>CPRIT initiated a major rulemaking project consistent with the APA in November 2013. This was the first major revision to agency policies since CPRIT adopted administrative rules in 2009. The new rules and rule revisions 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, and conform agency practices to legislative requirements enacted by the 83rd legislative session. Many of the policy changes implemented through the new rules and rule changes prescribe behavior of agency staff, board members, applicants, reviewers, and grant recipients. The changes increased the number of CPRIT's administrative rules from 33 rules to 48 rules. In addition to substantive changes made to 19 existing rules, 18 new rules were adopted. Since the major rulemaking project that concluded earlier this year, CPRIT has made several additional changes to administrative rules to further clarify agency policies and procedures.</p> <p>Since the new policies have been adopted via the rulemaking process, CPRIT has notified individuals affected by the new rules and rule changes through training, written communication, and updated forms. Agency staff is currently updating the Policies and Procedures Guide as an additional source of guidance about the rule requirements. CPRIT will establish a schedule to annually review and update the Policies and Procedures Guide to reflect any new rules or rule changes.</p> <p>With regard to the observation related to equipment; specifically that the Policies and Procedures Guide, "Should be updated to reflect approval from CPRIT is only required in instances where the purchases were not previously authorized as part of the grant contract." CPRIT notes that the grant contract already specifies that "an acquisition of equipment is deemed authorized if itemized in the Approved Budget for the Project." CPRIT will update the Policies and Procedures Guide to reflect this information.</p> <p>Person Responsible: Kristen Doyle / Lisa Nelson Target Date for Implementation: November 1, 2014</p> <p>Prior Year (FY 2013) Management's Response: CPRIT has formalized the process for closing and extending grants. These processes will be incorporated into the updated CPRIT Policies and Procedures Guide to reflect the processes being followed.</p> <p>Person(s) Responsible 2013: Kristen Doyle / Lisa Nelson Target Date for Implementation 2013: February 28, 2014</p>			

Description	Priority	Risk/Observation	Recommendation
4. HUB and Texas Suppliers Form	Medium	<p>It is the policy of the Institute to encourage grantees to undertake good faith efforts to utilize Texas vendors and historically underutilized businesses (HUBs) to promote full and equal business opportunities for all businesses.</p> <p>A Grant Recipient must report to the Institute at least annually regarding efforts undertaken by the Grant Recipient to utilize HUBs in the performance of the Grant Contract by completing the Historically Underutilized Business and Texas Supplier form submitted as part of the annual Grant Progress Report.</p> <p>Three out of the 35 grant records sampled in CGMS for testing did not have a completed Historically Underutilized Business and Texas Supplier report.</p>	CPRIT should ensure that all grantees complete the Historically Underutilized Business and Texas Supplier report. Grantees that make purchases outside Texas or do not use HUBs should provide an appropriate explanation.
<p>Management Response: Management concurs with the recommendation. CPRIT adopted new administrative rules (25 T.A.C. §§ 701.21 and 701.23) earlier this year related to the good faith efforts expected of grant recipients with regard to the purchase of goods and services with grant funds. The Historically Underutilized Business and Texas Supplier electronic report was created in the CPRIT Grants Management System (CGMS) and released earlier this year to facilitate receiving information for each grant recipient. (Prior to the release of the new electronic form, CPRIT received the information as a static PDF.) CPRIT is working with its third party grant administrator to input HUB data reported by grant recipients previously. The project is expected to be concluded in November 2014 and will provide accurate information for each grant recipient, including whether the annual report is delinquent. This information will be used by CPRIT staff to follow up on delinquent reports.</p> <p>Person Responsible: Kristen Doyle / Lisa Nelson Target Date for Implementation: December 1, 2014</p>			

Additional Recommendations

The following observation(s) were noted to improve overall efficiency and effectiveness of the Grants Management operations going forward. They will require CPRIT's ongoing monitoring and will be continue to be included in subsequent audits. The table below details the observation and impact to CPRIT.

Area(s) of Improvement	Impact	Observation	Operational Impact & Recommendation
1. OC Approval of Grants	High	Prior to January 2014, committee meeting minutes did not include grant details (grantee, grant ID or amount) for grants which were approved. The minutes only documented the approval of 'slate categories' for example 'individual investigator'. For this reason, we were unable to trace the grant amounts approved by the Committee to the grant amounts awarded. From January 2014, CPRIT began to include the details of the approved grants within the Committee Meeting Minutes.	CPRIT should continue to ensure that details of the grant such as grant ID and grant amount approved are included in the minutes of the Oversight Committee Meetings.
2. Performance Measurement	Low	Other than performance measurements monitoring conducted as required by legislation, there is no quarterly review of CPRIT's operating performance.	We recommend CPRIT staff monitor performance quarterly on items such as number and type of grants awarded, grant reimbursements processed, help desk calls/emails, progress of research including number of new drugs/patents, etc.

Information Technology Internal Audit Report

Report #2014-05

July 25, 2014



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

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Executive Summary

In support of the FY2014 Internal Audit Plan, a review of the information technology (IT) process was conducted in June 2014. The IT department is responsible for setting up and supporting IT operations at the Agency. The CPRIT primary offices are located in Austin, TX; and the Chief Scientific Officer has an office in Houston, which is also serviced and maintained by the CPRIT IT department. The department is also responsible for the Agency's various websites, cloud services operations, video conference system, data closet, and typical back-office IT operations.

An internal audit of the IT processes was performed previously in August 2013, June 2012 and May 2011. As a result of those audits, Internal Audit provided CPRIT findings and recommendations to improve overall efficiency and effectiveness within their IT operations. Although some steps have been made to remediate these findings, CPRIT still has some opportunity to improve and establish a strong IT governance structure.

CPRIT continues to work towards establishing leading practices within the IT operations. However, during the FY 2014 IT internal audit, the following improvement opportunities were noted, in descending priority:

- **IT Policies and Procedures not approved or communicated** – In efforts to remediate the findings in the FY 2012 and 2013 IT internal audit reports, the CPRIT IT department has created and updated 100% of the IT policies required by Texas Administrative Code. However, 14 of the 27 policies have not yet been reviewed and approved by management, and 26 of the policies have not been formally communicated to CPRIT employees.
- **Incomplete IT Risk Assessment** – As recommended as part of the FY 2012 and 2013 IT internal audit remediation plans, a detailed risk assessment of the IT environment has not been performed. It was also noted that remediation testing has not been performed for the vulnerabilities identified during penetration testing conducted during the audit period.
- **Security Access Reviews not performed** – Management has not conducted an annual review of user accounts and access permissions.
- **Insufficient Disaster Recovery Plan and Business Continuity Plan** – As recommended in the FY 2012 and 2013 IT internal audit remediation plan, the current disaster recovery plan and business continuity plan should be updated, implemented, and tested to reflect the current IT environment
- **Backup tapes not rotated offsite** – During the period audited, CPRIT was also under review of the Attorney General. As part of this review, the backup logs were maintained on site for inspection and were not rotated to an offsite location.

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 544 grants totaling \$1,020,947,235.¹

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 main objective of the audit was to verify that the IT infrastructure is appropriately safeguarded and that data reliability and accuracy are maintained within the environment.

The specific audit objectives were:

- Verify that prior year audit findings had been addressed and corrected
- Validate that the Agency's IT environment is compliant with the requirements identified in the Texas Administrative Code, Chapter 202, Subchapter B – Security Standards for State Agencies
- IT management and governance:
 - Assess the overall IT function to determine whether sufficient resources and skill sets have been appropriated to support the technology requirements
 - Validate that required policies and procedures are updated and approved by Management
- Information access, security, privacy and safeguarding:
 - Determine whether the security management structure is appropriate for support of business objectives
 - Evaluate whether appropriate access has been granted to the network and selected applications

¹ Figures provided by the CPRIT website. <http://www.cprit.state.tx.us/>

- Assess completion of non-disclosure agreements
- Evaluate the performance of risk assessment of information resources
- IT system availability and recoverability:
 - Validate whether databases are sufficiently backed-up and whether systems are correctly configured to reflect the backup policy
- IT system adequacy:
 - Evaluate sufficiency of the systems to support CPRIT's business objectives

Scope and Testing Approach

The audit performed was designed to evaluate and test compliance with established policies and procedures as of June 2014. Internal Audit interviewed staff and completed field work in June 2014. Our procedures included discussions with the following CPRIT personnel:

Name	Title
Alfonso Royal	Finance Manager
Lisa Nelson	Operations Manager
Therry Simien	Information Technology Officer

During the IT audit, Internal Audit performed procedures that included: inquiry, observation, inspection and re-performance. See the matrix below for a description listing of each type of test performed.

Type	Description
Inquiry	Inquired of appropriate personnel. Inquiries seeking relevant information or representation from CPRIT personnel were performed to obtain among other things: <ul style="list-style-type: none"> • Knowledge and additional information regarding the policy or procedure • Corroborating evidence of the policy or procedure
Observation	Observed the application or existence of specific controls as represented.
Inspection	Inspected documents and records indicating performance of the controls, including: <ul style="list-style-type: none"> • Examination of documents or records for evidence of performance, such as existence of required documentation and approvals. • Inspection of CPRIT systems documentation, such as policies and procedures, network diagrams, flowcharts and job descriptions.
Re-performance	Re-performed the control activity performed by CPRIT to gain additional evidence regarding the effective operation of the control activity.

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.

Findings, Observations, and Recommendations

Summary of Findings and Related Recommendations

The section below provides details regarding the audit findings and corresponding reference to the Texas Administrative Code.

IT Policies and Procedures

Texas Administrative Code (TAC) §202.25 lists suggested policies that should be created and implemented by the information security officer. Per the results of the FY 2012 IT audit, policies and procedures were scheduled to be completed and/or up-to-date by March 2013. As of June 2014, all policies and procedures have been updated. However, 14 out of 27 policy documents are awaiting Management review and communication to employees. See Appendix B for details around testing of IT recommended policies.

Recommendation: As recommended by TAC §202.25 and to ensure CPRIT has established proper IT governance and protocols, all IT policy documents should be reviewed periodically, approved by the state agency head or another designated representative, and communicated formally to all CPRIT employees.

Management's Response 2014:

All policies required by Texas Administrative Code (TAC) §202.25 have been created or updated to reflect the current IT operating environment. Additionally, an agency Intranet deployment is in progress so that policies can be reviewed at, maintained in and disseminated to staff from a central location. During this audit cycle, Management has reviewed drafts of over half of the updated policies and their recommended changes were incorporated and approved. Completion of management review, final updates, formal adoption, and dissemination to staff of all remaining policies will be completed by the end of November 2014.

Person Responsible 2014: Heidi McConnell / Therry Simien / Lisa Nelson

Revised Target Date for Implementation 2014: November 30, 2014

Management's Response 2013:

During this audit cycle, significant progress has been made in the review, updating and creation of IT policies. As shown in Appendix B of the report, nearly half of the recommended policies have been submitted to agency senior management for final approval. IT staff is now in the process of revising those policies to incorporate management's recommendations with the expectation to have this process completed within the next 30 days. The remaining policies and procedures will continue to be updated and/or created over the next several months.

Person Responsible 2013: Heidi McConnell / Therry Simien / Lisa Nelson

Revised Target Date for Implementation 2013: May 31, 2014

IT Risk Assessment

TAC §202.22 states that a “risk assessment of information resources shall be performed and documented” which ranks the associated risks as high, medium, or low. Per the results of the FY 2012 audit, an IT risk assessment was scheduled to be performed by December 2012. As of June 2014, a formal IT risk assessment has not yet been performed.

We also noted that per Management’s response in 2013, initial penetration testing was performed by a third party provider, the Department of Information Resources (DIR), during the audit period. While no exploits were found, a significant number of vulnerabilities were identified during the testing period. Although we understand from discussion with IT that remediation work has begun on these vulnerabilities, no remediation reports were prepared which evidence elimination or mitigation of these risks and acceptance of same by agency head or representative.

Recommendation: Based on the guidelines set forth in TAC §202.22, it was determined that CPRIT appears to be classified as “low-risk” and therefore should consider completing a biennial assessment. By completing a risk assessment periodically, CPRIT will be able to reassess changes that affect the IT environment. Please see Appendix A, for more detail around the risk classification levels in TAC §202.22.

However, in the interim, Management should ensure that vulnerabilities identified during penetration testing are remediated, documented and reviewed by management.

Management’s Response 2014:

CPRIT’s initial penetration test occurred at that beginning of the current audit period in September 2013 and was performed by the Department of Information Resources (DIR). Relocation planning for the agency began during this audit cycle as well. With its long-term lease expiring at the end of August 2014 and new state office space not being ready for occupancy until February 2015, it was determined that the agency would have to perform two physical moves, one at the end of August 2014 into temporary leased space and the second in February 2015.

With the requirement of two physical moves, IT began relocating public facing services and websites offsite onto a mixture of cloud platforms and government class datacenters. Where possible, consolidation of virtual machine hosts was also performed. As it has moved sites to external providers, CPRIT must secure permission from those providers to allow DIR’s testing to occur. Obtaining these permissions is still in process. The creation of formal remediation documentation was impacted by this change.

Now that the agency’s initial physical relocation has been completed and the majority of critical systems and services have been migrated offsite, IT can work with the agency’s new Chief Compliance Officer to implement formal assessment guidelines that meet or exceed state, federal and industry regulations and standards and to create and maintain formal remediation documentation for any future penetration testing.

Person Responsible 2014: Heidi McConnell / Therry Simien / Lisa Nelson / David Reisman

Revised Target Date for Implementation 2014: May 31, 2015

Management's Response 2013:

The tool CPRIT previously used to perform its initial risk assessment (Information Security Awareness, Assessment, and Compliance) ISAAC program was discontinued on August 1, 2013. After a new Chief Compliance Officer is on staff, that person will help define and implement new formal assessment guidelines. Once these guidelines have been established, CPRIT IT will work to implement them as quickly as possible.

CPRIT has contracted with the Department of Information Resources (DIR) to provide quarterly controlled penetration testing of infrastructure systems and services. After each testing cycle, a report will be created detailing vulnerabilities found and remediation recommendations. Once DIR has received confirmation that remediation processes have been established, a new cycle will be implemented to test again. An initial penetration test occurred at the end of September 2013. No exploits were found in the IT systems but some system vulnerabilities were noted. IT staff is addressing those items. The remediation of those items will be tested during the next penetration test DIR conducts.

Person Responsible 2013: Heidi McConnell / Therry Simien / Lisa Nelson / Chief Compliance Officer
Revised Target Date for Implementation 2013: May 31, 2014

Security Access Reviews

TAC §202.21 states that the agency should "review access lists based on documented risk management decisions." Per the results of the FY 2012 audit, CPRIT was scheduled to perform quarterly reviews of systems and network access lists, badge access lists, 3rd party agency sponsored system access (e.g. USAS, GMS), and user accounts. As of June 2014, a quarterly review has not been performed.

During the IT audit, Internal Audit also requested system access rights for new hires during the period; however, this information was not provided.

Recommendation: To prevent unauthorized use of proprietary information or programmatic information that could result in undesirable financial, reputational, regulatory, or operational impacts, CPRIT should consider conducting a semi-annual review of all network users, all badge access holders, and all users with access to USAS. Any exceptions should be noted and remediated immediately. Management should also ensure that all new user access documentation for employees is maintained.

Management's Response 2014:

Informal security audits are performed when staffing changes occur at the agency. The IT ticketing system also tracks the requests for additions of new and modifications to existing user accounts, security group and email accounts. In conjunction with the Comptroller of Public Accounts, CPRIT performs security access checks of USAS every six months.

With the agency's recent physical move and migration from on-site systems to an almost completely hosted infrastructure, new and existing access control systems and methods must be coordinated and centrally consolidated for documentation and monitoring purposes. Where possible, automated checks for access right modifications will be implemented and regular reporting scheduled. Formal assessments of all agency access control systems will be performed semi-annually, documented and reported to agency management.

Person Responsible 2014: Heidi McConnell / Therry Simien / Lisa Nelson
Revised Target Date for Implementation 2014: May 31, 2015

Management's Response 2013:

While informal security audits have been performed when staffing changes occurred, security access reviews have not been performed regularly. CPRIT will complete a second, formal review of user accounts, third-party agency sponsored accounts and physical access system lists. Final assessment report guidelines will be defined and documented, and quarterly reviews will be scheduled.

Person Responsible 2013: Therry Simien / Lisa Nelson
Target Date for Implementation 2013: March 31, 2014

Disaster Recovery Plan & Business Continuity Plan

TAC §202.24 states "agencies shall maintain written Business Continuity Plans that address information resources so that the effects of a disaster will be minimized, and the state agency will be able either to maintain or quickly resume mission-critical functions. The state agency head or his or her designated representative(s) shall approve the plan."

Based on the results of the FY 2012 audit, the agency was scheduled to update the Disaster Recovery Plan as well as the Business Continuity Plan to include an electronic records retention schedule by December 2013. However, the agency determined in the fall of 2013 that it was not feasible based on either cost or resource considerations to establish and maintain an electronic records systems at the standards required to implement such a system. While the two plans have not been completely updated, the combination of the existing paper document retention schedule, email policy and backup process for electronic files mitigate risks associated with business continuity.

In addition to the work on the electronic records retention schedule, the agency and its third-party grants management support vendor, SRA International, Inc. (SRA), defined a 24-hour recovery time objective for the primary grant application and award system which SRA manages and hosts for CPRIT.

We note that the agency is preparing to move to a cloud-based information technology infrastructure which will occur in conjunction with the agency's physical relocation by the end of August 2014.

Recommendation: Since IT systems are critical to CPRIT's operations, Management should implement an up to date disaster recovery plan to ensure the continued operation of the IT systems, or rapid recovery of the systems in case of a natural disaster.

Likewise, CPRIT should also ensure that a business continuity plan is kept updated to guarantee that all aspects of a business remain functioning in the midst of a disruptive event. These plans should include a business impact analysis, a risk assessment, and evidence of implementation, testing, and maintenance.

Management's Response 2014:

Substantial progress was made during this audit period in preparing updated disaster recovery and business continuity plans for the agency. Internally, a committee of stakeholders was formed to review agency electronic record storage options, usage of existing storage systems and the agency's paper retention schedule and physical filing systems. Additionally, as part of the agency's relocation planning, an assessment was performed on all internal agency IT infrastructure systems and where possible, planning began to relocate these resources, such as email, offsite. Finally, the agency has worked with SRA International, Inc. to establish a new level of recoverability for the agency's grants management system and lower the recovery time objective for CARS-CGMS from 24 hours to 12 hours.

After the agency's second physical move is completed in February 2015, a second round of assessments can be performed and the configuration for a cloud and on-premises hybrid can be fully defined and documented so the agency's consolidated disaster recovery and business continuity plans can be finalized.

Person Responsible 2014: Heidi McConnell / Therry Simien / Lisa Nelson

Revised Target Date for Implementation 2014: May 31, 2015

Management's Response 2013:

CPRIT has worked to reduce overall business impact on agency operations of the most common disasters by implementing a server room environmental monitoring and alert system and performing the relocation of several agency public facing resources to cloud provider systems that are geographically separated from the agency. This work continues and will focus on internal services that can be relocated off-site for redundancy or efficiency purposes.

CPRIT will update the agency's existing business continuity plan to reflect these infrastructure changes and will design and implement an effective routine testing schedule.

Person Responsible: Heidi McConnell / Therry Simien / Lisa Nelson

Revised Target Date for Implementation: December 31, 2014

Back Up Tapes

During our IT audit, we noted that backup tapes were not rotated offsite during the period. We understand that these were part of the investigations of the Attorney General and Travis County District Attorney. However, the rotation of backup tapes to an offsite location is essential to mitigate the risk of loss of data. It was also noted that email notification for backups are only run for non-windows applications. For Windows applications, a manual process is conducted to ensure the backup was performed. However, evidence of this check is not maintained.

Recommendation: Management should ensure that backup tapes are rotated off site and an action plan is implemented to reduce the risk of data loss while backup tapes are under investigation. Management should also implement email notifications of backups performed for windows applications to ensure that backups are performed successfully and to maintain an audit trail of same.

Management's Response:

All agency historical backup tapes have been catalogued and will be relocated offsite to the Texas State Library. As a result of our recent agency move, essential agency data including email and shared storage systems is also maintained in the data centers of the agency's new cloud providers.

New backup procedures must be established to incorporate both the agency's cloud infrastructure components and remaining on-premises systems to include auditable backup processes, which will produce email notifications. The backup mechanisms of the new cloud providers' data centers must be reviewed, and the agency's existing backup policy will be updated as necessary to ensure applicability to the agency's new environment.

