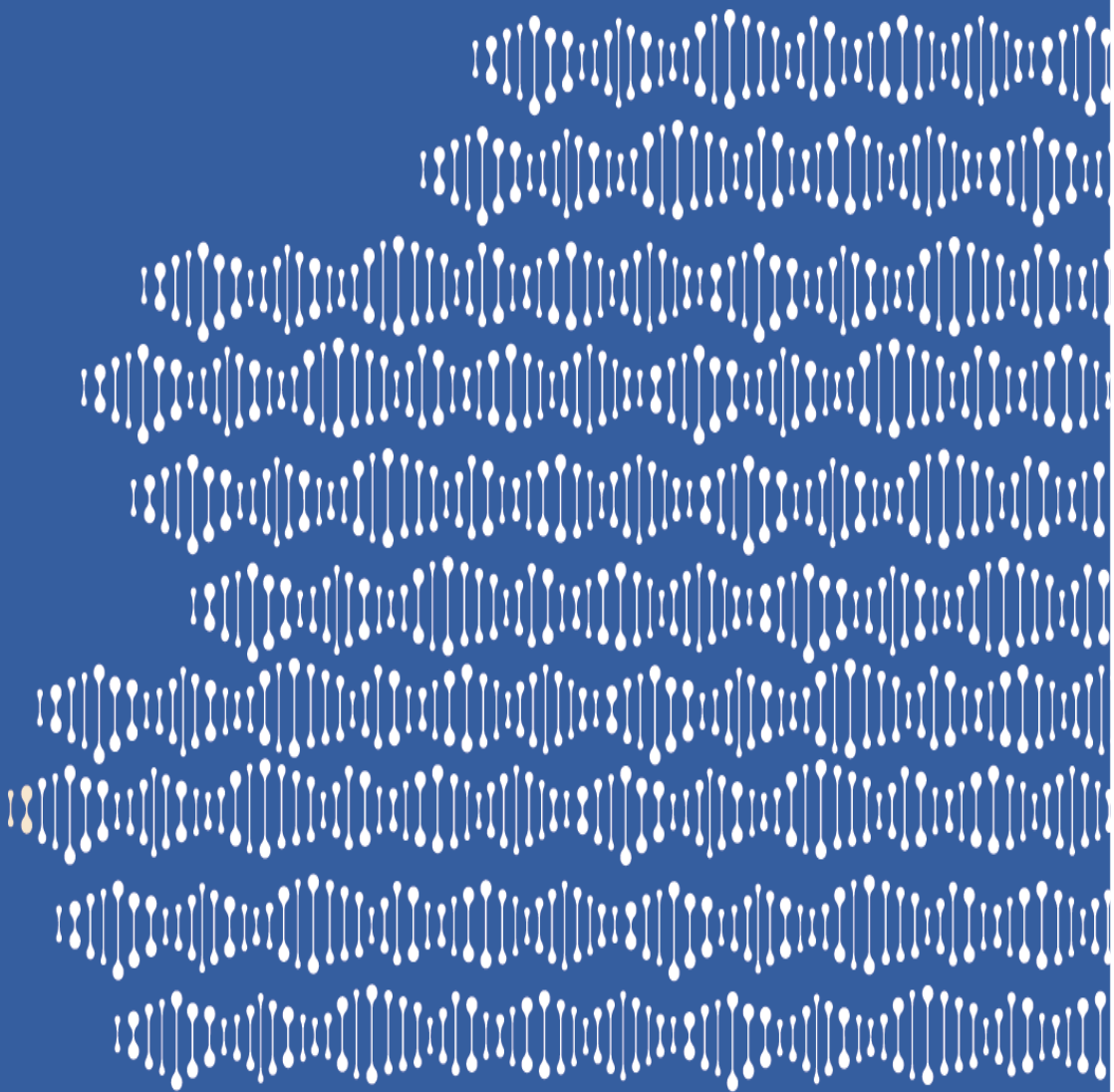
CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Meeting

November 16, 2022



CANCER PREVENTION & RESEARCH
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Summary Overview of the November 16, 2022, Oversight Committee Meeting

This summary provides an overview of major agenda items and background on key issues for Committee consideration at the November 16, 2022, Oversight Committee meeting.

Grantee Presentations
CPRIT grantees OncoNano and The University of Texas Health Science Center Houston will make presentations to the Oversight Committee about their CPRIT-funded work.

CEO Report
Mr. Roberts will present the CEO's report and address issues including grant funds available for fiscal year 2023, new personnel, and other topics as warranted.

Chief Compliance Officer Report
Mr. Burgess will report on the status of required grantee reports, financial status report reviews, desk reviews and site visits, annual compliance attestation, single audit tracking, and training. He will also certify that the proposed academic research awards complied with statutory and administrative rule requirements.

Chief Scientific Officer Report and Grant Award Recommendations
Dr. Le Beau will provide an update on the Academic Research Program, including four proposed requests for applications for the second cycle of fiscal year 2023. She will also present the Program Integration Committee's recommendation for approval of two Recruitment of Established Investigator awards totaling $11,999,198.

CPRIT will not publicly disclose information related to the Academic Research grant applications recommended for funding until the Oversight Committee meeting. The information is available to board members through a secure electronic portal.

Chief Prevention Officer Report
Ms. Magid will present an update the Oversight Committee on the Prevention Program, including four proposed requests for applications for the second cycle of fiscal year 2023.

Chief Product Development Officer Report
Dr. Smith will provide an update on the Product Development Program.

Program Priorities for FY 2024
Health and Safety Code Chapter 102 requires the Oversight Committee to establish program priorities on an annual basis. Mr. Roberts will present the program subcommittees' recommendations for the Program Priorities for FY 2024 for approval by the Oversight Committee.

Internal Auditor Report
Weaver and Tidwell, CPRIT's internal auditor, will provide an internal audit update and present an *Internal Audit Report over Vendor Contract Compliance*, an *Internal Audit Follow-Up Procedures Report Over Communications,* an *Internal Audit Follow-Up Procedures Report Over Disaster Recovery and Business Continuity Planning Advisory Audit,* and an *Internal Audit Follow-Up Procedures Report Over Governance*. Weaver will also present the Fiscal Year 2022 Annual Internal Audit Report.

Appointments - Scientific Research and Prevention Programs Committee
Mr. Roberts has provisionally appointed eight new members to CPRIT's Scientific Research and Prevention Programs Committees. CPRIT's statute requires the Oversight Committee to approve the CEO's recommendation before the appointments are final. CPRIT has provided the appointees' biographical sketches for the Oversight Committee's consideration.

Amendment to 25 TAC Chapter 703
Ms. Eckel will present a final order for Oversight Committee consideration that approves proposed changes to five sections of Chapter 703. The Oversight Committee initially considered these proposed changes at the August Oversight Committee meeting and authorized CPRIT to publish the rules to solicit comment from the public. CPRIT did not receive any comments on the proposed rules.

Chief Operating Officer Report and Contract Approvals
Ms. McConnell will discuss the operating budget, performance measures, and debt issuance history for the fourth quarter of fiscal year 2022. She will also present a recommendation to approve outside counsel contracts and due diligence services contract.

Communications Program Update
Mr. Loeffler will report on CPRIT's communications activities occurring since the August Oversight Committee meeting.

CANCER PREVENTION & RESEARCH
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Oversight Committee Meeting Agenda

November 16, 2022
9:00 a.m.

Texas State Capitol Extension
1100 Congress Avenue, Austin, Texas 78701
Room E1.012

The Oversight Committee may discuss or act on 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 purpose permitted by the Act. Also as authorized by Texas Government Code § 551.127, one or more Oversight Committee members may participate remotely in the meeting by videoconference. The Oversight Committee member presiding over the meeting will be physically present at the above-listed location, which will be open to the public. Anyone wishing to offer 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.

1. Call to Order
2. Roll Call/Excused Absences
3. Adoption of Minutes for the August 17, 2022, and September 14, 2022, meetings — Tab 1
4. Public Comment
5. Grantee Presentations — Tab 2
6. Chief Executive Officer Report — Tab 3
7. Chief Compliance Officer Report and Compliance Certification of Grant Award Process — Tab 4
8. Chief Scientific Officer Report — Tab 5
   - Grant Award Recommendations
   - FY 2023 Requests for Applications
9. Chief Prevention Officer Report — Tab 6
   - FY 2023 Requests for Applications
10. Chief Product Development Officer Report — Tab 7
11. Program Priorities for FY 2024 — Tab 8
12. Internal Auditor Report — Tab 9
    - Internal Audit Report over Vendor Contract Compliance
    - Internal Audit Follow-up Procedures Report over Communications
    - Internal Audit Follow-up Procedures Report over Disaster Recovery and Business Continuity Planning Advisory Audit
    - Internal Audit Follow-up Procedures Report over Governance
    - FY 2022 Annual Internal Audit Report
13. Scientific Research and Prevention Program Committee Appointments — Tab 10
14. Amendments to 25 T.A.C. Chapter 703 — Tab 11
    - Final Order Approving Amendments to Chapter 703
15. Chief Operating Officer Report — Tab 12

16. Contract Approval Tab 13
    - Due Diligence Review Services
    - Outside Counsel
17. Communications Program Update Tab 14
18. Subcommittee Business
19. Compliance Investigation Pursuant to Health & Safety Code § 102.2631
20. Consultation with General Counsel
21. Future Meeting Dates and Agenda Items
22. Adjourn

CANCER PREVENTION & RESEARCH
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Oversight Committee Meeting Minutes
September 14, 2022

NOTE: Unless the information is confidential, the reports, presentations, and grant award information referenced in the minutes are available at http://ocmeetings.cprit.texas.gov in the "Oversight Committee Board Packet" section for the corresponding meeting date.

Call to Order – Agenda Item 1

Presiding Officer Dr. Bill Rice announced a quorum present and called the meeting to order at 9:00 a.m.

Roll Call/Excused Absences – Agenda Item 2

Committee Members Present

Mahendra Patel, M.D., P.A. (via videoconference pursuant to Tex. Gov't Code § 551.127)
David Cummings, M.D. (via videoconference pursuant to Tex. Gov't Code § 551.127)
Donald (Dee) Margo (via videoconference pursuant to Tex. Gov't Code § 551.127)
Ambrosio Hernandez, M.D. (via videoconference pursuant to Tex. Gov't Code § 551.127)
Will Montgomery (via videoconference pursuant to Tex. Gov't Code § 551.127)
Cindy Barberio Payne (via videoconference pursuant to Tex. Gov't Code § 551.127)
Bill Rice, M.D.
Craig Rosenfeld, M.D. (via videoconference pursuant to Tex. Gov't Code § 551.127)

Presiding Officer Dr. Rice noted for the record that Oversight Committee members are attending the meeting via videoconference, as permitted by the Texas Open Meetings Act. He also noted that he is presiding over the meeting in accordance with Oversight Committee bylaws, which permit another member of the Oversight Committee to preside over the meeting when the Presiding Officer is not able to physically attend the open meeting.

Public Comment – Agenda Item 3

Presiding Officer Dr. Rice noted for the record that no member of the public requested to provide comments.

Chief Executive Officer Report – Agenda Item 4

Presiding Officer Dr. Rice recognized Chief Executive Officer Wayne Roberts to present his report. Mr. Roberts informed members CPRIT has sufficient funds available to support all grant awards proposed for approval today.

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Chief Compliance Officer Report and Compliance Certification for the Proposed Grant Awards – Agenda Item 5

Presiding Officer Dr. Rice recognized Chief Compliance Officer Vince Burgess to present the Compliance Report and Compliance Certification of Grant Award Process.

Mr. Burgess presented the Compliance Certification for the proposed Academic Research and Product Development Research grant awards, confirming that the proposed awards and review process complied with all applicable state and agency requirements.

Chief Scientific Officer Report and Grant Award Recommendations – Agenda Item 6

Presiding Officer Dr. Rice recognized Dr. Le Beau to present the academic research program award recommendations.

Dr. Le Beau directed Oversight Committee members to Table 1 on page 6 of the Proposed Grant Awards Book which displayed the Scientific Review Council (SRC) and Program Integration Committee (PIC) recommendations for the FY 2022 review cycle 2 and recruitment cycle 22.10, which included 25 awards totaling $36,768,514. She explained that due to limited funds available in FY 2022, the SRC waited to recommend these awards until the start of FY 2023.

Dr. Le Beau provided an overview of the recommended awards.

ID	RFA	Score	Application Title	PI	PI Organization	Budget
RP220582	CFSA	1.0	Establish New Cryo-EM Core Services to Drive Cancer Research and Drug Discovery at UT Southwestern Medical Center	Rosen, Michael	The University of Texas Southwestern Medical Center	$4,000,000
RP220646	CFSA	1.8	Patient-Derived Xenograft and Advanced In Vivo Models (PDX-AIM) Core Facility of Texas	Lewis, Michael	Baylor College of Medicine	$3,999,996
RP220544	ECI	1.8	CPRIT Early Clinical Investigator Award-Christopher Alvarez-Breckenridge	Draetta, Gulio	The University of Texas M. D. Anderson Cancer Center	$1,500,000
RP220606	HIHR	1.9	Developing a Novel Optogenetic Recombinase System to Study and Target Metastatic Cancer	Maddipati, Ravikanth	The University of Texas Southwestern Medical Center	$250,000
RP220662	CFSA	1.9	UTHSCSA Cancer Genome Sequencing and Computation Core	Chen, Yidong	The University of Texas Health Science Center at San Antonio	$3,998,688
RP220650	HIHR	1.9	Targeting Nitric Oxide Synthase (NOS) Pathway to Remodel Obesity-Induced	Chang, Jenny	The Methodist Hospital Research Institute	$250,000

ID	RFA	Score	Application Title	PI	PI Organization	Budget
			Tumor Inflammation in Patients With TNBC			
RP220631	CFSA	1.9	West Texas Pharmacology Core	Kang, Min	Texas Tech University Health Sciences Center	$3,369,480
RP220542	CTNA	1.9	Establish the Accelerating Clinical Oncology Research Network-Texas (ACORN-TX) to Enhance Clinical Trial Access in North and Central Texas	Beg, Muhammad	The University of Texas Southwestern Medical Center	$3,000,000
RP220626	HIHR	2.0	A Glia-to-Neuron Conversion for Treating Oral Cancer Pain	Tao, Feng	Texas A&M University System Health Science Center	$237,500
RP220558	HIHR	2.0	Novel Covalent Drugs for BCL6	Fast, Walter	The University of Texas at Austin	$249,999
RP220614	HIHR	2.0	Understanding the Impact of Immunity on Premalignant Somatic Mosaicism and Cancer Prevention	Zhu, Hao	The University of Texas Southwestern Medical Center	$237,501
RP220666	HIHR	2.0	Targeting Tumors and the Tumor Microenvironment with Banana Lectin-Expressing T Cells	McKenna, Katie	Baylor College of Medicine	$250,000
RP220567	HIHR	2.0	Fasting-Induced Microbiome Changes and Radioprotection	Piwnica-Worms, Helen	The University of Texas M. D. Anderson Cancer Center	$249,999
RP220645	HIHR	2.0	Ultrasensitive Nanosensor-Based Detection of Tumor Immunogenic Peptides to Enable Personalized Cancer Immunotherapy	Alexandrakis, Georgios	The University of Texas at Arlington	$250,000
RP220581	ECI	2.1	Hyperspectral, Quantitative Intraoperative Fluorescence Image-Guided Brain Surgery	Urban, Randall	The University of Texas Medical Branch at Galveston	$1,494,784
RP220599	CFSA	2.3	Texas Pediatric Cancer Testing (TPCT) Core	Houghton, Peter	The University of Texas Health Science Center at San Antonio	$3,935,480
RP220653	HIHR	2.3	Novel Modulators of Genomic Instability in Human Cells	Vasquez, Karen	The University of Texas at Austin	$249,932
RP220587	CFSA	2.3	Advanced Protein Therapeutics Core	Maynard, Jennifer	The University of Texas at Austin	$3,995,180

ID	RFA	Score	Application Title	PI	PI Organization	Budget
RP220592	HIHR	2.4	Restoration of Phagocytosis Function of Glioma-Associated Microglia/Macrophage by Activating QKI-PPARb-RXRa	Hu, Jian	The University of Texas M. D. Anderson Cancer Center	$250,000
RP220600	HIHR	2.4	In Vivo Akt Analysis via Chemical Genetics and Nanoparticle-Mediated Probe Delivery	Wang, Degeng	Texas Tech University	$249,999
RP220610	HIHR	2.8	Identification of Enhancers of T-Cell Antitumor Activity in PDAC Using CRISPR Activation Screening	Maitra, Anirban	The University of Texas M. D. Anderson Cancer Center	$250,000
RP220553	HIHR	2.9	Reversing Aging-Associated Resistance to Cancer Immunotherapy	Jiang, Wen	The University of Texas M. D. Anderson Cancer Center	$249,976
RP220639	HIHR	2.9	Targeting NHE6 to Improve Clinical Efficacy of Daratumumab in Myeloma	Yang, Jing	The Methodist Hospital Research Institute	$250,000

ECI – Early Clinical Investigator Award
CFSA – Core Facilities Support Award
HIHR – High Impact High Risk Research Award
CTNA – Clinical Trial Network Award

Dr. Le Beau noted that the SRC and the PIC recommended two recruitment applications, totaling $4,000,000. However, the applicant institutions withdrew the applications after the PIC meeting and prior to the Oversight Committee Meeting.

There were no questions for Dr. Le Beau.

Approval Process – Academic Research Awards

Presiding Officer Dr. Rice noted for the record that no Oversight Committee member had reported a conflict with any award recommendation presented today.

MOTION:
On a motion made by Mr. Margo and seconded by Mr. Montgomery, the Oversight Committee members voted unanimously to approve the PIC's recommendations for the High-Impact/High Risk Awards, Core Facility Support Awards, Clinical Trial Network Awards and Early Clinical Investigator Awards.

MOTION:
On a motion made by Mr. Margo and seconded by Dr. Patel, the Oversight Committee members voted to approve the delegation of contract negotiation authority to CPRIT's CEO and staff and authorized the CEO to sign the contracts on behalf of CPRIT.

Chief Product Development Officer Report – Agenda Item 7

Presiding Officer Dr. Rice recognized Chief Product Development Officer Dr. Ken Smith to present the Product Development Research update and the recommended product development award. Dr. Smith presented the proposed product development award recommended by the PIC for ImmuneSensor, totaling $16,154,562. Dr. Smith noted that this proposed award was one of the applications submitted for Cycle 22.2. Due to limited funding available for product development awards in FY 2022, the PDRC did not act to make a final recommendation until early September.

There were no questions for Dr. Smith.

Approval Process – Product Development Research Awards

Presiding Officer Dr. Rice noted for the record that no Oversight Committee member had reported a conflict with the award recommendation presented today for ImmuneSensor.

MOTION:
On a motion made by Mr. Margo and seconded by Mr. Montgomery, the Oversight Committee members voted unanimously to approve the PIC's recommendation for the product development research award to ImmuneSensor as presented by Dr. Smith.

MOTION:
On a motion made by Mr. Margo and seconded by Mr. Montgomery, the Oversight Committee members voted to approve the delegation of contract negotiation authority to CPRIT's CEO and staff and authorized the CEO to sign the contracts on behalf of CPRIT.

MOTION:
On a motion made by Mr. Margo and seconded by Dr. Patel, the Oversight Committee unanimously voted to authorize CPRIT to disburse grant funds via advance upon execution of the award contracts and the successful completion of tranches to ImmuneSensor.

Scientific Research and Prevention Program Committee Appointments – Agenda Item 8

Presiding Officer Rice recognized Mr. Roberts to present his 23 appointments to the peer review panels.

MOTION:
On a motion by Mr. Margo and seconded by Dr. Patel, the Oversight Committee unanimously voted to approve the CEO's 23 appointments to the Scientific Research and Prevention Program Committee.

Future Meeting Dates and Agenda Items – Agenda Item 12

Presiding Officer Dr. Rice announced that the Oversight Committee would not take up standing agenda items 9, 10 and 11.

He reminded members that CPRIT will meet in person for its next regularly quarterly meeting on November 16, 2022.

Adjournment – Agenda Item 25

MOTION:
There being no further business, the Oversight Committee unanimously voted to approve Presiding Officer Dr. Rice's motion to adjourn, which Mr. Montgomery seconded.

Meeting adjourned at 9:28 a.m.

_____ _____

Signature Date

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Meeting Minutes
August 17, 2022

NOTE: Unless the information is confidential, the reports, presentations, and grant award information referenced in the minutes are available at http://ocmeetings.cprit.texas.gov in the "Oversight Committee Board Packet" section for the corresponding meeting date.

Call to Order – Agenda Item 1

Presiding Officer Dr. Mahendra Patel announced a quorum present and called the meeting to order at 9:00 a.m.

Roll Call/Excused Absences – Agenda Item 2

Committee Members Present
Mahendra Patel, M.D., P.A.
David Cummings, M.D. (attended by videoconference pursuant to by Tex. Gov't Code § 551.127)
Donald (Dee) Margo
Ambrosio Hernandez, M.D.
Will Montgomery (attended by videoconference pursuant to by Tex. Gov't Code § 551.127)
Cindy Barberio Payne
Bill Rice, M.D.
Craig Rosenfeld, M.D.

Presiding Officer Dr. Patel noted for the record that Oversight Committee members Mr. Montgomery and Dr. Cummings are attending the meeting via videoconference, as permitted by the Texas Open Meetings Act.

Adoption of Minutes from the May 18, 2022, Meeting – Agenda Item 3 – Tab 1

> **MOTION:**
> On a motion by Mr. Margo and seconded by Dr. Rice, the Oversight Committee unanimously voted to approve the minutes of the May 18, 2022, Oversight Committee meeting as presented.

Public Comment – Agenda Item 4

Presiding Officer Dr. Patel noted for the record that no member of the public requested to provide comments.

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Grantee Presentation – Agenda Item 5, Tab 2

Presiding Officer Dr. Patel recognized Dr. Le Beau to introduce Dr. Robert Alan Hromas, Dean of the Long School of Medicine at The University of Texas Health Science Center San Antonio. Dr. Hromas provided an overview of his CPRIT funded research and the overall impact of CPRIT funding at UTHealth San Antonio.

Following his presentation, Oversight Committee members discussed some of the scientific points of Dr. Hromas' report with him, including pancreatic cancer, prostate cancer, and FDA regulatory approval issues.

An Oversight Committee member talked with Dr. Hromas about the South Texas clinical trial catchment area and available training opportunities. They also discussed the timeline to clinical trials for Dr. Hromas' CPRIT-funded work with T-Cell lymphoma and T-Cell Lymphoma Consortium.

Dr. Patel and Oversight Committee members thanked Dr. Hromas for his presentation.

Chief Executive Officer Report – Agenda Item 6, Tab 3

Presiding Officer Dr. Patel recognized Chief Executive Officer Wayne Roberts to present his report.

Mr. Roberts informed members regarding the amount of funds available for the remainder of the fiscal year and indicated that if the board approved the 21 awards, a $3.5 million balance would exist for the remainder of the fiscal year.

Mr. Roberts introduced new staff to the Oversight Committee. He also reminded members that CPRIT will hold a special Oversight Committee meeting in September and one in January 2023.

Chief Compliance Officer Report and Compliance Certification for the Proposed Grant Awards – Agenda Item 7, Tab 4

Presiding Officer Dr. Patel recognized Chief Compliance Officer Vince Burgess to present the Compliance Report and Compliance Certification of Grant Award Process.

Following Mr. Burgess' presentation of the compliance activities, an Oversight Committee member commented that the approximately $170,000 in unallowable match expenses found by compliance staff is a relatively small amount. Mr. Burgess agreed that the extensive training CPRIT provides to the grantees likely helped keep the unallowable match expenses amount low.

An Oversight Committee member asked if CPRIT had made progress regarding allowing other grantee institutions that the statute does not define as Texas institutions of higher education to utilize their Federal Indirect Cost Rate to meet the CPRIT matching requirement. Mr. Roberts responded that a bill filed last legislative session addressed the issue but did not make it out of committee.

Following his report, Mr. Burgess presented the Compliance Certification for the proposed academic research grant awards, confirming that the proposed awards and review process complied with all applicable state and agency requirements.

Chief Scientific Officer Report and Grant Award Recommendations – Agenda Item 8, Tab 5

Presiding Officer Dr. Patel recognized Chief Scientific Officer Dr. Michelle Le Beau to present her program report and the academic research award recommendations.

Dr. Le Beau directed Oversight Committee members to Table 1 on page 6 of the Proposed Grant Awards Book which displayed the Scientific Review Council (SRC) and Program Integration Committee (PIC) recommendations for the FY2022 Recruitment Cycles 22.10 which included 3 applications totaling $10,000,000.

Cycle 22.10 Recommended Recruitment Awards

Rank	ID	RFA	Candidate	Organization	Budget	Overall Scores
1	RR220094	RFTFM	Steven Boeynaems, Ph.D.	Baylor College of Medicine	$2,000,000	1.0
2	RR220101	RFTFM	Siqi Liu, Ph.D.	University of Texas Southwestern Medical Center	$2,000,000	1.0
3	RR220067	REI	Zhiguo Zhang, Ph.D.	The University of Texas M. D. Anderson Cancer Center	$6,000,000	2.0
				Total	$10,000,000	

REI = Recruitment of Established Investigator
RFTFM = Recruitment of First-Time, Tenure Track Faculty Members

Approval Process – Academic Research Awards

Presiding Officer Dr. Patel noted for the record that no Oversight Committee member had reported a conflict with any award recommendations presented today.