Person Responsible: Heidi McConnell / Therry Simien / Lisa Nelson

Revised Target Date for Implementation: June 30, 2015

Appendix A –

Texas Administrative Code, §202.22

(a) A risk assessment of information resources shall be performed and documented. The risk assessment shall be updated based on the inherent risk. The inherent risk and frequency of the risk assessment will be ranked, at a minimum, as either "High," "Medium," or "Low," based primarily on the following criteria:

(1) High Risk-annual assessment--Information resources that:

- (A) Involve large dollar amounts or significantly important transactions, such that business or government processes would be hindered or an impact on public health or safety would occur if the transactions were not processed timely and accurately, or
- (B) Contain confidential or other data such that unauthorized disclosure would cause real damage to the parties involved, or
- (C) Impact a large number of people or interconnected systems.

(2) Medium Risk-biennial assessment--Information resources that:

- (A) Transact or control a moderate or low dollar value, or
- (B) Data items that could potentially embarrass or create problems for the parties involved if released, or
- (C) Impact a moderate proportion of the customer base.

(3) Low Risk-biennial assessment--Information resources that:

- (A) Publish generally available public information, or
- (B) Result in a relatively small impact on the population.

(b) A system change could cause the overall classification to move to another risk level.

(c) Risk assessment results, vulnerability reports, and similar information shall be documented and presented to the state agency head or his or her designated representative(s). The state agency head or his or her designated representative(s) shall make the final risk management decisions to either accept exposures or protect the data according to its value/sensitivity. The state agency head or his or her designated representative(s) shall approve the security risk management plan. This information may be exempt from disclosure under §2054.077(c), Government Code.

Appendix B – Texas Administrative Code §202.25 – IT Policies

TAC §202.25 Recommended IT Policy Area	Policy covers requirements of TAC?	Policy Created/ Updated?	Policy Approved by Management?	Policy Communicated to Employees?
Acceptable Use	✓	✓	✓	X
Account Management	✓	✓	X	X
Administrator/Special Access	✓	✓	✓	X
Application Security	✓	✓	X	X
Backup/Recovery	✓	✓	X	X
Change or Configuration Management	✓	✓	✓	X
Electronic Communication	✓	✓	X	✓
Encryption	✓	✓	✓	X
Firewall	✓	✓	✓	X
Incident Management	✓	✓	X	X
Identification/Authentication	✓	✓	✓	X
Internet/Intranet Use	✓	✓	X	X
Intrusion Detection	✓	✓	X	X
Network Access	✓	✓	X	X
Network Configuration	✓	✓	X	X
Physical Access	✓	✓	✓	X
Portable Computing	✓	✓	X	X
Privacy	✓	✓	✓	X
Security Monitoring	✓	✓	X	X
Security Awareness and Training	✓	✓	✓	X
Platform Management	✓	✓	X	X
Authorized Software	✓	✓	✓	X
System Development and Acquisition	✓	✓	X	X
Third Party Access	✓	✓	✓	X
Malicious Code	✓	✓	X	X
Wireless Access	✓	✓	✓	X
Vulnerability Assessment	✓	✓	X	X
Total	27/27	27 / 27	12/27	1/27

Internal Audit Report

Grantee: Molecular Templates

Report #2014-103

July 11, 2014



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

Introduction

As part of the Cancer Prevention Research Institute of Texas (“CPRIT”) FY 2014 Grantee Internal Audit plan, a review of Molecular Templates Inc. has been completed.

Background

Molecular Templates (MTEM) is a privately held, biopharmaceutical company based in Texas that aims to develop novel targeted biologic cancer therapeutics called Engineered Toxin Bodies that will have a clinically meaningful impact on patient outcomes for areas of high unmet medical need. MTEM was set up in 2009 and operates its own 4,000 sq. ft. wet-lab space at the Texas Life Sciences Collaboration Center where the company currently employs seventeen full-time and two part-time employees. Four employees with PhD degrees in biotechnology and three with MBAs were recruited to Texas specifically to work with Molecular Templates.

Since CPRIT’s establishment in 2008, Molecular Templates has been awarded one product development grant (CC121020) totaling \$10,600,000¹. This CPRIT grant provides funds to advance research on MT-3724, its lead drug, by:

- Completing the required studies and manufacturing that enable an investigational new drug application (IND) for MT-3724 to be submitted to the FDA.
- Conducting a phase I trial in patients with non-Hodgkin’s lymphoma (NHL) to determine safety, pharmacokinetics, and the recommended phase II dose (RP2D) for MT-3724.
- Demonstrating efficacy of MT-3724 in a phase II study in NHL cancer patients that can lead to a pivotal phase 3 trial.

Audit Objectives and Scope

Objectives

1. To determine if expenditures were appropriate, adequately documented, and in compliance with CPRIT’s policies.
2. To evaluate the effectiveness and timeliness of current administrative processes related to the CPRIT grant.
3. To evaluate the internal control environment for expenses related to the CPRIT grant.
4. To determine if CPRIT award recipients have an amount of matching funds equal to one-half of the award dedicated to the research that is the subject of the grant request.
5. To determine if CPRIT award recipients are utilizing matching funds towards the same area of cancer research that is the subject of the award.

Scope

1. Molecular Template’s expenses and matching funds related to the CPRIT grant identified above, between September 2012 and May 2014 were covered under the scope of this audit.
2. Detailed testing of selected expense transactions was performed.
3. Detailed testing of matching fund expenditures was performed.

Note: This audited grant did not receive funds to purchase equipment so this area was not in scope.

Summary of Findings

Internal audit did not note any significant findings or exceptions during the audit of Molecular Templates.

¹ Figures provided by the CPRIT website. <http://www.cprit.state.tx.us/funded-grants/>

Testing Approach

Analytical and substantive procedures for Molecular Template's expenses and matching funds related to the CPRIT grant were performed to ensure the grantee complied with CPRIT policy. Through interviews with appropriate personnel, detailed testing of expenditures and analysis of the matching funds process, Internal Audit developed an understanding of the key processes and activities related to the CPRIT grant expense reimbursement and matching funds process.

Our procedures included discussions with the following Molecular Templates personnel:

Name	Title
Jason Kim	Chief Financial Officer
Deborah May	Director of Finance and Administration

Substantive testing was performed on subjectively selected transactions. These transactions were selected from financially material categories (including supplies, contractual, and other) comprising approximately 80% of expenditures within the CPRIT Financial Status Report (FSR) submitted during the period. For each sample selected, supporting documents were reviewed for accuracy, completeness, appropriateness, classification and timing. Supporting documents consisted of invoices from suppliers. Internal Audit also verified that each sampled expense was allowable per CPRIT's Expense Reimbursement Policy.

Detailed testing of matching funds was performed to ensure that the required 50% match to CPRIT funds was achieved. Documentation was obtained and reviewed for selected expenditures to support the appropriateness of the monies being used as match and to ensure that the expenditure was related to advance Molecular Template's lead drug, MT-3724.

Audit Results

Expense Reimbursements

Interviews with key personnel regarding the expense reimbursement process were conducted to ensure that appropriate controls were in place to comply with CPRIT policies and procedures. To evaluate the effectiveness of Molecular Template's expense reimbursement process, Internal Audit performed substantive testing on 227 expense reimbursement transactions totaling over \$2.5 million during the period of September 2012 – May 2014 for the grants selected as part of the review. Internal Audit vouched the expenses per the general ledger to the supporting documents.

Internal Audit then traced the transactions within the general ledger to the Form 269A to ensure that all amounts were accurately reported and that expenses were appropriately categorized and reported to CPRIT. Internal Audit also determined that all expenses were incurred within the dates set forth in the CPRIT grant contract and that no expense was reimbursed prior to it being incurred by the grantee. Upon review of all requested documentation, it was noted that appropriate supporting documentation was available for all samples selected and all expenses claimed were allowable.

Matching Funds

To support Molecular Template's matching funds certification claimed in attachment C of the CPRIT contract, Internal Audit obtained evidence of income used to meet the matching funds requirement. The income originated from funds independent of CPRIT and was used within the same research area as the CPRIT grant selected for testing. Molecular Templates provided sufficient and appropriate evidence to support the income which made up the matching funds amount. From conversations with the Chief Financial Officer and the Director of Finance and Administration, it was validated that the matching funds were also provided to advance Molecular Template's lead drug, MT-3724. Internal Audit concluded that the funds being used for the CPRIT required match are appropriate and meet the requirements described in CPRIT policies and procedures.

Internal Audit Report

Grantee: Rice University

Report #2014-110

August 18, 2014



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

Introduction

As part of the Cancer Prevention Research Institute of Texas (“CPRIT”) FY 2014 Grantee Internal Audit plan, a review of Rice University has been completed.

Background

William Marsh Rice University, commonly referred to as Rice University (“Rice” or “University”), is a private research university located in Houston, Texas, United States. The University was opened in 1912 after the murder of its namesake William Marsh Rice. Rice is now a research university with an undergraduate focus. There are 3,920 undergraduate and 2,567 graduate degree-seeking students. The university is organized into eleven residential colleges and eight schools of academic study. The university has a very high level of research activity, with approximately \$94 million in annual research expenditures during the academic year 2012-13. Rice is noted for its applied science programs in the fields of artificial heart research, structural chemical analysis, signal processing, space science, and nanotechnology.

Since CPRIT’s establishment in 2008, the University has received 12 recruitment and research grants totaling over \$29 million¹. The three audited CPRIT grants provided funds for:

- Recruitment of an Established Investigator to establish the center for Theoretical Biological Physics at Rice University to conduct research on the evolution and ecology of cancer, alternate splicing and other molecular mechanism’s underlying cancer and genetic noise and cellular differentiation (R1110)
- Recruitment of an Established Investigator to set up an organic chemical synthesis and cancer biology laboratory focused on the creation of new medicines for oncology (R1226)
- A collaboration of scientists, engineers, clinicians and a corporate partner for research of cancer screening and diagnostic testing procedures in prostate, oral and ovarian cancers (RP01382-P01)

Audit Objectives and Scope

Objectives

1. To determine if expenditures were appropriate, adequately documented, and in compliance with CPRIT’s policies.
2. To evaluate the effectiveness and timeliness of current administrative processes related to the CPRIT grant.
3. To evaluate the internal control environment for expenses related to the CPRIT grant.
4. To determine if CPRIT award recipients have an amount of matching funds equal to one-half of the award dedicated to the research that is the subject of the grant request.
5. To determine if CPRIT award recipients are utilizing matching funds towards the same area of cancer research that is the subject of the award.
6. To determine if equipment was approved appropriately prior to acquisition, adequately documented, and in compliance with CPRIT’s policies.
7. To observe and verify existence of acquired equipment.

¹ Figures provided by the CPRIT website. <http://www.cprit.state.tx.us/funded-grants/>

Scope

1. The University's expenses, inventory, and matching funds related to the three CPRIT grants identified above, between September 2012 and May 2014 were covered under the scope of this audit.
2. Detailed testing of selected expense transactions was performed.
3. Selected equipment over \$5,000 was observed on-site.
4. Detailed testing of selected matching fund expenditures was performed.

Summary of Findings

Internal audit did not identify any significant issues related to Rice University's expense reimbursement or matching funds documentation. During the inventory observation, Internal Audit noted that one piece of inventory did not have a University asset number assigned; however, this issue was addressed and remediated at the time of the audit. Rice University appears to be in compliance with CPRIT policies for grantees.

Testing Approach

Analytical and substantive procedures for Rice's expenses, inventory, and matching funds related to the three selected CPRIT grants were performed to ensure the grantee complied with CPRIT policy. Through interviews with appropriate personnel, detailed testing of expenditures, observation of equipment, and analysis of the matching funds process, Internal Audit developed an understanding of the key processes and activities related to the CPRIT grant expense reimbursement, inventory, and matching funds process.

Our procedures included discussions with the following Rice University personnel:

Name	Title
Charles Tarantino	Assistant Controller
Terry Whitt	Research Accounting Manager

Substantive testing was applied subjectively to selected CPRIT expense transactions. These transactions were selected from financially material categories (such as payroll, fringe benefits, travel, equipment, supplies, contractual, and other) comprising approximately 70% of expenditures within the CPRIT Financial Status Report (FSR). One to five expenditures were sampled for each material category and supporting documents were reviewed for accuracy, completeness, appropriateness, classification and timing. Examples of supporting documents include invoices, receipts, and employee expense reports. Internal Audit also verified that each sampled expense was allowable per CPRIT's Expense Reimbursement Policy.

Internal Audit obtained a complete listing of inventory from the CPRIT Grants Management System (CGMS) for the selected grants and randomly selected items to observe. Observations were performed on selected inventory to ensure the equipment existed, was properly identified and recorded, and was in working condition.

Detailed testing of the University's matching funds was performed to ensure that Rice met the required match of 50% of CPRIT funds. Documentation was obtained and reviewed for selected expenditures to support the appropriateness of the monies being used as match and to ensure that the expenditure was related to cancer research.

Audit Results

Expense Reimbursements

To evaluate the effectiveness of the University's expense reimbursement process, Internal Audit performed substantive testing on almost 3,000 expense reimbursement transactions totaling over \$2.7 million during the period of September 2012 – May 2014 for the three grants selected as part of the review. Internal Audit vouched the expenses per the general ledger to the supporting documents. Internal Audit then traced the transactions within the general ledger to the Financial Status Reports (Form 269A) to ensure that all amounts were accurately reported and that expenses were appropriately categorized and reported to CPRIT.

Upon review of the requested documentation for expense reimbursements, it was noted that all samples of CPRIT grant reimbursement requests were accompanied by complete, accurate, and appropriate supporting documentation. Internal Audit also determined that all expenses were incurred within the dates set forth in the CPRIT grant contract, and no expense was reimbursed prior to it being incurred by the grantee.

Inventory & Equipment

Internal Audit obtained a complete listing of inventory from the grantee for the selected grants and randomly selected 15 items to observe. Internal Audit observed the pieces of equipment to verify the existence and proper recording of inventory purchased with CPRIT funds. Internal Audit noted the following:

- One piece of equipment, for grant R1226, did not have a University asset number assigned; however, the equipment's serial number tied back to the inventory listing.

Before the audit was completed, the University addressed this observation by appropriately labeling the piece of equipment. Internal Audit does not consider this to be an exception.

Matching Funds

To support Rice's matching funds certification claimed in Attachment C of their CPRIT contracts, Internal Audit obtained documentation to verify that the expenditures originated from funds independent of CPRIT.

Internal Audit noted that the matching funds document for grant R1226 was due for submission in February 2014, but has not yet been submitted in the grants management system, due to technical difficulties. Rice submitted a letter to CPRIT in June 2014 outlining this issue, however, at the time of the audit (August 2014), the system issue has not been rectified. Internal Audit obtained the matching funds documentation as part of testing and verified that it was available and sufficient.

Internal Audit concluded that the funds being used for the CPRIT required match are appropriate and meet the requirements described in CPRIT policies and procedures.

Recommendations

To improve the accuracy of monitoring their inventory, the University should perform periodic physical inventories of their assets to verify that their inventory listing is accurate and complete. The asset review should include a review of the serial number, asset number, and the item description. During the inventory observation, Internal Audit noted that one piece of inventory did not have a University asset number assigned; however, this issue was addressed and remediated at the time of the audit.

Internal Audit Report

Grantee: Texas A&M Health Science Center

Report #2014-105

July 25, 2014



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

Introduction

As part of the Cancer Prevention Research Institute of Texas (“CPRIT”) FY 2014 Grantee Internal Audit plan, a review of Texas A&M Health Science Center has been completed.

Background

Texas A&M Health Science Center (TAMHSC) is an independent state agency and academic unit of Texas A&M University which serves the state through campuses in Bryan-College Station, Dallas, Temple, Houston, Round Rock, Kingsville, Corpus Christi and McAllen. The Center is a premier assembly of colleges devoted to educating health professionals and researchers of extraordinary competence and integrity. It officially began operating in September 1999 and has focused on transforming health through innovative research, education and service in dentistry, medicine, nursing, pharmacy, public health and medical sciences.

Since CPRIT’s establishment in 2008, the TAMHSC at College Station, has received 9 research and prevention grants totaling over \$8 million¹. The three audited CPRIT grants provided funds to:

- Enhance colorectal cancer screening training in a family medicine residency program that serves low-income & underserved populations (PP110176)
- Develop interventions and biomarkers that can be used in future clinical trials to reduce the risk of endometrial and other cancers that can occur due to obesity (PP120855)
- Develop new cancer therapeutics through the combination of existing drugs (RP110532 – P2)

Audit Objectives and Scope

Objectives

1. To determine if expenditures were appropriate, adequately documented, and in compliance with CPRIT’s policies.
2. To evaluate the effectiveness and timeliness of current administrative processes related to the CPRIT grant.
3. To evaluate the internal control environment for expenses related to the CPRIT grant.
4. To determine if CPRIT award recipients have an amount of matching funds equal to one-half of the award dedicated to the research that is the subject of the grant request.
5. To determine if CPRIT award recipients are utilizing matching funds towards the same area of cancer research that is the subject of the award.
6. To determine if equipment was approved appropriately prior to acquisition, adequately documented, and in compliance with CPRIT’s policies.
7. To observe and verify existence of acquired equipment.

Scope

1. TAMHSC’s expenses, inventory, and matching funds related to the three CPRIT grants identified above, between September 2012 and May 2014, were covered under the scope of this audit.
2. Detailed testing of selected expense transactions was performed.
3. Selected equipment over \$5,000 was observed on-site.
4. Detailed testing of selected matching fund expenditures was performed.

¹ Figures provided by the CPRIT website. <http://www.cprit.state.tx.us/funded-grants/>

Summary of Findings

Texas A&M Health Science Center demonstrated some inaccuracies around their expense reimbursement and matching funds documentation processes. Internal Audit identified the following exceptions:

- One expense totaling \$1,650 was incorrectly categorized
- Fifteen transactions totaling \$98,436 were claimed in the subsequent Financial Status Report (FSR) period after the correct FSR reimbursement dates
- A reimbursement was made for \$5.29 for an unallowable penalty payment, and the associated indirect cost of \$0.28 was also claimed
- Several inconsistencies such as incorrect account descriptions in the system, cost share amounts due to an incorrect calculation formula, and missing expenditures used for matching funds were not included in the original matching funds documentation provided.

Although sufficient matching funds evidence was provided in the end, the inaccuracies noted above display potential deficiencies within the internal recording and matching funds processes.

Testing Approach

Analytical and substantive procedures for TAMHSC's expenses, inventory, and matching funds related to the three selected CPRIT grants were performed to ensure the grantee complied with CPRIT policy. Through interviews with appropriate personnel, detailed testing of selected expenditures, observation of equipment, and analysis of the matching funds process, Internal Audit developed an understanding of the key processes and activities related to the CPRIT grant expense reimbursement, inventory, and matching funds process.

Our procedures included discussions with the following TAMHSC personnel:

Name	Title
Michele Lacey	Director, Contracts & Grants, Sponsored Research Services
Evan Bryant	Senior Manager, Quality Assurance, Sponsored Research Services

Substantive testing was performed on subjectively selected transactions. These transactions were selected from financially material categories (such as payroll, fringe benefits, travel, equipment, supplies, contractual, and other) comprising approximately 70% of expenditures within the CPRIT Financial Status Reports (FSR). Expenditures were sampled from each material category and supporting documents were reviewed for accuracy, completeness, appropriateness, classification and timing. Examples of supporting documents include invoices, receipts, and employee expense reports. Internal Audit also verified that each sampled expense was allowable per CPRIT's Expense Reimbursement Policy.

Internal Audit obtained a complete listing of inventory from the CPRIT Grants Management System (CGMS) for the selected grants, and a sample of listed inventory items was selected for observation. Observations were performed on selected inventory to ensure the equipment existed, was properly identified and recorded, and was in working condition.

Detailed testing of matching funds was performed to verify TAMHSC evidenced the required 50% match of CPRIT funds. Documentation was obtained and reviewed for selected expenditures to support the appropriateness of the monies being used as match and to ensure that the expenditure was related to cancer research.

Audit Results

Expense Reimbursements

Interviews with key personnel regarding the expense reimbursement process were conducted to ensure that appropriate controls were in place to comply with CPRIT policies. To evaluate the effectiveness of TAMHSC's expense reimbursement process, Internal Audit performed substantive testing on 885 expense reimbursement transactions totaling over \$1.5 million during the period of September 2012 – May 2014 for the three grants selected as part of the review. Internal Audit vouched the expenses per the general ledger to the supporting documents. All supporting documentation was available for the selected sample.

Internal Audit then traced the transactions within the general ledger to the Form 269A to ensure that all amounts were accurately reported and that expenses were appropriately categorized and reported to CPRIT. Internal Audit also determined that all expenses were incurred within the dates set forth in the CPRIT grant contract and that no expense was reimbursed prior to it being incurred by the grantee. Upon review of all requested documentation, Internal Audit noted the following:

- One expense totaling \$1,650 was incorrectly categorized as 'Supplies' instead of 'Other'
- Fifteen transactions totaling \$98,436 were claimed in the subsequent FSR period after the actual payment date. All fifteen transactions were claimed within 30 days of the correct FSR period.
- An amount of \$5.29 was claimed in error for a late vendor payment penalty. An indirect cost of \$0.28 was also claimed in conjunction with this penalty payment. TAMHSC has acknowledged that this was claimed in error, and per conversation with CPRIT staff, will include a credit of \$5.57 in the next possible FSR submission.

Inventory & Equipment

During the inspection of the five randomly selected pieces of equipment, Internal Audit noted the following:

- One item had been sent off for repair, and the related repair form was observed. The asset number on the repair form tied to the asset number included on the inventory listing.
- Two items of inventory were maintained at TAMHSC's Houston location. Internal audit obtained photographs of the pieces of inventory and their serial and inventory numbers.

Matching Funds

To support TAMHSC's matching funds certification claimed in attachment C of the CPRIT contract, Internal Audit obtained the accounting record of all the funds and expenditures which were used to meet the matching funds requirement. The selected expenditures originated from funds independent of CPRIT and were categorized within the same research areas as the two CPRIT grants which required matching funds. TAMHSC was able to provide sufficient and appropriate evidence to support the matching funds. Internal Audit concluded that the funds being used for the CPRIT match required are appropriate and meet the requirements described in CPRIT policies and procedures.

The original evidence of matching funds provided to Internal Audit was not sufficient to meet the 50% match requirement for grant RP110532-P2, year 1. However, upon making the accounting department aware of this, a reassessment was performed, and the errors were identified and rectified.

Internal Audit noted the following items related to TAMHSC's matching funds:

- An account description in the system was labeled "Rice University" and not "TAMHSC" – upon further research, this was incorrectly input and subsequently changed to TAMHSC.

- TAMHSC reported incorrect matching funds amounts due to an incorrect calculation formula on the documentation provided. The original amount entered was less than the funds set aside for match and underreported their potential matching funds.
- Expenditures for salary, fringe benefits, and other matching funds were not included in the original matching funds calculation. However, corrections were made during the audit.

Although these errors were identified during the audit, TAMHSC was able to show evidence that the 50% matching funds requirement was met. The inaccuracies identified may also point to other potential deficiencies within TAMHSC internal matching funds recording process.

Recommendations

Prior to their FSR submission to CPRIT, TAMHSC should verify that all reimbursements are categorized correctly. TAMHSC should also verify that all costs being claimed are allowable and are included in the correct FSR period. TAMHSC should also work with the CPRIT staff to ensure that the unallowable amount of \$5.57 claimed in error is credited on the next FSR submission.

Finally, TAMHSC should work towards developing appropriate review procedures to ensure the appropriate expenses and matching funds information is input accurately and completely. These procedures may include verifying the description of the funding source, validating the formula being used to calculate the matching funds, and corroborating the completeness of funds used in the calculation.

TAMHSC Management's Response

- **Finding #1:** One expense totaling \$1,650 was incorrectly categorized
 - TAMUHSC concurs with this finding. The expense was categorized as "supplies" and should have been categorized as "other."
- **Finding #2:** Fifteen transactions totaling \$98,436 were claimed in the subsequent Financial Status Report (FSR) period after the correct FSR reimbursement dates
 - We disagree with these findings based upon processes that have been agreed upon with CPRIT and other extenuating circumstances.
 - On sample items 108, 235, 236, 110, 365, 366, 378, and 433 the posting date is the date we use to report expenditures. The check or ACH date is usually 1 to 2 business days following the posting date. Our process has verbal approval from CPRIT.
 - On sample items 90, 91 and 92 the posting date of 9/14/2012 was the date these costs were posted to the correct budget period on which we reported. They were previously posted and paid to the prior year's budget, and then corrected to the correct budget period on 9/14/12 and reported correctly on the FSR for period 9/1/12 – 11/30/12 using the posting date.
 - On sample items 444, 214 and 217, we reported the costs for the budget period on which the services were performed. We were unable to request carry forward during CPRIT's "reconciliation period" due to the short deadlines.
 - On sample item 368, the FSR period of 6/1/13 – 6/30/13 was the final financial reporting period for that budget period. The invoice date on the vendor invoice was prior to 6/30/13, and we reported it for the period of time reflected by the invoice date.

- **Finding #3:** A reimbursement was made for \$5.29 for an unallowable penalty payment, and the associated indirect cost of \$0.28 was also claimed
 - TAMUHSC concurs with this finding. A refund check was issued to CPRIT on 09/08/14 in the amount of \$5.57.

- **Finding #4-6:** Several inconsistencies such as incorrect account descriptions in the system, cost share amounts due to an incorrect calculation formula, and missing expenditures used for matching funds were not included in the original matching funds documentation provided.
 - TAMUHSC concurs with the finding of inconsistencies and has implemented a review process prior to reporting cost sharing to CPRIT. However, the matching was allowable, the calculations and the documentation was corrected.

Internal Audit Report

Grantee: Texas AgriLife Extension Service

Report #2014-107

August 1, 2014



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

Introduction

As part of the Cancer Prevention Research Institute of Texas (“CPRIT”) FY 2014 Grantee Internal Audit plan, a review of Texas AgriLife Extension Service has been completed.

Background

Texas AgriLife Extension Service (the “Agency”) is a unique education agency that reaches into every Texas county to address local priority needs. Texas A&M University was founded in 1876 and is one of the largest systems of higher education in the nation, with a statewide network of 11 universities, seven state agencies, two service units and a comprehensive health science center. Texas AgriLife Extension Service was established in 1915 and has a network of 250 county offices and 900 professional educators.

Since CPRIT’s establishment in 2008, the Agency has received two prevention grants totaling over \$3 million¹. The audited CPRIT grant provided funds to:

- Increase breast and cervical cancer screening and diagnostic services in 49 rural, frontier, and border counties to improve early detection (PP120099)

Audit Objectives and Scope

Objectives

1. To determine if expenditures were appropriate, adequately documented, and in compliance with CPRIT’s policies.
2. To evaluate the effectiveness and timeliness of current administrative processes related to the CPRIT grant.
3. To evaluate the internal control environment for expenses related to the CPRIT grant.

Scope

1. The Agency’s expenses related to the CPRIT grant identified above, between September 2012 and December 2013 were covered under the scope of this audit.
2. Detailed testing of selected expense transactions was performed.

Note: This audited grant did not receive funds to purchase equipment so this area was not in scope. This grant is categorized as a prevention grant so the matching funds requirement was not in scope.

Summary of Findings

Internal Audit did not note any significant issues related to the Agency’s expense reimbursement process. All samples tested were accompanied by complete, accurate, and appropriate supporting documentation.

Testing Approach

Analytical and substantive procedures for the Agency’s expenses related to the selected CPRIT grant were performed to ensure the grantee complied with CPRIT policy. Through interviews with appropriate personnel and detailed testing of expenditures, Internal Audit developed an understanding of the key processes and activities related to the CPRIT grant expense reimbursement process.

¹ Figures provided by the CPRIT website. <http://www.cprit.state.tx.us/funded-grants/>

Our procedures included discussions with the following Texas AgriLife Extension Service personnel:

Name	Title
Evan Bryant	Senior Manager – Quality Assurance

Substantive testing was applied subjectively to selected CPRIT expense transactions. These transactions were selected from financially material categories (such as payroll, fringe benefits, travel, equipment, supplies, contractual, and other) comprising approximately 60% of expenditures reported on the CPRIT Financial Status Report (FSR). One to five expenditures were sampled for each material category and supporting documents were reviewed for accuracy, completeness, appropriateness, classification and timing. Examples of supporting documents include invoices, receipts, employee expense reports, and accounts payable subledger reports. Internal Audit also verified that each sampled expense was allowable per CPRIT's Expense Reimbursement Policy.

The selected expenditures claimed in the CPRIT FSRs were selected from categories including personnel, travel, equipment, supplies, contractual, services and other. For all expenditures claimed, supporting documents were reviewed for accuracy, completeness, appropriateness, classification and timing. Examples of supporting documents include invoices, receipts, employee expense reports and the accounts payable subledger reports. Internal Audit also verified that each sampled expense was allowable per CPRIT's Expense Reimbursement Policy.

Audit Results

Expense Reimbursements

To evaluate the effectiveness of the Agency's expense reimbursement process, Internal Audit performed substantive testing on 285 judgmentally selected expense reimbursement transactions totaling approximately \$560,000 during the period of September 2012 – December 2013 for the grant selected as part of the review. All supporting documentation was available for each sample. Internal Audit vouched the expenses per the general ledger to the supporting documents.

Internal Audit then traced the transactions within the general ledger to the FSRs (Form 269A) to verify that all amounts were accurately reported and that expenses were appropriately categorized and reported to CPRIT. Upon review of all documentation requested, Internal Audit noted that appropriate supporting documentation was available and all expenses claimed were allowable.

Internal Audit Report

Grantee: Texas Nurses Foundation

Report #2014-102

June 27, 2014



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

Introduction

As part of the Cancer Prevention Research Institute of Texas ("CPRIT") FY 2014 Grantee Internal Audit plan, a review of the Texas Nurses Foundation has been completed.

Background

The Texas Nurses Foundation (TNF) was founded in 1982 and is a non-profit organization created to provide public education, encourage nursing excellence and advance scientific enquiry. TNF is the non-profit arm of the Texas Nurses Association (TNA). With a vision of: "Healthy Texans through excellence in Nursing", TNF advances the charitable, scientific and educational initiatives of the TNA and creates and implements projects that improve health and enhance the nursing profession.

TNF has multiple programs including the Nurse Oncology Educational Program (NOEP) for which CPRIT awarded grant PP110102 from September 2012 – February 2014. As NOEP is a program which is run under the TNA, all payments relating to expenses incurred to fulfill the program objectives of NOEP were paid by TNA and then reimbursed by NOEP upon receipt of reimbursement payments from CPRIT.

Since CPRIT's establishment in 2008, the Foundation has received five prevention grants totaling over \$2,107,900¹. The CPRIT grant selected for audit has provided funds to educate Texas primary care nurses on primary cancer prevention behaviors and role-modeling those behaviors. This included education around tobacco cessation, balanced diet and increased physical activity.

Audit Objectives and Scope

As the grant being audited is a prevention grant, matching funds were not required. Grant funds were not used to purchase equipment. Therefore these two areas are not in scope.

Objectives

1. To determine if expenditures were appropriate, adequately documented, and in compliance with CPRIT's policies.
2. To evaluate the effectiveness and timeliness of current administrative processes related to the CPRIT grant.
3. To evaluate the internal control environment for expenses related to the CPRIT grant.

Scope

1. Expenses related to the CPRIT grant identified above, between September 2012 and February 2014 were covered under the scope of this audit.
2. Detailed testing of selected expense transactions was performed.

¹ Figures provided by the CPRIT website. <http://www.cprit.state.tx.us/funded-grants/>

Summary of Findings

Internal Audit noted the following during the audit:

- Subjective allocation of employee time to the NOEP program – the percentage of compensation, taxes and benefits expensed seemed arbitrary since detailed timesheets were not maintained
- Expenses totaling \$517.30 were classified incorrectly in the Financial Status Reports
- Unallowable expenses totaling \$2044.35 was claimed for the lease of IT equipment not originally included in the grant budget and for the purchase of promotional items

Testing Approach

Analytical and substantive procedures were performed around the expenses claimed from CPRIT to ensure the grantee complied with CPRIT policy. Through interviews with appropriate personnel and detailed testing of expenditures, Internal Audit developed an understanding of the key processes and activities related to the CPRIT grant expense reimbursement process.

Approximately 65% of expenditures claimed within the CPRIT Financial Status Reports were selected from all categories including personnel, fringe benefits, travel, equipment, supplies, contractual, and other. For all expenditures claimed, supporting documents were reviewed for accuracy, completeness, appropriateness, classification and timing. Examples of supporting documents include invoices, receipts, and employee expense reports. Internal Audit also verified that each sampled expense was allowable per CPRIT's Expense Reimbursement Policy.

Interviews with the following key personnel regarding the expense reimbursement process were conducted to ensure that appropriate controls were in place to comply with CPRIT policies;

Name	Title
Cindy Zolnierrek	Executive Director
Margaret Hobbs	Director, Finance
Mason Kinard	Program Coordinator

Audit Results

Expense Reimbursements

To evaluate the effectiveness of the Texas Nurses Foundation's expense reimbursement process, Internal Audit performed substantive testing on over \$83,500 in expenses claimed from CPRIT during the period of September 2012 – February 2014. Internal Audit vouched the expenses per the general ledger to the supporting documents and verified that the amount, date, and classification of each expense were properly recorded in the general ledger.

Internal Audit then traced the transactions within the general ledger to the Financial Status Reports to ensure that all amounts were accurately reported and that expenses were appropriately categorized and reported to CPRIT. Internal Audit also determined that all expenses were incurred within the dates set forth in the CPRIT grant contract and that no expense was reimbursed prior to it being incurred by the grantee. Upon review of all requested documentation, it was noted that all samples of CPRIT grant expenses were accompanied by complete, accurate, and appropriate supporting documentation. However, internal audit noted the following during the review of the reimbursements:

- Allocation of NOEP employee time spent on the CPRIT grant was subjective. An estimated percentage of time spent on each grant area was determined by the program staff and not tracked on

timesheets. Compensation, taxes, and benefits were expensed to CPRIT based on this allocation. The total amount claimed over the period of the grant for these categories of expenses was \$106,588; therefore an inaccurate allocation of time could be material to the grant as a whole.

- NOEP's reimbursement claims for payroll and benefit amounts were maintained separately from the other CPRIT expenses making it difficult to substantiate the figures allocated for TNA.
- The allocation of certain expenses across various grants was unsubstantiated. Internal Audit noted that in one instance, a receipt of \$297.47 for office supplies was split between two grants, one from CPRIT and one from another organization; however, there was no clear documentation behind the allocation of funds between the two grants.
- A combined unallowable expense of \$1,729.35 was claimed for the purchase of lip balms used for promotional purposes. Promotional expenditure is specifically unallowable per CPRIT's policies and procedures.
- An unallowable expense of \$315 was claimed for the lease of IT equipment as part of the Financial Status Report. This type of expenses was not included as part of the detailed budget agreed upon by CPRIT.
- Travel expenses of \$322.72 were incorrectly allocated to the 'supplies' category and another \$194.58 incorrectly allocated to the 'other' category.

Recommendations

The Texas Nurses Foundation should implement a more accurate method of monitoring time spent on CPRIT grant areas. This could include the modification of the ADP module to allow detailed time allocation within the system. Alternatively, TNF could maintain a detailed spreadsheet which tracks the hours spent by each employee on a CPRIT grant, including a narrative of the work performed. Proper documentation of time records for the allocation will help support their reimbursement claims.

TNF should ensure that only expenses which are specifically claimable per the detailed budget are included in the expense reimbursement request. TNF should review the reimbursements and verify that expenses are allocated to the correct category on the Financial Statement Report submitted to CPRIT.

TNA pays and subsequently allocates expenses across multiple grants, including the CPRIT grant. Likewise, TNF incurs expenses that are allocated across multiple grant areas and are eligible for reimbursement from various grants. This introduces an additional challenge for TNF to track proper allocation between grants. For all expense claims, TNF should include and maintain documentation with clear explanations for the allocation of expenses to a CPRIT grant.

TNF was able to produce all documentation that Internal Audit requested. However, as the TNA pays all expenses relating to the NOEP program and is reimbursed by NOEP, supporting documentation to support the overall payment of payroll and benefits is currently stored in different location. Although TNF was able to present all documentation in a timely manner, storing all documents related to individual CPRIT grants in a central location would increase efficiencies and enable documents to be more readily available for review.

Internal Audit noted that, due to the nature of the allocation of expenses to the various grants, there is a key dependence on the Program Coordinator, Mason Kinard, who has in-depth knowledge of the requirements of each of the grants received by the Texas Nurses Foundation. The organization should consider cross training other NOEP employees to familiarize themselves with the CPRIT grant allocation and reimbursement process.

TNF Management's Response

Findings 1-3: Subjective allocation of employee time to the NOEP program – the percentage of compensation, taxes and benefits expensed seemed arbitrary since detailed timesheets were not maintained.

Response: A former CPRIT finance employee and former NOEP Program Director designed and approved the method for allocating the percentage of staff compensation, taxes and benefits to be expensed to each grant. This CPRIT/NOEP designed/approved method was used with CPRIT's approval throughout the grant. The online ADP payroll system is used by all TNA employees and it is detailed with sign in, sign outs and approvals. For privacy reasons, some of the detailed records are kept in confidential files that are not NOEP files.

Findings 4-5: Unallowable expenses totaling \$2,044.35 was claimed for lease of IT equipment not originally included in the grant budget and for the purchase of promotional items.

Response: The \$315 for IT expense claimed was budgeted for a different CPRIT grant at the time. The \$1,729.35 claimed for lip balms was determined by the NOEP Program Director, at the time, as being included under the grant's "Marketing: Incentives for Education Activity Participation" category. "Free Online CNE" with the website address printed on the lip balms which were distributed at conferences and exhibits and are much more likely to be acquired and retained by nurse attendees than are print marketing materials. NOEP had been assured by former CPRIT Prevention Program Manager that this expense was allowable with the NOEP website address included.

Finding 6: Expenses totaling \$517.30 were classified incorrectly in Financial Status Report.

Response: Travel expense of \$322.72 was claimed for "Other". Travel expense of \$194.58 was claimed for "Supplies". These CPRIT grant expenses were listed in an incorrect expense category.

Internal Audit Report

Grantee: The Methodist Hospital Research Institute

Report #2014-109

August 18, 2014



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

Introduction

As part of the Cancer Prevention Research Institute of Texas (“CPRIT”) FY 2014 Grantee Internal Audit plan, a review of The Methodist Hospital Research Institute (“TMHRI”) has been completed.

Background

The Methodist Hospital Research Institute’s mission of leading medicine is grounded in a commitment to translational and interdisciplinary research and education. Their mission is to innovate in health care technology and train current and future clinicians and translational researchers from around the world in cutting edge health care advances. TMHRI supports a global research collaboration network of faculty with nontraditional platform technologies and research programs, administrative support, staff, and facilities that are needed to rapidly translate discoveries made in the laboratory and the clinic into new diagnostics, therapies and treatments.

Since CPRIT’s establishment in 2008, TMHRI has received 11 research grants totaling over \$25 million.¹ The three audited CPRIT grants provided funds for:

- Recruitment of an established investigator to validate the most promising candidate cancer genes by determining whether the structure or expression of a cancer gene is altered in human samples (R1112)
- Recruitment of an established investigator to complete transposon screens initiated overseas, continue research on several new screens for lung and ovary cancers, and research which genes are important for different stages of cancer development: initiation, progression and metastasis (R1113)
- Development of a multimodality image-guided system for early diagnosis and treatment of lung cancer (RP100627)

Audit Objectives and Scope

Objectives

1. To determine if expenditures were appropriate, adequately documented, and in compliance with CPRIT’s policies.
2. To evaluate the effectiveness and timeliness of current administrative processes related to the CPRIT grant.
3. To evaluate the internal control environment for expenses related to the CPRIT grant.
4. To determine if CPRIT award recipients have an amount of matching funds equal to one-half of the award dedicated to the research that is the subject of the grant request.
5. To determine if CPRIT award recipients are utilizing matching funds towards the same area of cancer research that is the subject of the award.
6. To determine if equipment was approved appropriately prior to acquisition, adequately documented, and in compliance with CPRIT’s policies.
7. To observe and verify existence of acquired equipment.

Scope

1. TMHRI’s expenses, inventory, and matching funds related to the three CPRIT grants identified above, between September 2012 and May 2014 were covered under the scope of this audit.
2. Detailed testing of selected expense transactions was performed.
3. Selected equipment over \$5,000 was observed on-site.

¹ Figures provided by the CPRIT website. <http://www.cprit.state.tx.us/funded-grants/>

4. Detailed testing of selected matching fund expenditures was performed.

Summary of Findings

Internal Audit did not note any significant findings or exceptions during the audit of TMHRI. During the review of TMHRI, Internal Audit did note some confusion around the matching funds requirement. However, supporting documentation for matching funds was provided after clarification of the requirement was discussed with TMHRI staff for their CPRIT awards under review. No additional issues related to expense reimbursements or inventory were identified during the audit.

Testing Approach

Analytical and substantive procedures for TMHRI's expenses, inventory, and matching funds related to the three selected CPRIT grants were performed to ensure the grantee complied with CPRIT policy. Through interviews with appropriate personnel, detailed testing of expenditures, observation of equipment, and analysis of the matching funds process, Internal Audit developed an understanding of the key processes and activities related to the CPRIT grant expense reimbursement, inventory, and matching funds requirement.