MOTION:
On a motion made by Mr. Margo and seconded by Dr. Rice the Oversight Committee members voted unanimously to approve the PIC's recommendations for the Recruitment of First-Time, Tenure-Track Faculty Members and Recruitment of Established Investigators.

MOTION:
On a motion made by Mr. Margo and seconded by Dr. Rice, the Oversight Committee members voted to approve the delegation of contract negotiation authority to CPRIT's CEO and staff and authorized the CEO to sign the contracts on behalf of CPRIT.

Chief Prevention Officer Report and Grant Award Recommendations – Agenda Item 9, Tab 6

Presiding Officer Patel recognized Chief Prevention Officer Ramona Magid to present the prevention awards and to update the Oversight Committee on the prevention program. Ms. Magid first provided an update on the status of applications for the first review cycle of FY2023.

Following her update, Ms. Magid introduced the nine prevention program projects, totaling $14,443,836, recommended for awards in the second cycle of FY 2022 by the Prevention Review Council (PRC) and PIC. She explained that applicants submitted the recommended applications in response to two grant mechanisms: *Evidence-Based Cancer Prevention Services and Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations.* Ms. Magid reported that all applications address one or more of the Prevention Program priorities.

Cycle 22.2 Recommended Prevention Program Awards

ID	RFA	Project	PD	Organization	Score	Rank Order	Budget
PP220036	EBP	Increasing the use of HPV vaccination services among medically underserved young adults	Roncancio, Angelica M	University of Houston	1.6	1	$991,308
PP220034	EPS	Screening to Optimize Prevention of CRC in East Texas (STOP CRC ET)	McGaha, Paul	The University of Texas Health Center at Tyler	1.8	2	$2,482,127
PP220038	EPS	Advancing Implementation of Evidence-Based Strategies for Tobacco Prevention and HPV Vaccination in Pediatric Safety Net Settings	Montealegre, Jane R	Baylor College of Medicine	2.3	3	$2,499,180
PP220045	EBP	Inpatient Screening and Treatment for Unhealthy Alcohol Use and Tobacco Use as a means of cancer prevention	Ramesh, Jananie	The University of Texas at Austin	2.6	4	$999,957
PP220037	EPS	Project ACCESS: Increasing Access to Cervical Cancer Screening & Treatment Services in Texas	Schmeler, Kathleen M	The University of Texas M. D. Anderson Cancer Center	2.9	5	$2,498,445
PP220024	EBP	Promoting Prevention in Survivorship Care in Rural Texas	Kvale, Elizabeth	The University of Texas at Austin	3.3	6	$975,851
PP220041	EBP	Fecal Immunochemical Testing for Screening and Treatment of Occult Neoplasia (FIT-STOP)	Layeequr Rahman, Rakhshanda	Texas Tech University Health Sciences Center	4.0	7	$999,999

ID	RFA	Project	PD	Organization	Score	Rank Order	Budget
PP220051	EPS	Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations- Program title: GetFIT	Mika, Virginia	University Health System	4.5	8	$1,999,849
PP220035	EBP	DEFEAT breast cancer: Delivering Education, Focused navigation, and Equitable Access throughout East Texas.	McGaha, Paul	The University of Texas Health Center at Tyler	5.0	9	$997,120
						TOTAL	$14,443,836

EBP: Evidence-Based Cancer Prevention Services
EPS: Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations

An Oversight Committee member asked Ms. Magid to provide more detail on the project scoring 5.0. She responded that the PRC conducts a programmatic portfolio review, taking into consideration geographic distribution, population served, type of program and cancer type, to balance the portfolio. She explained that the PRC felt that the need addressed by the project justified the award and that the project weaknesses noted during review were ones that CPRIT and the grantee could address during contract negotiation. The PRC considered the success of projects led by the Program Director in making the assessment.

Approval Process – Prevention Grant Awards

Presiding Officer Dr. Patel noted for the record that no Oversight Committee member had reported a conflict with any award recommendations presented today.

MOTION:
On a motion made by Mr. Margo and seconded by Dr. Rice the Oversight Committee members voted unanimously to approve the PIC's award recommendations for the Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations and Evidence-Based Cancer Prevention Services grant mechanisms.

MOTION:
On a motion made by Dr. Margo and seconded by Dr. Rice, the Oversight Committee members voted to approve the delegation of contract negotiation authority to CPRIT's CEO and staff and authorized the CEO to sign the contracts on behalf of CPRIT.

Chief Product Development Officer Report – Agenda Item 10, Tab 7

Presiding Officer Dr. Patel recognized Interim Chief Product Development Officer Dr. Ken Smith to present the Product Development Research update and the recommended product development awards.

Dr. Ken Smith updated the Oversight Committee on the product development program including the anticipated release of FY 2023 RFAs.

Following his report, Dr. Smith presented the nine award recommendations.

Cycle 22.2 Recommended Product Development Research Program Awards

Rank	ID	RFA	Company	Project	Score*	Budget
1	DP220039	TXCO	PLUS Therapeutics Inc.	Single-Dose 186RNL for Leptomeningeal Metastases: Multicenter Phase 1/2a Study to Determine MTD/MFD, Safety and Efficacy, Leading to Pivotal Registrational Trial	2.2	$17,613,605
2	DP220028	SEED	Stellanova Therapeutics Inc.	Development of DKK3-Targeted Therapeutic Antibodies for Cancer	2.3	$3,000,000
3	DP220038	SEED	Asylia Therapeutics	Humanization, Validation, and Clinical Translation of Cell Surface Heat Shock Protein 70-Targeted Antibody-Drug Conjugates for T-Cell Non-Hodgkin Lymphomas	2.3	$3,000,000
4	DP220055	TXCO	Atom Mines	Commercial-Scale Enrichment of Stable Ytterbium-176 for Production of No-Carrier-Added Lutetium-177 for Use in Prostate Cancer Therapy	2.0	$2,500,000
5	DP220053	TXCO	Rapamycin Holdings Inc.	Development of eRapa for the Treatment of Familial Adenomatous Polyposis, a Rare Genetic Disease Associated with a High Risk of Colorectal Cancer	2.7	$16,999,999
6	DP220043	SEED	Xerient Pharma Inc.	Oral Amifostine as an Upper GI Tract Radioprotectant for Effective Radiotherapy Treatment of Pancreatic Cancer	2.2	$2,934,737
7	DP220063	SEED	InformAI Inc.	RadOnc-AI: An Artificial Intelligence Guided Dose-Prediction Platform for Radiation Oncology	2.2	$1,552,000
8	DP220066	RELCO	PanTher Therapeutics Inc.	Enhancing Cancer Treatment through Direct, Localized, and Sustained Delivery of Therapeutic Agents: Clinical Evaluation in Locally Advanced Pancreatic Cancer	3.6	$14,268,315
9	DP220054	SEED	Nucore Medical	Clinical Validation of the MiTR Core (Minimally Invasive Targeted Resection) Technology for Early Lung Cancer Intervention	3.4	$2,999,999
					TOTAL	**$ 64,868,655**

An Oversight Committee member asked how CPRIT determines whether a company has relocated to Texas. Dr. Smith explained that CPRIT has specific criteria in its administrative rules that the company must fulfill.

<u>Approval Process – Product Development Research Awards</u>

Presiding Officer Dr. Patel noted for the record that Oversight Committee member Dr. Cummings reported a conflict of interest with one application, submitted by Rapamycin Holdings, recommended for an award. No other members reported any conflicts.

Presiding Officer Dr. Patel requested a vote on Rapamycin Holdings.

MOTION:
On a motion made by Mr. Margo and seconded by Dr. Rice the Oversight Committee members voted unanimously by members present and able to vote to approve the PIC's recommendation for the product development research award to Rapamycin Holdings as presented by Dr. Smith.

Presiding Officer Dr. Patel noted for the record that Dr. Cummings did not vote on the award recommendation.

MOTION:
On a motion made by Mr. Margo and seconded by Dr. Rice the Oversight Committee members voted unanimously to approve the PIC's recommendations for the product development research awards to the remaining eight companies as presented by Dr. Smith.

MOTION:
On a motion made by Mr. Montgomery and seconded by Dr. Rice, the Oversight Committee members voted to approve the delegation of contract negotiation authority to CPRIT's CEO and staff and authorized the CEO to sign the contracts on behalf of CPRIT.

MOTION:
On a motion made by Mr. Margo and seconded by Dr. Rice, the Oversight Committee unanimously voted to authorize CPRIT to disburse grant funds via advance upon execution of the award contracts and the successful completion of tranches to the nine companies approved by the Oversight Committee.

Internal Auditor Report – Agenda Item 11, Tab 8

Presiding Chair Patel recognized Dan Graves of Weaver and Tidwell, LLP, CPRIT's contracted internal auditor, to give the Internal Auditor's Report. Mr. Graves summarized the schedule of audits and highlighted the two in progress, vendor contract compliance and a compliance check on procurement. He presented the proposed internal audit plan for FY 2023. If approved, CPRIT will include the audit plan in the 2023 Annual Internal Audit Report that is due to the State Auditor's Office, Legislative Budget Board and Governor's Office in November.

An Oversight Committee asked Mr. Graves about the status of the records management audit that Weaver proposed to cancel. Mr. Graves explained that due to several reasons, including that IT staff would need to be heavily involved in the records management work while they would be undertaking substantial work on other follow up procedures, CPRIT and Weaver determined that cancelling the audit at this time was appropriate. Mr. Graves noted that he had previously informed the Oversight Committee of the decision at the May meeting.

MOTION:
On a motion by Mr. Margo and seconded by Dr. Rice, the Oversight Committee unanimously voted to approve the fiscal year 2023 Audit Plan.

Scientific Research and Prevention Program Committee Appointments – Agenda Item 12, Tab 9

Presiding Chair Patel recognized Mr. Roberts to present his 27 appointments to the peer review panels.

MOTION:
On a motion by Mr. Margo and seconded by Dr. Rice, the Oversight Committee unanimously voted to approve the CEO's 27 appointments to the Scientific Research and Prevention Program Committee.

Advisory Committees – Item 13, Tab 10

Clinical Trial Advisory Committee presentation

Presiding Officer Dr. Patel called on Dr. Le Beau to introduce Dr. Gail Eckhardt, Chair of the Clinical Trials Advisory Committee (CTAC) to provide the CTAC Annual Report.

Dr. Le Beau introduced Dr. Eckhardt

Dr. Eckhardt presented the CTAC annual report.

Following the presentation, an Oversight Committee member encouraged CPRIT to be more aggressive in moving clinical trial resources to rural areas.

In response to a question by an Oversight Committee member inquiring of the ethnicity of patients enrolled in clinical trials, Dr. Le Beau explained that of the 40,165 individuals in CPRIT-supported clinical trials, 10,931 are Hispanic, about 27%.

Oversight Committee members discussed the appropriate target for enrollment of cancer patients in rural areas in clinical trials. Dr. Eckhardt explained that NCI designated centers provide some data, but that data were lacking for areas of West Texas. More data are necessary to set the goal. Another Oversight Committee member asked Ms. Magid about whether data from cancers detected in prevention program screenings may help provide the data needed. Ms. Magid explained that CPRIT does not collect cancer detection information by specific county because of HIPAA regulations.

An Oversight Committee asked Dr. Eckhardt about clinical trial lead centers and regional centers and the incentives for lead centers to support regional centers. Dr. Eckhardt responded that NCI mandates that NCI-designated cancer center provide trials equally throughout the catchment area but fulfilling the requirement can be difficult.

Presiding Officer Dr. Patel and the Oversight Committee members thanked Dr. Eckhardt for the presentation.

FY 2023 Honoraria Policy – Item 14, Tab 11

Presiding Chair Patel recognized Mr. Roberts to present the FY 2023 Honoraria Policy.

Mr. Roberts summarized the changes to the FY 2023 honoraria policy, which impacted the product development research program. The changes were necessary to accommodate the changes in the product development research program review process.

> **MOTION:**
> On a motion made by Dr. Rosenfeld and seconded by Mr. Margo, the Oversight Committee unanimously voted to approve the FY 2023 honoraria policy.

Health & Safety Code § 102.1062 Waivers – Item 15, Tab 12

Presiding Chair Patel recognized Mr. Roberts. He presented the FY 2023 conflict of interest waivers provided behind tab 12 in the meeting book.

> **MOTION:**
> On a motion made by Dr. Rosenfeld and seconded by Mr. Margo, the Oversight Committee unanimously voted to approve the FY 2023 § 102.1062 Waivers.

Amendments to 25 T.A.C. Chapters 703 – Item 16, Tab 13

Presiding Chair Patel recognized Cameron Eckel. Ms. Eckel presented five proposed rule changes to Chapter 703.

In response to a question by an Oversight Committee member to restate the grantee relocation expenses, Ms. Eckel answered that TAC § 703.11 provides examples and categories for eligible expenses and CPRIT has added relocation expenses.

> **MOTION:**
> On a motion made by Mr. Montgomery and seconded by Mr. Margo, the Oversight Committee unanimously voted to publish the proposed changes to the Texas Administrative Code Chapter 703 in the *Texas Register*.

Chief Operating Officer Report – Agenda Item 17, Tab 14

Presiding Chair Patel recognized Chief Operating Officer Heidi McConnell. Ms. McConnell presented her report, including an update on FY 2023 contracts for financial audit services and outside counsel services that are under the $100,000 threshold. She also informed members that the agency is working on assigning each member a CPRIT-specific email address, which will also require members to undergo training regarding information security.

In response to a question by an Oversight Committee member inquiring why CPRIT-domain email addresses are necessary for members, Ms. McConnell responded that CPRIT initiated this project pursuant to requests from several OC members.

Contract Approvals – Agenda Item 18, Tab 15

Ms. McConnell reviewed the proposed contracts with The Perryman Group, Weaver and Tidwell, and Moody Gardens Hotel, Spa and Convention Center.

Ms. McConnell clarified the contract with Moody Gardens Hotel in Galveston includes estimated costs for food and beverage catering ($200,000) and for audiovisual support services ($52,000). However, the catering costs may end up being higher if conference registrations are greater than the estimated 750 attendees used in the bidding process. She explained that CPRIT selected Moody Gardens Hotel as the conference venue because of the available dates, various concessions and discounts, and the fact that the conference facilities and hotel are co-located in one venue.

There were no questions for Ms. McConnell.

> **MOTION:**
> On a motion made by Dr. Rosenfeld and seconded by Dr. Rice, the Oversight Committee unanimously voted to approve the contracts with The Perryman Group, Weaver and Tidwell, and Moody Gardens Hotel.

Intellectual Property Project Update – Agenda Item 19, Tab 16

Presiding Chair Dr. Patel recognized Chief Strategic Initiatives and Intellectual Property Officer Tracey Davies. Ms. Davies updated the Oversight Committee on CPRIT's ongoing project to streamline and standardize grantees' reporting of CPRIT-funded intellectual property.

In response to a question by an Oversight Committee member inquiring if CPRIT grantees routinely provide disclosure notices, Ms. Davies confirmed that grantees regularly submit disclosures pursuant to the grant contract requirements and that CPRIT considers the information confidential.

Ms. Davies responded to another Oversight Committee member's question, explaining that grantees have reported 557 published patent applications and 110 patents issued.

Oversight Committee members discussed with Ms. Davies the future opportunity to share information about invention disclosures.

Communication Report – Agenda Item 20, Tab 17

Presiding Chair Dr. Patel recognized Communications Director Mark Loeffler to present his report. Mr. Loeffler updated the committee members on communications activities.

Future Meeting Dates and Agenda Items – Agenda Item 24, Tab 18

Presiding Chair Dr. Patel announced that the Oversight Committee would not take up standing agenda items 21, 22 and 23.

He referred to the proposed dates for regular quarterly meetings and subcommittee meetings for FY 2023 in the meeting book behind tab 18.

> **MOTION:**
> On a motion made by Mr. Margo and seconded by Dr. Rice, the Oversight Committee unanimously voted to approve the proposed meeting dates for the regular meetings of the Oversight Committee and subcommittees for FY 2023.

He reminded members that CPRIT will hold a special meeting on September 14.

Adjournment – Agenda Item 25

> **MOTION:**
> There being no further business, the Oversight Committee unanimously voted to approve Presiding Chair Patel's motion to adjourn, which Dr. Rosenfeld seconded.

Meeting adjourned at 12:18 p.m.

_____ _____

Signature Date

Aubree Shay is an Assistant Professor in the department of Health Promotion and Behavioral Sciences at UTHealth Houston School of Public Health in San Antonio. Dr. Shay is a behavioral scientist whose research is focused on patient-provider communication and decision making in the context of cancer prevention and control, with a particular focus on cancer survivorship among adolescents and young adults. Her background as a pediatric hematology and oncology social worker provided her with hands-on experience supporting, advocating for, and cancer patients and their caregivers. Because of this experience, her research focuses on how to actively engage cancer patients and caregivers to enable them to make informed, value-concordant decisions about their cancer prevention and care with the goal of improving health outcomes. Dr. Shay has a master's in social work from the University of Texas at Austin and a PhD from Virginia Commonwealth University in Richmond, Virginia.

Dr. Grimes is a Pediatric Oncologist and Assistant Professor in the Department of Pediatrics at the University of Texas Health San Antonio and member of the Mays Cancer Center (MCC) where she serves on the Population Science and Prevention Committee (PSP).. Dr. Grimes' research is focused on supportive care and cancer care delivery in childhood and adolescent and young adult (AYA) cancer. Dr. Grimes is the inaugural Director of the AYA Cancer Program at a minority-based safety-net hospital, University Health System. Her clinical experience drives her commitment to ongoing improvements in supportive care and access for all childhood cancer patients. This effort is supported nationally by her involvement in the Children's Oncology Group as the Vice Chair for Adolescent and Young Adult Cancer and the Chair of the Nutrition committee within Cancer Control. Dr. Grimes is involved in clinical trial development and trial conduct in cancer care delivery, cancer control & prevention, and supportive care research across the state of Texas and nationally. Dr. Grimes received her undergraduate degree at Baylor University and her Medical Degree at UT Health San Antonio where she completed her Pediatric residency and Hematology/Oncology fellowship training and where she now serves as faculty.

HPV vaccination in a pediatric minority-based community oncology network

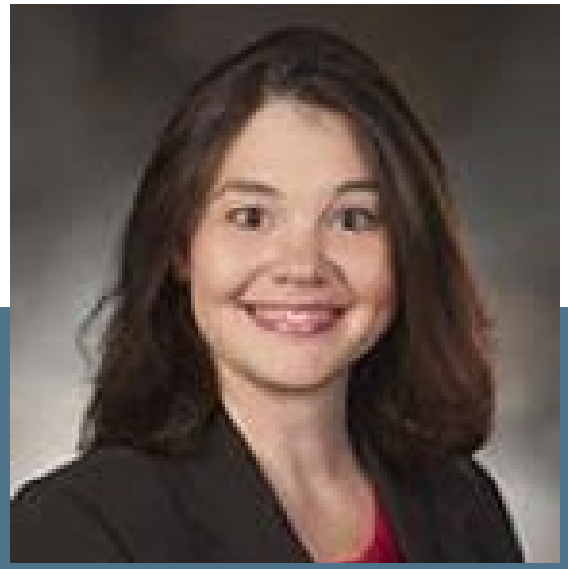
Aubree Shay, PhD

Allison Grimes, MD

PP180080

UT Health San Antonio
Greehey Children's Cancer Research Institute

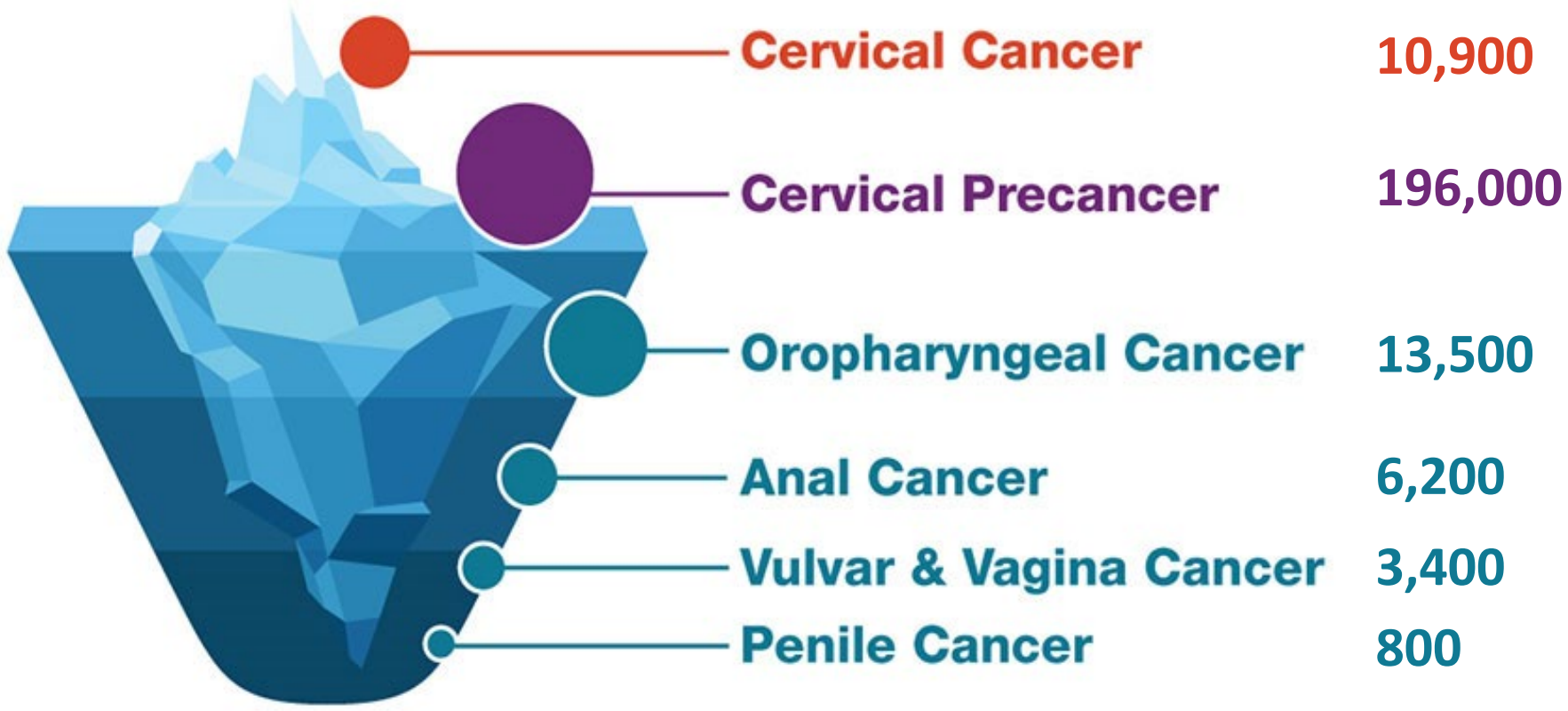
UTHealth Houston
School of Public Health
San Antonio Campus



Allison Grimes, MD, MSCI
Co-Project Director
GrimesA@uthscsa.edu

Aubree Shay, PhD, MSSW
Co-Project Director
Laura.Aubree.Shay@uth.tmc.edu

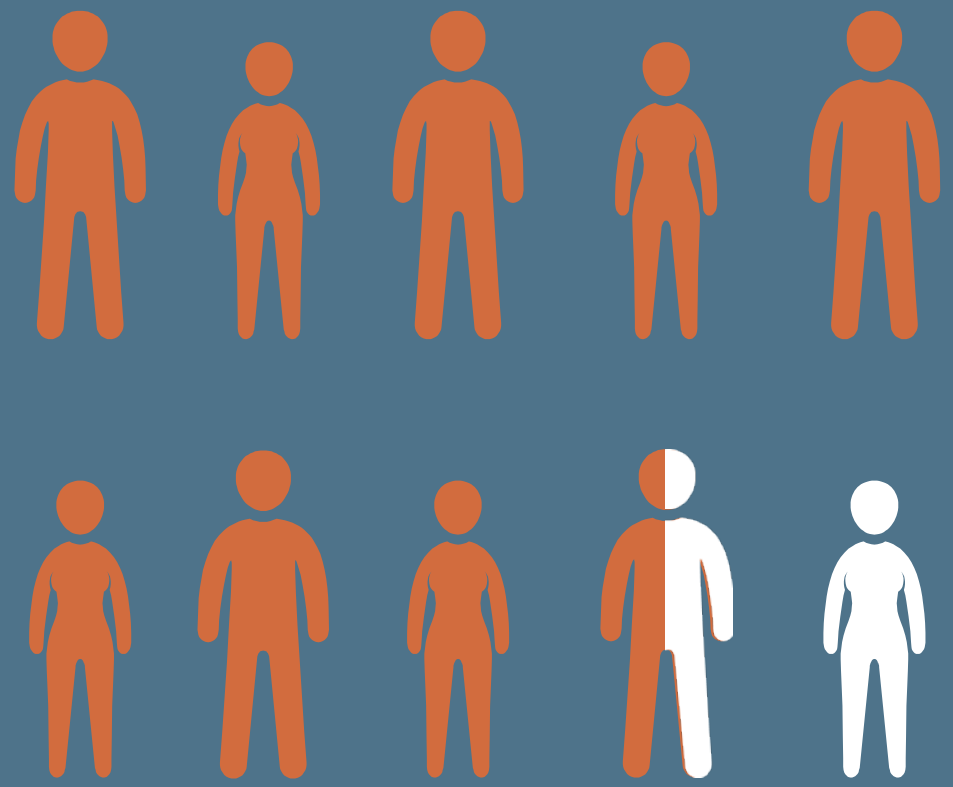
HPV vaccination is the best protection against 6 types of cancers.