Our procedures included discussions with the following TMHRI personnel:

Name	Title
Gary Lingle	Director, Office of Grants and Contracts
Rhonda Davenport	Finance Manager – Post Award, Office of Grants and Contracts
Alecia Rister	Director, Financial Reporting and Budgets

Substantive testing was applied subjectively to selected CPRIT expense transactions. These transactions were selected from financially material categories (such as payroll, fringe benefits, travel, equipment, supplies, contractual, and other) comprising approximately 60% of expenditures within the CPRIT Financial Status Report (FSR). Expenditures greater than \$1,500 were sampled for each material category, and supporting documents were reviewed for accuracy, completeness, appropriateness, classification and timing. Examples of supporting documents include invoices, receipts, and employee expense reports. Internal Audit also verified that each sampled expense was allowable per CPRIT's Expense Reimbursement Policy.

Internal Audit obtained a complete listing of inventory from the provided Asset Register for the selected grants and selected the 29 items greater than \$5,000 to observe. Observations were performed to verify the equipment existed, was properly identified and recorded, and was in working condition.

Detailed testing of matching funds was performed to validate that TMHRI met the required match of 50% of CPRIT funds. Documentation was obtained and reviewed for selected expenditures to support the appropriateness of the monies being used as match was related to cancer research.

Audit Results

Expense Reimbursements

To evaluate the effectiveness of TMHRI's expense reimbursement process, Internal Audit performed substantive testing on approximately 160 expense reimbursement transactions totaling over \$2.3 million during the period of September 2012 – May 2014 for the three grants selected as part of the review. Internal Audit vouched the expenses per the general ledger to the supporting documents.

Internal Audit then traced the transactions within the general ledger to the submitted FSR (Form 269A) to verify that all amounts were accurately reported and that expenses were appropriately categorized and reported to CPRIT. Internal Audit also determined that all expenses were incurred within the dates set forth in the CPRIT grant contract and that no expense was reimbursed prior to it being incurred by the grantee. Upon review of the requested documentation for expense reimbursements, it was noted that all samples of CPRIT grant expenses were accompanied by complete, accurate, and appropriate supporting documentation.

Inventory & Equipment

Internal Audit obtained a complete listing of inventory from the grantee for the selected grants and observed equipment over \$5,000. Internal Audit noted that the cost of assets was shared between grant R1112 and R1113. Internal Audit observed 29 pieces of equipment to verify the existence and proper recording of inventory purchased with CPRIT funds. All pieces of inventory were accessible during the audit and were included in the original approved budget.

Matching Funds

To support TMHRI's matching funds certification claimed in Attachment C of the CPRIT contract for the research grants audited, Internal Audit requested the accounting records of all the funds and expenditures which were used to meet the matching funds. Testing was performed to ensure that TMHRI met the required match of 50% of CPRIT funds. Evidence of expenditure in relation to each fund was obtained in order to validate that the expenditure was related to cancer research.

While TMRHI was not specifically setting aside funds to match CPRIT awards at the beginning of each period, TMRHI was able to provide appropriate supporting documentation that a match of at least 50% was provided from non-CPRIT awards to correspond with the amount reimbursed by CPRIT. The selected expenditures originated from funds independent of CPRIT. Internal Audit concluded that the funds being used for the CPRIT required match were appropriate and met the requirements described in CPRIT policies and procedures.

Recommendations

TMHRI should verify that their program staff members are aware of CPRIT's matching funds requirement and understand the documentation requirements. Appropriate, accurate and sufficient matching funds documentation to support all grants should be maintained by TMRHI programs staff.

TMHRI's Management Response

Grants management staff are aware of the CPRIT Matching Funds requirement. Non-CPRIT cancer-related awards will be identified as received. A schedule will be maintained listing the non-CPRIT cancer awards and the specific CPRIT awards they are being used to match. At the anniversary of each CPRIT award, the expenses associated with these awards will be reflected in the schedule and reported in a timely manner.

Internal Audit Report

Grantee: The University of Texas at Austin

Report #2014-106

July 24, 2014



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

Introduction

As part of the Cancer Prevention Research Institute of Texas (“CPRIT”) FY 2014 Grantee Internal Audit plan, a review of The University of Texas at Austin (“University”) has been completed.

Background

The University was founded in 1883 and is one of the largest and most respected universities in the United States. The University is comprised of 18 colleges and schools with over 170 undergraduate fields of study as well as 154 master’s degree and 86 doctoral programs.

The University is one of the world’s leading research universities. Its faculty and research staff generated more than \$628 million in federal and corporate funding in 2013. This research funding and the graduate students it attracts help contribute about \$2.8 billion and about 16,000 jobs annually to the Texas economy. Since CPRIT’s establishment in 2008, the University has received 29 research and prevention grants totaling over \$35 million.¹ The three audited CPRIT grants provided funds for:

- Recruitment of a first-time, tenure-track faculty member (R1003)
- Development of a preclinical protein therapeutic for the treatment of a variety of cancers with a poor prognosis, including liver cancer and metastatic melanoma (RP100890)
- A training program for pre- and post-doctoral students in fundamental and translational cancer research (RP101501)

Audit Objectives and Scope

Objectives

1. To determine if expenditures were appropriate, adequately documented, and in compliance with CPRIT’s policies.
2. To evaluate the effectiveness and timeliness of current administrative processes related to the CPRIT grant.
3. To evaluate the internal control environment for expenses related to the CPRIT grant.
4. To determine if CPRIT award recipients have an amount of matching funds equal to one-half of the award dedicated to the research that is the subject of the grant request.
5. To determine if CPRIT award recipients are utilizing matching funds towards the same area of cancer research that is the subject of the award.
6. To determine if equipment was approved appropriately prior to acquisition, adequately documented, and in compliance with CPRIT’s policies.
7. To observe and verify existence of acquired equipment.

Scope

1. The University’s expenses, inventory, and matching funds related to the three CPRIT grants identified above, between September 2012 and May 2014 were covered under the scope of this audit.
2. Detailed testing of selected expense transactions was performed.
3. Selected equipment over \$5,000 was observed on-site.
4. Detailed testing of selected matching fund expenditures was performed.

¹ Figures provided by the CPRIT website. <http://www.cprit.state.tx.us/funded-grants/>

Summary of Findings

During the review, the University demonstrated some inaccuracies related to interdepartmental charges for mice supplies being categorized inconsistently between budget categories. While the inconsistencies noted are immaterial to the grant as a whole, they may display potential deficiencies within the University's internal recording processes.

Other minor observations noted during the review included:

- Supporting documentation for matching funds was provided after clarification of the requirement was discussed with the University staff
- A difference in the serial number on one inventory item and the serial number reported to CPRIT by the University for the same inventory item

Testing Approach

Analytical and substantive procedures for the University's expenses, inventory, and matching funds related to the three selected CPRIT grants were performed to ensure the grantee complied with CPRIT policy. Through interviews with appropriate personnel, detailed testing of expenditures, observation of equipment, and analysis of the matching funds process, Internal Audit developed an understanding of the key processes and activities related to the CPRIT grant expense reimbursement, inventory, and matching funds process.

Our procedures included discussions with the following UT Austin personnel:

Name	Title
David Hawkins	Associate Director, Office of Sponsored Projects
Jason Richter	Associate Director, Office of Sponsored Projects
David Dockwiller	Assistant Director, Office of Sponsored Projects
Karen Norman	Federal Reporting

Substantive testing was applied subjectively to selected CPRIT expense transactions. These transactions were selected from financially material categories (such as payroll, fringe benefits, travel, equipment, supplies, contractual, and other) comprising approximately 70% of expenditures within the CPRIT Financial Status Report (FSR). Expenditures were sampled for each material category and supporting documents were reviewed for accuracy, completeness, appropriateness, classification and timing. Examples of supporting documents include invoices, receipts, and travel expense documents. Internal Audit also verified that each sampled expense was allowable per CPRIT's Expense Reimbursement Policy.

Internal Audit obtained a complete listing of inventory from the CPRIT Grants Management System (CGMS) for the grants reviewed. Observations were performed on selected inventory to ensure the equipment existed, was properly identified and recorded, and was in working condition.

Detailed testing of matching funds was performed for the period for each grant to verify that the pool of funds the University uses to match the required 50% of CPRIT funds is appropriate. Documentation was obtained and reviewed for selected expenditures to support the appropriateness of the monies being used as match and to ensure that the expenditure was related to cancer research.

Audit Results

Expense Reimbursements

To evaluate the effectiveness of the University's expense reimbursement process, Internal Audit performed substantive testing on approximately 650 expense reimbursement transactions totaling over \$1.35 million during the period of September 2012 – May 2014 for the three grants selected. Internal Audit vouched the expenses per the general ledger to the supporting documents.

Internal Audit then traced the transactions within the general ledger to the FSR (Form 269A) to ensure that all amounts were accurately reported and that expenses were appropriately categorized and reported to CPRIT. Internal Audit also determined that all expenses were incurred within the dates set forth in the CPRIT grant contract and that no expense was reimbursed prior to it being incurred by the grantee. Internal Audit noted the following:

- Inconsistencies in the categorization of the supply of mice and the care of the mice in a central animal resource center – the interdepartmental charges were categorized as both 'other' and 'supplies' in different FSRs

Inventory & Equipment

Internal Audit obtained a complete listing of inventory for grant R1003 and randomly selected 14 items to observe. For the samples, Internal Audit verified the existence and proper recording of inventory purchased with CPRIT funds. Internal Audit noted the following exception:

- For one inventory item sampled, the serial number from CPRIT's annual inventory report differed from the serial number observed on the piece of inventory

Matching Funds

Internal Audit noted that for Grant R1003, the supporting documentation originally provided for matching funds was not sufficient to match the total grant reimbursement of \$1,820,276 that has been requested and paid. However, after discussion with the University, further clarification was provided and appropriate supporting documentation was provided. The University was able to provide sufficient and appropriate evidence to support the matching funds, and Internal Audit concluded that the funds being used for the CPRIT match are appropriate and meet the requirements described in CPRIT's policies and procedures.

Recommendations

To improve the accuracy of the Financial Status Reports submitted, the University should decide which budget category the mice supply and housing expenses should be charged. This approach should then be consistently applied across all future FSRs.

The University should also verify that the serial number per the fixed asset register reconciles to the serial number on the machine. Accurate recording and reporting of equipment is integral to their asset management process. The University should consider performing periodic physical inventories of their assets to ensure that their internal records match the inventory records submitted to CPRIT. The asset review should include a review of the serial number, asset number, and the item description.

Furthermore, the University should ensure that all parties involved with the research grants are aware of the matching funds requirement and understand the documentation requirements. Appropriate, accurate and sufficient matching funds documentation to support all CPRIT grants should be maintained by the University.

UT Austin's Management Response

- 1) **Expense Reimbursements:** Inconsistencies in the categorization of the supply of mice and the care of the mice in a central animal resource center – the interdepartmental charges were categorized as both “other” and “supplies” in different FSRs.

Response: The University's accounting system allows such purchases to be classified as “other” or “supplies”. Regardless of the classification, University provides full support on all charges to CPRIT by category and CPRIT has not had an issue with such purchase being applied to either category. The University will also provide reminders to its CPRIT grantees to share budget justifications with all individuals coding charges to the grant so that charges are applied consistently.

- 2) **Inventory & Equipment:** Internal Audit obtained a complete listing of inventory for grant R1003 and randomly selected 14 items to observe. For the samples, Internal Audit verified the existence and proper recording of inventory purchased with CPRIT funds. Internal Audit noted the following exception: For one inventory item sampled, the serial number from CPRIT's annual inventory report differed from the serial number observed on the piece of inventory.

Response: For the inventory item in question, it was determined that the serial number reported was done so due to human error.

- 3) **Matching Funds:** Internal Audit noted that for Grant R1003, the supporting documentation originally provided for matching funds was not sufficient to match the total grant reimbursement of \$1,820,276 that has been requested and paid. However, after discussion with the University, further clarification was provided and appropriate supporting documentation was provided. The University was able to provide sufficient and appropriate evidence to support the matching funds, and Internal Audit concluded that the funds being used for the CPRIT match are appropriate and meet the requirements described in CPRIT's policies and procedures.

Response: It is important to note that Grant R1003 is currently ongoing and the investigator still has dedicated funding sources accessible that would apply toward match of these CPRIT funds. After discussions with CPRIT's Internal Audit, it was determined that a wider source of expenditures could be applied toward the match required for the Grant and that information was provided by the University. We continue to monitor matching expenditures to assure that the total 50% match requirement over the life of the award will be met.

Internal Audit Report

Grantee: The University of Texas Health Science Center at Houston

Report #2014-104

July 16, 2014



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

Introduction

As part of the Cancer Prevention Research Institute of Texas (“CPRIT”) FY 2014 Grantee Internal Audit plan, a review of The University of Texas Health Science Center at Houston has been completed.

Background

The University of Texas Health Science Center at Houston (“UT Health”) is recognized as a premier academic health science center and is known for excellence in education, research and patient care. UT Health was founded in 1972 and is the most comprehensive academic health center in the UT System and the U.S. Gulf Coast region. UT Health educates more healthcare professionals than any other health-related institution in the state of Texas. It is home to biomedical informatics, biomedical sciences, dentistry, medicine, nursing and public health schools. The medical school is the nation's sixth largest.

Since CPRIT's establishment in 2008, UT Health has received 25 research and prevention grants totaling over \$26 million¹. The audited CPRIT grants in this report provided funds for:

- A combinatorial drug discovery program to develop or improve cancer chemotherapeutic drug combinations for clinical testing (RP110532-P2)
- Enhanced colorectal cancer screening training in a Family Medicine Residency Program that serves low-income and underserved populations (PP110176)
- Recruitment of a first-time tenure-track faculty member (R1215)

Audit Objectives and Scope

Objectives

1. To determine if expenditures were appropriate, adequately documented, and in compliance with CPRIT's policies.
2. To evaluate the effectiveness and timeliness of current administrative processes related to the CPRIT grant.
3. To evaluate the internal control environment for expenses related to the CPRIT grant.
4. To determine if CPRIT award recipients have an amount of matching funds equal to one-half of the award dedicated to the research that is the subject of the grant request.
5. To determine if CPRIT award recipients are utilizing matching funds towards the same area of cancer research that is the subject of the award.
6. To determine if equipment was approved appropriately prior to acquisition, adequately documented, and in compliance with CPRIT's policies.
7. To observe and verify existence of acquired equipment.

Scope

1. The expenses, inventory, and matching funds, if applicable, related to the three CPRIT grants identified above, between September 2012 and May 2014 were covered under the scope of this audit.
2. Detailed testing of selected expense transactions was performed.
3. Selected equipment over \$5,000 was observed on-site.
4. Detailed testing of selected matching fund expenditures was performed.

¹ Figures provided by the CPRIT website. <http://www.cprit.state.tx.us/funded-grants/>

Summary of Findings

During the review, UT Health demonstrated some inaccuracies related to expenses being reimbursed prior to the University's payment date. While the inconsistencies noted are immaterial to the grant as a whole, they may display potential deficiencies within the University's internal recording processes.

Testing Approach

Analytical and substantive procedures for UT Health's expenses, inventory, and matching funds related to the selected CPRIT grant were performed to ensure the grantee complied with CPRIT policy. Through interviews with appropriate personnel, detailed testing of expenditures, observation of equipment, and analysis of the matching funds process, Internal Audit developed an understanding of the key processes and activities related to the CPRIT grant expense reimbursement, inventory, and matching funds process.

Our procedures included discussions with the following UT Health personnel:

Name	Title
Victoria Briscoe	Asst. Director, Post Award Finance

Substantive testing was applied subjectively to selected CPRIT expense transactions. These transactions were selected from financially material categories (such as payroll, fringe benefits, travel, equipment, supplies, contractual, and other) comprising approximately 60% of expenditures within the CPRIT Financial Status Report (FSR). The expenditures were sampled for each material category and supporting documents were reviewed for accuracy, completeness, appropriateness, classification and timing. Examples of supporting documents include invoices, receipts, and employee expense reports. Internal Audit also verified that each sampled expense was allowable per CPRIT's Expense Reimbursement Policy.

Internal Audit obtained a complete listing of inventory from the grantee for the selected grants and observed all equipment over \$5,000. Observations were performed on selected inventory to ensure the equipment existed, was properly identified and recorded, and was in working condition.

For the applicable research grants, detailed testing of matching funds was performed to verify UT Health had evidence of the required 50% match of CPRIT funds. Documentation was obtained and reviewed for selected expenditures to support the appropriateness of the monies being used as match and to ensure that the expenditure was related to cancer research.

Audit Results

Expense Reimbursements

To evaluate the effectiveness of UT Health's expense reimbursement process, Internal Audit performed substantive testing on 150 judgmentally selected expense reimbursement transactions totaling over \$1.0 million during the period of September 2012 – May 2014 for the three grants selected as part of the review. Internal Audit vouched the expenses per the general ledger to the supporting documents. All supporting documentation was available for each selected sample.

Internal Audit then traced the transactions within the general ledger to the Financial Status Reports to ensure that all amounts were accurately reported and that expenses were appropriately categorized and reported to CPRIT. Upon review of the requested documentation for expense reimbursements, Internal Audit noted the following:

- All samples of CPRIT grant expenses were accompanied by complete, accurate, and appropriate supporting documentation
- Five expenses, totaling approximately \$53,000, were incurred within the dates of the FSR period in which they were submitted; however, the payment date was outside of the FSR period. All transactions were claimed within 30 days of the correct FSR period.

Inventory & Equipment

Internal Audit obtained a complete listing of inventory from the grantee for the selected grants and observed all equipment over \$5,000. For the sampled seven items, Internal Audit observed and verified the existence and proper recording of inventory purchased with CPRIT funds. Internal Audit noted that there were no exceptions.

Matching Funds

To support UT Health's matching funds certification claimed in Attachment C of the CPRIT contract for the two research grants audited, Internal Audit obtained the accounting records of all the funds and expenditures which were used to meet the matching funds. Internal Audit verified that the selected expenditures originated from funds independent of CPRIT and were categorized within the same research areas as the two CPRIT research grants that required matching funds. UT Health was able to provide sufficient and appropriate evidence to support the matching funds, and Internal Audit concluded that the funds being used for the CPRIT match are appropriate and meet the requirements described in CPRIT's policies and procedures.

Recommendations

UT Health should continue to work with the CPRIT staff to determine which expenses are allowable during each period. UT Health should verify that all reimbursable expenses included on their requests have been incurred and paid prior to submission.

UT Health's Management Response

All 5 transactions in question were reviewed and shown to have been paid prior to any billing/FSR submission to CPRIT was made for reimbursement, in compliance with CPRIT guidelines.

Internal Audit Report

Grantee: The University of Texas Health Science Center at San Antonio

Report #2014-108

August 6, 2014



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

Introduction

As part of the Cancer Prevention Research Institute of Texas (“CPRIT”) FY 2014 Grantee Internal Audit plan, a review of The University of Texas Health Science Center at San Antonio (“UTHSCSA”) has been completed.

Background

The University of Texas Health Science Center at San Antonio serves San Antonio and the 50,000 square-mile area of South Texas. It extends to campuses in the metropolitan border communities of Laredo and the Rio Grande Valley. More than 3,000 students a year train in an environment that involves more than 100 affiliated hospitals, clinics and health care facilities in South Texas.

The Cancer Research Program of UTHSCSA provides training that spans undergraduate and postgraduate students. The overall program goal is to train individuals in all aspects of cancer research so that they will have an appreciation of the basic science, translational and clinical areas of research. Faculty in this program possess a broad range of expertise in cancer research including genomics/proteomics, cell signaling and receptor biology, DNA repair, metastasis, radiology, drug discovery, pediatric oncology, and carcinogenesis and prevention. The curriculum stresses both basic and translational research to provide the broad background in oncology needed for today’s research. These experienced mentors guide the trainees in developing and executing a research project and aiding them in the development of their careers.

The three audited CPRIT grants provided funds to:

- Recruit a first-time, tenure-track faculty member (R1001)
- Provide cancer research training for undergraduate students with mentors who have expertise in genomics/proteomics, cell signaling and receptor biology, DNA repair, metastasis, radiology, drug discovery, pediatric oncology, and carcinogenesis and prevention (RP101491)
- Upgrade the nuclear magnetic resonance spectrometer to enhance the discovery of novel cancer therapeutics (RP120867)

Audit Objectives and Scope

Objectives

1. To determine if expenditures were appropriate, adequately documented, and in compliance with CPRIT’s policies.
2. To evaluate the effectiveness and timeliness of current administrative processes related to the CPRIT grant.
3. To evaluate the internal control environment for expenses related to the CPRIT grant.
4. To determine if CPRIT award recipients have an amount of matching funds equal to one-half of the award dedicated to the research that is the subject of the grant request.
5. To determine if CPRIT award recipients are utilizing matching funds towards the same area of cancer research that is the subject of the award.
6. To determine if equipment was approved appropriately prior to acquisition, adequately documented, and in compliance with CPRIT’s policies.
7. To observe and verify existence of acquired equipment.