34,800
HPV-related cancers each year in US

CDC

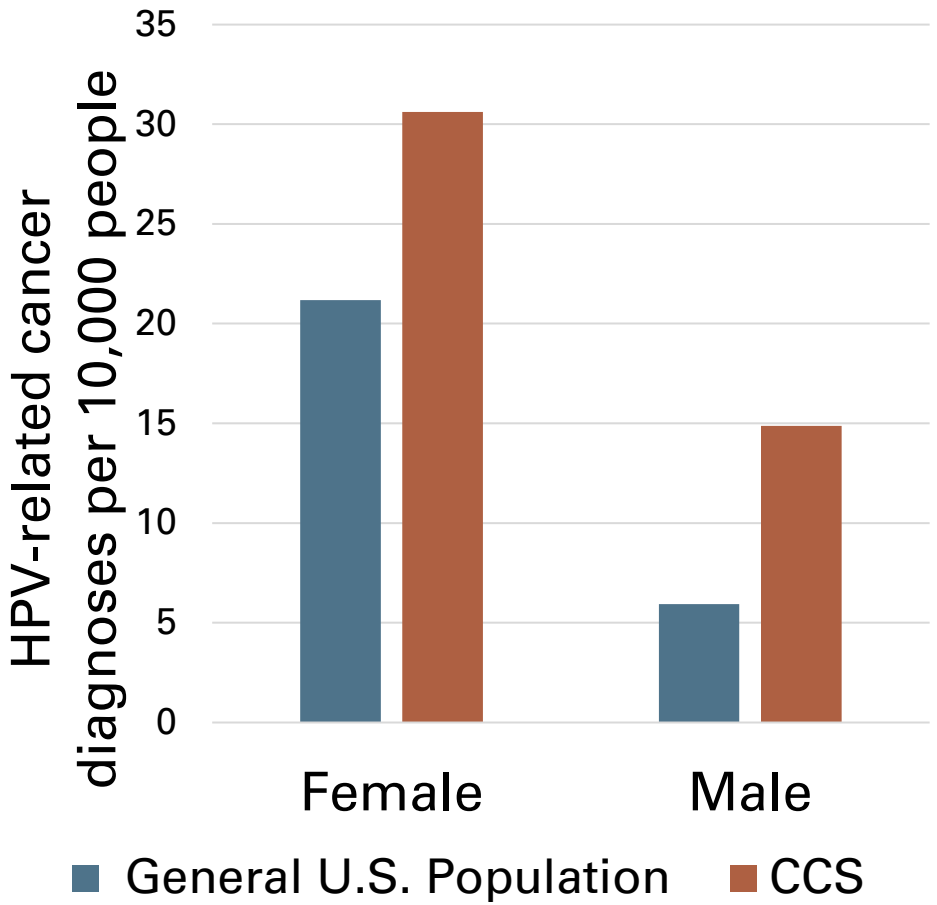
HPV is a common virus that infects teens and adults.



85%

of people will get an HPV infection in their lifetime.

Childhood cancer survivors (CCS) are at increased risk of HPV-related cancer



Risk compared to general population

- 40% increase for female CCS
- 150% increase for male CCS

(Ojha et al., 2013)

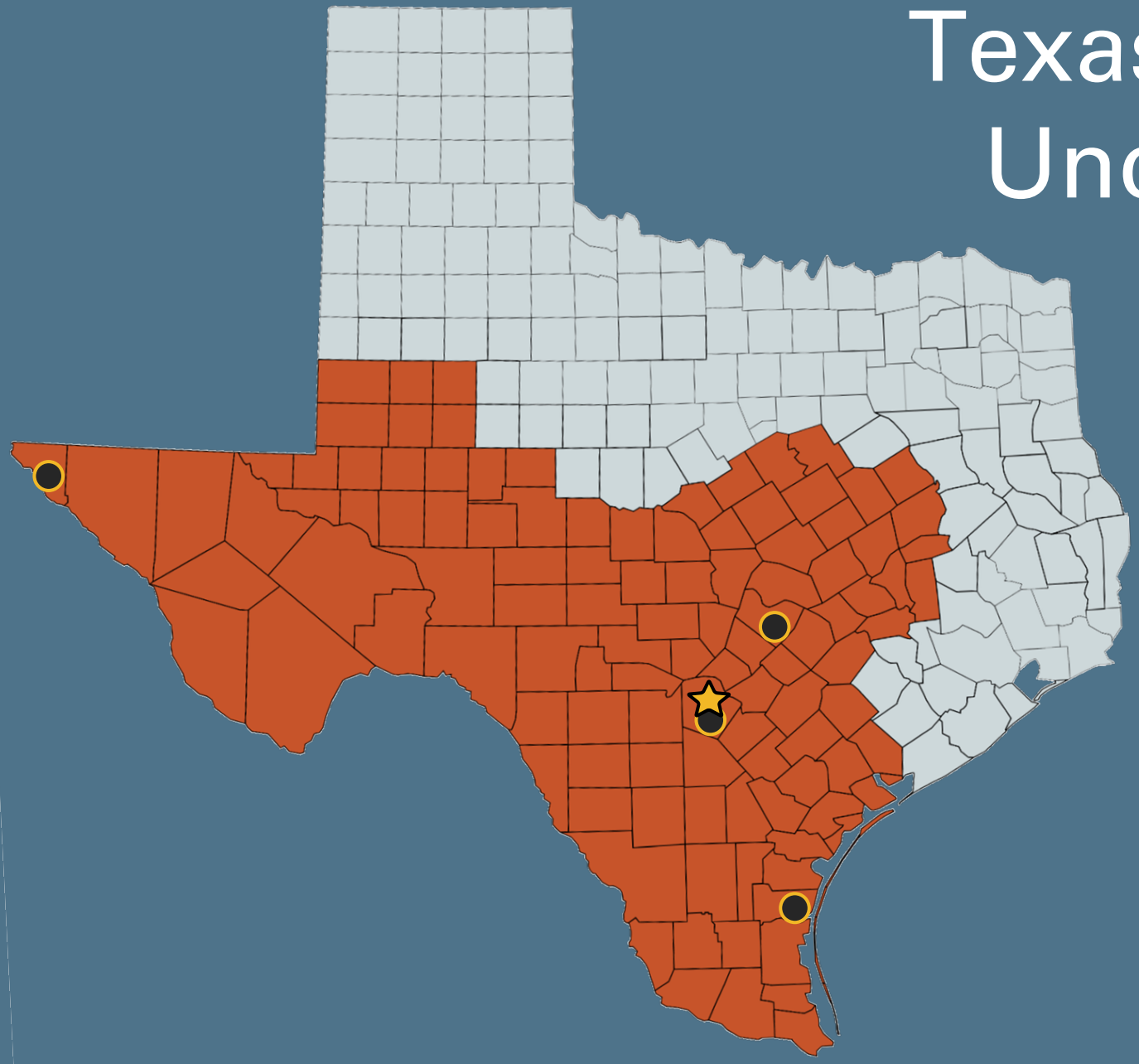
The Problem

Many childhood cancer survivors do not transition back to a general pediatrician for preventive care, instead continuing to see their oncologist.

Most oncologists do not routinely provide vaccines for their patients.

Survivors may fall behind on vaccines – particularly the HPV vaccine which is not required for schools in Texas.

Texas Pediatric Minority Underserved NCORP



Participating Sites:

- UT Health San Antonio (Primary)
- Methodist Children's Hospital, San Antonio
- Dell Children's Medical Center, Austin
- Driscoll Children's Hospital, Corpus Christi
- El Paso Children's Hospital

Catchment Area:

Population 9,893,039

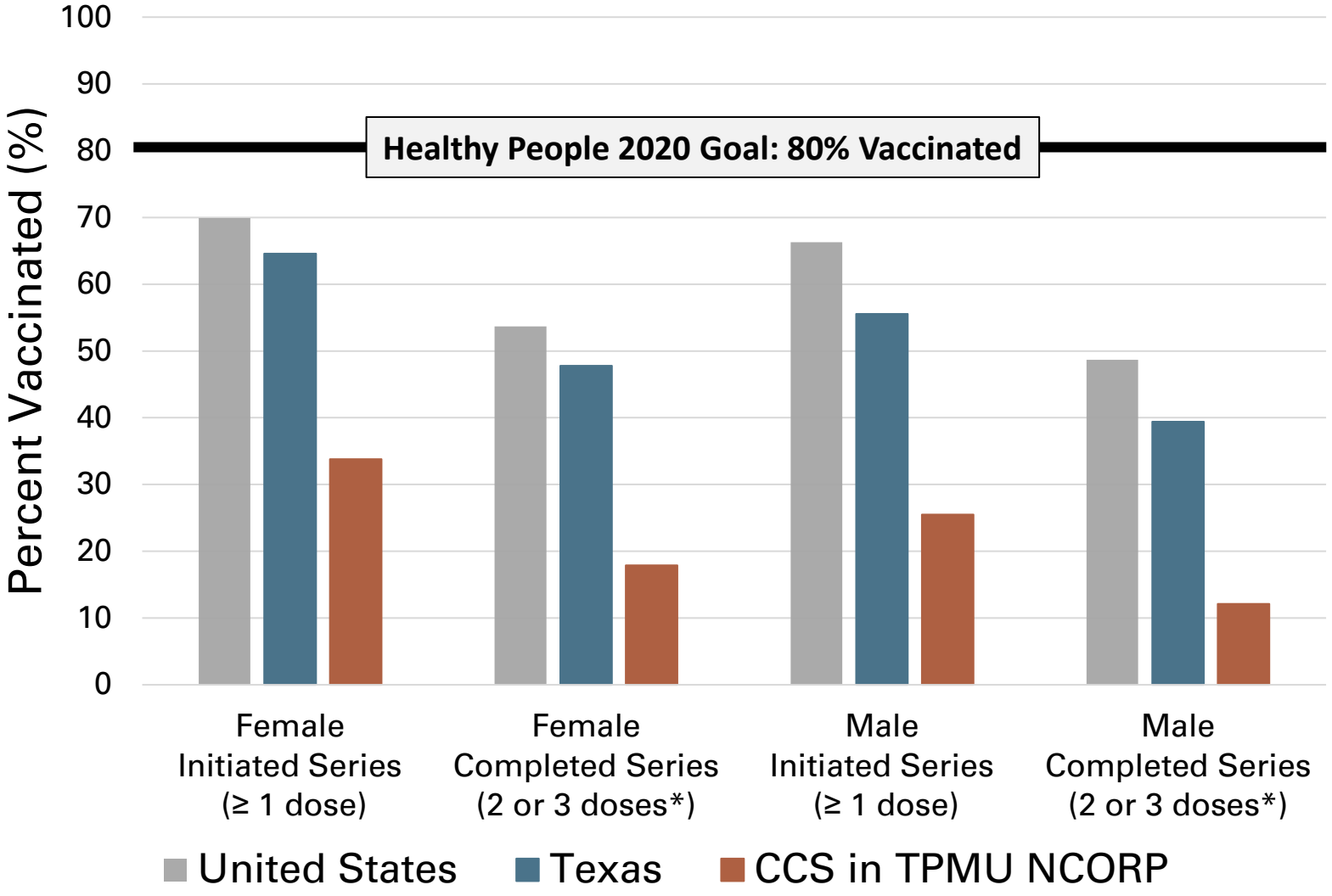
113 Counties

139,942 Square Miles

Project Goals

1. Increase HPV vaccine recommendation practices in participating pediatric oncology sites.
2. Increase HPV vaccine initiation among CCS aged 9-26 who are at least 6 months off active treatment.
3. Increase HPV vaccine completion among CCS aged 9-26 who are at least 6 months off active treatment.

Comparison of 2018 HPV vaccination rates in the US, Texas, and among CCS at TPMU NCORP



Overall completion rates at project start:

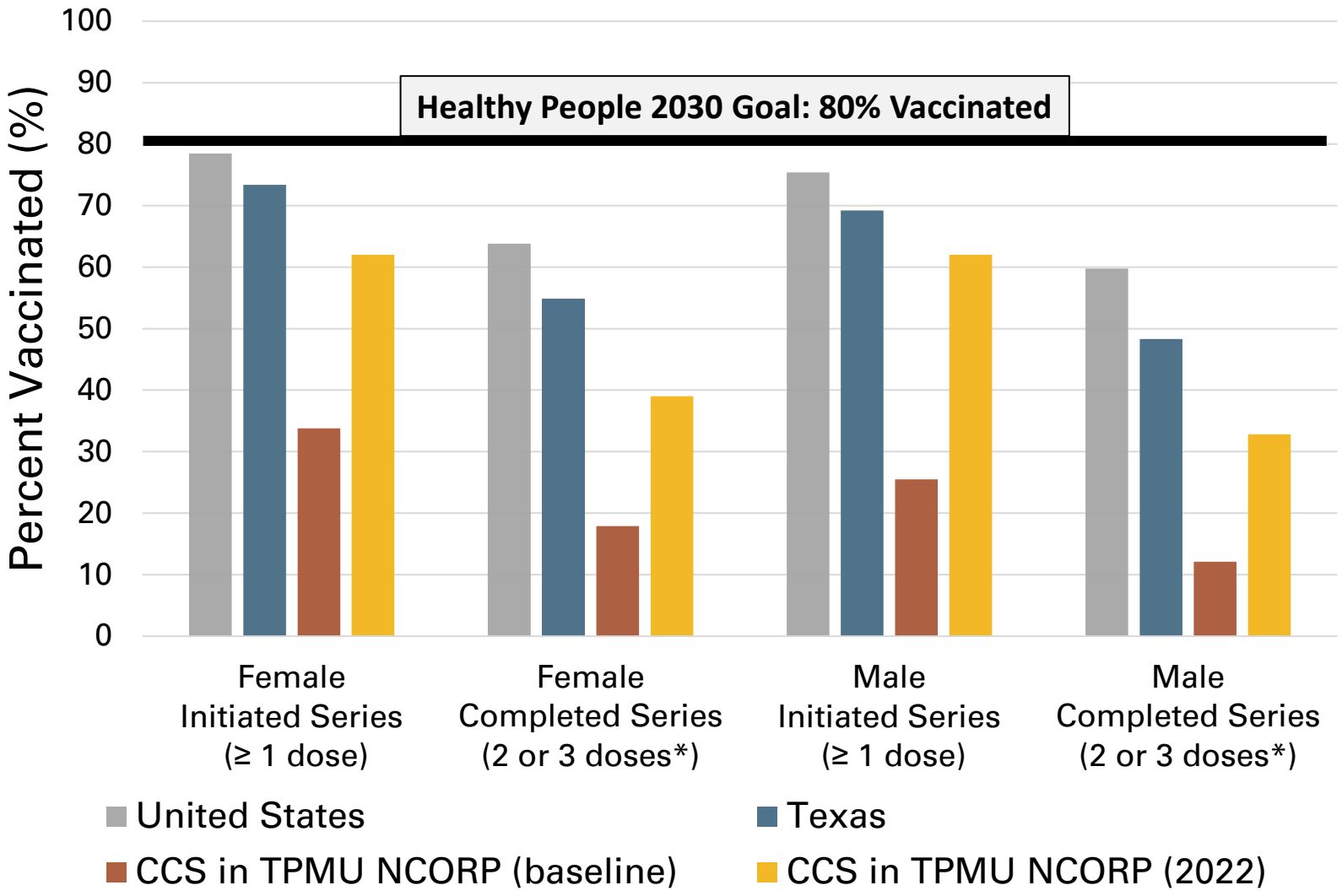
14.7% in CCS
vs
55% in general US population

2-11

To accomplish our goals:

1. Delivered an evidence-based HPV provider and staff continuing education program focused on the unique risks and needs of CCS
2. Implemented practice-level changes to build an HPV vaccine-friendly culture among CCS at five participating pediatric oncology sites
3. Offered on-site delivery of the HPV vaccine to eligible childhood cancer survivors at participating clinics

Updated CCS HPV vaccine rates as of 2022 for entire clinic lists (many are inactive patients)

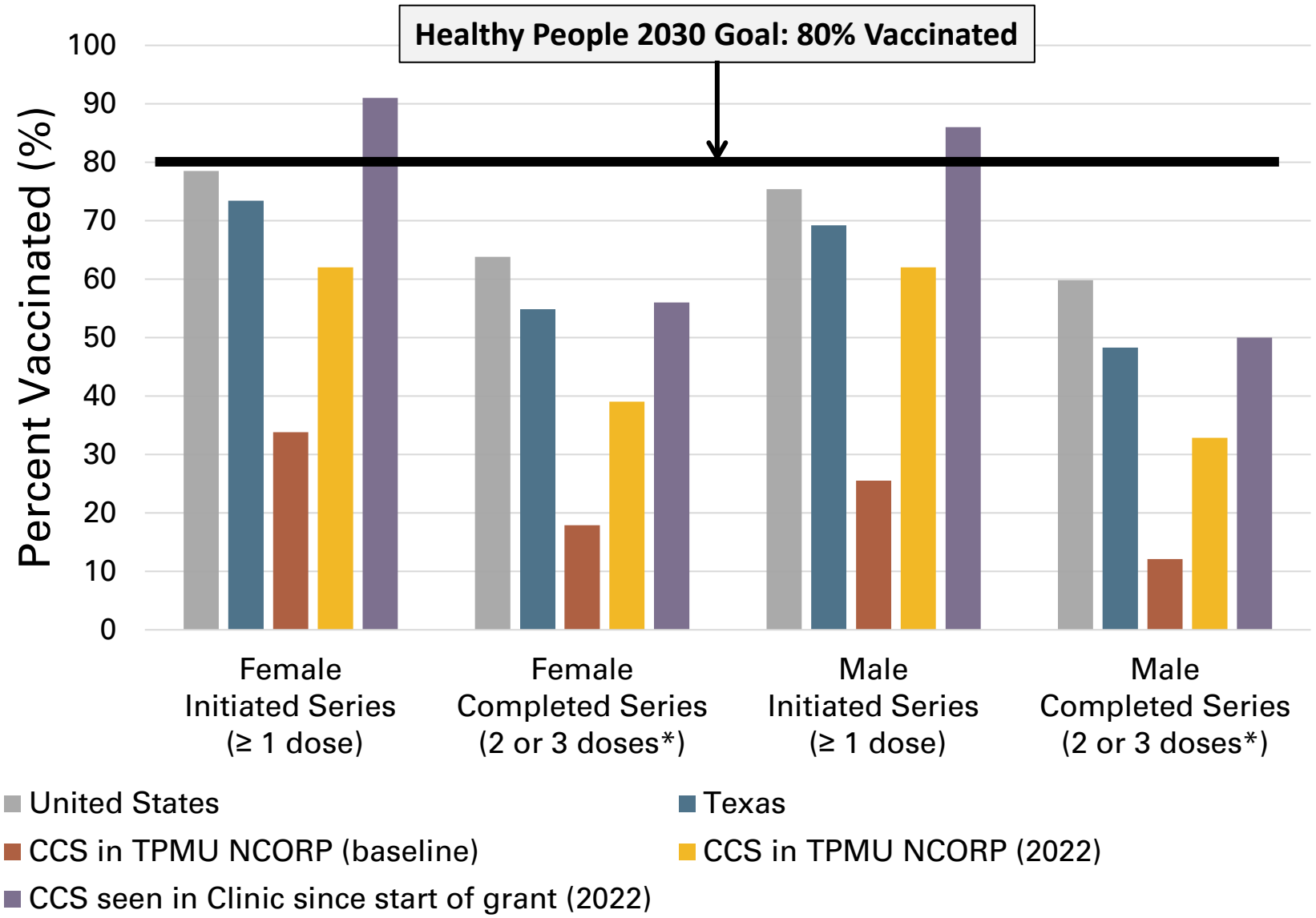


Current overall completion rates:

37% in CCS
vs
52% in Texas
&
62% in general US population

2-13

Updated CCS HPV vaccine rates as of 2022 for those seen in the clinic since the start of the grant



Current overall Completion rates:

53% in active CCS
vs
52% in Texas
&
62% in general US population

1,142

doses of HPV vaccine given to at-risk childhood cancer survivors

92%

of eligible childhood cancer survivors were given a HPV vaccine recommendation at their visit

261%

increase in HPV vaccine completion rates for childhood cancer survivors since 2018

It has been wonderful to offer cancer prevention in our pediatric oncology clinic - we can emphasize the importance of keeping our patients as healthy as possible - it is so important to offer HPV vaccines at every opportunity.

Participating
Pediatric Oncologist

The communication training we received about HPV vaccination and how to deal with hesitancy was a big help as we began talking to parents about the importance of the COVID vaccine for their children.

We felt like we were already experts in handling vaccine hesitancy just when everyone else began to think about it!

Participating
Pediatric Oncologist

THANK YOU

for helping to save the lives of childhood cancer survivors in Texas.

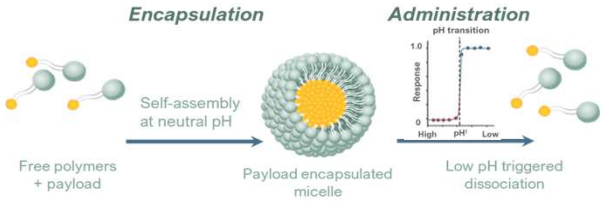
Progress Update for the Oversight Committee of the Cancer Prevention & Research Institute of Texas

November 16, 2022

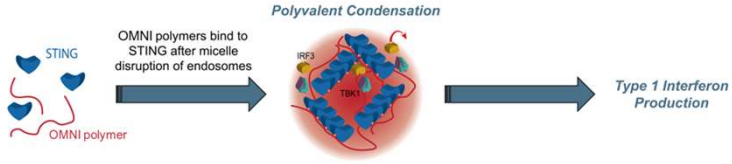
OncoNano Medicine Snapshot

- Clinical stage biopharmaceutical development company focused on targeted oncology
  - Founded in 2014 by two noted University of Texas Southwestern Medical Center scientists
  - 27 employees currently – all but 3 located in TX – HQ in Southlake, TX
  - 9 scientists working in leased laboratory space at UTSW
- Company has raised >$100m in capital thus far
- Extensive partnership with CPRIT - $31.4 million across 3 grant awards
  - $6m for pegsitacianine program in 2014 (DP140072)
  - $15.4m for "STING activator" program in 2019 (DP190066)
  - $10m for pegsitacianine program in 2020 (DP200081)
  - Landmark conversion of grant commitments to Series B equity ($18.4M) in October 2021
    - 100% of DP190066 + $3m of DP200081
- **Core Technology**

ON-BOARD ™



OMNI ™



Advancing a Portfolio of Novel Oncology Interventions

Platform	Program	Opportunity	Current status					Anticipated next steps
			Discovery	Preclinical	Phase 1	Phase 2	Phase 3	
***OMNI*™** **Polymeric micelles technology to activate immune response**	**ONM-501** CPRIT	Dual-activating STING agonist						•IND submission expected 1H'23 •Initiation of Phase 1/2 clinical trial in the US mid-'23
***ON-BOARD*™** **Tumor specific delivery technology with multiple applications**	**Pegsitacianine** CPRIT	Adjunct intraoperative optical imaging agent				Peritoneal carcinomatosis		•Data readout from two Phase 2 trials in 2H'22 •Initiation of Phase 3 clinical trials expected in mid-'23
	Immuno-oncology therapeutic	Targeted delivery of a cytokine or bi-specific antibody						• Will advance to IND-enabling activities in 2023

onconano

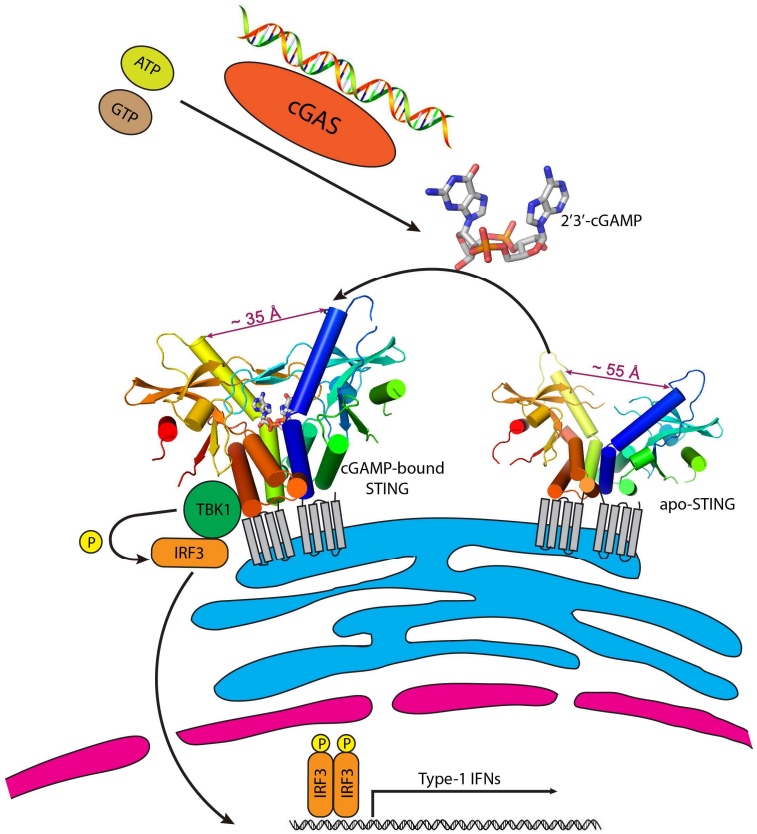
OMNI™ Platform

Polymeric micelle technology to induce an anti-tumor immune response

STING - a Compelling Immuno-Oncology Target

STING pathway in cancer

- Damaged tumor cells shed DNA into cytoplasm
- cGAS and DNA form polyvalent condensates, facilitating synthesis of cGAMP as a secondary messenger
- cGAMP binds and activates **ST**imulator of **IN**terferon **G**enes (STING), elevating Type I interferons activating anti-cancer immune response



Chen et al. Science, 339, 786 (2013)

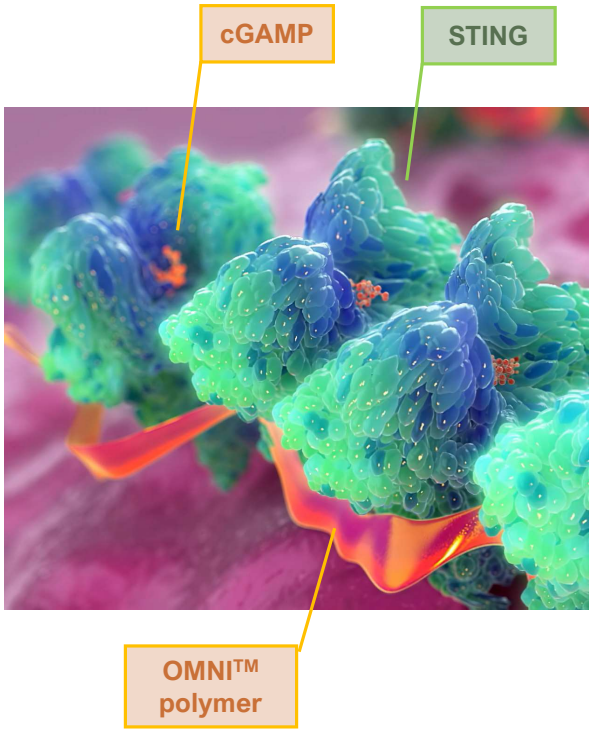
Challenges with prior STING agonists:

- Achieving effective intra-cellular delivery
- At sufficiently high doses, earlier STING agonist induced T-cell death, resulting in impaired T-cell activation[1]

[1]Meric-Bernstam, F., et al. (2021). "Phase I Dose-Escalation Trial of MIW815 (ADU-S100), an Intratumoral STING Agonist, in Patients with Advanced/Metastatic Solid Tumors or Lymphomas." Clinical Cancer Research 28(4): 677-688.