Scope

1. UTHSCSA’s expenses, inventory, and matching funds related to the three CPRIT grants identified above, between September 2012 and May 2014 were covered under the scope of this audit.

2. Detailed testing of selected expense transactions was performed.
3. Selected equipment over \$5,000 was observed on-site.
4. Detailed testing of selected matching fund expenditures was performed.

Summary of Findings

Internal audit did not note any significant findings or exceptions during the audit of The University of Texas Health Science Center at San Antonio.

Testing Approach

Analytical and substantive procedures for UTHSCSA's expenses, inventory, and matching funds related to the selected CPRIT grant were performed to ensure the grantee complied with CPRIT policy. Through interviews with appropriate personnel, detailed testing of expenditures, observation of equipment, and analysis of the matching funds process, Internal Audit developed an understanding of the key processes and activities related to the CPRIT grant expense reimbursement, inventory, and matching funds process.

Our procedures included discussions with the following UTHSCSA personnel:

Name	Title
Chris Green	Director Office of Sponsored Programs (OSP)
Kit Ramzinski	Manager, Accounting – Plant/Agency Funds
Christelle Farias	Assistance Director of Purchasing

Substantive testing was applied subjectively to selected CPRIT expense transactions. These transactions were selected from financially material categories (such as payroll, fringe benefits, travel, equipment, supplies, contractual, and other) comprising approximately 75% of expenditures within the CPRIT Financial Status Report (FSR). The expenditures were sampled for each material category and supporting documents were reviewed for accuracy, completeness, appropriateness, classification and timing. Examples of supporting documents include invoices, receipts, and employee expense reports. Internal Audit also verified that each sampled expense was allowable per CPRIT's Expense Reimbursement Policy.

Internal Audit obtained a complete listing of inventory from the grantee for the selected grants and observed all equipment over \$5,000. Observations were performed on selected inventory to ensure the equipment existed, was properly identified and recorded, and was in working condition.

For the applicable research grants, detailed testing of matching funds was performed to verify UTHSCSA had evidence of the required 50% match of CPRIT funds. Documentation was obtained and reviewed for selected expenditures to support the appropriateness of the monies being used as match and to ensure that the expenditure was related to cancer research.

Audit Results

Expense Reimbursements

To evaluate the effectiveness of UTHSCSA's expense reimbursement process, Internal Audit performed substantive testing on approximately 380 judgmentally selected expense reimbursement transactions totaling over \$3.5 million during the period of September 2012 – May 2014 for the three grants selected as part of the review. Internal Audit vouched the expenses per the general ledger to the supporting documents. All supporting documentation was available for the selected sample.

Internal Audit then traced the transactions within the general ledger to the Financial Status Reports to ensure that all amounts were accurately reported and that expenses were appropriately categorized and reported to CPRIT. Upon review of the requested documentation for expense reimbursements, it was noted that all samples of CPRIT grant expenses were accompanied by complete, accurate, and appropriate supporting documentation.

Inventory & Equipment

Internal Audit obtained a complete listing of inventory from the grantee for the selected grants and observed equipment over \$5,000. Internal Audit observed 3 pieces of equipment for the applicable grant (RP120867) to verify the existence and recording of inventory purchased with CPRIT funds. All pieces of inventory were accessible during the audit and were included in the original approved budget.

Matching Funds

To support UTHSCSA's matching funds certification claimed in Attachment C of the CPRIT contract for the research grants audited, Internal Audit requested the accounting records of all the funds and expenditures which were used to meet the matching funds. Testing was performed to ensure that UTHSCSA met the required match of 50% of CPRIT funds. Evidence of expenditure in relation to each fund was obtained in order to validate that the expenditure was cancer research related.

Internal Audit noted that UTHSCSA would expend the necessary grant funds and verify that at least 50% of the funds expended were non-CPRIT related funds and that they would not request a reimbursement for more than the CPRIT amount awarded for each period. During the review, UTHSCSA was able to show that a match of at least 50% was provided from non-CPRIT awards corresponded with the amount reimbursed by CPRIT. UTHSCSA was able to provide sufficient and appropriate evidence to support the matching funds. Internal Audit concluded that the funds being used for the CPRIT required match were appropriate and met the requirements described in CPRIT policies and procedures.

Internal Audit Report

Grantee: University of Texas Southwestern Medical Center

Report #2014-101

August 28, 2014



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

Introduction

As part of the Cancer Prevention Research Institute of Texas (“CPRIT”) FY 2014 Grantee Internal Audit plan, a review of the University of Texas Southwestern Medical Center (UTSW) has been completed.

Background

The University of Texas Southwestern Medical Center was founded in 1943 and is a multifaceted academic institution nationally recognized for its excellence in educating physicians, biomedical scientists, and health-care personnel. The institution’s mission is not only to educate the next generation of leaders in patient care, biomedical science, and disease prevention, but also to conduct high-impact research and deliver patient care.

Since CPRIT’s establishment in 2008, UTSW has received 158 research, prevention, research and recruitment grants totaling over \$198.9 million.¹ The three audited CPRIT grants provided funds to:

- Recruit an established investigator (R1109)
- Train predoctoral and postdoctoral students through the Cancer Intervention and Prevention Discoveries Program (RP101496)
- Develop cutting-edge proteomics core facility based on high resolution, high accuracy mass spectrometry and high throughput, web-based bioinformatics technology (RP120613)

Audit Objectives and Scope

Objectives

1. To determine if expenditures were appropriate, adequately documented, and in compliance with CPRIT’s policies.
2. To evaluate the effectiveness and timeliness of current administrative processes related to the CPRIT grant.
3. To evaluate the internal control environment for expenses related to the CPRIT grant.
4. To determine if CPRIT award recipients have an amount of matching funds equal to one-half of the award dedicated to the research that is the subject of the grant request.
5. To determine if CPRIT award recipients are utilizing matching funds towards the same area of cancer research that is the subject of the award.
6. To determine if equipment was approved appropriately prior to acquisition, adequately documented, and in compliance with CPRIT’s policies.
7. To observe and verify existence of acquired equipment.

Scope

1. UT Southwestern’s expenses, inventory, and matching funds related to the three CPRIT grants identified above reported between September 2012 and May 2014 were covered under the scope of this audit.
2. Detailed testing of selected expense transactions was performed.
3. Selected equipment over \$5,000 was observed on-site.
4. Detailed testing of selected matching fund expenditures was performed.

Summary of Findings

During the audit, Internal Audit noted some inaccuracies related to the timeliness of the reimbursement claims. Several of the sampled expenses had either:

- 1) Not yet been paid by UTSW (1 transaction totaling \$2,304.09)
- 2) Claimed after the allowed reporting period (50 transactions totaling \$544,634.70), or

¹ Figures provided by the CPRIT website. <http://www.cprit.state.tx.us/funded-grants/>

3) Claimed prior to the reporting period (12 transactions totaling \$24,856.95).

The inconsistencies noted above are immaterial (3.3%) to the total grant award amounts, but display potential deficiencies within the UT Southwestern's internal recording processes.

Testing Approach

Analytical and substantive procedures for UTSW's expenses, inventory, and matching funds related to the three selected CPRIT grants were performed to ensure the grantee complied with CPRIT policy. Through interviews with appropriate personnel, detailed testing of expenditures, observation of equipment, and analysis of the matching funds process, Internal Audit developed an understanding of the key processes and activities related to the CPRIT grant expense reimbursement, inventory, and matching funds process.

Our procedures included discussions with the following UTSW personnel:

Name	Title
Deborah Sauer	Associate Director – Dean's Office
Laura Hunt	Accountant III
Michael Stapp	Sr. Database Analyst
Nell Cryer	Supervisor of Outreach and Communication
Sheryl Overturf	Manager of Data Analytics

Substantive testing was applied subjectively to selected CPRIT expense transactions. These transactions were selected from financially material categories (such as payroll, fringe benefits, travel, equipment, supplies, contractual, and other) comprising approximately 75% of expenditures within the CPRIT Financial Status Report (FSR). One to five expenditures were sampled for each material category and supporting documents were reviewed for accuracy, completeness, appropriateness, classification and timing. Examples of supporting documents include invoices, receipts, and employee expense reports. Internal Audit also verified that each sampled expense was allowable per CPRIT's Expense Reimbursement Policy.

Internal Audit obtained a complete listing of inventory from the CPRIT Grants Management System (CGMS) for the selected grants, and a sample of inventory items listed were selected for observation. Observations were performed on selected inventory to ensure the equipment existed, was properly identified and recorded, and was in working condition.

Detailed testing of matching funds was performed on ten randomly selected funds that were included in the pool of funds UTSW utilizes to match the required 50% of CPRIT funds. Documentation was obtained and reviewed for selected expenditures to support the appropriateness of the monies being used as match and to ensure that the expenditure was related to cancer research.

Audit Results

Expense Reimbursements

To evaluate the effectiveness of UTSW's expense reimbursement process, Internal Audit performed substantive testing on 379 judgmentally selected expense reimbursement transactions totaling over \$3.5 million during the period of September 2012 – May 2014 for the three grants selected as part of the review. Internal Audit vouched the expenses per the general ledger to the supporting documents. Internal Audit then traced the transactions within the general ledger to the Financial Status Reports submitted to ensure that all amounts were accurately reported and that expenses were appropriately categorized and reported to CPRIT.

Upon review of the requested documentation for expense reimbursements, it was noted that all samples of CPRIT grant reimbursement requests were accompanied by complete, accurate, and appropriate supporting documentation. However, Internal Audit noted that 62 selected expenses (16%), totaling \$569,491, were not incurred within the dates of the FSR period in which they were submitted. Fifty transactions, totaling \$544,635 were claimed after the allowed reporting period, and twelve transactions, totaling \$24,857, were claimed prior to the reporting period.

In addition, an expense for \$2,304.09 was claimed in the FSR period for Grant #RP120613 which had not yet been paid by UTSW. Internal Audit verified that a credit for the entire amount (\$2,304.09) posted to the UTSW general ledger on 8/13/14.

Inventory & Equipment

Internal Audit obtained a complete listing of inventory from the grantee for the selected grants and observed equipment over \$5,000. For the 10 samples, Internal Audit verified the existence and proper recording of inventory purchased with CPRIT funds. Internal Audit noted that there were no exceptions.

During the inventory observation for RP120613, the Principal Investigator informed Internal Audit that one of the items listed was going to be returned to the vendor and that they would be submitting the refund on the appropriate FSR period when incurred.

Matching Funds

To support UTSW's matching funds certification claimed in attachment C of their CPRIT contracts, Internal Audit obtained the accounting records of all the funds and expenditures which were used to meet the matching funds requirement along with the institution's CPRIT Award Matching Policy. The selected expenditures originated from funds independent of CPRIT and were categorized within the same research areas as the three CPRIT grants which required matching funds. UTSW was able to provide sufficient and appropriate evidence to support the matching funds. Internal Audit concluded that the funds being used for the CPRIT required match are appropriate and meet the matching funds requirements described in CPRIT policies and procedures.

Recommendations

While UTSW has an established review process for expenses, they should continue to work towards inspecting expenses closely to ensure that the expenses being claimed for reimbursement are being submitted in the appropriate claim period. Furthermore, additional processes should be put into place to ensure that only paid expenses are submitted in the FSR reports.

UTSW Management's Response

Sponsored Programs Administration has recently undertaken a comprehensive reorganization of the department – addressing key people, processes, policies, procedures, training, and compliance functions. This reorganization will strengthen overall controls and increase the level of fiscal compliance and monitoring activities across sponsored programs activities – particularly those activities related to cash management and reporting.

Additionally, in accordance to additional single audit recommendations, Sponsored Programs Administration will schedule a meeting with CPRIT and seek clarification on the issue of whether expenses have to be paid prior to a grantee requesting reimbursement. In parallel, UT Southwestern will continue to define, clarify, document, and implement processes and procedures which assure it liquidates obligations, reconciles, and reports sponsored program awards in a timely manner. Further, the Medical Center will continue to monitor all sponsored award activities to help mitigate risk, increase efficiencies, and encourage fiscal compliance to the maximum extent possible.

Implementation Status: In-progress

Implementation Date: November 2014

Responsible Person: David Ngo, Assistant Vice President, Sponsored Programs Administration

Fiscal Year 2014 Internal Audit Annual Report

November 10, 2014



CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

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I. Compliance with House Bill 16

House Bill 16 requires state agencies and higher education institutions, as defined in the bill, to post their Internal Audit Plan, Internal Audit Annual Report, and other audit information on the Internet.

The CPRIT Oversight Committee will review and approve the agency's internal audit plan and internal audit annual report at the recommendation of the Audit Subcommittee. Once the Oversight Committee has approved these reports at an open meeting, the reports will be posted to the agency's website in a section designated for audit reports within 30 days of approval. In addition, the agency will post to the website the individual internal audit reports related to the internal audit annual report.

II. Planned Work Related to the Proportionality of Higher Education Benefits

On May 29, 2014, Governor Perry requested that internal auditors for higher education institutions conduct work to determine whether “proportionality is being applied according to the established guidelines.” This section does not apply to CPRIT.

III. Internal Audit Plan for Fiscal Year 2014

The internal audits planned for fiscal year 2014 were selected to address the agency's highest risk areas, based on the risk assessment process conducted during the fall of 2013, which included input from CPRIT management. The audits conducted during fiscal year 2014 are listed below, along with a brief description of each.

Audit Name & Description	Report #	Report Date	Status
Expenditures – this review took into consideration whether controls are in place to help validate that the Agency's expenditure process and controls are operating effectively to mitigate the risk of fraudulent activity.	2014 – 01	6/9/14	Completed
Governance – this audit will validate if activities and communication of information among the board, external parties and management is present to promote appropriate ethics and values within the organization. Areas to review may include conflict of interest disclosures, on-boarding and training of Oversight Committee members, and understanding of policies and procedures.	2014 – 02	6/19/14	Completed
SRA International Managed Information Systems – this review focused on understanding the control environment at CPRIT's third-party grants management administrator.	2014 – 03	6/18/2014	Completed

Audit Name & Description	Report #	Report Date	Status
Grants Management – this audit consisted of a review of the grants management processes and controls to determine whether controls are in place to help validate that the grant application process and the subsequent review of programmatic and financial activities are operating effectively. The audit will also review whether grantee activity is adequately monitored periodically and throughout the duration of grant programs.	2014 – 04	7/25/14	Completed
Information Technology – this audit considered whether controls are in place to help validate that the Agency’s IT environment is compliant with Texas Administrative Code. The internal audit will also consider whether general computer controls are in place and operating effectively.	2014 – 05	7/25/14	Completed
Grantee Field Audit – UT Southwestern – this audit validated if the grantee had a clear understanding of CPRIT’s policies and procedures and reviewed whether CPRIT funds were used in accordance with the established guidelines.	2014 – 101	8/28/14	Completed
Grantee Field Audit – Texas Nurse’s Foundation – this audit validated if the grantee had a clear understanding of CPRIT’s policies and procedures and reviewed whether CPRIT funds were used in accordance with the established guidelines.	2014 – 102	6/27/14	Completed
Grantee Field Audit – Molecular Templates – this audit validated if the grantee had a clear understanding of CPRIT’s policies and procedures and reviewed whether CPRIT funds were used in accordance with the established guidelines.	2014 – 103	7/11/2014	Completed
Grantee Field Audit – UT Health Science Center – Houston – this audit validated if the grantee had a clear understanding of CPRIT’s policies and procedures and reviewed whether CPRIT funds were used in accordance with the established guidelines.	2014 – 104	7/16/2014	Completed

Audit Name & Description	Report #	Report Date	Status
Grantee Field Audit – Texas A&M Health Science Center – this audit validated if the grantee had a clear understanding of CPRIT’s policies and procedures and reviewed whether CPRIT funds were used in accordance with the established guidelines.	2014 – 105	7/25/2014	Completed
Grantee Field Audit – UT Austin – this audit validated if the grantee had a clear understanding of CPRIT’s policies and procedures and reviewed whether CPRIT funds were used in accordance with the established guidelines.	2014 – 106	7/24/2014	Completed
Grantee Field Audit – Texas AgriLife Extension Service – this audit validated if the grantee had a clear understanding of CPRIT’s policies and procedures and reviewed whether CPRIT funds were used in accordance with the established guidelines.	2014 – 107	8/1/2014	Completed
Grantee Field Audit – UT Health Science Center – San Antonio – this audit validated if the grantee had a clear understanding of CPRIT’s policies and procedures and reviewed whether CPRIT funds were used in accordance with the established guidelines.	2014 – 108	8/6/2014	Completed
Grantee Field Audit – The Methodist Hospital Research Institute – this audit validated if the grantee had a clear understanding of CPRIT’s policies and procedures and reviewed whether CPRIT funds were used in accordance with the established guidelines.	2014 – 109	8/18/2014	Completed
Grantee Field Audit – Rice University – this audit validated if the grantee had a clear understanding of CPRIT’s policies and procedures and reviewed whether CPRIT funds were used in accordance with the established guidelines.	2014 – 110	8/18/2014	Completed

There were no deviations from the audit plan that was previously submitted in the fiscal year 2013 internal audit annual report.

IV. Consulting Services & Non-Audit Services Completed

As defined in the Institute of Internal Auditors' *International Standards for the Professional Practice of Internal Auditing* and the *Government Auditing Standards*, 2011 Revision, Sections 3.33 – 3.58, CPRIT completed the following consulting and non-audit services for FY 2014:

- CPRIT engaged Grant Thornton as the third party to observe each in-person and telephone conference peer review meetings. The purpose of the peer review panel observations was to document that:
 - Procedures on conflict of interest are followed during peer review sessions (e.g., reviewers leave room or do not participate in the telephone conference if they are conflicted on a certain proposal, etc.);
 - CPRIT program staff participation is appropriate, offering points of information when asked by the peer review panel and not engaging in the panel's discussion on the merits of applications; and
 - The discussion by the peer review panel is appropriately focused on the merits of each application.
 - The following meetings were attended:

Review Panel	Report #	Report Date	Status
Scientific Review Council Meeting – Recruitment of First-Time Tenure-Track Faculty Members	2014-201	12/20/2013	Completed
Product Development Review Council Meeting	2014-202	1/13/2014	Completed
Scientific Review Council Meeting – Research Training Awards	2014-203	1/31/2014	Completed
Scientific Review Council Meeting – Multi-Investigator Research Awards	2014-204	2/3/2014	Completed
Product Development Screening Review Panel 1 (teleconference)	2014-205	2/27/2014	Completed
Product Development Screening Review Panel 2 (teleconference)	2014-206	2/28/2014	Completed
Product Development Screening Review Panel 1 (in-person)	2014-207	4/1/2014	Completed

Review Panel	Report #	Report Date	Status
Product Development Screening Review Panel 2 (in-person)	2014-208	4/1/2014	Completed
Scientific Review Council Meeting - Recruitment Review Panel - 2	2014-209	4/17/2014	Completed
Prevention Peer Review Panel A	2014-210	5/6/2014	Completed
Prevention Peer Review Panel A	2014-211	5/7/2014	Completed
Product Development Review Council Meeting	2014-212	5/8/2014	Completed
Scientific Research Cancer Biology Panel Review Meeting	2014-213	6/12/2014	Completed
Scientific Research Imaging Technology and Informatics Panel Review Meeting	2014-214	5/30/2014	Completed
Basic Cancer Research-1 Panel Review Meeting	2014-215	6/12/2014	Completed
Cancer Prevention Research Panel Review Meeting	2014-216	6/12/2014	Completed
Basic Cancer Research-2 Panel Review Meeting	2014-217	6/12/2014	Completed
Translational Cancer Research Panel Review Meeting	2014-218	6/12/2014	Completed
Clinical and Translational Cancer Research Panel Review Meeting	2014-219	6/12/2014	Completed
Scientific Review Council Meeting – High-Impact/High- Risk Research Awards & Individual Investigator Research Awards	2014-220	7/7/2014	Completed
Prevention Review Council Meeting	2014-221	7/7/2014	Completed
Product Development Review Council Meeting	2014-222	7/7/2014	Completed
Scientific Review Council Meeting – Recruitment Program Applications	2014-223	7/12/2014	Completed
Product Development Screening Review Panel - 1	2014-224	7/16/2014	Completed
Product Development Screening Review Panel - 2	2014-225	7/16/2014	Completed
Product Development Review Panel - 1	2014-226	8/13/2014	Completed
Product Development Review Panel - 2	2014-227	8/15/2014	Completed

- CPRIT also engaged Weaver and Tidwell for consulting services to develop a plan that provided strategic guidance and direction to CPRIT in the design of a comprehensive compliance program.

V. External Quality Assurance Review (Peer Review)

In accordance with professional standards, and to meet the requirements of the Texas Internal Auditing Act, Internal Audit is required to undergo an external quality assurance review at least once every three years. CPRIT did not engage in an external quality assurance review during FY 2014. CPRIT intends to have a quality assurance review take place in spring 2015.

VI. Internal Audit Plan for Fiscal Year 2015

The internal audits planned for fiscal year 2015 were selected to address the agency's highest risk areas, based on the agency's risk assessment performed in fall 2013. Although the Internal Audit Plan contains various audits, it is not intended to cover every risk, and it does not provide coverage for all CPRIT's activities. This internal audit plan may be adjusted if significant changes in risk occur. Additional projects, such as management requests, may be conducted or some of the audits included may not be performed. Adjustments in the audit plan will be communicated to the CPRIT Audit Subcommittee, as appropriate. The internal audit plan for FY 2015 is as follows (*pending Oversight Committee approval on November 19, 2014*):

Internal Audit	Description	Budgeted Hours
Grants Management	An internal audit of grants management processes and controls will consider whether controls are in place to help validate that the grant application process and the subsequent review of programmatic and financial activities are operating effectively. The audit will also review whether grantee activity is adequately monitored periodically and throughout the duration of grant programs.	400
Expenditures	An internal audit of expenditures will consider whether controls are in place to help validate that the Agency's expenditure process and controls are operating effectively to mitigate the risk of fraudulent activity.	150
Information Technology	An internal audit of information technology will determine whether controls are in place to help validate that the Agency's IT environment is compliant with Texas Administrative Code. The internal audit will also consider whether general computer controls are in place and operating effectively.	100
Grantee Field Audits	Internal audits of various grantees will help validate if the grantees have a clear understanding of CPRIT's policies and procedures and will review whether CPRIT funds have been used in accordance with the established guidelines.	800
Special Projects	To be determined by Management or the Audit Subcommittee.	TBD
Total Hours		1,450

VII. External Audit Services Procured in Fiscal Year 2014

CPRIT engaged McConnell & Jones, LLP, a certified public accounting and consulting firm, as their external auditors for FY 2014. McConnell & Jones, LLP is registered with the Public Company Auditor Oversight Board (PCAOB).

VIII. Reporting Suspected Fraud and Abuse

Reference	Description of Entity's Actions
Fraud Reporting (Article IX Section 7.09, 83rd Legislature, Conference Committee Report)	On the CPRIT website, the agency provides the State Auditor's Office toll free fraud, waste, and abuse hotline and website address for individuals to anonymously and directly report suspected fraud, waste, and abuse involving CPRIT or other state resources.
Coordination of Investigations (Chapter 321, Texas Government Code, §321.022)	The CPRIT Chief Compliance Officer is the designated staff member within the agency to receive written or verbal allegations of suspected fraud, waste, and abuse. The Compliance Officer has the authority to examine and investigate those allegations and turn over information of verified instances of fraud, waste, or abuse to the State Auditor's Office.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: CPRIT OVERSIGHT COMMITTEE MEMBERS
FROM: HEIDI MCCONNELL, CHIEF OPERATING OFFICER
SUBJECT: FY 2015 INTERNAL AUDIT SERVICES CONTRACT APPROVAL
DATE: NOVEMBER 11, 2014

CPRIT staff is seeking authorization to proceed with contracting for fiscal year 2015 internal audit services. Services are being procured through the Comptroller's Texas Multiple Awards Schedule (TXMAS) program from a certified public accounting firm that participates in the program. We anticipate continuing with Grant Thornton LLP as CPRIT's internal audit firm. With the Oversight Committee's approval of the FY 2015 Internal Audit Plan and its similarity to the FY 2014 Internal Audit Plan, staff estimates that the cost of these services should be similar to the cost of services in fiscal year 2014, approximately \$200,000.

Staff request approval for a contract for internal audit services not to exceed \$200,000.

Because these services exceed \$100,000, CPRIT must request approval from the Legislative Budget Board before proceeding with contract execution. CPRIT must also request audit delegation from the State Auditor's Office.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: CPRIT OVERSIGHT COMMITTEE MEMBERS
FROM: REBECCA GARCIA, PHD, CHIEF PREVENTION AND COMMUNICATIONS OFFICER
SUBJECT: 2015 CONFERENCE BUDGET AND HOTEL CONTRACT
DATE: NOVEMBER 10, 2014

Recommendation:

That Oversight Committee direct staff to proceed to plan a 2015 conference based on the budget estimate provided and proceed to contract with the Renaissance Hotel based on their response to the Request for Proposal (RFP) issued.

Background:

CPRIT's annual conference has been designed to provide educational and networking opportunities for grantees, highlight the accomplishments of CPRIT grantees, and communicate to the public how CPRIT uses its state appropriations. CPRIT has held three conferences in the fall of 2010, 2011 and 2012.

Audience

Each conference has attracted about 850 people. The primary audience for the conference has been CPRIT grantees with about two-thirds being researchers and one-third being public health professionals. CPRIT grantees are encouraged to attend and may use grant funds to register up to two people involved in a funded project.

Program Structure

The proposed conference would be two full days over November 9 -10, 2015. We anticipate the format to include up to four keynote speakers in plenary sessions, grantee presentations, and abstract and poster presentations in concurrent breakout sessions. Afternoons would be comprised of three tracks, one for each program--Prevention, Research and Product development.

Venue and date

CPRIT issued an RFP for hotel venues in the Austin area. We received one response from the Renaissance hotel, the site of the last two CPRIT conferences. This hotel has worked well for this event in the past and it will meet our needs. We see no major conflicts with the proposed dates of November 9-10, 2015 at the present time.

Costs and Funding for the Conference

We estimate total costs for this conference to be \$305,700. Registration fees will offset a portion of the conference cost; remaining costs will be funded through CPRIT's operational budget. The largest line item is for food and beverage followed by meeting planning services and meeting décor. Food and beverage is a variable cost based on number of attendees and must be covered

through registration revenue. We propose registration fees that range from \$320 for early registration to \$380 for late registration. Meeting planning services will be required to assist staff with the planning and execution of the conference. A request for quote will be issued for this service. The estimated cost for this service is based on previous budgets. The largest expense under meeting décor is the set up required for the poster session. This cost is also dependent on the number of abstracts we accept for presentation and we have budgeted based number of posters at previous conferences. A request for quote will also be issued for meeting décor services.

Although the food and beverage contract is expected to exceed \$100,000, the amount will be offset by conference registration fees. As is customary with hotel contracts, CPRIT is expected to guarantee a certain amount of overall expenditures and/or room occupancy in order to achieve cost savings in other areas. The guarantees, described below, are set out in the contract that CPRIT will sign. The guarantees are set based on experience and careful projection; however, in the unlikely event that conference attendance is far less than projected then CPRIT will be responsible for additional costs.

Hotel contract

Room rates and reservations: There is a 20% allowable attrition; if attendance is less than expected then CPRIT will be responsible for making up any deficiency for 80% of the group block. Single rates will be guaranteed at the 2015 Federal Per Diem. Double and other room rates will be offered at discounted rate.

Function space rental and catering: Based upon a minimum catering of \$125,000.00 and 80% room pick up, the meeting room rental will be waived. Should the catering or meeting space requirements change, the meeting room rental is subject to change as well.

See the attached budget for additional detail.

2015 CPRIT CONFERENCE EXPENSE BUDGET (Fall 2015)

CATEGORY	ITEM DESCRIPTION	FY 2015 Estimate	FY 2016 Estimate	Variable costs	Notes
INNOVATIONS IN CANCER P&R CONFERENCE					
Venue					
	Hotel Room Rentals/Fees	\$ -	\$ -		no room rental w \$125K min F&B
A/V, Posters, Staging					
	Audio system/mics, screens, projectors, stage, pipe and drape, labor	\$ -	\$ 20,000		Basic audiovisual in multiple meeting rooms
	Meeting room décor	\$ -	\$ 25,000		Minimal backdrops, poster session \$21K.
	Set up/tear down labor fees				no costs in previous years
Food and Beverage					
	Conference Meals		\$ 132,800	800	\$43 X 2 lunch (Days 1 & 2)+\$ 20 breaks X4= \$166
CPRIT Speakers					
	Speaker Hotel Rooms (state rate \$126++)	\$ -	\$ 600	4	Assumes 4 presenters, assume \$150 per room
	Meals/per diem	\$ -	\$ 600	4	Per diem for speakers(\$75 per day * 2days)
	Aifare to/from Austin	\$ -	\$ 4,000	4	\$1000/speaker airfare
	Speaker Fees	\$ -	\$ 12,000	4	Up to 4 speakers @\$3,000 honoraria each
ONLINE Registration and Abstracts					
	Online Abstract Receipt System Management Fee	\$ 4,000	\$ 2,000		
	Online Hosted Event Registration Service/Integrated Texas.gov Credit Card System	\$ 6,000	\$ -		
	Registration system--accounting		\$ 300		
	Online event scheduling service (Sched.org)	\$ 500	\$ -		
PRINTING & Design					
	Program books (including abstracts)	\$ -	\$ 8,000		1000 copies
	Program book design and layout		\$ 1,500		
	Design time for signage	\$ -	\$ 750		10 hours at \$75/hr
	Signage throughout hotel and outside rooms				printing included in decorating costs
Registration Supplies					
	Name badge holders and lanyards		\$ 2,000		badge holders + inserts + lanyards
	Badge Ribbons		\$ 150		
	Supplies for registration table		\$ 500		paper, file boxes, tape, first aid, poster pins, etc.
Miscellaneous					
	Meeting Planner	\$ 35,000	\$ 40,000		
	Unexpected conference fees	\$ -	\$ 10,000		Added as buffer for unplanned items. Actuals will be included in appropriate areas.
	TOTAL ESTIMATED BUDGET	\$ 45,500	\$ 260,200		
		\$ 45,500	\$ 260,200	\$ 305,700	Total Estimated Conference Cost
				\$ 206,600	Estimated Registration Revenue
				\$ 99,100	Estimated Conference Costs Agency Would Cover

	\$ 57	\$ 325	\$ 382	Estimated Actual cost per attendee
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CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: CPRIT OVERSIGHT COMMITTEE MEMBERS
FROM: GERRY GEISTWEIDT, BOARD GOVERNANCE SUBCOMMITTEE
ACTING CHAIR
SUBJECT: PROPOSED ADOPTION OF CHARTER FOR THE ADVISORY
COMMITTEE ON CHILDHOOD CANCER
DATE: NOVEMBER 10, 2014

Summary and Recommendation:

The Board Governance subcommittee recommends that the Oversight Committee vote to approve the Advisory Committee on Childhood Cancer (ACCC) 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 ACCC charter with CPRIT's General Counsel, Kristen Doyle, at its meeting on November 6, 2014.

Background:

The ACCC is a statutorily-created committee to advise the Oversight Committee regarding the issues related to childhood cancer. CPRIT's administrative rule §701.13(6) requires the ACCC to create a committee charter for Oversight Committee approval that delineates the ACCC's role and expected activities. The ACCC submitted its charter for approval on November 4, 2014.



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

THE CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS ADVISORY COMMITTEE ON CHILDHOOD CANCERS CHARTER

BACKGROUND

Texas Health and Safety Code §102.155 establishes the ad hoc committee of experts to address childhood cancers, known as the Advisory Committee on Childhood Cancers (“ACCC”), and to advise the Cancer Prevention and Research Institute of Texas (“Institute”). This Charter (“ACCC Charter”), adopted by the ACCC members and approved by the Oversight Committee of the Cancer Prevention and Research Institute of Texas (“Oversight Committee”) on November 19, 2014, supersedes any other documents relating to the ACCC.

PURPOSE

The primary purpose of the ACCC is to advise the Oversight Committee and each of the Scientific Research and Prevention Programs Committees regarding opportunities for innovative research on the prevention, control, and cure of childhood cancers, opportunities for implementation of prevention and survivorship programs, and current information regarding treatment programs in Texas designed to prevent and control childhood cancers.

COMPOSITION

The ACCC shall be composed of at least ten members appointed by the Oversight Committee. Of the ten members, at least two members shall be patient advocates. Additionally, the Oversight Committee should consider individuals with research and/or clinical expertise in the care of children with cancer and/or knowledge and expertise in laboratory, translational, and clinical research relevant to childhood cancer biology, causes of childhood cancer, childhood cancer treatment and care delivery, and the long-term care of childhood cancer survivors when making appointments to the ACCC. ACCC members shall serve two-year terms, at the end of which the Oversight Committee may renew the appointment of the ACCC member or appoint a new member. The two-year terms of the ACCC already constituted at the time the ACCC Charter is approved shall begin on the day after approval.

If an ACCC member is unable to complete his or her term, the Oversight Committee shall appoint someone to fulfill the remainder of the term.

ELECTION OF OFFICERS

The ACCC Chairperson, Vice-Chairperson, and Secretary shall be elected by a majority of ACCC members present and able to vote at the first regular meeting held with a quorum of members present. Thereafter, the election shall take place at the first meeting held on or after September 1. The term of an officer shall not extend longer than the officer's term on the ACCC.

MEETINGS AND QUORUM

The ACCC shall meet as often as deemed necessary by the ACCC Chairperson. At a minimum, the ACCC 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. Communication by email can be used to advance the work of the committee between formal meetings.

A meeting of the ACCC 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 ACCC 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 Secretary or his/her designate shall record the minutes for each ACCC meeting. The Secretary 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 ACCC 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 ACCC shall submit a written report, at least annually, to the Oversight Committee regarding the work undertaken by the ACC for the previous year and the ACCC's recommendations for the Institute. The report shall be submitted by the end of each calendar year to the Oversight Committee's Presiding Officer for distribution to the Oversight Committee.

The ACCC Chairperson shall present the report at the first regular meeting of the Oversight Committee following the submission of the written report. If the Chairperson is unable to attend, then the Vice-Chairperson or other designee may present the report.

The report shall inform the Oversight Committee regarding:

- Cancer research relating to childhood cancer including the state of research and promising areas of research such as basic science, translational science, clinical trials, and health care delivery;
- Cancer prevention programs relating to childhood cancer including the state of cancer prevention programs, the most innovative approaches to cancer prevention programs, the most effective approaches to delivering cancer prevention programs, and the most promising cancer prevention program opportunities, including design and initial implementation of programs, execution of programs, and researching of effective programs;
- Information on the control and cure of childhood cancers; and
- Other issues that will advance the goals and mission of the Institute.

Additionally, the ACCC may provide to the Oversight Committee and to each Scientific Research and Prevention Programs Committee on-going advice, input and support related to the development of programs that will have a lasting impact on childhood cancer research and prevention efforts in Texas.

OTHER DUTIES

In addition to duties and responsibilities stated herein, the Oversight Committee's Presiding Officer may authorize additional, official duties of the ACCC.

AMENDING OR REPEALING THE CHARTER

The ACCC retains the ability to make, alter, amend, or repeal the ACCC Charter in order to best conduct business. Proposed changes to the ACCC Charter shall be made pursuant to a majority vote of the ACCC members. Proposed changes are final once approved by a vote of the Oversight Committee.

CHARTER APPROVAL

As reflected by the signatures of the ACCC Chairperson and Oversight Committee's Presiding Officer, the ACCC was adopted and approved in compliance with the process specified herein on the dates stated below.

Adopted by the ACCC

Chair, ACCC

Date: _____

Approved by the Oversight Committee

William Rice, M.D.

Presiding Officer, Oversight Committee

Date: _____



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

To: WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
From: KRISTEN DOYLE, GENERAL COUNSEL
Subject: ADVISORY COMMITTEES – CONFLICT OF INTEREST POLICY
Date: NOVEMBER 13, 2014

Summary and Recommendation:

Advisory committees play an important role for the Oversight Committee by providing feedback on specific issues and policy recommendations. CPRIT's statute and administrative rules do not require that advisory committee members abide by CPRIT's conflict of interest rules applicable to individuals that participate in the grant review process; advisory committee members are not involved with grant award decisions. The potential exists for advisory committee members to offer self-serving recommendations in the course of developing policy recommendations. The consensus-driven process of the committee should diminish the ability of a single member to advance his or her own agenda. No action is recommended at this time. However, the Oversight Committee has several options to implement in the future should potential conflicts appear to affect the policy input.

Background:

Texas Health & Safety Code §§ 102.154 and 102.155 authorizes committees of experts to be created whose purpose is to advise the Oversight Committee on various issues related to cancer and to inform CPRIT policies and procedures. Within the past year, the Oversight Committee has reconstituted two existing advisory committees, the University Advisory Committee (UAC) and the Advisory Committee on Childhood Cancer (ACCC), and will establish a new Advisory Committee on Product Development (ACPD). CPRIT's administrative rule §701.13 addresses advisory committees issues, including the appointment process, membership qualifications and governance requirements.

During the recruitment process potential advisory committee candidates have requested guidance regarding the applicability of CPRIT conflict of interest policy to advisory committee members.

Discussion:

CPRIT's statute and administrative rules detail CPRIT's extensive conflict of interest policy regarding the grant award process. (See, *e.g.*, Texas Health & Safety Code §§ 102.106 – 102.1064, 25 T.A.C. §702.11 – 702.19.) Both the statute and the administrative rules list the

individuals that must abide by the conflict of interest disclosure and recusal process. For example, Texas Health & Safety Code § 102.106(a) requires the Oversight Committee to adopt conflict of interest rules “to govern members of the oversight committee, the program integration committee, the research and prevention programs committees [peer review committees], and institute employees.” Generally, all parties that are involved in grant award decisions must abide by the conflict of interest rules.

Notably, advisory committee members are not subject to the conflict of interest rules. This is consistent with the committees’ advisory role. Advisory committee members provide valuable input and expert opinions related to cancer topics. However, advisory committees do not participate in the review, discussion, or vote on grant applications. In fact, CPRIT’s administrative rules prohibit a peer review committee member from serving as a member of a CPRIT advisory committee. (See 25 T.A.C. § 701.13(4)(B).)

Many advisory committee members are grant applicants and/or grant recipients. All members of the UAC and most ACCC members represent institutions that have at least one CPRIT grant award. This is specifically condoned by the CPRIT’s administrative rule § 701.13(4)(C), which states, “Grant applicants and grant recipients may be advisory committee members.”

Certainly, the potential exists for advisory committee members to offer self-serving recommendations. Generally, the consensus-driven process to develop policy recommendations subject to agreement by the committee as a whole will mitigate the impulse of a single member to advance his or her own agenda. Regardless, the Oversight Committee is under no obligation to adopt policy recommendations made by the advisory committees. To the extent that concerns surface about potential conflicts affecting the policy input, the Oversight Committee can take action by changing the committee membership, adopting conflict of interest rules applicable to advisory committees, and/or requiring the advisory committees to address mitigation of potential conflicts via the committee charter.

Nominees - Advisory Committee on Product Development

Nominee	Education	Title	Company/Entity
Bruce Butler	Ph.D., Physiology and Biophysics, University of Texas Medical Branch	Vice President, Research & Technology; Director, Office of Technology Management	The University of Texas Health Science Center at Houston
Kevin M. Lalande	BS, MBA Harvard	Managing Director	Santé Ventures
Martin Lindenberg	MD, Wits Medical School; MBA, BSci Univ. of Witwatersrand	Partner	Newport Board Group
Bruce Mackler	Ph.D., Immunology/Microbiology, University of Oregon Medical School; MS, Immunology/Microbiology, Penn State University; JD, South Texas School of Law	Board member of 3 companies, Venture Partner, FDA Advisor	Board member: Prairie Plant Systems, Inc.; OncoFluor, Inc.; Immunomic Therapeutics, Inc.; Venture Partner: TVM-Capital
Jonathan MacQuitty	Ph.D., Chemistry, University of Sussex; MBA, Stanford	Partner	Abingworth
George McLendon	Ph.D., Inorganic Chemistry, Texas A&M; BS, The University of Texas at El Paso	Provost, Rice University; Co-Director, Texas Medical Center Accelerator (TMCx)	Texas Medical Center Accelerator
Debra Peattie	Ph.D., Biochemistry & Molecular Biology; MBA, Harvard	Entrepreneur in Residence	GlaxoSmithKline
Emma Schwartz	BA, Stanford; MPH, UCLA	President	Medical Center of the Americas Foundation
James (Jamie) Topper	M.D., Ph.D. (Biophysics), Stanford	General Partner	Frazier Healthcare



Bruce D. Butler, PhD

Vice President, Research & Technology

Office of Technology Management

Office of Global Health Initiatives

UTHealth

www.uth.tmc.edu/otm

Dr. Bruce D. Butler is Vice President of Research and Technology and Director of the Office of Technology Management at the University of Texas Health Science Center at Houston (UTHealth). The technology office handles the technology transfer activities including the creation of new start-ups for the 6 UTHealth schools and the UTHealth faculty at the Texas Heart Institute, as well as manages the 20,000 sq. ft. Biotechnology Commercialization Center (BCC) Incubator. The office manages over 1000 issued and pending patents and executed over 290 license/option agreements. Cumulative gross revenues exceed \$48 million. UTHealth has 24 active portfolio companies, 2 of which are publicly traded. Dr. Butler holds an academic position as Professor of Anesthesiology at the Medical School and has over 200 published papers, abstracts and book chapters. Dr. Butler's pioneering work with NASA established protocols for space walk (EVA's) preparation used by astronauts to prevent decompression sickness. This work earned the Special Scientific Achievement Award from NASA's Space and Life Science Directorate. Dr. Butler is an inventor on 10 US and associated foreign patents; 6 have been commercialized through UTHealth and include respiratory healthcare products and bio-pharmaceuticals. One of his patented technologies of note, the EasyCap™ device, is used worldwide for emergency intubation, with sales in the millions of units. Dr. Butler has been involved with product development for medical and home-care devices, including FDA regulatory approvals and clinical trials. He has been personally involved in the creation of 5 life-science start-up companies and numerous other business development partnerships.