ONM-501 : Overcomes the Limitations of Earlier STING Agonists

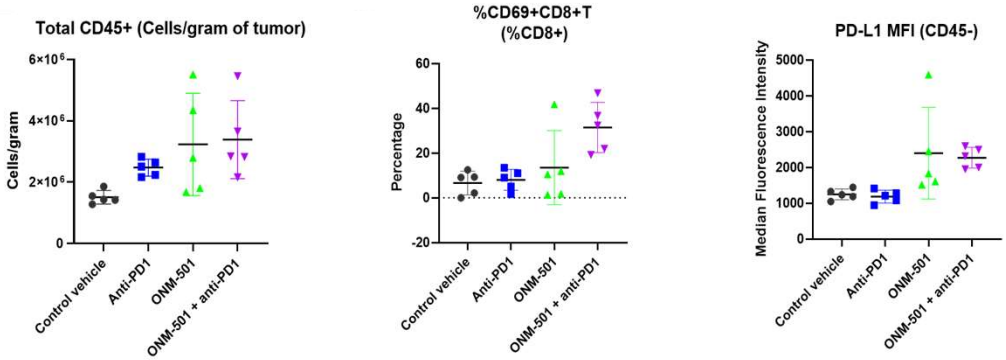
Limitations with STING Agonists	ONM-501 Differentiation
1 Limited cell entrance to reach cytosolic STING target	1 Efficient cytosolic delivery through **OMNI™**-mediated endosomal disruption
2 Lack of cell selectivity – high dose causes T cell ablation	2 Selective targeting to antigen presenting cells that activates cDC1 and shift macrophages toward pro-inflammatory status
3 Short-term STING activation with tepid antitumor efficacy	3 Dual STING activation with robust antitumor efficacy in a broad set of cancers including immune 'cold' tumors
4 Perfusion loss from tumor site results in elevated systemic exposure and toxicity	4 High tumor retention via nanoparticle PKBD with minimal systemic exposure



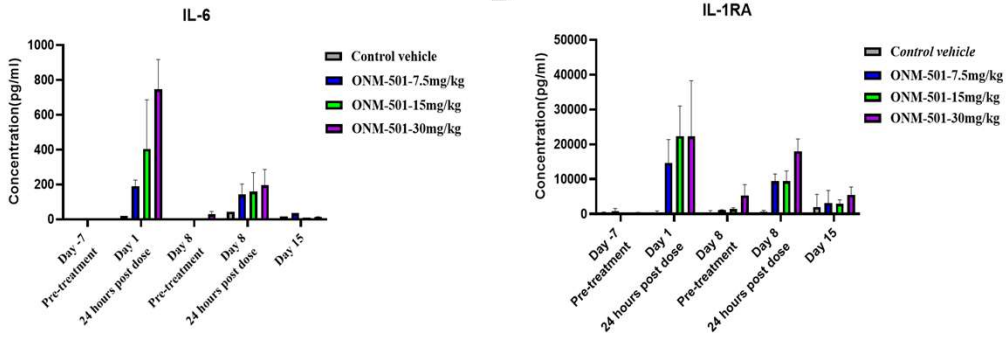
onconano

Pre-clinical Studies Support ONM-501 as a *Differentiated* STING Agonist

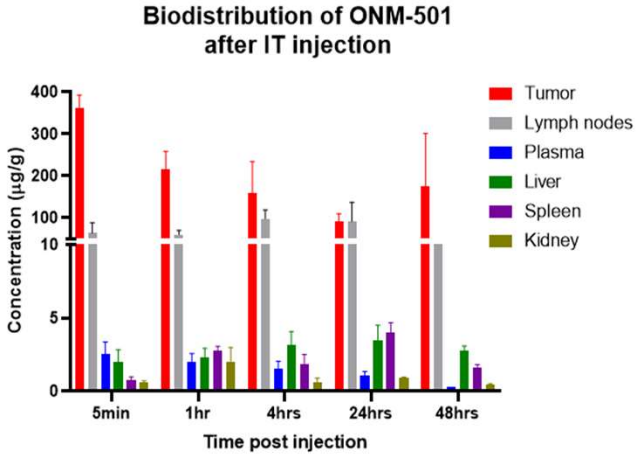
- **Treatment of tumor-bearing mice results in immune cell infiltration into tumors**

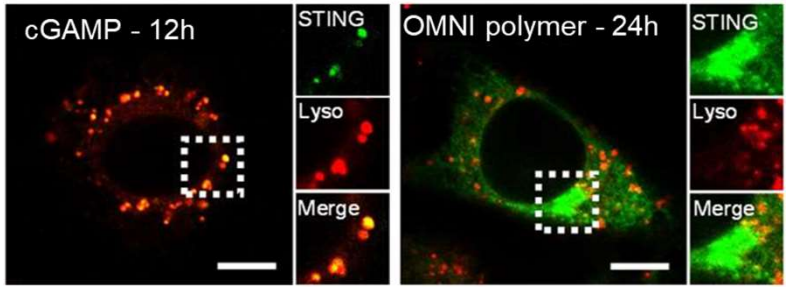


- **Markers of inflammation are elevated in NHP (STING is activated) but *non-adverse***



- **ONM-501 is retained in tumors following intratumoral injection**



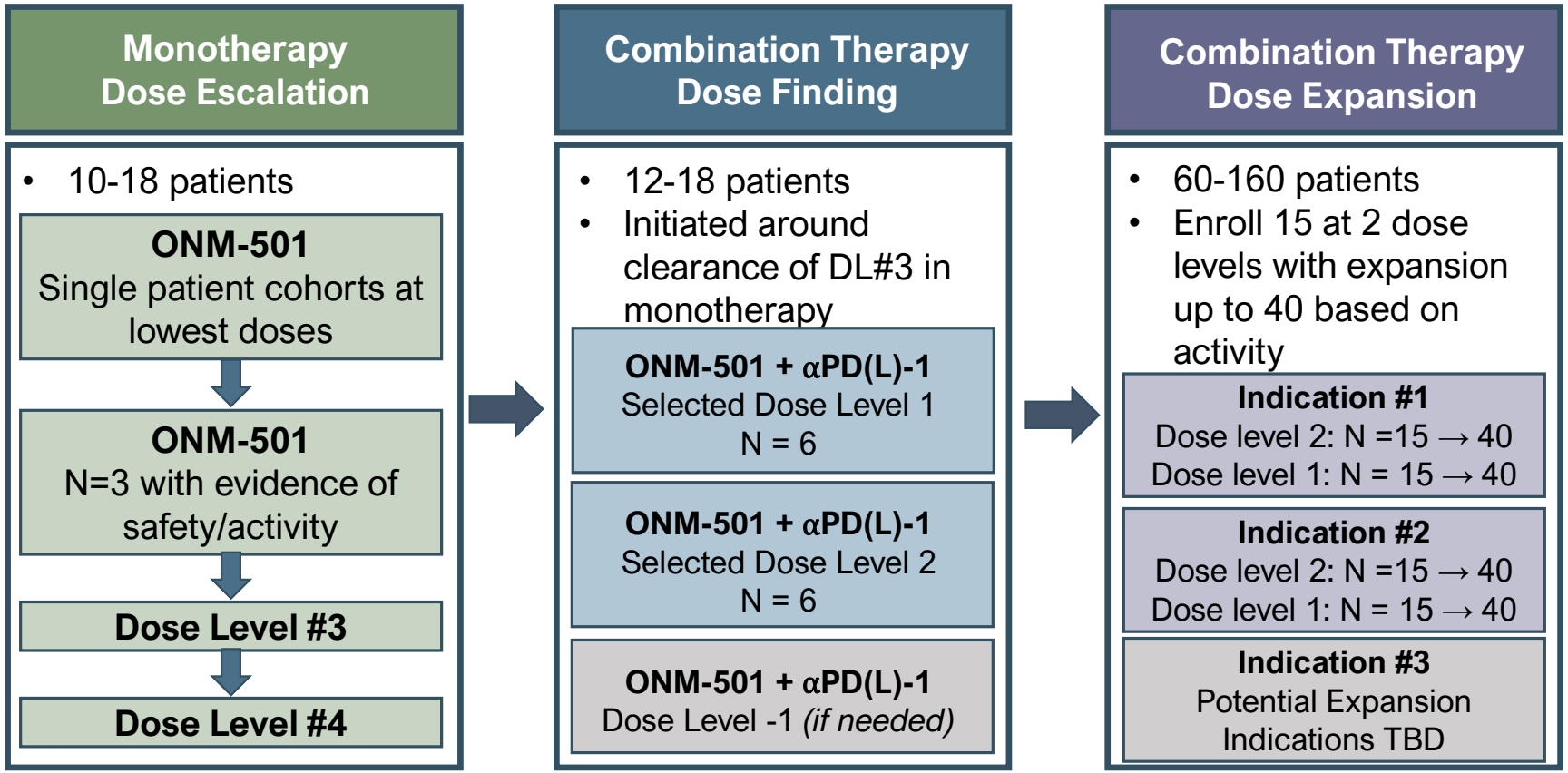


Advancing the Clinical Program for ONM-501

- Pre-clinical (GLP) program supports clinical development
  - Highest non-severely toxic dose in multi-dose NHP study is 2.4mg/kg (human equivalent)
  - By comparison, highest planned dose in FIH is 2.4mg per tumor injection – *wide safety margin*
- FIH study plan has been shared with experienced investigators at 3 institutions (2 TX based)
- CRO for FIH trial has been selected – contracting underway
- Pre-IND meeting request and briefing package has been submitted to the US FDA
  - Written feedback to be returned in December 2022
- IND, informed by pre-IND feedback, to be submitted in Q1 2023
- IND clearance and First Site Initiation anticipated in Q2 2023
- First Patient Enrolled and Dosed in Q2 – Q3 2023

ONM-501 First in Human Trial

Anticipated Start Q2 2023



ON-BOARD™ Platform

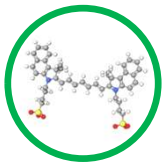
Polymeric micelle technology for tumor-specific delivery & improved therapeutic index

ON-BOARD™ - Overcomes Challenges with Delivery of Interventions for Cancer Patients

Why ON-BOARD™

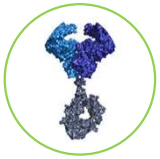
- Efficient extracellular delivery to cancer TME
- Mask payload toxicity and minimize systemic exposure
- Validated safety and tumor specificity in human patients
- Large universe of potential payloads

Payload Category


Imaging agent


Cytokine


Bispecific antibody

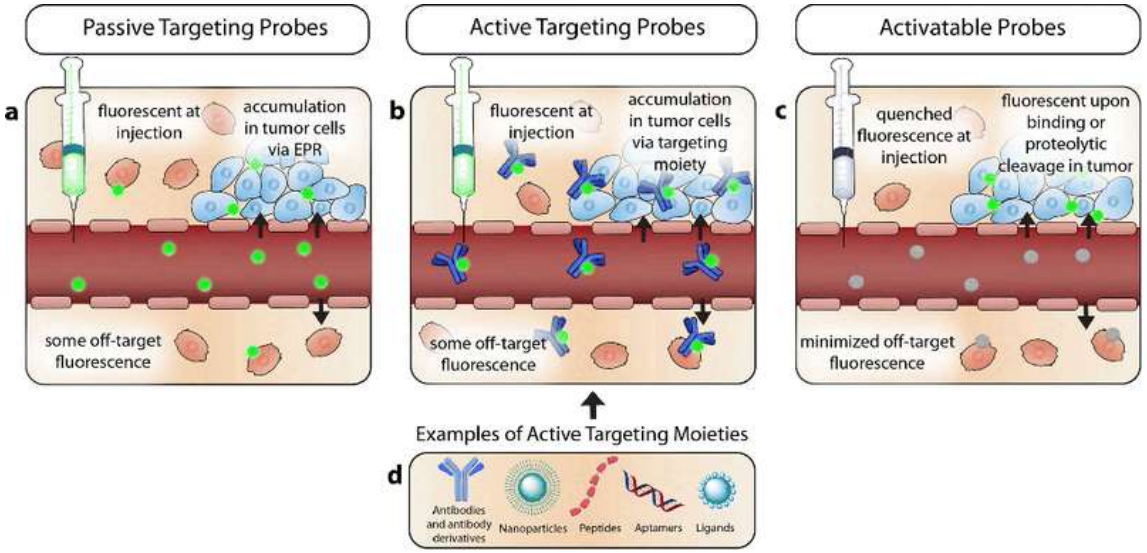

Fusion protein


Monoclonal antibody

∞
Opportunities to encapsulate additional payloads

Pegsitacianine - Improving Intraoperative Tumor Visualization

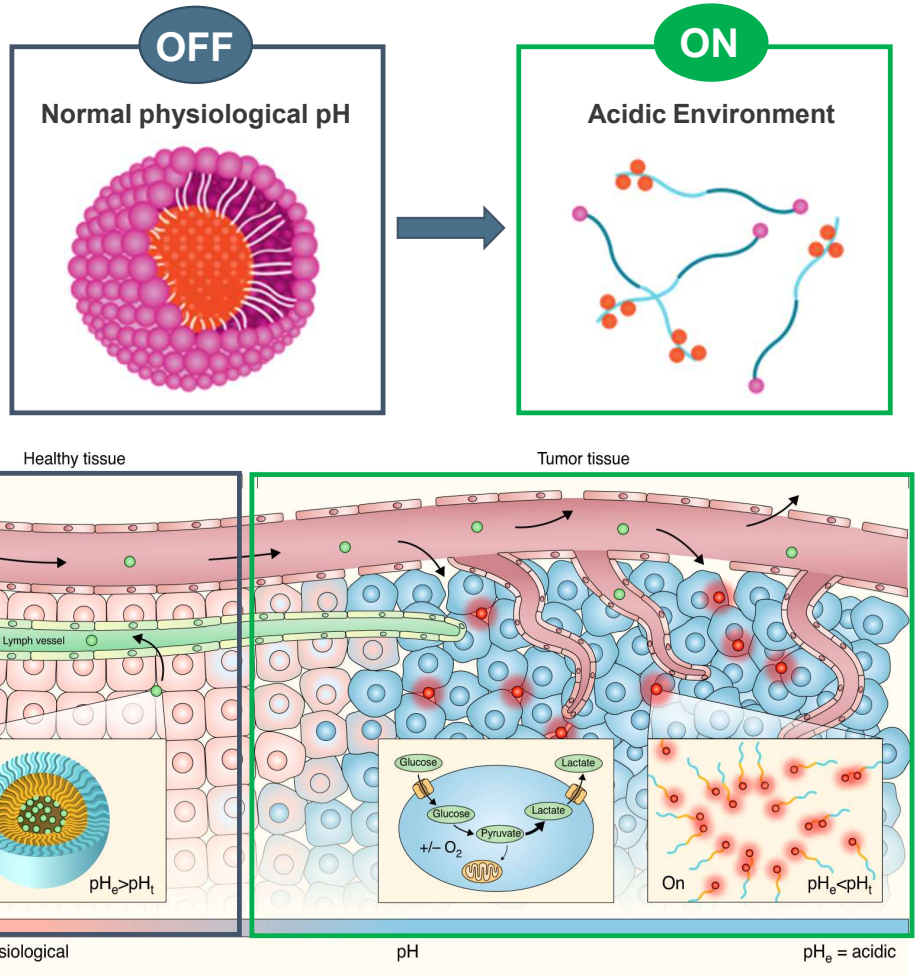
- Challenges translating preoperative images to intraoperative setting
- Real-time optical imaging has emerged as potential tool to address lack of intraoperative tumor visualization
  - Instantaneous feedback
  - Small footprint
  - Ease of use, interpretation
  - Opportunities for detection of residual disease
- Variety of targeting moieties and strategies for optical imaging agents in development



Olson, M.T. et al. (2018)

Pegsitacianine: An Activatable Probe for Targeting the Acidic Tumor Microenvironment

- Micellar fluorescent imaging agent
  - Components:
    - PEG – outer hydrophilic polymer
    - PMMA – core hydrophobic polymer
    - ICG – fluorescent dye conjugate
- Designed as an activatable probe, with binary response to pH changes
  - **Fluorescence OFF** at physiological pH (i.e., circulation, healthy tissue)
  - **Fluorescence ON:** micelle dissociates in acidic environments (i.e., tumor microenvironment)
- Administered as a single IV infusion 1 – 3 days prior to surgery
- Most common adverse event – transient, self-resolving mild to moderate infusion-related reactions



Bennett Z.T. et al. 2019, Zhao T. et al. 2016
Voskuil, F.J. et al 2020.

onconano

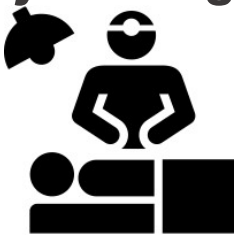
Study Design:

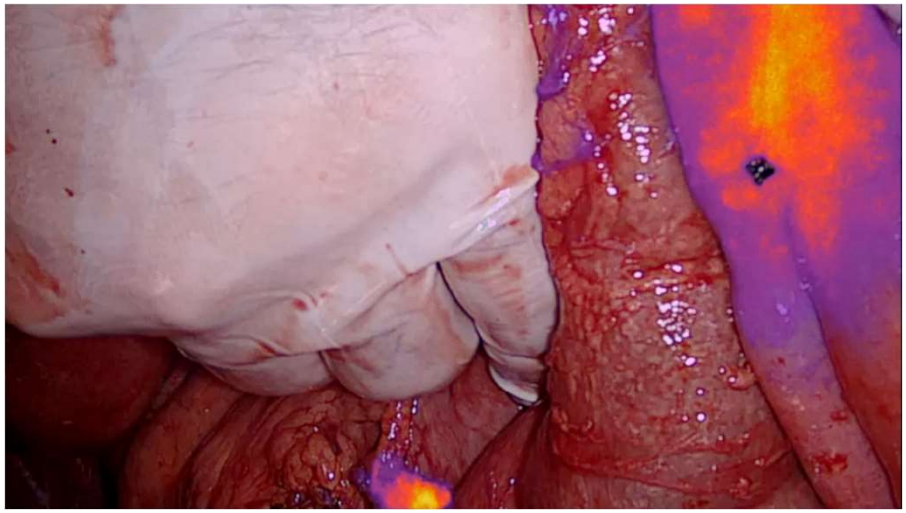
Day 0

Pegsitacianine Infusion
Dose: 1 mg/kg
Rate: 10 mL/min

24-72 Hours

Day of Surgery

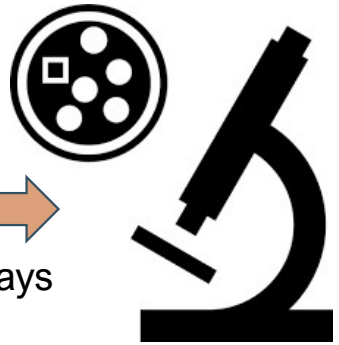




1. SOC Surgery
2. Imaging of 10 SOC suspected tumor nodules and 5 areas of normal tissue
3. Examination of peritoneal cavity with NIR camera
4. Excision of additional disease

7-10 Days

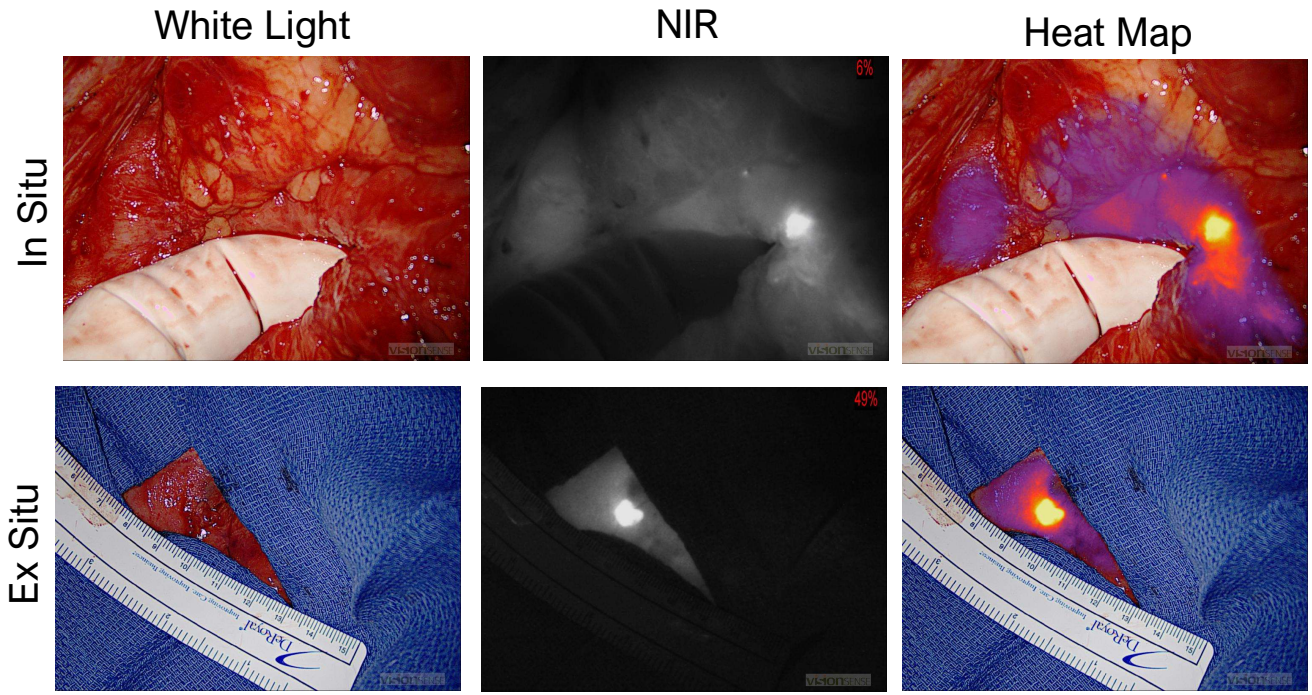
Pathology Results



- Correlation of imaging observations and pathological outcomes of specimens
- Calculations of CC scores and finding of CSEs

Ongoing Peritoneal Metastasis Phase II Trial Overview

- **32** patients have undergone imaging during surgery with pegsitacianine to date
- Detection of disease demonstrated in **6** tumor types
  - Appendiceal
  - Colorectal
  - Mesothelioma
  - Endometrial
  - Pancreatic
  - Ovarian
- No significant differences observed in detection of mucinous and non-mucinous disease



Residual Disease – Colon cancer left upper quadrant nodule

Summary of Interim Results:

Safety:
- Well tolerated in patients
- No drug-related SAEs
- Infusion-related reaction ~27%

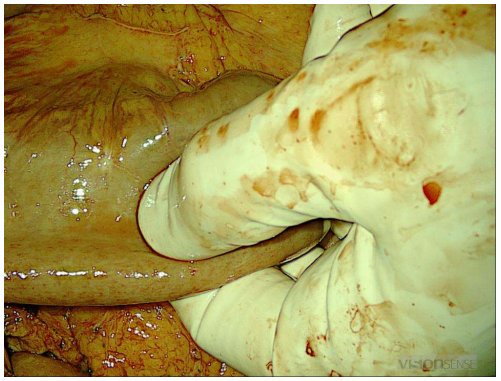
Performance:
- Tumors appear to take up and activate pegsitacianine
- Capable of detecting small tumor deposits
- Healthy tissue shows little to no activation
- Anticipated background fluorescence observed in liver, spleen, small bowel, and lymph nodes
- Consistently detects residual disease, can alter CC score

Tumor Detection Performance

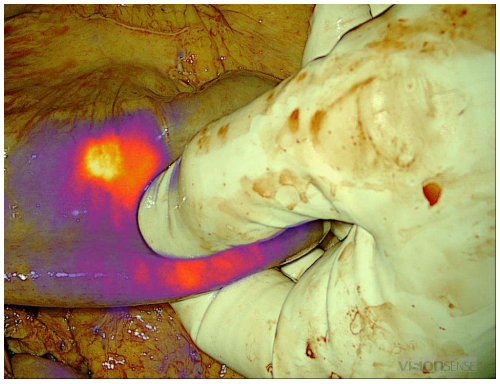
Detection of Residual Disease (Clinically Significant Events)	
15/27 evaluable patients	55%

Sample Type	N	Sensitivity (TP/TP+FN)	NPV	pFPR
SOC and Fluorescent	466	86%	78%	27%

White Light Only



NIR Heat Map Overlay



*Evaluable population– patients who received >75% intended dose of pegsitacianine with a minimum of 1 image captured, and opportunity for post-SOC exploration

ON-BOARD™: the Best-in-Class Technology for **Masked Extracellular Delivery** of **Protein Therapeutics** to Tumor

Traditional Nanomedicine

- Requires targeting ligands
- Slow payload release
- Limited payload diversity
- Limited extracellular specificity
- Difficult to manufacture and customize

Protein Engineering

- Unvalidated activating MOA (i.e. MMP)
- Slow activation/cleavage-low potency
- Sophisticated protein engineering
- Masked binding site = loss of tumor specificity

ON-BOARD™

- Mask payload toxicity without sacrificing tumor targeting
- Clinically validated tumor specificity

- Diverse payload compatibility
- Rapid pH-triggered payload release
- No protein engineering required
- Manufactured at large scale

Int J Pharm. 154(2):123-140.
J Drug Target. 15(1): 1–20.
Nature 533(7603), 304–305.
APL Bioeng. 3(1): 011503

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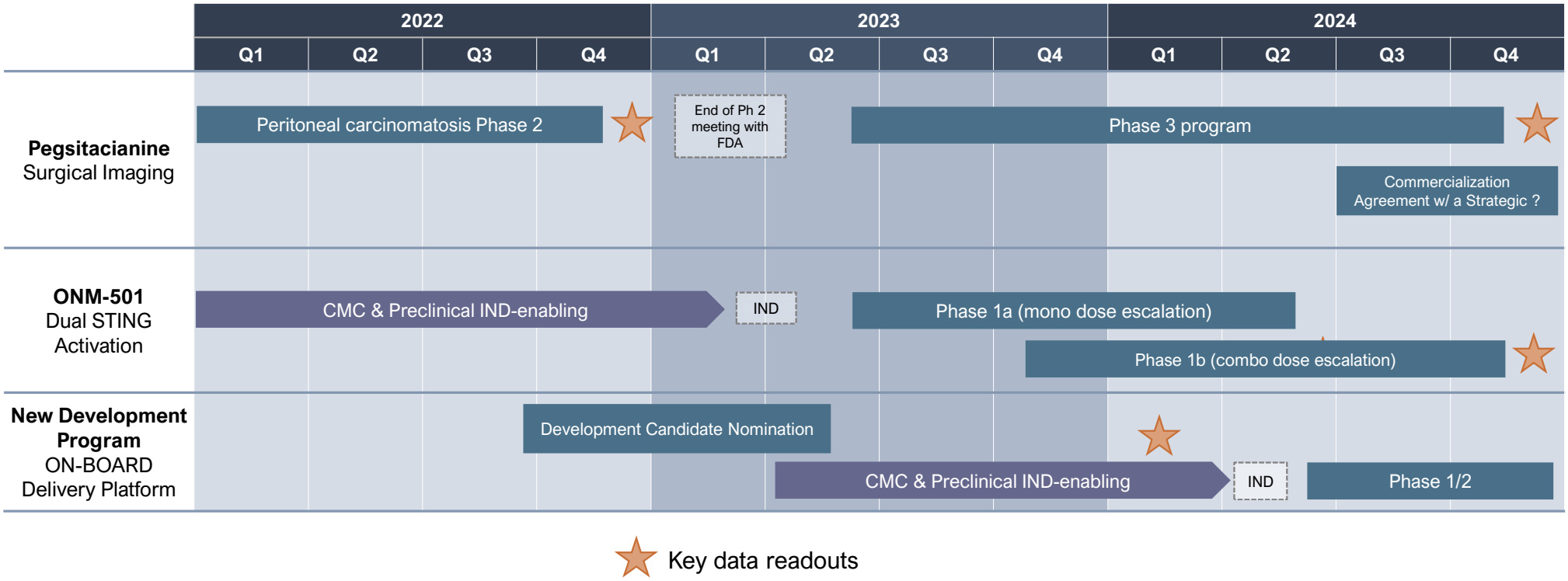
Near Term Milestones & Potential Catalysts



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Additional Key Corporate Information

Exclusive Licensed Technology

- Platform technology licensed from UTSW
  - Exclusive, global license with full sub-license capability
  - Favorable economic terms with low single-digit royalties

Product/ Platform	Market Exclusivity Through
Pegsitacianine	2040
ON-BOARD™	2040
ONM-501	2037

Successful History of Raising Capital

- >$100m in private capital raised
  - $68m+ Series B financing round closed in 2H'21
  - Current cash position finances company into 2H'24
- >$33m in grant awards from Cancer Prevention & Research Institute of Texas (CPRIT) & NIH SBIR
  - $7m still available
- Clean balance sheet – 3 years of audited financials available in 4Q'22
- Investors:

Cancer Prevention & Research Institute of Texas

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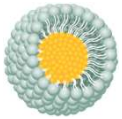
SALEM PARTNERS

Clinical stage biopharma company focused on targeted oncology

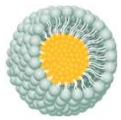


Unique Delivery Platform

- A **library of adaptable polymeric-micelles** that exploit the pH of solid tumors
- **ON-BOARD™**
- **OMNI™**
- Future potential to monetize the platform by improving the therapeutic index for oncology payloads

Targeted Immuno-Oncology Therapeutics

- **ONM-501 – a targeted immuno-oncology therapeutic**
  - Dual-activating STING agonist utilizing **OMNI™**
  - Will enter the clinic in 1H'23
- **2nd Therapeutic Program**
  - IND-enabling activities in 1H'23



Late-Stage Clinical Asset

- **Pegsitacianine – a fluorescent nanoprobe for real-time surgical imaging**
  - Ph 2 completion YE'22 with Ph 3 initiation 1H'23
- Clinical and CMC validation of the **ON-BOARD™** technology platform

Company with Strong Potential

- **R&D Discovery team** advancing the development of new payloads encapsulated in our core technology
- Experienced private and public company management team
- Financed into 2H'24
- Partnered with Cancer Prevention & Research Institute of TX

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	AGENDA ITEM 6: CHIEF EXECUTIVE OFFICER REPORT
DATE:	NOVEMBER 7, 2022

The Chief Executive Officer Report presented at the November 16 Oversight Committee meeting will include the following items. In addition, attached behind this memo are copies of the August/September 2022 and October 2022 CPRIT Activity Updates for your reference.

FY 2023 Grant Awards Funds Available and CPRIT Dashboard (Attachments 1 and 2)

If the Oversight Committee approves the 2 awards at the recommended level of nearly $12.0 million, we will have $212.2 million remaining for awards in FY 2023.

Also attached is CPRIT's dashboard of metrics that we track on a regular basis.

Personnel

CPRIT currently has 41 of our 44 full-time equivalent (FTE) positions filled. New staff will be recognized.

Digital Communications Specialist, Justin Rand, began work on November 1.

Program Manager for Research and Prevention, Carlton Allen, began work on November 14.

The second Product Development Manager Position is in progress and we expect to post the Grant Compliance Specialist Support positions this month.

*****

Additional items will be added as warranted.

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CPRIT has awarded **1,818** grants totaling **$3.173 billion**

- 274 prevention awards totaling $327.9 million
- 1,544 academic research and product development research awards totaling $2.845 billion

Of the $2.845 billion in academic research and product development research awards,

- 31.0% of the funding ($882.6 million) supports clinical research projects
- 23.8% of the funding ($676.3 million) supports translational research projects
- 29.4% of funding ($835.6 million) supports recruitment awards
- 12.6% of the funding ($359.8 million) supports discovery stage research projects
- 3.2% of funding ($90.4 million) supports training programs.

CPRIT has 6 open Requests for Applications (RFAs)

- 2 Academic Research Recruitment
- 4 Product Development Research

FY 2023 GRANT AWARD FUNDS AVAILABLE

General Obligation Bond Proceeds

	Prevention	Academic / Product Development Research	1% Grant Funding Buffer	Operating Budget	Total Appropriations
Available Appropriated Funds	$ 27,660,780	$ 251,369,432		$ 20,969,788	$ 300,000,000
Appropriations Transfer to DSHS		$ (3,118,032)		$ 3,118,032	
Adjusted Appropriations	$ 27,660,780	$ 248,251,400		$ 24,087,820	$ 300,000,000
Total Available for All Grants			$ 275,912,180		
1% of Total Available Grant Funding			$ 2,759,122		
Adjusted Grant Award Funding	27,660,780	$ 245,492,278			$ 273,153,058

	Prevention Grants	Academic Research Grants	PD Research Grants			
Total Available for Grant Awards (Total GO Bond Proceeds Less Operating Budget)	$ 27,660,780	$ 173,775,980	$ 74,475,420			$ 275,912,180
Total Available for Grant Awards Incorporating 1% Grant Funding Buffer	$ 27,660,780	$ 171,844,595	$ 73,647,683			$ 273,153,058
Announced Grant Awards						
Core Facility Support Awards (6)	$ -	$ 23,298,824	$ -			
Clinical Trials Network Awards (1)	$ -	$ 3,000,000	$ -			
Early Clinical Investigator Awards (2)	$ -	$ 2,994,784	`			
High-Impact/High Risk Awards (14)	$ -	$ 3,474,906	$ -			
Company Grant Award (1)	$ -	$ -	$ 16,154,562			
Announced Grant Award Subtotal	**$ -**	**$ 32,768,514**	**$ 16,154,562**	$ -		**$ 48,923,076**
Available Grant Funds as of November 1, 2022	**$ 27,660,780**	**$ 139,076,081**	**$ 57,493,121**			**$ 224,229,982**
Pending Grants-PIC Recommendations						
Recruitment Awards (2)	$ -	$ 11,999,198	$ -			
Pending Award Subtotal	**$ -**	**$ 11,999,198**	**$ -**			**$ 11,999,198**
Total Potential Grant Funding Committed	**$ -**	**$ 44,767,712**	**$ 16,154,562**			**$ 60,922,274**
Uncommitted Grant Funds as of November 16, 2022	**$ 27,660,780**	**$ 127,076,883**	**$ 57,493,121**			**$ 212,230,784**
1% Grant Funding Buffer	**$ -**	**$ 1,931,385**	**$ 827,737**			**$ 2,759,122**
Total Remaining Funds	**$ 27,660,780**	**$ 129,008,268**	**$ 58,320,858**			**$ 214,989,906**

Operating Budget Detail	
Indirect Administration	$ 4,910,893
Grant Review & Award Operations	$ 16,058,895
Subtotal, CPRIT Operating Costs	$ 20,969,788
Cancer Registry Operating Cost Transfer	$ 3,118,032
Total, Operating Costs	24,087,820

CPRIT MANAGEMENT DASHBOARD
FISCAL YEAR 2022

	SEPT	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	CUMULATIVE (ANNUAL)	CUMULATIVE (TO DATE)
ACCOUNTABILITY														
Announced Grant Awards			12			76			17			21	126	
New Grant Contracts Signed	22	26	16	10	6	2	24	42	4	3	1	8	164	
New Grant Contracts In Negotiation			9			12			10			28	59	
Grant Reimbursements Processed (#)	126	162	156	129	133	189	176	145	182	170	95	169	1832	
Grant Reimbursements Processed ($)	$ 21,921,638	$ 28,164,298	$ 11,711,647	$ 17,758,038	$ 18,810,529	$ 22,750,016	$ 22,615,358	$ 13,764,043	$ 12,038,375	$ 21,573,811	$ 10,989,010	$ 13,887,869	$ 215,984,631	
Revenue Sharing Payments Received	$ 2,341,908	$ 22,365	$ 6,579	$ 2,442	$ 25,645	$ 3,582	$ 114,600	$ 5,712	$ 161,825	$ 27,550	$ 11,246	$ 62,468	$ 2,785,921	$ 7,725,539
Grants Awarded (#)/ Applications Rec'd (#)	18%	18%	18%	18%	18%	19%	19%	19%	19%	18%	18%	18%		
Grantee Compliance Trainings	2	3	2	1	0	3	4	1	3	3	0	0	22	
Grantee Compliance Monitoring Visits	0	0	1	3	1	3	3	2	2	2	4	6	27	
Awards with Delinquent Reimbursement Submission (FSR)			0			1			2			2		
Awards with Delinquent Matching Funds Verification			2			6			4			4		
Awards with Delinquent Progress Report Submission			2			0			2			2		
MISSION														
Open RFAs	3	7	11	13	13	6	8	8	6	11	3	10		
Prevention Applications Received	16	0	0	0	0	16	0	0	0	0	0	28	60	963
Product Development Applications Received	0	0	0	0	34	0	0	0	0	0	0	0	34	644
Academic Research Applications Received	5	3	4	4	124	12	10	12	0	329	0	5	508	8,673
Help Desk Calls/Emails	113	116	77	94	159	138	95	137	163	124	119	155	1,490	
Number of Research Grants Announced (Annual)	0		12			65			17			3	97	
Recruited Scientists Contracted														269
Number of Product Development Grants Announced (Annual)			0			2			0			9	11	
Life Science Companies Recruited (in TX)													0	14
Number of Product Development Jobs Created & Maintained														1,228
Number of Prevention Grants Announced (Annual)			0			7			0			9	16	
Total Number of Education, Navigation and Training Services			147,482			149,504			153,879			176,791	627,656	
Total Number of Clinical Services			56,122			46,422			50,720			54,042	207,306	
Published Articles on CPRIT-Funded Projects (#)													1,153	
Clinical Studies (#)														228
Number of Patent Applications													51	
Number of Patents Resulting from Research													2	
TRANSPARENCY														
Total Website Hits (Sessions)	9,694	8,961	9,110	7,619	9,559	12,521	10,114	8,138	11,406	9,291	8,411	13,181		
Total Unique Visitors to Website (Users)	7,737	7,065	7,184	6,004	7,192	9,215	8,014	6,285	8,490	7,047	6,658	9,615		

CPRIT MANAGEMENT DASHBOARD
FISCAL YEAR 2023

	SEPT	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	CUMULATIVE (ANNUAL)	CUMULATIVE (TO DATE)
ACCOUNTABILITY														
Announced Grant Awards	25												25	
New Grant Contracts Signed	10	11											21	
New Grant Contracts In Negotiation													0	
Grant Reimbursements Processed (#)	172	150											322	
Grant Reimbursements Processed ($)	$ 16,461,776	$ 18,449,931											$ 34,911,706	
Revenue Sharing Payments Received	$ 20,611	$ 10,783											$ 31,395	$ 7,756,934
Grants Awarded (#)/ Applications Rec'd (#)	18%	18%												
Grantee Compliance Trainings	2	4											6	
Grantee Compliance Monitoring Visits	0	0											0	
Awards with Delinquent Reimbursement Submission (FSR)														
Awards with Delinquent Matching Funds Verification														
Awards with Delinquent Progress Report Submission														
MISSION														
Open RFAs	7	6												
Prevention Applications Received	0	0											0	963
Product Development Preliminary Applications Received	26	11											37	681
Product Development Full Applications Received	0	0												
Academic Research Applications	4	3											7	8,680
Help Desk Calls/Emails	175	221											396	
Number of Research Grants Announced (Annual)	24												24	
Recruited Scientists Contracted														274
Number of Product Development Grants Announced (Annual)	1												1	
Life Science Companies Recruited (in TX)													0	14
Number of Product Development Jobs Created & Maintained														1,228
Number of Prevention Grants Announced (Annual)													0	
Total Number of Education, Navigation and Training Services													0	
Total Number of Clinical Services													0	
Published Articles on CPRIT-Funded Projects (#)														
Clinical Studies (#)														228
Number of Patent Applications														
Number of Patents Resulting from Research														
TRANSPARENCY														
Total Website Hits (Sessions)	10,994	9,456												
Total Unique Visitors to Website (Users)	8,280	7,276												

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	CPRIT ACTIVITIES UPDATE FOR AUGUST AND SEPTEMBER 2022
DATE:	OCTOBER 3, 2022

Topics in this memo address CPRIT activities in August and September, including recent milestones in our fight against cancer, a staffing summary, outreach efforts, and updates from Compliance, Programs, and Operations.

Recent Milestones in the Fight Against Cancer

CPRIT Grantees in the News

- Baylor College of Medicine announced August 4 that a team of investigators, led by Hashem El-Serag, MD, PhD, chair of Baylor College of Medicine's Department of Medicine, leveraged several CPRIT-funded resources to receive a multi-investigator $5.5 million grant from the National Cancer Institute (P01CA263025). The five-year NCI grant is to reduce the burden of Hepatocellular carcinoma (HCC)-related mortality, to identify biomarkers, and to develop prevention measures, such as novel chemoprevention and surveillance approaches.

  An urgent need exists to develop effective strategies to reduce HCC burden in the growing metabolic-associated fatty liver disease (MAFLD) population. There has been an epidemic increase over the past decade in MAFLD-related cirrhosis and HCC, especially in Texas. HCC is the fastest growing cause of cancer deaths among Americans, with Texas now leading the nation in the incidence and mortality of liver cancer. CPRIT has awarded several research grants addressing HCC, including the HCC Collaborative Action Program to reduce liver cancer in Texas (CPRIT RP190641), and the Texas HCC Consortium Cohort (CPRIT RP150587), a multi-city, prospective cohort of persons with MAFLD-related cirrhosis.

- The National Academy of Medicine (NAM) announced September 1 that it selected CPRIT-grantee Swathi Arur, PhD, Professor and Deputy Chair of Genetics at The University of Texas MD Anderson Cancer Center, as one of its 2022 Emerging Leaders in Health and Medicine (ELHM) Scholars. Dr. Arur is the first MD Anderson faculty member selected for this prestigious group. NAM initiated the ELHM program in 2016 to increase the academy's engagement with exceptional, interdisciplinary early-mid career professionals in biomedical sciences, population health, health care, health policy, and other related fields. ELHM Scholars serve three-year terms, creating a network that encourages collaboration and innovation as well as contributing to shaping the priorities of NAM by focusing on pressing

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medical challenges and improving health policies and health equity. Dr. Arur received a $900,000 CPRIT research award (RP160023) in November 2015 to research the impact of female nutrition on fertility and how it affects the onset and progression of metastatic cancers.

- On September 6, Plus Therapeutics, Inc. released a summary of its Type C clinical meeting minutes with the FDA reflecting the agreement that the company's ReSPECT-GBM clinical trial should proceed to the planned Phase 2 clinical trial. The ReSPECT-GBM clinical trial is evaluating the company's lead investigational targeted radiotherapeutic, Rhenium-186 NanoLiposome (186RNL), in recurrent glioblastoma (GBM). Dr. Andrew Brenner, Professor of Medicine, Neurology, and Neurosurgery at The University of Texas Health Science Center at San Antonio, presented the positive Phase 1 data from the ReSPECT-GBM Phase 1/2a dose escalation clinical trial on September 12 at the European Society for Medical Oncology Congress 2022 held in Paris, France.

  Austin-based Plus is a clinical-stage pharmaceutical company developing innovative, targeted radiotherapeutics for rare and difficult-to-treat cancers. CPRIT approved a $17 million Product Development Research Award in August (DP220039) to develop the company's lead investigational targeted radiotherapeutic 186RNL.

- The September 15 edition of *UHD News* featured Dr. Angelica Roncancio, project director for University of Houston-Downtown's first CPRIT award. https://news.uhd.edu/uhd-receives-first-grant-for-cancer-prevention--research/

- The research team of the Horizon 2020 project RIVER-EU (Reducing Inequalities in Vaccine Uptake in the European Region – Engaging Underserved Communities) selected the approach used by Dr. Jennifer Molokwu and Dr. Jessica Calderon-Mora in Texas Tech University Health Sciences Center's HPV vaccination project (PP190058) as most promising for a successful translation of the intervention to Europe. The RIVER-EU research team determined that Dr. Molokwu and Dr. Calderon-Mora's approach of working closely with the community as well as employing the tools developed through participatory methods lends itself to integration into European settings. The RIVER-EU communities include Turkish and Moroccan women in the Netherlands, refugees in Greece, Ukrainian migrants in Poland, and the Roma community in Slovakia.

- Aravive Biologics' CEO Dr. Gail McIntyre and CFO Rudy Howard participated in the H.C. Wainwright 24th Annual Global Investment Conference and the Cantor Fitzgerald Oncology & HemOnc Conference, both held in New York City in September. The company's lead product candidate batiraxcept (formerly AVB-500) is in an active registrational Phase 3 trial in platinum resistant ovarian cancer (NCT04729608), a Phase 1b/2 trial in clear cell renal cell carcinoma (NCT04300140), and a Phase 1b/2 trial in pancreatic adenocarcinoma (NCT04983407). Batiraxcept received Fast Track Designation from the FDA and Orphan Drug Designation from the European Commission in platinum-resistant recurrent ovarian cancer.

The Houston-based company received a $20 million Product Development Research Award (DP150127) in 2015 to develop AVB-500, a targeted therapy against acute myeloid lymphoma and certain solid tumor indications including ovarian, pancreatic, and breast cancer.

- On September 23, Jerome Boyd-Kirkup, PhD, Hummingbird Bioscience's Chief Scientific Officer, presented at the 2nd Annual VISTA Symposium. The symposium focused on VISTA's function and applicability in cancer immunology, as well as the latest research and development in programs targeting VISTA. Houston-based Hummingbird received a $13 million Product Development Research Award (DP190027) in 2019 to develop transformative biologic medicines for hard-to-treat diseases.

- On September 29, Perimeter Medical Imaging AI, Inc. announced the commercial placement of its flagship Perimeter S-Series OCT system at a hospital that is part of a major national healthcare system and one of the largest healthcare networks in North Texas. Perimeter is a medical technology company transforming cancer surgery with ultra-high-resolution, real-time, advanced imaging tools to address high unmet medical needs. The commercial placement of the company's S-Series OCT system at a hospital in a major healthcare network is a significant milestone as Perimeter continues to validate its commercial model.

  Perimeter, which is based in Toronto and Dallas, aims to improve patient outcomes and lower healthcare costs with ground-breaking technology. The company received a $7.4 million CPRIT Product Development award (DP190087) in August 2019 to develop the breakthrough-device-designated investigational Perimeter B-Series OCT with ImgAssist AI. The company is evaluating the next-generation AI technology in a pivotal clinical trial.

<u>Notable CPRIT-Supported Research Accomplishments</u>

- As the most frequently mutated gene in human tumors, the TP53 gene has long been a major focus of cancer research. The TP53 protein plays a central role when cells undergo stress from factors that damage their DNA, such as chemotherapy or ionizing radiation, by activating a cascade of downstream genes, that effectively put "the brakes on cellular proliferation" until the cell has recovered or, in the presence of extreme damage, undergoes a type of cell suicide called apoptosis. Cells with mutant TP53 fail to recognize and respond to DNA damage and accumulate alterations to their genome. Precisely how TP53 functions has been a mystery for over four decades, and numerous attempts to develop therapeutic approaches have been unsuccessful. Unanswered questions include "Do mutated TP53 proteins that have lost their ability to maintain their normal function also gain a new function(s)?" Two CPRIT-funded investigators now provide new answers to old questions.

  - In elegant experimental work using the quintessential lab model – the fruit fly Drosophila melanogaster – John Abrams, PhD, Professor of Cell Biology and member of the Simmons Comprehensive Cancer Center at The University of Texas Southwestern Medical Center, demonstrated that TP53, well known for its role in turning on tumor suppressor genes when cells become stressed, also keeps potential tumor-driving genes

turned off. When TP53 becomes mutated in tumor cells critical genes and cellular programs promoting tumor growth that should otherwise be silent become reactivated. Scientists have not understood the mechanism TP53 uses to accomplish both activation and suppression of gene expression.