SANTÉ VENTURES

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KEVIN M. LALANDE

MANAGING DIRECTOR

Prior to founding Santé Ventures, Kevin spent seven years with Austin Ventures, a prominent venture firm with \$3.9 billion under management. Before joining Austin Ventures, he was a management consultant with McKinsey & Company. Previously, Kevin co-founded and sold three successful start-up companies: NetProfit, sold to a privately held advertising agency in 1996; Serus, sold to Netopia (Nasdaq: NTPA) in 1998; and TimeMarker, sold to PrimeHoldings (OTCBB: PRIM) in 2001. Kevin received an MBA with highest distinction (Baker Scholar) from the Harvard Business School and holds a BS in Electrical and Computer Engineering.



News

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Martin Lindenberg, Houston

Martin is a seasoned business leader with a record of accomplishment in varied industries over 40 years including 15 years in family businesses. His industry experience includes medical and IT technology, healthcare, professional services, food, manufacturing, distribution and retail. As Chairman, CEO, senior executive, board member and consultant, he has expanded family, private and public companies through organic growth, stabilization, start-up, diversification and divestment. One company Martin led grew from two people to a public offering in the mid-1990s at a valuation of over \$70 million. Martin has built and led teams and boards of directors and advisors in different industries. He has executed transactions successfully with companies from small to major multinationals such as DuPont. Martin's strong board perspective on strategy is based on 18 years' experience on boards of directors, including Audit, Governance, Board Nominating, Budget and Finance Committees. He served as Founding Chairman of the Houston Technology Center, which Forbes in 2010 called "one of the ten incubators changing the world."

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Biosketch

BRUCE F. MACKLER, Ph.D., J.D.

Dr. Mackler's **30 years of FDA legal/regulatory experience** in biomedical products includes biologics, drugs, nutraceuticals, medical and *in vitro* diagnostic devices, food and cosmetics manufactured by traditional and biotechnology processes (recombinant proteins, genomics, cell and gene therapy). Dr. Mackler has advised financial groups on integrated FDA, technical and business issues, when performing due diligence assessments on biomedical opportunities prior to their making initial investments and during bridging. These due diligence activities integrate his business acumen from working in sales/manufacturing in a family business, owning and managing several bioservice businesses and being a university/NIH researcher for 15 years, followed by 28 years in a FDA legal / regulatory practice with premier law firms, and as a resource for numerous financial groups. He also serves on several Boards of Directors and Scientific Advisory Boards of biomedical companies, and is an active investor through financial groups and as an angel investor. He has served as interim COO and Regulatory Affairs Vice-President in several start-up biomedical companies.

Dr Mackler has a **Ph.D.** and **M.S.** in the area of Immunology/Microbiology and has authored more than 100 published scientific papers and abstracts in immunology, immunopathology, and various disease models, as well as numerous additional articles and briefing papers on FDA and FDA-related legal and regulatory issues. Dr. Mackler now advises biomedical companies and venture capital groups on FDA regulatory approval strategies, pre-INDs, problems regarding manufacturing / QA/QC facilities and how to effectively interact with FDA to obtain approval of drugs, biologics and devices..

Dr. Mackler has advised and counseled a number of traditional and biopharmaceutical companies developing **drug** products to treat various diseases including multiple sclerosis, ALS, stroke, spinal cord injuries as well as endocrine hormones, ophthalmics, anti-infectives, pulmonary delivery, to name a few of the clinical areas, using traditional organic (new chemical entities & generic) compounds, and **biotech-derived therapeutics** (monoclonal antibodies, cytokines, fusion proteins), classic and new technology-driven **vaccines**, and **cellular and gene therapy**. Particularly in the **orthopedic device field** he has previous represented a number of the larger European and US orthopedic regarding product approvals, cGMP compliance and labeling. Dr. Mackler has assisted venture funded US biomedical companies in initiating early stage safety and proof of concept clinical studies of drugs, biologics and devices in Europe, Eastern Europe and India, along with manufacturing strategies to export investigational products.

Dr. Mackler was previously an Advisor with **TVM-Capital** in Boston & Munich, **Paul Capital Royalty Fund** (Advisor) in New York City, **Apax Partners** (London & Israel), **Index Ventures** (Geneva), **ABN AMRO Capital/Life Sciences** (Amsterdam), **UNUS Ventures** (Birmingham, AL), **D.E. Shaw Group** (New York & Houston), **NGN Capital** (Heidelberg), **Gilde Healthcare Partners** (Utrecht) **Canaccord Adams** (Toronto/New York), **Neponset Research Equity/SOLEIL Securities Corporation** (Boston/New York) and other venture capital groups, performing in depth FDA due

diligence evaluations prior to investing, and assisting portfolio companies with FDA strategy. He has written/edited the *Life Science Due Diligence and Regulatory Newsletter* and the *TVM-Capital Regulatory Bulletin* (copies available upon request). Dr. Mackler served as author of the Spotlight on FDA, a column previously published in **Genetic Engineering News**.

Dr. Mackler received his **J.D.** from the South Texas College of Law (*magna cum laude*, 1979), his **Ph.D. (Immunology/Microbiology)** from the University of Oregon Medical School (1970), his **M.S. (Immunology/Microbiology)** from the Pennsylvania State University (1965), and his B.A. (Biology) from Temple University (1964). He was a member of the District of Columbia Bar, and was admitted to practice before the Federal District and Appeals Court and before the U.S. Supreme Court. Dr. Mackler founded and grew the Association of Biotechnology Companies (ABC) into over 250 members, before it merged to form the current Biotechnology Industry Organization (BIO). He was the organizer of the annual ABC BioConference, which is now the annual BIO Conference. He also was a partner and organizer with Genetic Engineering News [GEN] of BioEast, BioWest & BioEurope, workshops and focus groups. Since his retirement from the active practice of FDA law, he has organized an advisory group to assist financial groups with FDA due diligence assessments and also provide regulatory assistance to their portfolio companies.



Jonathan MacQuitty

Partner



has more than 15 years of operational experience in life science companies and over 14 years of venture capital experience. His directorships include Gynesonics, Labcyte, Personalis and SFJ Pharmaceuticals. He joined Abingworth in 1999 and is based at the firm's offices in Menlo Park, California. Before joining Abingworth he was an adviser to a Japanese venture capital firm. Between 1988 and 1997 he was CEO of GenPharm International, a biotech company in which Abingworth invested. He has served on the Board of the Biotechnology Industry Organization. Jonathan has an MA in Chemistry from Oxford University, a PhD in Chemistry from the University of Sussex and an MBA from Stanford University. Jonathan focuses on West Coast deals.

[Back](#)



George L. McLendon

George L. McLendon became the Howard R. Hughes Provost and Professor of Chemistry for Rice University in July, 2010. The Provost is the chief academic officer of the University.

The mission of the Provost's Office is to promote and support excellence in all dimensions of the University's academic, research, scholarly and creative programs and activities. The Provost works with the University's deans, as well as a team of Vice and Associate Provosts in fulfilling the academic leadership and administrative roles of the University and Provost's Office. The Provost is a member of the University's major planning and academic committees, including the Strategic Planning and Budget Priorities Committee, and serves ex officio as a member of the Faculty Senate. He continues to teach undergraduates, and conduct research in dry design for oncology

George L. McLendon was dean of the faculty of Arts and Sciences at Duke University, a position he assumed in July 2004. He was also professor of Chemistry and professor of Biochemistry and Experimental Cancer Therapeutics in the School of Medicine. In July 2008, he was also named dean of Trinity College, the undergraduate administrative unit of Arts and Sciences. Dr. McLendon was previously the R.W. Moore Professor and chair of the Department of Chemistry at Princeton University. A Texas native, he received his BS from the University of Texas at El Paso in 1972 and his Ph.D. from Texas A&M in 1976. He also taught at the University of Rochester, where he was the Tracy H. Harris Professor of Chemistry and professor of Biochemistry in the School of Medicine.



McLendon's research is focused on inorganic and physical biochemistry. He has published over 200 peer reviewed papers and received national research awards, including the American Chemistry Society Pure Chemistry Award, the Eli Lilly Award in Biochemistry, Sloan, Dreyfus, and Guggenheim Fellowships. His publications range from solar nanotechnology to cell death pathways. His most recent research has direct implications for the diagnosis and treatment of cancer and other diseases. He has been involved in launching several biotech startups, including Tetralogic Pharmaceuticals. Most recently, he has expanded to K-12 STEM education with spinouts of STEMscopes™ and STEAMtrax, which together serve over 1.5 million students.

Biography Downloads

 [George L. McLendon CV](#)



Debra Peattie, PhD, MBA

Debra Peattie, PhD, MBA, is Director and Entrepreneur-in-Residence in the Alternative Discovery & Development division of GlaxoSmithKline. Based in Boston, she leads Biology efforts for GSK's Discovery Partnerships with Academia team, which concentrates on sourcing and establishing academic partnerships to translate innovative research into novel medicines. Prior to joining GSK, Dr Peattie held positions in business development at Harvard University and in strategy and planning at Cubist Pharmaceuticals. She has also founded several companies to drive healthcare innovation: Pleiades Advisors to offer strategic consulting services to life science companies; Valeo Medical to develop a serum diagnostic for endometriosis; and RCT BioVentures NE to translate university technologies to market. Prior to those accomplishments, she co-founded MPM Capital's first global healthcare venture fund and was a founding scientist at Vertex Pharmaceuticals, where she led Molecular Biology. Before joining the private sector, Dr Peattie was a professor at Harvard University. She has served on numerous biotechnology company boards and has published extensively in peer-reviewed journals. Dr Peattie currently holds board positions at Harvard Business School and within the Faculty of Arts and Sciences at Harvard University.



(home)

EMMA SCHWARTZ

Emma W. Schwartz – President

MISSION/VISION (MISSION-
VISION)

LEADERSHIP (LEADERSHIP)

HONORARY &
INSTITUTIONAL
DIRECTORS (HONORARY)
TEAM (STAFF)

EMMA SCHWARTZ
(EMMA-
SCHWARTZ)
ALBERT DI
RIENZO (AL)
NOEMI HERRERA
ROJAS (NOEMI-
HERRERA-ROJAS)
MARIANNE
MIJARES
(MARIANNE-
MIJARES)
CARLOS ORTEGA
(CARLOS-
ORTEGA)
MARTHA HOOD
(HOOD)
STEPHEN
VOGLEWEDE
(VOGLEWEDE)

FLAGSHIP PROGRAMS (FLAGSHIP-
PROGRAMS)

IMPACT FUND & PROJECTS
(IMPACT-FUND)

ORGANIZATIONAL CHART (ORG-
CHART)

MCA PROPERTY (MCA-PROPERTY)

CONTACT (CONTACT)

BACK

Emma Wollschlager Schwartz, MPH, serves as President for the Medical Center of the Americas (MCA) Foundation, a non-profit organization known as the “keeper of the vision” of the MCA campus. The Foundation is in the process of developing the first private biomedical research facility in the region and a biomedical research and commercialization institute created to help biomedical firms emerge and succeed in the region.

Ms. Schwartz was also Founder and President of Wollschlager Consulting, LLC, d/b/a W Consulting, LLC, a healthcare management and regulatory compliance consulting company. Prior to launching her own consulting firm, she was Director of Compliance Consulting for Sinaiko Healthcare Consulting, Inc. in Los Angeles, California (now Altegra). While at Sinaiko, she regularly lead operational performance improvement projects, prepared detailed business and strategic plans, created operational and billing related policies and procedures, audited claims and processes for specific audit protocols, and developed and monitored compliance programs for environments as varied as hospitals, physician practices, clinical laboratories, dialysis facilities and diagnostic imaging centers. She also gained extensive experience in the areas of Organ Transplant, Cardiology and Dialysis billing, reimbursement and compliance. Prior to consulting, she was Assistant Director of Legal Compliance for Sierra Providence Health Network, a multi-hospital Tenet Healthcare System in El Paso, Texas. At Tenet, she directed legal and contract compliance efforts.

She is a co-author of the Society of Corporate Compliance and Ethics’s “The Complete Compliance and Ethics Manual,” and she has been published in the Journal of Health Care Compliance, Bureau of National Affairs’ Health Care Fraud Report, Chimera (the quarterly Journal for the American Society of Transplant Surgeons), American College of Cardiology Annual Abstract Compilation and Cardiovascular Disease Management. She has given many presentations on healthcare and corporate compliance, as well as presentations on the development of the life sciences industry and MCA in the Paso del Norte region.

Ms. Schwartz’s involvement in the community is extensive. She is a director of WestStar Bank in El Paso and the Paso del Norte Center of Hope, an anti-human trafficking outreach and victim support organization. She is a member of the Borderplex Alliance, which was formerly the Paso del Norte Group where she served on the Executive and Civic Committees, in addition to being a founding member of the Young Leadership Group and co-chair of the Membership Committee. She is also on the Advisory Board of the Greater El Paso Chamber of Commerce and previously served as a trustee on the YWCA Foundation Board, a director of the La Fe Preparatory Academy board and a lay member of the TTUHSC Institutional Animal Care and Use Committee.

Her Bachelor of Arts degree is in Human Biology from Stanford University with a concentration in Comparative Health Policy. Her Masters is from the UCLA School of Public Health in Health Services Management. She is married to Doug Schwartz, they have two daughters, Sienna and Milan.

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Team

James Topper, M.D., Ph.D.

General Partner, Menlo Park



Dr. Topper joined Frazier Healthcare in 2003 as a Venture Partner and became a General Partner in 2005. Dr. Topper has co-led the life science practice at Frazier Healthcare since 2005. Since joining Frazier Healthcare, Dr. Topper has led multiple Biopharma Venture investments which have resulted in acquisitions totaling over 2.2 Billion dollars in aggregate value, and created over 2 Billion in market value in the public markets. These companies include Rempex Pharmaceuticals, Incline Therapeutics, Calistoga Pharmaceuticals, Portola Pharmaceuticals, among others. Dr. Topper currently serves on the boards of Amicus Therapeutics (Nasdaq FOLD), Atterocor, Semnur Pharmaceuticals, Anaptys Biosciences, Allena Pharmaceuticals, Alcresta, and ProNai Therapeutics. In 2011 Dr. Topper was named to the Forbes Midas list representing the top 100 venture capitalists, and in 2013 was listed by Forbes as one of the top 10 healthcare investors.

Prior to joining Frazier Healthcare, he served as head of the cardiovascular research and development franchise at Millennium Pharmaceuticals and ran Millennium San Francisco (formerly COR Therapeutics). Prior to the merger of COR and Millennium, Dr. Topper served as the Vice President of Biology at COR and was responsible for managing all of its research activities. He served on the faculties of Stanford Medical School and Harvard Medical School prior to joining COR, where he functioned as a clinician, instructor and basic investigator.

Dr. Topper received his M.D. and Ph.D. (in Biophysics) from Stanford University School of Medicine in 1991 under the auspices of the Medical Scientist Training Program. He completed his postgraduate training in Internal Medicine and Cardiovascular Disease at the Brigham and Women's Hospital in Boston and is board certified in both disciplines. After completing a research fellowship in the Vascular Research Division in the department of Pathology at the Brigham and Women's hospital, he joined the faculty of Harvard Medical School from 1997 to 1998, and subsequently Stanford University as an Assistant Professor of Medicine (Cardiovascular) in July 1998. He has authored over 50 publications and was the recipient of a Howard Hughes Scholars Award while on the faculty at Stanford University. He continues to hold an appointment as a Clinical Assistant Professor of Medicine at Stanford University and as a Cardiology Consultant to the Palo Alto Veterans Administration Hospital.

Feel free to contact him at james@frazierhealthcare.com

CURRENT INVESTMENTS

Alcresta
 Allena Pharmaceuticals
 Amicus Therapeutics
 Anaptys Biosciences
 Atterocor
 Portola Pharmaceuticals

EXITED INVESTMENTS

Alnara Pharmaceuticals
 Calistoga Pharmaceuticals
 CoTherix
 Incline Therapeutics
 Rempex Pharmaceuticals
 Threshold Pharmaceuticals (THLD)



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: CPRIT OVERSIGHT COMMITTEE MEMBERS
FROM: GERRY GEISTWEIDT, BOARD GOVERNANCE SUBCOMMITTEE
ACTING CHAIR
SUBJECT: INTENTION TO RECOMMEND APPROVAL OF THE FINAL
ORDERS ADOPTING ADMINISTRATIVE RULE CHANGES
DATE: NOVEMBER 10, 2014

Summary and Recommendation:

The Board Governance subcommittee recommends that the Oversight Committee vote to approve changes to CPRIT administrative rules at its November 19, 2014 meeting. The Board Governance Subcommittee discussed the rule changes with CPRIT's General Counsel, Kristen Doyle, at its meeting on November 6, 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 November 6, 2014, to discuss the administrative rule changes proposed for final adoption.

The changes made to CPRIT's administrative rules implement a required practice allowing the public to request initiation of a rulemaking project, clarify matching fund agency requirements and increase efficiency for the required audits of public institutions expending CPRIT funds. The proposed administrative rule changes were provisionally approved by the Oversight Committee at the August 20, 2014, meeting. The proposed rules were published in the *Texas Register* in September and October 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 701 and 703.

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) adopts a proposed new rule § 701.35 relating to how the public may petition the Institute for adoption of rules. The proposed new rule § 701.35 was published in the September 5, 2014, issue of the Texas Register (39 TexReg 7072).

Reasoned Justification

Chapter 2001, Texas Government Code, requires state agencies to prescribe by rule the form and procedure for accepting, considering, and disposing of petitions to adopt rules. The proposed new rule sets forth the procedure an interested party 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.

The Institute accepted public comments in writing and by fax through November 3, 2014. No comments were received concerning the proposed new rule § 701.35. The proposed new rule § 701.35 will be adopted as published in the September 5, 2014, edition of the *Texas Register* and will not be republished.

The Oversight Committee approved the final order adopting the amendment to Chapter 701 rules on November 19, 2014.

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.

Certification

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 November 20, 2014.

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) adopts the amendments to §§ 703.11 and 703.13. The proposed amendments for Chapter 703 were published in the October 3, 2014, issue of the *Texas Register* (39 TexReg 7874).

Reasoned 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.

The Institute accepted public comments in writing and by fax through November 3, 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 October 3, 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 November 19, 2014.

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.

Certification

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 November 20, 2014.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: CPRIT OVERSIGHT COMMITTEE MEMBERS
FROM: GERRY GEISTWEIDT, BOARD GOVERNANCE SUBCOMMITTEE
ACTING CHAIR
SUBJECT: INTENTION TO RECOMMEND APPROVAL OF PROPOSED
ADMINISTRATIVE RULE CHANGES
DATE: NOVEMBER 10, 2014

Summary and Recommendation:

The Board Governance subcommittee recommends that the Oversight Committee vote to approve publication of the proposed rule changes to 25 T.A.C. Chapter 703 in the *Texas Register* to solicit public comment. These recommendations were reviewed by the Board Governance subcommittee and discussed with CPRIT's General Counsel, Kristen Doyle, at its meeting on November 6, 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 November 6, 2014, to discuss the proposed changes to the administrative rules. A summary of the proposed changes are attached to this memo.

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.