Dr. Abrams' team showed that TP53 accomplished this simultaneous feat by producing multiple forms or "isoforms" of the protein. By selectively deleting the DNA sequences that encode the unique isoforms in the tractable Drosophila genome one by one, the investigators demonstrated that previously silent (suppressed) gene programs became activated. The study results published August 8 in *Developmental Cell* (Wylie A, et al., 57:1833-1846, 2022) have several important implications. First, ongoing efforts to develop new cancer treatments that can replace TP53's function as a gene activator must also replicate its role as a gene silencer. Second, genes that "normal" TP53 keeps inactivated may play previously unrecognized roles in promoting cancer and warrant further studies. Dr. Abrams received two CPRIT Individual Investigator Awards totaling $1.6 million (RP11076, RP170086) in 2010 and 2017 to support this work.

- C. Patrick Reynolds, MD, PhD, Director of the Texas Tech University Health Sciences Center School of Medicine Cancer Center, and his team expanded upon their earlier research to demonstrate that many tumors share a vulnerability to reactivation of mutant TP53 protein that researchers can exploit for cancer therapy. To continue multiplying, cancer cells must maintain the integrity of their genome, particularly the telomeres, or the caps on the ends of chromosomes that serve to protect the genetic information. The most common mechanism is to turn on the telomerase enzyme that replenishes the DNA at the telomeres. However, as reported in the September 15 edition of *Cancer Research* (Macha S et al., Cancer Res 82:3345-3358, 2022), Dr. Reynolds and his colleagues discovered that this mechanism is inactive in 10-80% of pediatric cancers (neuroblastomas and sarcomas) and adult cancers (breast, colon, and lung cancers), which use another mechanism - alternate lengthening of telomeres (ALT) - only found in malignant cells.

  Uncontrolled telomere damage in ALT+ cancer cells normally activate the DNA damage and repair pathway through TP53, but cancer cells have turned off this pathway by inactivating TP53. The research team demonstrated that "normalization" of mutant TP53 protein function, using a new and promising class of TP53 targeting drug eprenetapopt (APR-246), drives the cell to undergo cell death when combined with DNA-damaging chemotherapy. Importantly, in vivo studies showed that the combination therapy led to the eradication of tumors in mice injected with human neuroblastomas, sarcomas, or breast cancer cells. These seminal findings indicate a potential strategy to overcome therapeutic resistance, and support clinical evaluation of a combinatorial approach using APR-246 and chemotherapy in patients with ALT+ cancers, which currently lack targeted therapeutic approaches, and have a poor prognosis. Dr. Reynolds received a $1.3 million CPRIT Individual Investigator Award for Cancer in Children and Adolescents (RP220460) in February to support this discovery.

- A team at The University of Texas Southwestern Medical Center led by CPRIT Scholar Samuel McBrayer, PhD, has identified a metabolic pathway that researchers can target to stop an aggressive form of brain cancer known as glioma. A critical feature of cancer cells is their ability to reprogram and rewire metabolism, the process by which cells produce and use energy or critical protein and DNA building blocks. Glioma is the most common primary malignant brain tumor in adults, and is associated with poor outcomes. Despite intensive efforts over the past decade to develop novel therapies, the FDA has not approved any new treatments for adults with gliomas. Mutations involving the isocitrate dehydrogenase 1 and 2 (IDH1/2) genes occur at a high frequency in gliomas and myeloid leukemias, and result in metabolic reprogramming. Scientists have developed IDH-targeted therapies that show high efficacy in leukemias, but are less active for aggressive gliomas.

  As reported in the September 12 edition of *Cancer Cell* 40:1-18, 2022, Dr. McBrayer's team took a novel approach to exploit the collateral vulnerabilities engendered by IDH1/2 mutations to identify alternative therapeutic strategies. Using a chemical synthetic lethality screen, the investigators found that IDH-mutant gliomas are metabolically dependent on synthesizing their own pyrimidine nucleotides (thymidine and cytidine) for DNA replication. Blocking this pyrimidine synthesis pathway with a drug from Bayer Pharmaceuticals (BAY 2402234) that can pass through the blood-brain barrier displayed efficacy against gliomas using a single therapy. This critical finding identifies a biomarker-driven therapeutic strategy ready for clinical translation. UT Southwestern recruited Dr. McBrayer to the Department of Pediatrics in 2019 with a $2 million First-Time, Tenure-Track for Faculty Member Recruitment Award (RR190034).

- OncoNano Medicine, Inc. announced September 29 positive interim clinical results from an ongoing Phase 2 study of its lead clinical development candidate, pegsitacianine, for the detection of residual disease following cytoreductive surgery. The company presented the study results at the World Molecular Imaging Congress in Miami. The interim results from this trial provide evidence that pegsitacianine could offer surgeons a real-time optical imaging capability that enhances their ability to detect residual cancerous tissue otherwise left behind from their standard of care process for cytoreductive surgery of peritoneal metastases. OncoNano's Chief Medical Officer Kartik Krishnan, MD, PhD, also presented at the Cantor Fitzgerald Oncology, Hematology & HemOnc Conference in New York City on September 28.

  Southlake-based OncoNano is developing a new class of products that utilize principles of molecular cooperation in their design to use pH as a biomarker to diagnose and treat cancer with high specificity. The company's lead development candidate is pegsitacianine, a novel fluorescent nanoprobe using the ONBOARD™ platform. ONM-501, OncoNano's second development program is a next generation STING (STimulator of INterferon Genes) agonist that is advancing towards a first in human trial in the first half of 2023. OncoNano received three Product Development Research Awards totaling $31.3 million (DP140072, DP190066, DP200081) in 2014, 2019, and 2020 to develop Pegsitacianine and ONM -501.

Personnel

- CPRIT has filled 38 of our 44 full-time equivalent positions.

- Shannon Cusick accepted the position of Information Resources Manager. She previously served as Interim Resources Manager and Systems Analyst for CPRIT.

- CPRIT has three positions in progress: Program Manager for Research and Prevention, Digital Communications Specialist, and Product Development Program Manager.

CPRIT Outreach

Texas-Israel Trade Delegation

As reported at the May 18 Oversight Committee meeting, Chief Strategic Initiatives and Intellectual Property Officer Tracey Davies and I participated in a trade delegation trip to Israel sponsored by the Texas-Israel Alliance in late April/early May. Our participation promoted CPRIT's Product Development Research Program to early-stage Israel cancer life science companies and major Israeli health-related academic institutions interested in establishing a US presence. We continue to discuss collaborative and recruitment opportunities.

The Texas-Israel Alliance will host its second healthcare innovation summit on November 14 on the Rice University campus in Houston. The summit will highlight technologies that drive innovation in digital health, biotech, and medical devices, explore the nexus between data and biology, and assemble thought leaders from various institutions and companies.

CPRIT is co-sponsoring the summit along with the Israel Consulate General Southwest, DLA Piper, Rice University Ken Kennedy Institute, and Lyda Hill Philanthropies. Please let me know if you would like to attend.

Other Staff Outreach

Staff outreach activities during August and September include:

- On September 12 Deputy Executive Officer and General Counsel Kristen Doyle, Chief Operating Officer Heidi McConnell and I updated Representative Stephanie Klick, Chair of the House Committee on Public Health, on CPRIT activities. We also discussed CPRIT's priorities for the 88th Texas Legislature that convenes on January 10, 2023.

- Program Manager for Product Development Dr. Abria Magee, Ms. Doyle, Ms. McConnell, Ms. Davies and I attended presentations by the 2022 cohort of the TMCi Accelerator for Cancer Therapeutics in Houston on September 15. Chief Scientific Officer Dr. Michelle Le Beau and Research Director Dr. Patty Moore attended the summit virtually. The accelerator is a 2019 CPRIT Core Facility Support Award designed to instruct and coach cancer

researchers on how to move their discoveries into the early stages of commercialization. The instruction includes market research, FDA regulations, intellectual property, licensing, financing, fundraising, legal, and other critical needs for successful entrepreneurship. Graduates of the program are likely to submit product development funding applications to CPRIT. While there, we met with several companies interested in CPRIT funding.

- On September 16 I toured Helix Park in TMC3, which is under construction. The University of Texas Health Science Center at Houston, The University of Texas MD Anderson Cancer Center and Texas A&M University plan to share the first building scheduled for completion.

- Dr. Moore attended the Third Annual Multi-Stakeholder TeCH (Texas Collaborative Center for Hepatocellular Cancer) Symposium on September 17.

- I participated on the "The State of Biotech in Texas" panel at the 8th Annual BioNTX IC3 Summit held September 21-23 in Grapevine. Ms. Doyle also attended and was a member of the "Preparing for your Start Up for Investor Presentation" panel. She also introduced the annual Dennis K. Stone Award. Ms. Doyle and I met with representatives of the American Cancer Society's venture fund, BrightEdge, to explore possible co-investment opportunities.

- Dr. Moore represented CPRIT at the 13th Annual Childhood Cancer Summit held September 21- 22 in Washington DC, sponsored by the Congressional Childhood Cancer Caucus.

- I attended several panels and events over September 22-24 at the *Texas Tribune's* annual Tribfest. Panels addressed state, local and national issues of topical interest.

- I presented CPRIT's priorities and accomplishments on September 28 at an in-person and live-streamed meeting of the Healthcare Think Tank in Austin. This organization provides companies and individuals with opportunities to connect through a speaker series on healthcare-related topics that impact local, state and national communities.

- Dr. Moore attended the Governor's Commission on Women and State Agency Council "2022 Outstanding Women in Texas Government Awards" luncheon held on September 28 at the AT&T Conference Center at The University of Texas at Austin.

- Throughout August and September Chief Product Development Officer Dr. Ken Smith and/or Dr. Magee met with several companies interested in applying for product development research awards in FY 2023, including Israeli-based device company, Insightec, Inc., ScenXO, MUSIQ Bio, Cellula Therapeutics, Serene, LLC., and EtiraRX.

Compliance Program Update

Submission Status of Required Grant Recipient Reports

As of September 22, nine entities had not filed nine Academic Research reports, one Prevention reports, and two Product Development reports. CPRIT's grant accountants and compliance specialists review and process incoming reports and reach out to grantees to resolve filing issues. In most cases, CPRIT does not disburse grant funds until the grantee files the required reports. In some instances, grantee institutions may be ineligible to receive a future award if the grantee does not submit required reports.

Financial Status Report Reviews

CPRIT's compliance specialists performed 345 second-level reviews of grantee Financial Status Reports (FSRs) in August and September. Thirty FSRs (9%) needed resubmission due to insufficient or inaccurate documentation sent by the grantee. CPRIT's grant accounting staff completes the first review of the FSRs and supporting documentation before routing them to the compliance specialists for final review and disposition.

Desk Reviews

Compliance specialists performed three enhanced desk-based financial monitoring reviews in August and September. Enhanced desk reviews verify that grantees spend funds in compliance with specific grant requirements and guidelines and may target an organization's internal controls, current and past fiscal audits, and timeliness of required grantee report submission. Compliance specialists are working with one grantee to remediate enhanced desk review findings.

Onsite Reviews

CPRIT completed five virtual onsite reviews in August and September. Onsite reviews examine the grantees' financial and administrative operations, subcontract monitoring, procurement and contracting procedures, inventory procedures, personnel policies and procedures, payroll and timesheet policies, travel policies and records, and single audit compliance. Compliance specialists are working with six grantees to remediate onsite review findings.

Match Expenditures Review

CPRIT requires academic research and product development research grantees to show that they have available unused funds equal to at least one-half of the CPRIT grant award that the grantee will spend on the CPRIT-funded project. This obligation, often referred to as "CPRIT's matching funds requirement," requires the grantee to first certify that it has available matching funds, and then at the end of the grant year, to verify that the grantee spent the matching funds on the project. CPRIT's statute allows an institution of higher education to use its federal indirect cost rate as a credit toward the required 50% match.

Product development grantees and those academic research grantees whose indirect cost rate credit does not fully offset the required match must supply a detailed match expenditure report that includes the amount and date paid, vendor, description, and budget category. Compliance staff review grantees' match expenditures for appropriateness and allowability and work with CPRIT's grant accountants and the grantee to address any deficiencies. Compliance staff performed three annual match expenditure reviews for three grantees in August. The total amount of match expenses reviewed by compliance staff for FY 2022 is $14,734,045.19.

Training and Support

CPRIT staff conducted two new Authorized Signing Official (ASO) training webinars in August and September for Rice University and Southern Methodist University. The trainings covered grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. CPRIT requires new ASOs to complete a compliance training within 60 days of the change.

Academic Research Program Update

Recruitment FY 2023 Review Cycle 1

CPRIT's Scientific Review Council (SRC) reviewed recruitment applications for the first quarter of FY 2023 (Cycle 23.1) on September 15. Dr. Le Beau will present the SRC's award recommendations for 23.1 recruitment awards to the Program Integration Committee (PIC) and the Oversight Committee in November.

FY 23.1 Mechanism	Received	Funds Requested	Recommended	Recommended Funds
Recruitment Established Investigators	4	$23,999,198	2	$11,999,198
Recruitment of First-Time, Tenure Track Faculty Members	1	$2,000,000	0	N/A
TOTAL	**5**	**$25,999,198**	**2**	**$11,999,198**

Texas Regional Excellence in Cancer (TREC) FY 2023 Review Cycle

CPRIT opened the portal May 16 to receive applications for Texas Regional Excellence in Cancer (TREC) Awards. We received four applications requesting $23,998,422 by the September 8 deadline. Virtual Peer Review will occur in November and Dr. Le Beau will present the TREC Award recommendations to the PIC and Oversight Committee at a proposed special Oversight Committee meeting in January 2023.

Academic Research FY 2023 Review Cycle 1 (23.1)

CPRIT released several RFAs for the first cycle of FY 2023 (23.1) in January and began accepting applications for targeted and untargeted Individual Investigator Research Awards in

March through June 8. Dr. Le Beau will present the Individual Investigator Research Award recommendations to the PIC and the Oversight Committee in February 2023.

Cycle 23.1 RFA Mechanism	Applications	Requested Funding
Individual Investigator Research Awards	235	$241,561,941
Individual Investigator Research Awards for Cancer in Children and Adolescents	30	$42,048,859
Individual Investigator Research Awards for Clinical Translation	19	$35,897,103
Individual Investigator Research Awards for Computational Systems Biology of Cancer	23	$26,041,589
Individual Investigator Research Awards for Prevention and Early Detection	22	$36,681,588
Total	**329**	**$382,231,080**

Product Development Research Program Update

Product Development FY 2023 Review Cycle

The Oversight Committee approved four FY 2023 requests for applications (RFAs) for the Product Development Research program at its May 18 meeting. The new RFAs included changes to CPRIT's product development application and review process for the FY 2023 review cycle. CPRIT released the RFAs and opened the portal to receive preliminary applications on August 24.

The use of a preliminary application and review process is the most notable change to the FY 2023 review process. CPRIT accepts preliminary applications on a rolling basis. The Product Development Review Council (PDRC) reviews the preliminary applications and provides applicants with a faster indication (3 – 5 weeks) of whether the company's proposed project demonstrates sufficient scientific merit and a compelling premise to warrant submitting a full application. Only those companies submitting preliminary applications reviewed favorably by the PDRC receive an invitation to submit a full application.

CPRIT issues an invitation to submit a full application on a rolling basis to the companies recommended by the PDRC after preliminary review. All companies submitting a full application will also present their application to a review panel and answer questions about their proposal. Companies may choose to submit their full application in one of the three award cycles offered by CPRIT in FY 2023:

- The first full application deadline is November 1. Companies will present their applications to review panels convening the week of December 12 – 16, with award recommendations scheduled for February 2023.

- The second deadline for full applications is February 1, 2023. Companies will present their applications to review panels convening the week of March 13 – 17, with award recommendations scheduled for May 2023.

- The final deadline to submit full applications for award consideration in FY 2023 is May 1, 2023. Companies will present their applications to review panels convening the week of June 12 – 16, with award recommendations scheduled for August 2023.

Like previous years, an application that the review panel considers exceptional will also undergo due diligence review. At the conclusion of due diligence review, the panel will decide whether to recommend the application for funding. The PDRC will submit the recommendation(s) to the PIC and the Oversight Committee for approval.

Product Development FY 2023 Review Cycle 1 (23.1)

CPRIT opened the portal to receive preliminary applications for the first cycle of review on August 24. As of September 30, CPRIT has received 29 preliminary applications requesting $336,056,599. Ten companies submitting preliminary applications are currently located outside of Texas, including California, Washington, Massachusetts, Maryland, North Carolina, India and Sweden.

FY23 Mechanism Review Cycle 1	Prelim Apps Submitted	Funds Requested
Seed Company	5	$12,861,442
Therapeutics Company	15	$241,870,655
Device and Diagnostics Company	4	$35,220,126
New Technologies Company	5	$46,104,376
TOTAL	**29**	**$336,056,599**

CPRIT will limit the number of full applications it will accept for review in the first cycle to the first ten applications received on or before the November 1 deadline. CPRIT will defer all other full applications to the next review cycle. Restricting the number of full applications in this first review cycle is necessary to accommodate schedule constraints during the holidays.

Prevention Program Update

Prevention FY 2023 Review Cycle 1 (23.1)

The Prevention Program released three RFAs on May 6 for the first cycle of FY 2023. CPRIT received 24 proposals totaling $29,628,112 through the August 31 deadline. Peer review panels will meet by teleconference December 5 - 6. Chief Prevention Officer Ramona Magid will present the PRC's recommendations to the PIC and the Oversight Committee in February.

Cycle 23.1 Mechanism	Applications	Funds Requested
Primary Prevention of Cancer	12	$13,965,009
Cancer Screening and Early Detection	7	$13,417,478
Dissemination of CPRIT-Funded Cancer Control Interventions	5	$2,245,625
TOTAL	**16**	**$29,628,112**

Prevention FY 2023 Review Cycle 2 (23.2)

CPRIT is preparing three RFAs for release in October. CPRIT will accept applications through February 8, 2023. CPRIT has scheduled peer review for April - June 2023. Ms. Magid will present the Prevention Review Council's recommendations to the PIC and the Oversight Committee in August 2023.

Advisory Committee Meetings

The Geographic Diversity Advisory Committee met August 5 and September 2.

Operations, Audit and Finance Update

On September 12, I presented the agency's request for its constitutionally maximum budget of $300 million per year, or $600 million total for the 2024-25 biennium, at the joint budget hearing held by the Office of the Governor and Legislative Budget Board.

The annual audit over CPRIT's FY 2022 financial statements began September 28 with an entrance meeting between the audit team from McConnell & Jones LLP and CPRIT staff including Ms. Doyle, Ms. McConnell, Michelle Huddleston, Amaka Nwachukwu, Lisa Nelson, and me.

Don Brandy, contract specialist, is working on multiple solicitations for various services including fraud, waste, and abuse reporting; due diligence review (for product development research grant applications); outside counsel; and scientific editing.

CPRIT program staff finalized the schedule for the 2023 CPRIT Innovations Conference VI and will be reaching out to proposed speakers to confirm availability and attendance. The conference will take place October 2-3, 2023, at the Moody Gardens Hotel, Spa and Convention Center on Galveston Island.

Upcoming Subcommittee Meetings

Listed below are the subcommittee meetings in advance of the November 16 Oversight Committee meeting. We will send instructions for signing onto the Zoom platform along with the subcommittee agenda and meeting materials one week prior to the meeting.

Board Governance	November 3 at 10:00 a.m.
Audit	November 7 at 10:00 a.m.
Prevention	November 8 at 12:00 p.m.
Academic Research	November 9 at 10:00 a.m.
Product Development	November 10 at 10:00 a.m.

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CPRIT has awarded **1,818** grants totaling **$3.173 billion**

- 274 prevention awards totaling $327.9 million
- 1,544 academic research and product development research awards totaling $2.845 billion

Of the $2.845 billion in academic research and product development research awards,

- 31.0% of the funding ($882.6 million) supports clinical research projects
- 23.8% of the funding ($676.3 million) supports translational research projects
- 29.4% of funding ($835.6 million) supports recruitment awards
- 12.6% of the funding ($359.8 million) supports discovery stage research projects
- 3.2% of funding ($90.4 million) supports training programs.

CPRIT has 6 open Requests for Applications (RFAs)

- 2 Research Recruitment
- 4 Product Development Research

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	CPRIT ACTIVITIES UPDATE FOR OCTOBER 2022
DATE:	NOVEMBER 3, 2022

Topics in this memo address the upcoming November 16 Oversight Committee meeting and CPRIT activities in October, including recent milestones in our fight against cancer, a staffing summary, outreach efforts, program priorities for FY 2024, and updates from Compliance, Programs, and Operations.

Planning for the November 16 Oversight Committee Meeting

The Oversight Committee will meet Wednesday, November 16, in the Texas Capitol Extension. We have a full agenda with grant award recommendations as well as grantee presentations and approval of the program priorities for FY 2024. Please notify me as soon as possible if you are unable to attend the November 16 meeting or have schedule constraints that require you to arrive at the meeting after 9:00 a.m. or leave prior to 12:00 p.m.

You will receive an email from CPRIT by November 4 with a link and password to access the Program Integration Committee's recruitment award recommendations via the grant award portal. The portal has a summary of the award slates, as well as supporting documentation for the proposed awards, including the applications, CEO affidavits, summary statements, and grant pedigrees. Please allow some time to complete the individual conflict of interest checks and review the supporting material.

I have attached a draft meeting agenda. CPRIT will post the final agenda for the Oversight Committee meeting by November 8. Oversight Committee members will receive an electronic copy of the agenda packet by November 9. We will provide hard copies of the agenda and proposed award packets at the meeting.

Recent Milestones in the Fight Against Cancer

<u>CPRIT Grantees in the News</u>

- On September 22, *UTHealth News* featured "All for Them," a CPRIT-funded HPV vaccination project (PP200017) directed by Dr. Paula Cuccaro of The University of Texas Health Science Center School of Public Health in Houston. To learn more about the "All for

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Them" project, visit www.allforthemvaccines.com https://sph.uth.edu/news/story/all-for-them-hpv-vaccination-project-expands-lifesaving-reach-across-texas.

- U.S. Department of Health and Human Services announced September 23 that Harlingen-based Su Clinica Familiar was one of eleven community health centers in the country to receive a Health Resources and Services Administration grant to facilitate access to and improve equity in cancer screening. The $500,000 "Accelerating Cancer Screening" grant award brings together health centers with National Cancer Institute (NCI) Designated Cancer Centers to facilitate access to life-saving cancer screenings and early detection services for underserved populations. The awards advance President Biden's Cancer Moonshot goals, which aim to close the cancer screening gap, decrease the impact of preventable cancers, and support patients and caregivers. Su Clinica Familiar is a service provider partner for two CPRIT Prevention projects at The University of Texas MD Anderson Cancer, Project ACCESS: Increasing Access to Cervical Cancer Screening and Treatment Services in Texas directed by Dr. Kathleen Schmeler (PP220037) and Alliance for Colorectal Cancer Testing 3.0 directed by Dr. Lewis Foxhall (PP220005).

- Lubbock's Fox34.com news featured the newly awarded colorectal cancer screening project, FIT-STOP, directed by Dr. Rakhshanda Rahman and colleagues at Texas Tech University Health Science Center (PP220041), on September 28. https://www.fox34.com/2022/09/28/grant-money-provides-free-testing-find-colorectal-cancer/

- Leveraging support from the initial $5.8 million Texas Regional Excellence in Cancer (TREC) grant that CPRIT awarded to The University of Texas at El Paso in 2021 (RP210153), Taslim Al-Hilal, Ph.D., received three grants totaling $3.8 million from the National Institutes of Health (NIH) in early October to advance his research to reduce mortality rates in lung, ovarian, and pancreatic cancer.

  The National Institute of General Medical Sciences awarded Dr. Al-Hilal, an Assistant Professor in the Department of Pharmaceutical Sciences at UTEP, $1.5 million to test the use of blood thinning agents to improve the efficacy of cancer immunotherapy in pancreatic cancer, where there is a high risk for the formation of blood clots within the tumor that impede blood circulation and the effectiveness of cancer therapies.

  Dr. Al-Hilal also received two grants from the National Cancer Institute including $1.8 million to study how scientists can target the prion-like Doppel protein commonly found in male reproductive glands to treat lung cancer. In previous studies, Dr. Al-Hilal and his collaborators observed that the Doppel protein is responsible for the formation of new blood vessels in lung tumors supporting growth of the tumors, and facilitating their survival against attacks from the body's immune system. He received a second NCI award of $400,000 to continue his research evaluating the Doppel protein as a new predictive biomarker for the early detection and diagnosis of ovarian cancer using a simple blood test, with a focus on the Latina population.

CPRIT's TREC award is a multicomponent award designed to strengthen cancer research through supporting program leadership, investigator-initiated research projects, recruitment of new junior faculty, and research infrastructure at institutions located in regions of Texas that have historically received low levels of peer-reviewed cancer research funding.

- On October 11, the Healthcare Technology Report named executives from two Austin-based CPRIT companies to its list of the "Top 25 Healthcare Technology Leaders of Austin for 2022." Jason Kim is President and Chief Operating Officer of Molecular Templates, a clinical-stage biopharmaceutical company focused on the discovery and development of the next generation of immunotoxins called engineered toxin bodies (ETBs). CPRIT awarded Molecular Templates two product development awards totaling $25.8 million in 2012 and 2016 (CC121020, DP160071) for to develop ETBs. Boris Fischer is Vice President, Business Process and Systems, for Apollo Endosurgery, Inc., a medical technology company in Austin focused on developing next-generation, less invasive devices to advance therapeutic endoscopy to treat a variety of gastrointestinal conditions. CPRIT awarded Apollo one of its first product development awards in 2010 (RP101216) to develop medical devices to treat cancerous lesions in the gastrointestinal tract.

- The economic think tank Heartland Forward released its ranking of institutions that are commercializing new biomedical technologies on October 27. The University of Texas Southwestern Medical Center ranked fourth in the nation and first in Texas. The ranking included peer institutions from across the country, including Mayo Clinic (No. 1), Cedars-Sinai Medical Center in Los Angeles (No. 5), Massachusetts General Hospital (No. 6) and Cleveland Clinic (No. 8) . The University of Texas System ranks third nationally among university systems on the list. Five other Texas institutions made the top 25 list.

- In recognition of her trailblazing work uncovering the mechanisms of the p53 tumor suppressor, the Association of American Medical Colleges (AAMC) awarded Guillermina "Gigi" Lozano, Ph.D., chair of Genetics at The University of Texas MD Anderson Cancer Center, the 2022 Award for Distinguished Research in the Biomedical Sciences on October 27. Since its inception in 1947, the AAMC Award for Distinguished Research in the Biomedical Sciences has annually honored an individual whose research contributes to significant scientific discoveries benefitting human health and well-being, who participate in research beyond their own work through mentorship or review panels, and whose standards of professional ethics and scientific integrity are of the highest caliber. Dr. Lozano is the second MD Anderson researcher selected for this award, with James Allison, Ph.D., honored in 2014. CPRIT awarded Dr. Lozano four research grants totaling $3.4 million, three of which directly supported her work with p53 (RP100535, RP170231, RP180313, RP200240).

<u>Notable CPRIT-Supported Research Accomplishments</u>

- Navin Varadarajan, Ph.D., an engineer in the Department of Chemical and Biomolecular Engineering at the University of Houston, identified a method to determine which patients with Non-Hodgkin B cell Lymphoma will respond to CAR-T cell therapy. Non-Hodgkin B cell Lymphoma is the most responsive form of cancer to CAR-T cell therapy. Dr.

Varadarajan's discovery could save precious time in treating the disease, and spare those patients who are unlikely to respond from experiencing potential severe side effects.

Using a sophisticated approach called Timelapse Imaging Microscopy in Nanowell Grids (TIMING), researchers profiled the dynamic interactions between tumor cells and the CD19-specific CAR-T infusion cell therapy product. TIMING is a high-throughput single cell technology that merges artificial intelligence with a nanowell imaging platform to simultaneously evaluate how individual cells function (move, activate, interact, kill and survive) by integrating cell killing assays, cytokine secretion, and transcriptional profiling.

Dr. Varadarajan's findings, reported in the September 1 edition of the *Journal of Clinical Investigation* (Romain G. et al., J. Clin. Invest. Sep 1;132(17):e159402. doi: 10.1172/JCI159402), pointed to a relationship between a protein expressed on the surface of the tumor cell called CD58, and the corresponding binding partner, or receptor on the surface of the T cell (CD2), which work together to communicate a signal to the T cell, turning it into a cancer cell killer. The study showed that tumors of lymphoma patients who respond better to CAR-T cell treatment expressed the ligand for CD2, CD58 at higher levels, making CD58 detection a powerful biomarker and clinical tool for oncologists. CPRIT awarded Dr. Varadarajan a $1.8 million Individual Investigator Research Award in Clinical Translation in 20198 (RP180466) to support this work.

- Researchers at The University of Texas M.D. Anderson Cancer Center, led by Linghua Wang, M.D., Ph.D., Associate Professor of Genomic Medicine, used cutting-edge genomics technologies to create a spatial map of early-stage lung cancers that illuminates the cross-talk between tumor cells and infiltrating immune cells, and highlights previously unappreciated roles of B lymphocytes and plasma cells (terminally differentiated B cells responsible for antibody production) in tumor development, response to therapy, and outcomes. Understanding the early interactions and crosstalk between cancer cells and immune cells could reveal new therapeutic targets in B cells and plasma cells and opportunities to block cancer growth or boost the anti-tumor immune response.

  Although scientists have long known that the tumor microenvironment plays an important role in regulating tumor growth and metastasis, the understanding of the interactions between the multiple cell types that comprise a tumor, and their role in tumorigenesis is incomplete, particularly in the early stages of tumor formation. Moreover, most of the focus on immune cells has been on T cells. Dr. Wang tackled the unknown – performing single cell RNA sequencing of over 50,000 unique B cells and plasma cells from 16 lung adenocarcinomas and 47 matching normal tissue samples to analyze their gene expression profiles.

  The investigators identified 12 different cell subsets and demonstrated that more differentiated (mature) B cells and plasma cells were enriched in the tumor tissue. They reported correlations with environmental features (smoking vs. non-smoking) and the molecule features of the tumors. Of note, the varied landscape of B cells within the tumor influenced patient outcomes and treatment responses in early-stage lung cancer. For example, an enrichment of plasma cells in the tumor was associated with improved responses

to anti-PD1/PD-L1 immune checkpoint inhibitors. MD Anderson received two CPRIT grants totaling $5.4 million (RP220101, RP160668) to support this research as reported in the September 13 edition of *Cancer Discovery* (CD-21-1658.DOI: https://doi.org/10.1158/2159-8290.CD-21-1658, Sept 13, 2022).

- New CPRIT-supported research reveals that dietary supplements may improve one of the life-threatening complications of life-saving hematopoietic stem cell transplants for a blood cancer, such as leukemia or lymphoma. Researchers at The University of Texas MD Anderson Cancer Center identified a specific bacterium - Bacteroides thetaiotaomicron (BT)- residing in the human gut that modulates the progression of graft-versus-host disease (GVHD.) GVHD is a severe complication where the newly transplanted hematopoietic stem cells launch an immune attack against the recipient patient's tissues following treatment with antibiotics.

  As reported in the September 29 edition of the journal *Cell* (Hayese E., et al., Cell 185:3705-3719, 2022), CPRIT Scholar Robert Jenq, M,D., Associate Professor and Deputy Department Chair, Department of Genomic Medicine, and his team examined animal models of GVHD, specifically mice treated with meropenem, a broad-spectrum antibiotic commonly used to treat patients following allogeneic hematopoietic stem cell transplant. Unexpectedly, they observed a significant decrease in the amount of sugar in the gut, and resultant inflammation. Further studies revealed that in a sugar-depleted environment, the bacteria turned against the mucin lining of the gut, now degrading and consuming the glycans in the mucin lining and thinning this protective tissue in the gut. Researchers alleviated this effect by administering oral xylose as a nutritional supplement, as the bacteria were able to preferentially consume this sugar, allowing repair of the gut lining.

  These seminal findings provide new insights into the relationship of the gut microbiome, inflammation, and GVHD, as well as identifying the bacteria contributing to thinning of the gut lining, and how antibiotics alter the sugar composition of the gut and its effect on GVHD. Moreover, these studies offer a compelling low-risk, sugar supplementation strategy for suppressing gut inflammation and the life-threatening GVHD. Next steps include translating this work to clinical trials in patients.

  MD Anderson recruited Dr. Jenq from Memorial Sloan-Kettering Cancer Center to Texas with a $4 million Rising Stars recruitment award in 2016 (RR160089.)

- Immatics reported on October 11 that data from the Phase 1a and Phase 1b cohort A trial clinically validated PRAME as a highly promising T cell target for solid cancers. Researchers confirmed clinical responses at high and low PRAME-expression levels above threshold, indicating IMA203's potential to provide clinical benefit for all PRAME biomarker-positive cancer patients. Houston-based Immatics US, Inc. is a clinical-stage biopharmaceutical company active in the discovery and development of T cell-redirecting cancer immunotherapies. The company received a $19.6 million CPRIT product development award in 2015 (DP150029) to develop personalized cellular immunotherapy against novel cancer targets.

- On October 12 Perimeter Medical Imaging AI Inc. presented research at the College of American Pathologists 2022 Annual Meeting validating the potential use of Perimeter S-Series OCT to intraoperatively image specimens across a variety of tissue types, such as breast, thyroid, kidney, liver, lung, colon, heart, pancreas, spleen, and adrenal glands. Perimeter, which is based in Toronto and Dallas, aims to improve patient outcomes and lower healthcare costs with ground-breaking technology. The company received a $7.4 million CPRIT Product Development award (DP190087) in August 2019 to develop the breakthrough-device-designated investigational Perimeter B-Series OCT with ImgAssist AI. The company is evaluating the next-generation AI technology in a pivotal clinical trial.

- On October 19, Plus Therapeutics, Inc. presented preliminary safety and feasibility data from two ongoing clinical trials at the 35th Annual Congress of the European Association of Nuclear Medicine held in Barcelona, Spain. The findings indicate the potential for 186RNL in patients diagnosed with leptomeningeal metastases. The conference selected the company's presentation for inclusion in the opening Plenary Highlights Lecture, signaling significant clinical interest in the field. Austin-based Plus is a clinical-stage pharmaceutical company developing innovative, targeted radiotherapeutics for rare and difficult-to-treat cancers. CPRIT approved a $17 million Product Development Research Award in August (DP220039) to develop the company's lead investigational targeted radiotherapeutic 186RNL.

- Iterion Therapeutics, Inc. presented results from a preclinical murine study of tegavivint in beta-catenin activated hepatocellular carcinoma at the 34th EORTC-NCI-AACR Symposium held October 26 – 28 in Barcelona, Spain. The European Organization for Research and Treatment of Cancer, the National Cancer Institute, and the American Association for Cancer Research jointly hosted the symposium. CPRIT awarded the Houston-based clinical-stage biotechnology company two product development program awards totaling $18.8 million in 2013 and 2022 (CP130058, DP220019) to develop tegavivint.

Personnel

CPRIT has filled 41 of our 44 full-time equivalent positions.

- CPRIT hired a Digital Communications Specialist and the Program Manager for Research and Prevention. Both employees will join CPRIT early November.

- The second Product Development Program Manager position is in progress.

- CPRIT expects to post Grant Compliance Specialist and Systems Support positions in November.

CPRIT Outreach

Texas-Israel Trade Delegation

As reported at the May 18 Oversight Committee meeting, Chief Strategic Initiatives and Intellectual Property Officer Tracey Davies and I participated in a trade delegation trip to Israel in late April that the Texas-Israel Alliance sponsored. Our participation promoted CPRIT's Product Development Research Program to early-stage Israel cancer life science companies and major Israeli health-related academic institutions interested in establishing a US presence. We continue to discuss collaborative and recruitment opportunities.

The Texas-Israel Alliance will host its second healthcare innovation summit on November 14 on the Rice University campus in Houston. The summit will highlight technologies that drive innovation in digital health, biotech, and medical devices, explore the nexus between data and biology, and assemble thought leaders from various institutions and companies.

CPRIT is co-sponsoring the summit along with the Israel Consulate General Southwest, DLA Piper, Rice University Ken Kennedy Institute, and Lyda Hill Philanthropies. Please let me know if you would like to attend.

Advanced Research Projects Agency for Health (ARPA-H)

Ms. Davies, Deputy Executive Officer and General Counsel Kristen Doyle and I are members of the Coalition for Health Advancement and Research in Texas (CHART) steering committee that coordinates state efforts to bring President Biden's new federal agency, ARPA-H, to Texas. This effort began in July 2021. In May 2022 Congress appropriated $1 billion for ARPA-H. Committees in both chambers of Congress voted out final enabling legislation; it is pending a full vote.

Other states or cities with known interest in hosting ARPA-H are California (San Francisco Bay area), Georgia (Atlanta), Illinois (Chicago), Philadelphia, Michigan, Massachusetts (Boston), North Carolina (Research Triangle), Ohio (Cleveland), Maryland and Missouri. I expect New York will enter the competition as well.

At CHART's behest, all but two members of the Texas congressional delegation signed a letter congratulating Dr. Renee Wegrzyn on her appointment as ARPA-H's inaugural director. I have attached a white paper outlining the state's assets that justify locating ARPA-H in Texas and how choosing Texas would benefit ARPA-H, the country, and facilitate implementation of its important mission. In addition, the mayors of Austin, Dallas, Houston and San Antonio wrote to the Senior Advisor and Assistant to the President for Intergovernmental Affairs requesting a meeting to discuss locating ARPA-H in one of their cities.

On October 25, Ms. Davies, along with other Texas members of CHART, including representatives of Lyda Hill Philanthropies/Pegasus Park, the Texas Medical Center, and The University of Texas Southwestern Medical Center, attended the introduction, town hall meeting

and discussion of ARPA-H by Dr. Wegrzyn and U.S. Department of Health and Human Services Secretary Xavier Becerra at Howard University in Washington D.C., where they were able to have brief discussions with Dr. Wegrzyn, Secretary Becerra and other ARPA-H, HHS, and White House staff involved in the initiative.

Ms. Davies and I briefed The University of Texas MD Anderson Cancer Center Board of Visitors in Houston on October 26 regarding the establishment of CHART and the specifics of our arguments for locating the new federal agency in Texas.

Several recent national news stories have reported on efforts by the competing states and cities to headquarter ARPA-H. The reports have all been positive when discussing Texas' activities.

CPRIT's involvement in the effort to locate ARPA-H in Texas is motivated by and consistent with CPRIT's statutory charge to "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 is consistent with our stated program priorities that include helping to enhance and expand the life sciences infrastructure of the state.

Discussions and activities related to this initiative occur continuously. We will keep you advised as developments warrant.

Other Staff Outreach

Staff outreach activities during October include:

- On October 10, Chief Scientific Officer Dr. Michelle Le Beau, Chief Product Development Officer Dr. Ken Smith, Product Development Program Manager Abria Magee, Ms. Doyle, Ms. Davies, and I met with several representatives from BrightEdge, the venture capital arm of the American Cancer Society about opportunities for CPRIT and BrightEdge to collaborate in their shared goals to advance cancer-related product development in Texas.

- Chief Prevention Officer Ramona Magid, Director of Academic Research Dr. Patty Moore, Chief Operations Officer Heidi McConnell, Dr. Le Beau, Ms. Doyle, Ms. Davies and I met with Dr. Ned Sharpless, former director of the National Cancer Institute, on October 12 to discuss CPRIT's priorities and how we might increase coordination with NCI. Dr. Sharpless was in town for a lecture at The University of Texas at Austin Dell Medical School, which several CPRIT staff attended.

- On October 12, Dr. Smith and Dr. Magee met with Dr. Ferran Prat, Senior Vice President of Research Administration and Industry Relations at The University of Texas MD Anderson Cancer Center to discuss CPRIT and funding opportunities in the product development research program. Dr. Magee also met with Anshuj Deva in the Office of Industry Ventures at MD Anderson. Mr. Deva and Dr. Magee discussed ways that MD Anderson could be a resource to potential companies and grantees.

- Ms. Doyle and I briefed new Interim Commissioner of the Department of State Health Services Dr. Jennifer Shuford on October 17 regarding her responsibilities as a member of the Program Integration Committee and what to expect to prepare for the PIC meeting on November 2.

- Dr. Le Beau participated as an invited speaker in the 2022 Early Detection of Cancer Conference held in Portland, Oregon on October 18-20. The Knight Cancer Institute at Oregon Health Sciences University, Cancer Research UK, and the Canary Center at Stanford for Cancer Early Detection sponsored the event. Dr. Le Beau organized and chaired a panel discussion entitled "How Should We Evaluate Multi-Cancer Early Detection Tests?"

- Ms. Doyle, Ms. McConnell, and I attended the Texas Healthcare and Biosciences Institute (THBI) Policy Summit and Luminary Dinner in Austin on October 20.

- On October 25, Dr. Magee met with Dr. Moshin Khan of Fortress Biotech. Fortress Biotech, Inc. is an innovative biopharmaceutical company focused on identifying, in-licensing, and developing high-potential marketed drugs and development-stage drug candidates. They develop and commercialize products both within the company and through partner companies. Fortress is interested in working with CPRIT grantees in the future.

- Ms. Davies and I attended U.S. Department of Health and Human Services Secretary Xavier Becerra's Cancer Moonshot announcement on October 26 at The University of Texas MD Anderson Cancer Center in Houston. A number of presenters at this meeting expressly acknowledged CPRIT's involvement in many of the notable initiatives ongoing in the state that are consistent with Cancer Moonshot efforts and goals. As of this writing I am following up with Secretary Becerra, the Regional HHS director and the Secretary's point person for the Cancer Moonshot initiative to identify ways that CPRIT, the Cancer Moonshot, and NCI can maximize and complement our shared missions.

- On October 26, Dr. Magee met with representatives with the Southwest Research Institute to discuss potential opportunities for collaboration. The Institute is a non-profit research institute with CMC and cGMP manufacturing capabilities in San Antonio.

- On October 27, Ms. Davies participated in a panel discussion regarding diversity in legal proceedings and patent-related matters, where she discussed CPRIT's programs and intellectual property interests, particularly as to how they relate to the increasingly diverse population of the state, at the Eastern District of Texas Bench and Bar Conference in Plano.

- Dr. Magee and Ms. Doyle attended the Life Sciences Investor Showcase held at Pegasus Park in Dallas on October 27 – 28. Events included The University of Texas Southwestern Medical Center pitch competition, the VIP investor dinner, and the "Breakfast at BioLabs" quick pitches.

- Throughout October Dr. Smith and/or Dr. Magee met with several companies interested in applying for CPRIT product development research awards in FY 2023, including Newco (nanotechnologies for cancer imaging, gene therapy and cancer immunotherapy), Revatis (Belgium-based company developing innovative process to sample, isolate, differentiate, and culture stem cells), Volition (Belgium-based company with technology using nucleosomes as biomarkers in cancer and other diseases), Renal Care & Research (Belgium-based company specializing in the diagnosis and personalized treatment for kidney stones), XCEED Pharma (planned manufacturing facility in the Brazos Valley), and a spin out company from The University of Texas Southwestern Medical Center.

Program Priorities for FY 2024

The three program subcommittees will discuss program priorities for FY 2024 in their upcoming subcommittee meetings in preparation for the Oversight Committee's vote to adopt the priorities at the November 16 meeting.

Compliance Program Update

Submission Status of Required Grant Recipient Reports

CPRIT has $1.4 billion in active grants under management, with 560+ grants that are either active or wrapping up grant activities. We receive an average of 560 grantee reports each month. As of October 21, six entities had not filed five Academic Research reports and three Product Development reports. CPRIT's grant accountants and compliance specialists review and process incoming reports and reach out to grantees to resolve filing issues. In most cases, CPRIT does not disburse grant funds until the grantee files the required reports. In some instances, grantee institutions may be ineligible to receive a future award if the grantee does not submit required reports.

Financial Status Report Reviews

CPRIT's compliance specialists performed 102 second-level reviews of grantee Financial Status Reports (FSRs) in October. Nine FSRs (9%) needed resubmission due to insufficient or inaccurate documentation sent by the grantee. CPRIT's grant accounting staff completes the first review of the FSRs and supporting documentation before routing them to the compliance specialists for final review and disposition.

Single Audit Tracking

Compliance specialists track the submission of grantees' independent audit reports and the resolution of issues named in these reports. Grantees who spend $750,000 or more in state awards in the grantee's fiscal year must undertake a single independent audit, a program specific audit, or an agreed upon procedures engagement. The grantee sends the independent audit report

with findings to CPRIT within 30 days of receipt, but no later than nine months after the grantee's fiscal year end.

Currently, all grantees have submitted the required audit. Grantees are unable to receive reimbursements or advances if they are delinquent in filing the required audit and corrective action plan unless the grantee requested more time by the due date of the required audit and CPRIT's CEO approves the request.

Desk Reviews

Compliance specialists performed five enhanced desk-based financial monitoring reviews in October. Enhanced desk reviews verify that grantees spend funds in compliance with specific grant requirements and guidelines and may target an organization's internal controls, current and past fiscal audits, and timeliness of required grantee report submission. Compliance specialists are working with two grantees to remediate enhanced desk review findings.

Onsite Reviews

CPRIT completed two virtual onsite reviews in October. Onsite reviews examine the grantees' financial and administrative operations, subcontract monitoring, procurement and contracting procedures, inventory procedures, personnel policies and procedures, payroll and timesheet policies, travel policies and records, and single audit compliance. Compliance specialists are working with three grantees to remediate onsite review findings.

Match Expenditures Review

CPRIT requires academic research and product development research grantees to show that they have available unused funds equal to at least one-half of the CPRIT grant award that the grantee will spend on the CPRIT-funded project. This obligation, often referred to as "CPRIT's matching funds requirement," requires the grantee to first certify that it has available matching funds, and then at the end of the grant year, to verify that the grantee spent the matching funds on the project. CPRIT's statute allows an institution of higher education to use its federal indirect cost rate as a credit toward the required 50% match.

Product development grantees and those academic research grantees whose indirect cost rate credit does not fully offset the required match must supply a detailed match expenditure report that includes the amount and date paid, vendor, description, and budget category. Compliance staff review grantees' match expenditures for appropriateness and allowability and work with CPRIT's grant accountants and the grantee to address any deficiencies. Compliance staff performed four annual match expenditure reviews for three product development grantees in October. The total amount of match expenses reviewed by compliance staff for FY 2023 is $4,329,057.38.

Training and Support

CPRIT staff conducted one new Authorized Signing Official (ASO) training webinars in October with Hummingbird Bioscience. The training covered grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. CPRIT requires new ASOs to complete a compliance training within 60 days of the change.

CPRIT staff conducted a series of annual compliance training webinars on October 12-13 for 134 grantee staff. Trainings are specific to each program area (Academic Research, Product Development Research, and Prevention) and allow for an interactive experience and opportunity to focus on topics relevant to each program. The trainings covered grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. This was the third and final training series offered this calendar year for the training requirement which requires the Authorized Signing Official and at least one other employee from each grantee organization to attend an annual compliance training by December 31 of each year.

Academic Research Program Update

Recruitment FY 2023 Review Cycle 1

CPRIT's Scientific Review Council (SRC) reviewed recruitment applications for the first quarter of FY 2023 (Cycle 23.1) on September 15. Dr. Le Beau will present the SRC's award recommendations for 23.1 recruitment awards to the Program Integration Committee (PIC) and the Oversight Committee in November.

FY 23.1 Mechanism	Received	Funds Requested	Recommended	Recommended Funds
Recruitment Established Investigators	4	$23,999,198	2	$11,999,198
Recruitment of First-Time, Tenure Track Faculty Members	1	$2,000,000	0	N/A
TOTAL	**5**	**$25,999,198**	**2**	**$11,999,198**

Texas Regional Excellence in Cancer (TREC) FY 2023 Review Cycle

CPRIT opened the portal May 16 to receive applications for Texas Regional Excellence in Cancer (TREC) Awards. We received four applications requesting $23,998,422 by the September 8 deadline. Virtual Peer Review will occur in November and Dr. Le Beau will present the TREC Award recommendations to the PIC and Oversight Committee in early 2023.

Academic Research FY 2023 Review Cycle 1 (23.1)

CPRIT released several RFAs for the first cycle of FY 2023 (23.1) in January and began accepting applications for targeted and untargeted Individual Investigator Research Awards in March through June 8. Peer review panels met in late October to consider the applications. Dr. Le Beau will present the SRC's recommendations for the Individual Investigator Research Awards to the PIC and the Oversight Committee in February 2023.

Cycle 23.1 RFA Mechanism	Applications	Requested Funding
Individual Investigator Research Awards	235	$241,561,941
Individual Investigator Research Awards for Cancer in Children and Adolescents	30	$42,048,859
Individual Investigator Research Awards for Clinical Translation	19	$35,897,103
Individual Investigator Research Awards for Computational Systems Biology of Cancer	23	$26,041,589
Individual Investigator Research Awards for Prevention and Early Detection	22	$36,681,588
Total	**329**	**$382,231,080**

Product Development Research Program Update

Product Development FY 2023 Review Cycle

CPRIT released four FY 2023 Product Development Research RFAs and opened the portal to receive preliminary applications on a rolling basis beginning August 24. As of November 2, CPRIT received 40 preliminary applications and invited 19 companies to submit full applications. The first deadline for full applications was November 1. Ten companies, requesting $149,091,114, will present their full applications to review panels the week of December 12 – 16. Following due diligence review, Chief Product Development Officer Dr. Ken Smith will present the Product Development Review Council's (PDRC) award recommendations to the PIC and the Oversight Committee in February.

More information about each stage in the product development review process is provided below.

Preliminary Applications

The PDRC reviews preliminary applications to determine those that demonstrate sufficient scientific merit and a compelling premise for more extensive review. This preliminary review process operates on a rolling basis and generally takes 3 – 5 weeks. Between August 24 and November 2, CPRIT received 40 preliminary applications requesting $473,588,454. Twelve companies submitting preliminary applications are currently located in states/countries outside of Texas, including California, Kansas, Massachusetts, Maryland, North Carolina, Washington, India, and Sweden.