Summary of Administrative Rule Changes to Chapters 703
Proposed for Publication to Solicit Public Comment

§ 703.6(g) The change authorizes the Chief Compliance Officer to observe and report that the agency's grant review processes are consistently followed at peer review and review council meetings, including observance of CPRIT's established conflict of interest rules. Currently, a third party observes and reports whether the appropriate review processes are utilized. Among other checks, the third party confirms that CPRIT staff did not influence the discussion or vote on a grant award and confirms that reviewers with conflicts of interest leave the room or the telephone call when the designated application comes up for review. The proposed amendment permits the Chief Compliance Officer to fill this role if necessary. This is consistent with the Chief Compliance Officer's duties related to attending and observing all Program Integration Meetings to confirm compliance with Texas Health & Safety Code Chapter 102 and CPRIT's administrative rules, as required by § 703.7(g). The amendment, if adopted, does not preclude CPRIT from continuing to engage a third party to fill this role.

§ 703.11(b) Texas Health and Safety Code § 102.255(d)(1) allows public and private universities to use their federal indirect cost rate as a credit towards their match requirement. The proposed rule change clarifies how a grantee should calculate the federal indirect cost rate when the institution's indirect cost rate changes during project year. The proposed amendment allows a grantee to use the new rate if it changes within six months of the anniversary of the effective date of the contract; after six months the grantee must use the rate in place at the beginning of the project year for the entire project year.

§ 703.11(c) The proposed change also affects the matching requirement and concerns subcontractors and subawardees on grant awards. The amendment allows funds contributed by a subcontractor or subawardee to a grant project to count towards the grantee's required matching funds. However, the amount used as a credit to the match should not exceed the percentage of the total grant funds paid to the subcontractor or subawardee for the project year.

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 §§ 703.6 and 703.11, regarding the grants review process and the matching fund requirements.

Background and Justification

As part of the grants review process, the Institute engages an independent third-party observer to attend peer review and review council meetings in order to confirm the correct processes are used. The proposed amendment to § 703.6(g) would allow the Institute's Chief Compliance Officer, in place of a third-party observer, to attend and observe those meetings. Following the meetings, the Chief Compliance Officer shall report any issues to the Oversight Committee before a vote on award applications is taken. The proposed amendment would not preclude the Institute from contracting with an independent third-party to observe meetings. If a third-party is utilized, the third-party shall issue a report to the Chief Compliance Officer.

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 the matching funds credit when the federal indirect cost rate changes during the project year. The proposed amendment to § 703.11(c) addresses how encumbered funds expended by subcontractors or subawardees on the grant project may be counted as matching funds.

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 changes 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 rule changes 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.

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 changes 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 [enter date – thirty days after publication]. 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 rule changes are proposed under the authority of the Texas Health and Safety Code Annotated, §§ 102.108 and 102.251, 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 §703.6 Grants Review Process

(a) For all Grant Applications that are not administratively withdrawn by the Institute for noncompliance or otherwise withdrawn by the Grant Applicant, the Institute shall use a two-stage Peer Review process.

(1) The Peer Review process, as described herein, is used to identify and recommend meritorious Cancer Research projects, including those projects with Cancer Research Product Development prospects, and evidence-based Cancer Prevention and Control projects for Grant Award consideration by the Program Integration Committee and the Oversight Committee.

(2) Peer Review will be conducted pursuant to the requirements set forth in Chapter 702 of this title (relating to Institute Standards on Ethics and Conflicts, Including the Acceptance of Gifts and Donations to the Institute) and Chapter 102, Texas Health and Safety Code.

(b) The two stages of the Peer Review Process used by the Institute are:

(1) Evaluation of Grant Applications by Peer Review Panels; and

(2) Prioritization of Grant Applications by the Prevention Review Council, the Product Development Review Council, or the Scientific Review Council, as may be appropriate for the Grant Program.

(c) Except as described in subsection (e) of this section, the Peer Review Panel evaluation process encompasses the following actions, which will be consistently applied:

(1) The Institute distributes all Grant Applications submitted for a particular Grant Mechanism to one or more Peer Review Panels.

(2) The Peer Review Panel chairperson assigns each Grant Application to no less than two panel members that serve as the Primary Reviewers for the Grant Application. Assignments are made based upon the expertise and background of the Primary Reviewer in relation to the Grant Application.

(3) The Primary Reviewer is responsible for individually evaluating all components of the Grant Application, critiquing the merits according to explicit criteria published in the Request for Applications, and providing an individual Overall Evaluation Score that conveys the Primary Reviewer's general impression of the Grant Application's merit. The Primary Reviewers' individual Overall Evaluation Scores are averaged together to produce a single initial Overall Evaluation Score for the Grant Application.

(4) The Peer Review Panel meets to discuss the Grant Applications assigned to the Peer Review Panel. If there is insufficient time to discuss all Grant Applications, the Peer Review Panel chairperson determines the Grant Applications to be discussed by the panel. The chairperson's decision is based largely on the Grant Application's initial Overall Evaluation Score; however a Peer Review Panel member may request that a Grant Application be discussed by the Peer Review Panel.

(A) If a Grant Application is not discussed by the Peer Review Panel, then the initial Overall Evaluation Score serves as the final Overall Evaluation Score for the Grant Application. The Grant Application is not considered further during the Grant Review Cycle.

(B) If a Grant Application is discussed by the Peer Review Panel, each Peer Review Panel member submits a score for the Grant Application based on the panel member's general impression of the Grant Application's merit and accounting for the explicit criteria published in the Request for Applications. The submitted scores are averaged together to produce the final Overall Evaluation Score for the Grant Application.

(i) The panel chairperson participates in the discussion but does not score Grant Applications.

(ii) A Primary Reviewer has the option to revise his or her score for the Grant Application after panel discussion or to keep the same score submitted during the initial review.

(C) If the Peer Review Panel recommends changes to the Grant Award funds amount requested by the Grant Applicant or to the goals and objectives or timeline for the proposed project, then the recommended changes and explanation shall be recorded at the time the final Overall Evaluation Score is set.

(5) At the conclusion of the Peer Review Panel evaluation, the Peer Review Panel chairperson submits to the appropriate Review Council a list of Grant Applications discussed by the panel ranked in order by the final Overall Evaluation Score. Any changes to the Grant Award funding amount or to the project goals and objectives or timeline recommended by the Peer Review Panel shall be provided to the Review Council at that time.

(d) The Review Council's prioritization process for Grant Award recommendations encompasses the following actions, which will be consistently applied:

(1) The Review Council prioritizes the Grant Application recommendations across all the Peer Review Panels by assigning a Numerical Ranking Score to each Grant Application that was discussed by a Peer Review Panel. The Numerical Ranking Score is substantially based on the final Overall Evaluation Score submitted by the Peer Review Panel, but also takes into consideration how well the Grant Application achieves program priorities set by the Oversight Committee, the overall Program portfolio balance, and any other criteria described in the Request for Applications.

(2) The Review Council's recommendations are submitted simultaneously to the presiding officers of the Program Integration Committee and Oversight Committee. The recommendations, listed in order by Numerical Ranking Score shall include:

(A) An explanation describing how the Grant Application meets the Review Council's standards for Grant Award funding;

(B) The final Overall Evaluation Score assigned to the Grant Application by the Peer Review Panel, including an explanation for ranking one or more Grant Applications ahead of another Grant Application with a more favorable final Overall Evaluation Score; and

(C) The specified amount of the Grant Award funding for each Grant Application, including an explanation for recommended changes to the Grant Award funding amount or to the goals and objectives or timeline.

(e) Circumstances relevant to a particular Grant Mechanism or to a Grant Review Cycle may justify changes to the dual-stage Peer Review process described in subsections (c) and (d) of this section. Peer Review process changes the Institute may implement are described in this subsection. The list is not intended to be exhaustive. Any material changes to the Peer Review process, including those listed in this subsection, shall be described in the Request for Applications or communicated to all Grant Applicants.

(1) The Institute may use a preliminary evaluation process if the volume of Grant Applications submitted pursuant to a specific Request for Applications is such that timely review may be impeded. The preliminary evaluation will be conducted after Grant Applications are assigned to Peer Review Panels but prior to the initial review described in subsection (c) of this section. The preliminary evaluation encompasses the following actions:

(A) The criteria and the specific Grant Application components used for the preliminary evaluation shall be stated in the Request for Applications;

(B) No less than two Peer Review Panel members are assigned to conduct the preliminary evaluation for a Grant Application and provide a preliminary score that conveys the general impression of the Grant Application's merit pursuant to the specified criteria; and

(C) The Peer Review Panel chairperson is responsible for determining the Grant Applications that move forward to initial review as described in subsection (c) of this section. The decision will be based upon preliminary evaluation scores. A Grant Application that does not move

forward to initial review will not be considered further and the average of the preliminary evaluation scores received becomes the final Overall Evaluation Score for the Grant Application.

(2) The Institute shall assign all Grant Applications submitted for recruitment of researchers and clinicians to the Scientific Review Council.

(A) The Scientific Review Council members review all components of the Grant Application, evaluate the merits according to explicit criteria published in the Request for Applications, and, after discussion by the Review Council members, provide an individual Overall Evaluation Score that conveys the Review Council member's recommendation related to the proposed recruitment.

(B) The individual Overall Evaluation Scores are averaged together for a final Overall Evaluation Score for the Application.

(C) If more than one recruitment Grant Application is reviewed by the Scientific Review Council during the Grant Review Cycle, then the Scientific Review Council shall assign a Numerical Ranking Score to each Grant Application to convey its prioritization ranking.

(D) If the Scientific Review Council recommends a change to the Grant Award funds requested by the Grant Application, then the recommended change and explanation shall be recorded at the time the final Overall Evaluation Score is set.

(E) The Scientific Review Council's recommendations shall be provided to the presiding officer of the Program Integration Committee and to the Oversight Committee pursuant to the process described in subsection (d) of this section.

(3) The Institute may assign continuation Grant Applications to the appropriate Review Council.

(A) The Review Council members review all components of the Grant Application, evaluate the merits according to explicit criteria published in the Request for Applications, and, after discussion by the Review Council members, provide an individual Overall Evaluation Score that conveys the Review Council member's recommendation related to the progress and continued funding.

(B) The individual Overall Evaluation Scores are averaged together for a final Overall Evaluation Score for the Application.

(C) If more than one continuation Grant Application is reviewed by the Review Council during the Grant Review Cycle, then the Review Council shall assign a Numerical Ranking Score to each continuation Grant Application to convey its prioritization ranking.

(D) If the Review Council recommends a change to the Grant Award funds or to the scope of work or timeline requested by the continuation Grant Application, then the recommended change and explanation shall be recorded at the time the final Overall Evaluation Score is set.

(E) The Review Council's recommendations shall be provided to the presiding officer of the Program Integration Committee and to the Oversight Committee pursuant to the process described in subsection (d) of this section.

(4) The Institute's Peer Review process described in subsections (c) and (d) of this section may include the following additional process steps for Product Development of Cancer Research Grant Applications:

(A) A Grant Applicant may be invited to deliver an in-person presentation to the Peer Review Panel. The Product Development Review Council chairperson is responsible for deciding which Grant Applicants will make in-person presentations. The decision is based upon the initial Overall Evaluation Scores of the primary reviewers following a discussion with Peer Review Panel members, as well as explicit criteria published in the Request for Applications.

(i) Peer Review Panel members may submit questions to be addressed by the Grant Applicant at the in-person presentation.

(ii) A Grant Application that is not presented in-person will not be considered further. The average of the primary reviewers' initial Overall Evaluation Scores will be the final Overall Evaluation Score for the Grant Application.

(iii) Following the in-person presentation, each Peer Review Panel member submits a score for the Grant Application based on the panel member's general impression of the Grant Application's merit and accounting for the explicit criteria published in the Request for Applications. The submitted scores are averaged together to produce the final Overall Evaluation Score for the Grant Application.

(B) A Grant Application may undergo business operations and management due diligence review and an intellectual property review conducted by third parties. The Peer Review Panel decides which Grant Applications will undergo business operations and management due diligence and intellectual property review. The decision is based upon the Grant Application's final Overall Evaluation Score, but also takes into consideration how well the Grant Application achieves program priorities set by the Oversight Committee, the overall Program portfolio balance, and any other criteria described in the Request for Applications. A Grant Application that is not recommended for due diligence and intellectual property review will not be considered further.

(C) After receipt of the business operations and management due diligence and intellectual property reviews for a Grant Application, the Product Development Review Council and the Primary Reviewers meet to determine whether to recommend the Grant Application for a Grant Award based upon the information set forth in the due diligence and intellectual property reviews. The Product Development Review Council may recommend changes to the Grant Award budget and goals and objectives or timeline.

(D) The Product Development Review Council assigns a Numerical Ranking Score to each Grant Application recommended for a Grant Award.

(f) Institute Employees may attend Peer Review Panel and Review Council meetings. If an Institute Employee attends a Peer Review Panel meeting or a Review Council meeting, the Institute Employee's attendance shall be recorded and the Institute Employee shall certify in writing that the Institute Employee complied with the Institute's Conflict of Interest rules. The Institute Employee's attendance at the Peer Review Panel meeting or Review Council meeting is subject to the following restrictions:

(1) Unless waived pursuant to the process described in Chapter 702, §702.17 of this title (relating to Exceptional Circumstances Requiring Participation), the Institute Employee shall not be present for any discussion, vote, or other action taken related to a Grant Applicant if the Institute Employee has a Conflict of Interest with that Grant Applicant; and

(2) The Institute Employee shall not participate in a discussion of the merits, vote, or other action taken related to a Grant Application, except to answer technical or administrative questions unrelated to the merits of the Grant Application and to provide input on the Institute's Grant Review Process.

(g) The Institute's Chief Compliance Officer shall ~~engage an independent third party to~~ observe meetings of the Peer Review Panel and Review Council where Grant Applications are discussed.

(1) The Chief Compliance Officer ~~independent third party~~ shall ~~serve as a neutral observer to~~ document that the Institute's Grant Review Process is consistently followed, including observance of the Institute's established Conflict of Interest rules and that participation by Institute employees, if any, is limited to providing input on the Institute's Grant Review Process and responding to committee questions unrelated to the merits of the Grant Application. Institute Program staff shall not participate in a discussion of the merits, vote, or any other action taken related to a Grant Application.

(2) The ~~independent third party reviewer shall issue a report to the~~ Chief Compliance Officer shall report to the Oversight Committee prior to a vote on the award recommendations specifying issues, if any, that are inconsistent with the Institute's established Grant Review Process.

(3) Nothing herein shall prevent the Institute from contracting with an independent third party to serve as a neutral observer of meetings of the Peer Review Panel and/or the Review Council where Grant Applications are discussed and to assume the reporting responsibilities of the Chief Compliance Officer described in this subsection. In the event that the independent third party observes the meeting of the Peer Review Panel and/or the Review Council, then the independent third party reviewer shall issue a report to the Chief Compliance Officer specifying issues, if any, that are inconsistent with the Institute's established Grant Review Process.

(h) Excepting a finding of an undisclosed Conflict of Interest as set forth in §703.9 of this chapter (relating to Limitation on Review of Grant Process), the Review Council's decision to not include a Grant Application on the prioritized list of Grant Applications submitted to the Program Integration Committee and the Oversight Committee is final. A Grant Application not included on the prioritized list created by the Review Council shall not be considered further during the Grant Review Cycle.

(i) At the time that the Peer Review Panel or the Review Council concludes its tasks for the Grant Review Cycle, each member shall certify in writing that the member complied with the Institute's Conflict of Interest rules.

(j) The Institute shall retain a review record for a Grant Application submitted to the Institute, even if the Grant Application did not receive a Grant Award. Such records will be retained by the Institute's electronic Grant Management System. The records retained by the Institute must include the following information:

(1) The final Overall Evaluation Score and Numerical Ranking Score, if applicable, assigned to the Grant Application;

(2) The specified amount of the Grant Award funding for the Grant Application, including an explanation for recommended changes to the Grant Award funding amount or to the goals and objectives or timeline;

(3) The Scientific Research and Prevention Programs Committee that reviewed the Grant Application;

(4) Conflicts of Interest, if any, with the Grant Application identified by a member of the Scientific Research and Prevention Programs Committee, the Review Council, the Program Integration Committee, or the Oversight Committee; and

(5) Documentation of steps taken to recuse any member or members from the Grant Review Process because of disclosed Conflicts of Interest.

(k) For purposes of this rule, a Peer Review Panel chairperson or a Review Council chairperson that is unable to carry out his or her assigned duties due to a Conflict of Interest with regard to one or more Grant Applications or for any other reason may designate a co-chairperson from among the appointed Scientific Research and Prevention Programs committee members to fulfill the chairperson role. Such designation shall be recorded in writing and include the specific time and extent of the designation.

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;

(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; ~~and~~

(4) If the Grant Recipient's federal indirect cost rate changes less than six months following the anniversary of the Effective Date of the Grant Contract, then the Grant Recipient may use the new federal indirect cost rate for the purpose of calculating the Grant Recipient's Matching Funds credit for the entirety of the Project Year.

(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.

(6) Funds contributed by a subcontractor or subawardee and spent on the Grant Project, so long as the subcontractor's or subawardee's portion of otherwise allowable Matching Funds for a Project Year may not exceed the percentage of the total Grant Funds paid to the subcontractor or subawardee for the same Project Year.

(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.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: CPRIT OVERSIGHT COMMITTEE MEMBERS
FROM: CYNTHIA MULROW, MD
SUBJECT: DIVERSITY SUBCOMMITTEE REPORT
DATE: NOVEMBER 10, 2014

The subcommittee met on November 7 and discussed the following significant items.

Status of Data Collection and Promotion of Historically Underutilized Businesses (HUB)

Heidi McConnell, Chief Operating Officer, and Wayne Roberts, Chief Executive Officer, presented on ethnicity and gender reporting of principal investigators of CPRIT research awards for grant applications. Currently reporting of such information is optional. However, since CPRIT records indicate that 99 percent of applicants choose to report the information, changing the reporting to mandatory was deemed unnecessary at this time. Dr. Mulrow noted that at least some federal granting entities, e.g., National Institutes of Health, require ethnic and gender data.

Grantee use of Historically Underutilized Businesses (HUB) is a required report. Ms. McConnell reviewed information discussed at a prior subcommittee meeting that grantees report spending \$905,000 of CPRIT award total expenditures with HUB vendors. The apparently small amount results from the fact that most of CPRIT's funds are used for salaries. Necessary equipment and supplies are seldom available from HUB vendors. Staff volunteered to promote use of HUB suppliers by emphasizing this state requirement in the Requests for Applications that are issued and links from the CPRIT website to the HUB vendor lists maintained on the website of the Comptroller of Public Accounts.

Research Training Grants

Michael Brown, Senior Program Manager for Research, reported on the status of Research Training Grant Awards. These are awards to institutions to promote research and medical careers to expand interest in science and medicine as a career. Generally, these awards provide hands-on research and training experience for undergraduate and early graduate students by providing positions, stipends, and tuition assistance. To date, about five percent of students in these programs are Black and 15 percent are Hispanic. CPRIT intends to develop another RFA for training grants for release around March 2015 and will consider adding extra "weights" or "points," which will be one of other factors for proposals that focus on training students for groups underrepresented in medicine and research science. Those applications that do target underrepresented groups will be compared against all applications reviewed by peer review panels under the training grant RFA. The committee expressed interest in finding ways to expand these programs to high school students to stimulate interest in the medical sciences at earlier ages in order to impact college enrollment in science programs.

Michael Brown also reported that the Gulf Coast Consortium (six Houston-area universities established to promote collaborative research groups and interdisciplinary training opportunities for PhD students and postdocs) is having a two day meeting with CPRIT training grant recipients and their trainees on January 30-31 in Houston. Dr. Margaret Kripke, Chief Scientific Officer, Michael Brown, and Wayne Roberts plan on attending. Dr. Mulrow also expressed interest in attending on behalf of the Oversight Committee.

National Institutes of Health (NIH) Effort to Improve Racial Diversity in the Medical Workforce

The subcommittee discussed a recent report on a new NIH initiative awarding more than \$31 million to 12 universities with documented success for training minority scientists. The universities (including The University of Texas at El Paso) will look at modifying enrollment processes, revamping undergraduate courses, and improving mentoring, among other efforts. The awards were limited to smaller-budget institutions with a history of training minority students, while expecting them to collaborate with a wide range of universities. The goal is to provide empirical data on what works. This initiative, which philosophically parallels the goals of CPRIT training grants, is to recruit students from underrepresented groups into careers in science by providing opportunities to participate in meaningful scientific research experiences at the undergraduate level. Wayne Roberts expressed an interest in CPRIT reaching out to this initiative to remain informed on their progress and to consider using their findings for CPRIT initiatives.

The subcommittee has no recommendations for action by the Oversight Committee at this time. The subcommittee intends to monitor the above activities to identify meaningful ways to improve diversity in CPRIT agency operations and award programs.