RFA	Invited	Not Invited	Pending	Total Apps
Texas Therapeutics Company (TTC)	14	5	3	22
Texas Device and Diagnostics Company (TDDC)	1	4	0	5
Texas New Technologies Company (TNTC)	2	3	0	5
Seed Company	2	5	1	8
TOTAL	**19**	**17**	**4**	**40**

Invitation to Submit a Full Application

CPRIT invites companies that score favorably in preliminary review to submit a full application and present their proposal to a review panel. CPRIT invited 19 companies to submit full applications. Companies invited to submit full applications may choose one of the three FY 2023 award cycles, which link to the full application submission deadlines:

	Full App Deadline	Panel Presentations	Oversight Committee Approval
Cycle 1	November 1, 2022	December 12 – 16, 2022	February 15, 2023
Cycle 2	February 1, 2023	March 13 – 17, 2023	May 17, 2023
Cycle 3	May 1, 2023	June 12 – 16, 2023	August 16, 2023

Due to scheduling and resource constraints, CPRIT notified applicants that we are limiting the number of full applications that the review panels will consider in Review Cycle 1 to the first ten applications received on or before the November 1 deadline. CPRIT received 14 applications by the deadline. The ten companies that CPRIT will review in the first cycle are requesting $149,091,114 and include four applicants that are currently located outside of Texas. CPRIT will defer the companies that submitted full applications but did not receive a panel presentation slot in December to the second review cycle.

The table below reflects the information about the preliminary and full applications CPRIT has received by November 2.

RFA	Prelim Apps	Prelim Apps $ Request	Invited Apps	Invited Apps $ Request	Full Apps	Full Apps $ Request	Full Apps Review Cycle 1	Review Cycle 1 $ Request
TTC	22	$357,139,372	14	$217,614,448	9	$150,026,040	7	$118,109,015
TDDC	5	$48,483,264	1	$3,489,000	1	$3,644,032	0	$0
TNTC	5	$46,104,376	2	$32,000,000	2	$27,982,099	2	$27,982,099
Seed	8	$21,861,442	2	$5,958,768	2	$5,983,763	1	$3,000,000
TOTAL	**40**	**$473,588,454**	**19**	**$259,062,216**	**14**	**$183,991,902**	**10**	**$149,091,114**

Due Diligence Review

Like previous years, a full application that the review panel considers exceptional after the in-person presentation review will also undergo due diligence review. At the conclusion of due diligence review, the panel will decide whether to recommend the application for funding. The PDRC will submit the recommendation(s) to the PIC and the Oversight Committee for approval.

Prevention Program Update

Prevention FY 2023 Review Cycle 1 (23.1)

The Prevention Program released three RFAs on May 6 for the first cycle of FY 2023. CPRIT received 24 proposals totaling $29,628,112 through the August 31 deadline. Peer review panels will meet by teleconference December 5 - 6. Chief Prevention Officer Ramona Magid will present the PRC's recommendations to the PIC and the Oversight Committee in February.

Cycle 23.1 Mechanism	Applications	Funds Requested
Primary Prevention of Cancer	12	$13,965,009
Cancer Screening and Early Detection	7	$13,417,478
Dissemination of CPRIT-Funded Cancer Control Interventions	5	$2,245,625
TOTAL	**24**	**$29,628,112**

Prevention FY 2023 Review Cycle 2 (23.2)

CPRIT plans to release four prevention RFAs in November. CPRIT will accept applications through February 8, 2023. CPRIT has scheduled peer review for April - June 2023. Ms. Magid will present the Prevention Review Council's recommendations to the PIC and the Oversight Committee in August 2023.

Advisory Committee Meetings

- The Geographic Diversity Advisory Committee met October 7.
- The Clinical Trials Advisory Committee met October 14.
- The Product Development Advisory Committee met November 3.

Operations, Finance, and Conference Update

CPRIT staff including Heidi McConnell, Michelle Huddleston, Amaka Nwachukwu, and Lisa Nelson are working with the audit team from McConnell & Jones LLP on requested documents for the audit of CPRIT's FY 2022 financial statements. The audit team is reviewing the requested documents as they come in, including the fraud risks and related party questionnaires requested from Oversight Committee members and CPRIT's executive staff.

Don Brandy, contract specialist, continued work on multiple solicitations for various services including fraud, waste, and abuse reporting; due diligence review (for product development research grant applications); outside counsel; and scientific editing.

CPRIT program staff is reaching out to proposed speakers to confirm availability for the 2023 CPRIT Innovations Conference VI. The conference will take place October 2-3, 2023, at the Moody Gardens Hotel, Spa and Convention Center on Galveston Island.

Upcoming Subcommittee Meetings

Listed below are the subcommittee meetings in advance of the November 16 Oversight Committee meeting. We will send instructions for signing onto the Zoom platform along with the subcommittee agenda and meeting materials one week prior to the meeting.

Board Governance	November 3 at 10:00 a.m.
Audit	November 7 at 10:00 a.m.
Prevention	November 8 at 12:00 p.m.
Academic Research	November 9 at 10:00 a.m.
Product Development	November 10 at 10:00 a.m.

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CPRIT has awarded **1,818** grants totaling **$3.173 billion**

- 274 prevention awards totaling $327.9 million
- 1,544 academic research and product development research awards totaling $2.845 billion

Of the $2.845 billion in academic research and product development research awards,

- 31.0% of the funding ($882.6 million) supports clinical research projects
- 23.8% of the funding ($676.3 million) supports translational research projects
- 29.4% of funding ($835.6 million) supports recruitment awards
- 12.6% of the funding ($359.8 million) supports discovery stage research projects
- 3.2% of funding ($90.4 million) supports training programs.

CPRIT has six open Requests for Applications (RFAs)

- 2 Research Recruitment
- 4 Product Development Research

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	VINCE BURGESS, CHIEF COMPLIANCE OFFICER
SUBJECT:	COMPLIANCE PROGRAM UPDATE
DATE:	NOVEMBER 7, 2022

The Chief Compliance Officer is responsible for apprising the Oversight Committee and the Chief Executive Officer of institutional compliance functions and activities, and assuring the Oversight Committee that controls are in place to prevent, detect and mitigate compliance risk. The required reporting includes quarterly updates to the Oversight Committee on CPRIT's compliance with applicable laws, rules, and agency policies. In addition, the Compliance Officer is responsible for monitoring the timely submission status of required grant recipient reports and notifying the Oversight Committee and General Counsel of a grant recipient's failure to meaningfully comply with reporting deadlines.

Submission Status of Required Grant Recipient Reports

CPRIT has $1.4 billion in active grants under management, with 560+ grants that are either active or wrapping up grant activities. We receive an average of 560 grantee reports each month. As of October 28, three entities had not filed three Academic Research reports and two Product Development reports. CPRIT's grant accountants and compliance specialists review and process incoming reports and reach out to grantees to resolve filing issues. In most cases, CPRIT does not disburse grant funds until the grantee files the required reports. In some instances, grantee institutions may be ineligible to receive a future award if the grantee does not submit the required reports.

Financial Status Report Reviews

CPRIT's compliance specialists performed 541 second-level reviews of grantee Financial Status Reports (FSRs) in August - October. Fifty-eight FSRs (11%) needed resubmission due to insufficient or inaccurate documentation sent by the grantee. CPRIT's grant accounting staff completes the first review of the FSRs and supporting documentation before routing them to the compliance specialists for final review and disposition.

Desk Reviews

PO Box 12097 | Austin, Texas 78711 | PH: 512-463-3190 | F: 512-475-2563 | cprit.texas.gov

Compliance specialists performed eight enhanced desk-based financial monitoring reviews in August - October. The goal of the desk review is to confirm financial, administrative, and programmatic compliance. Desk reviews focus on an organization's internal controls, current and previous fiscal audits, grantee report submission timeliness, and include a sample review of grant expenditures. Desk reviews also aid in the identification of potential problems and technical assistance issues for follow-up during an onsite visit, as well as areas of non-compliance and grantee performance issues. Desk reviews are performed throughout the grant's life cycle to ensure that grantees are expending funds and administering the grant in accordance with applicable laws, rules, policies, and the grant contract. Compliance specialists are collaborating with one grantee to address enhanced desk review findings.

Onsite Reviews

CPRIT completed seven virtual onsite reviews in August - October. Onsite reviews are one of the most extensive monitoring activities conducted by CPRIT and include virtual or field visits led by compliance specialists. The grantee's financial and administrative operations, subcontract monitoring, procurement and contracting procedures, inventory procedures, personnel policies and procedures, payroll and timesheet policies, travel policies and records, and compliance with single audits are all monitored during onsite reviews. Onsite monitoring enables CPRIT compliance staff to assess a grantees' capability, performance, and compliance with applicable laws, rules, and policies. Compliance specialists are collaborating with five grantees to address onsite review findings.

Annual Matching Expenditures Reviews

CPRIT requires academic research and product development research grantees to show that they have available unused funds equal to at least one-half of the CPRIT grant award that the grantee will spend on the CPRIT-funded project. This obligation, often referred to as “CPRIT’s matching funds requirement,” requires the grantee to first certify that it has available matching funds, and then at the end of the grant year, to verify that the grantee spent the matching funds on the project. CPRIT’s statute allows an institution of higher education to use its federal indirect cost rate as a credit toward the required 50% match.

Product development grantees plus those academic research grantees whose indirect cost rate credit does not fully offset the required match must supply a detailed match expenditure report that includes the amount and date paid, vendor, description, and budget category. Compliance staff review grantees’ match expenditures for appropriateness and allowability and work with CPRIT’s grant accountants and the grantee to address any deficiencies. Compliance staff performed eight annual matching expenditures reviews for seven grantees in August - October. Compliance staff reviewed a total of $9,453,312.81 matching expenditures during this period.

Training and Support

CPRIT staff conducted four new Authorized Signing Official (ASO) training webinars in August - October for Texas A&M University - Corpus Christi, Rice University, Southern Methodist

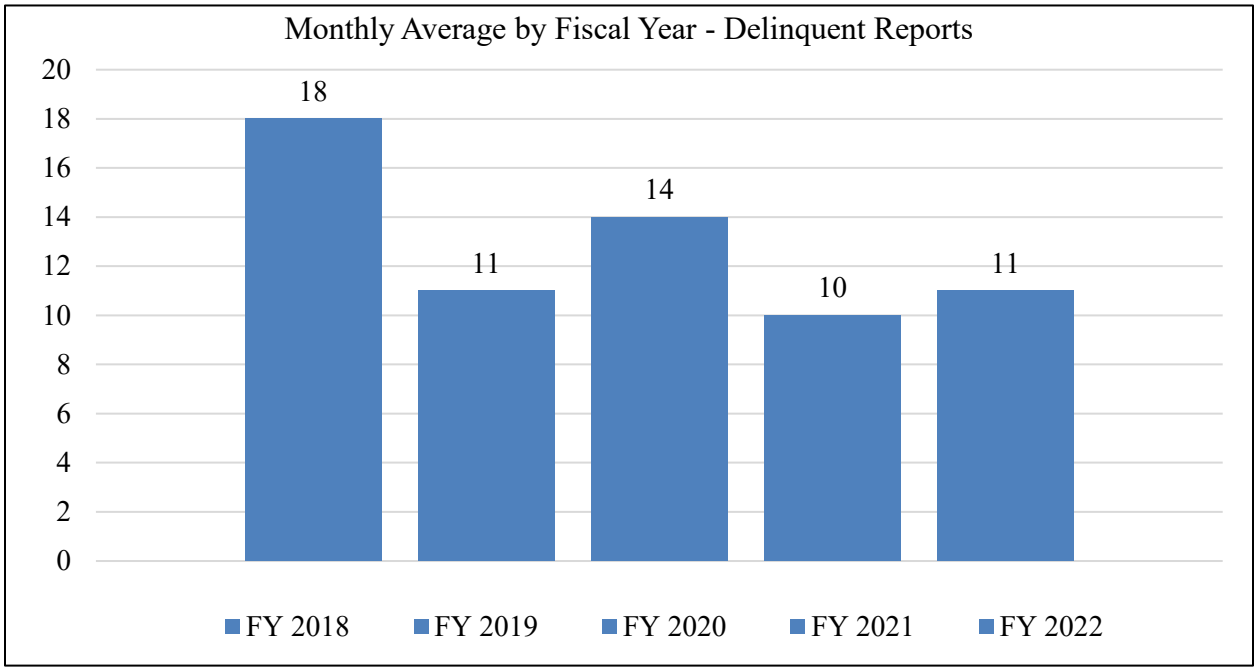
University, and Hummingbird Therapeutics. The trainings covered grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. Pursuant to Texas Administrative Code §703.22, CPRIT requires new ASOs to complete a compliance training within 60 days of the change.

CPRIT staff conducted a series of annual compliance training webinars on October 12-13 for 134 grantee staff. Trainings are specific to each program area (Academic Research, Product Development Research, and Prevention) and allow for an interactive experience and opportunity to focus on topics relevant to each program. The trainings covered grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. This was the third and final training series offered this year for the annual compliance training requirement which requires the Authorized Signing Official and at least one other employee from each grantee organization to attend an annual compliance training by December 31 of each year.

FY 2022 Compliance Program Activities Summary

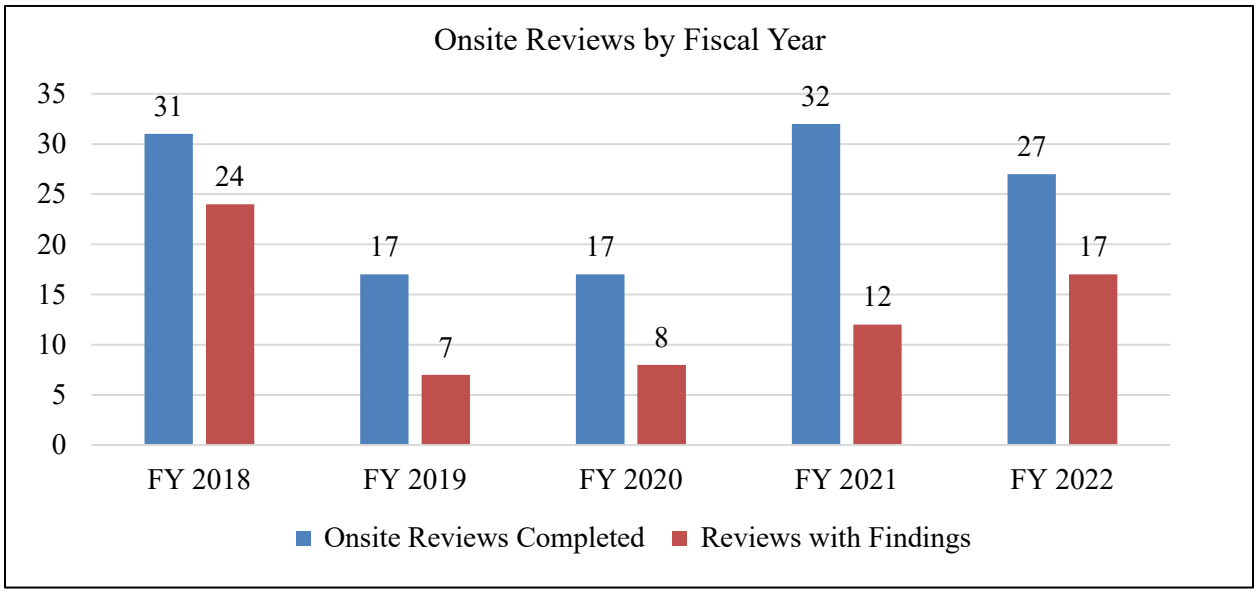
CPRIT's Compliance Program functions are designed to actively support the integrity and transparency of CPRIT's agency processes. FY 2022 Compliance Program highlights include:

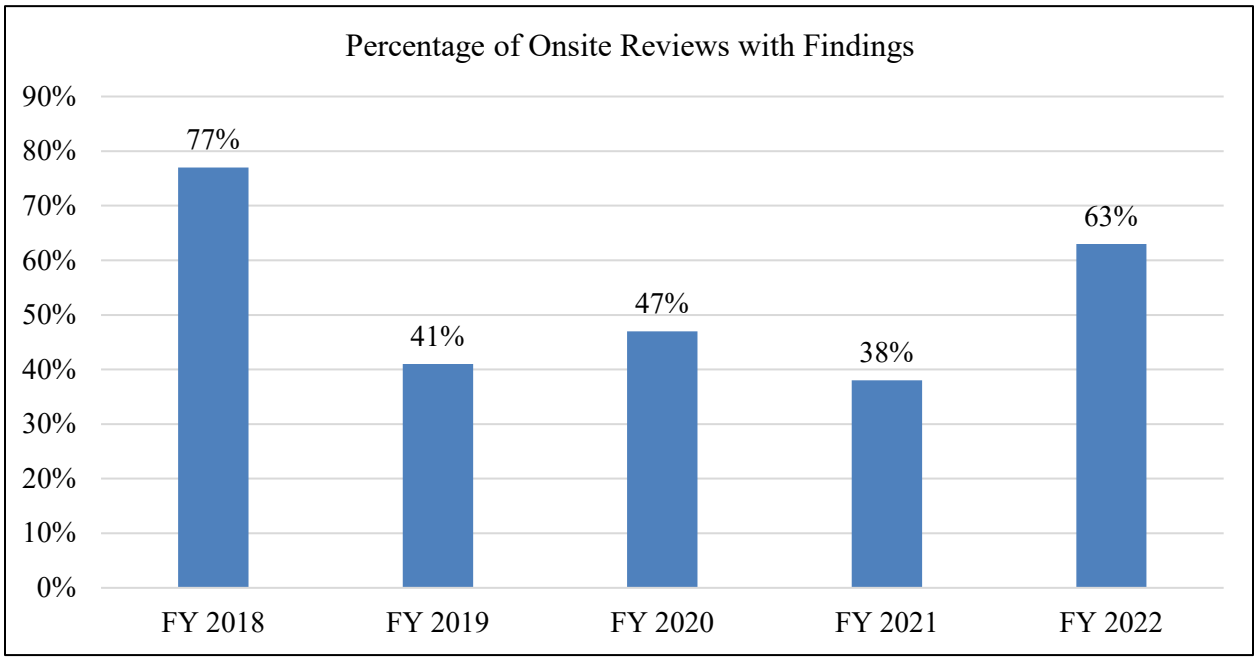
- Grant Recipient Report Monitoring - CPRIT receives approximately 560 required grantee reports each month. The number of delinquent reports in FY 2022 averaged 11 reports per month. CPRIT staff meet weekly to review and discuss delinquent reporting and actively work with grantees to submit required reports timely. The average number of delinquent reports for the past five fiscal years are represented below:



- Second-Level Reviews of Financial Status Reports (FSRs) - The compliance team performed a second-level review of 2,048 FSRs in FY 2022. Financial Status Reports are grantee expenditure reports that detail how project costs from the previous quarter were incurred. CPRIT's grant accounting staff completes the initial review of the FSRs and supporting documentation before routing them to the compliance specialists for final review and disposition.

- Compliance Monitoring Reviews (Enhanced Desk and Onsite) - The compliance team performed 113 compliance monitoring reviews (86 enhanced desk reviews, 27 onsite reviews) during FY 2022.



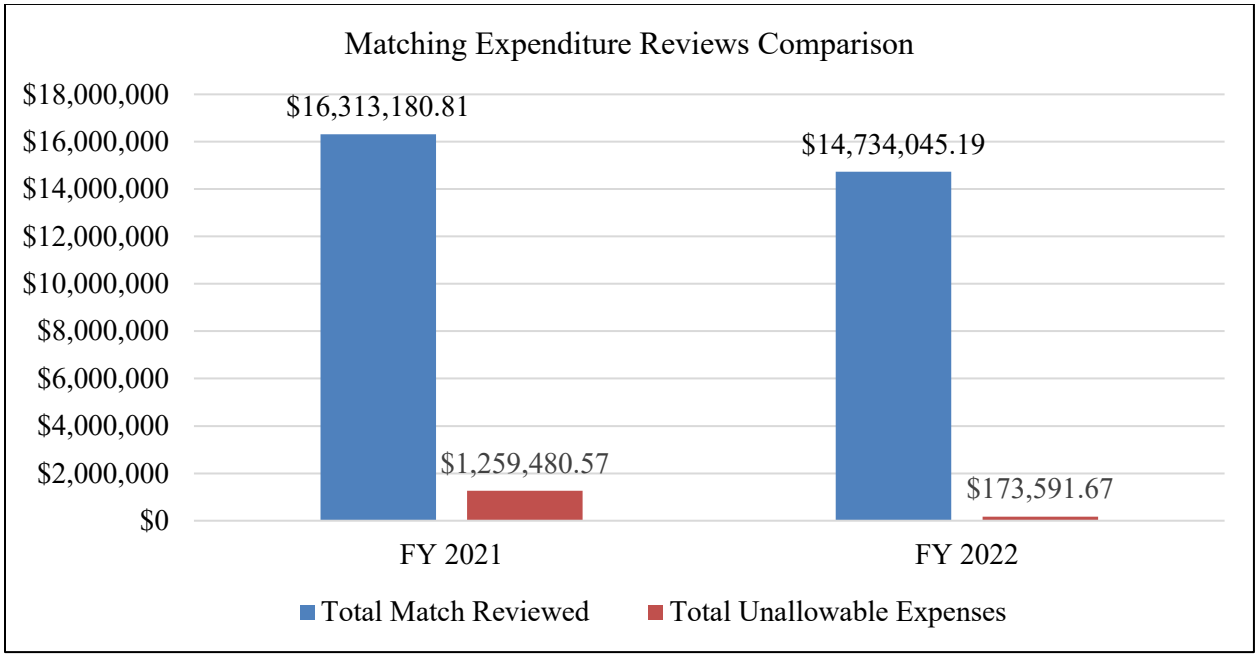


- Training and Education - In FY 2022, CPRIT staff provided 22 grantee trainings including annual compliance trainings, new grantee trainings, ad hoc trainings, and trainings for new Authorized Signing Officials (ASOs). Over 660 grantee staff attended these training opportunities provided to our active grantees.

- Annual Compliance Attestation - The compliance team reviewed and processed 54 attestations submitted by grantees. CPRIT requires grantees to submit an annual attestation form, demonstrating compliance with statutory and administrative grant requirements, CPRIT's policies and procedures, grant contract terms, and the Texas Grant Management Standards.

- Single Audit Reviews - The compliance team reviewed 35 audits and agreed upon procedures (AUP) reports and actively worked with one grantee to remediate audit findings.

- Annual Matching Expenditures Reviews - Compliance staff performed 15 annual matching expenditures reviews in FY 2022 with a total amount reviewed of $14,734,045.19. These reviews identified $173,591.67 as unallowable expenses towards the matching requirement. The year-over-year decrease in unallowable matching expenditures may be a direct result of the training provided to our product development grantees, along with the implementation of the annual matching expenditures process.



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: MICHELLE LE BEAU, PH.D., CHIEF SCIENTIFIC OFFICER

SUBJECT: ACADEMIC RESEARCH PROGRAM UPDATE

DATE: NOVEMBER 14, 2022

FY2023 Cycle 1 RFA's

CPRIT released six RFAs for the first cycle of FY2023 as displayed in Table 2. Dr. Le Beau will present the PIC recommendations to the Oversight Committee in January 2023 (Texas Regional Excellence in Cancer Awards (TREC) and February 2023 for the Individual Investigator Research Awards (targeted and untargeted).

Table 1: **FY2023 Cycle 1 (23.1) Submission Data and Requested Funding**

RFA Mechanism	# Applications Submitted	Requested Funding
Individual Investigator Research Awards (IIRA)	235	$241,561,941
Individual Investigator Research Awards for Cancer in Children and Adolescents (IIRACCA)	30	$42,048,859
Individual Investigator Research Awards for Clinical Translation (IIRACT)	19	$35,897,103
Individual Investigator Research Awards for Computational Systems Biology of Cancer (IIRACSBC)	23	$26,041,589
Individual Investigator Research Awards for Prevention and Early Detection (IIRAP)	22	$36,681,588
Texas Regional Excellence in Cancer Awards (TREC)	4	$23,998,422
Total	**333**	**$406,229,502**

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Recruiting experts to Academic Research FY23 Peer Review Panels

Drs. Le Beau and Moore have diligently worked with the Scientific Review Council (SRC), CPRIT Advisory Committee members and GDIT to identify and recruit the scientific expertise to meet the scientific rigor of the FY23 RFA applications.

Proposed Academic Research RFAs for Fiscal Year 2023 Cycle 2 (23.2)

- **Texas CONNECT for Cancer Prevention Study Awards (RFA R-23.2 TCCPA):** Solicits applications from institutions to establish a Texas CONNECT for Cancer Prevention Study of 25,000-30,000 adults in collaboration with the NCI CONNECT Study. This prospective study will address priorities in cancer prevention, early detection, and etiology research, which include emerging exposures, novel biomarkers, genomics; current-edge methodology and diverse and special populations. The CONNECT Study has the long-term potential to identify social, environmental, and behavioral, and genetic factors that underlie cancer risk among Texans.
  Award: Up to $7.5 million over a period of 5 years.

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- **TREC Pilot Study Award (RFA R-23.2 TREC-PSA):**
  Provides short-term funding to explore the feasibility of cancer research projects at TREC-eligible institutions that, if successful, would contribute new insights into the etiology, diagnosis, treatment, or prevention of cancers forming the basis for applications for peer-reviewed funding from CPRIT or other organizations.
  Award: Total of $200,000 over a period of 2 years.

- **TREC Institutional Postdoctoral Training Award (RFA R-23.2 TREC PDTA):** Solicits applications from TREC-eligible institutions to support training and the conduct of research and, ultimately, the retention as faculty of outstanding post-doctoral students

recognized by their institutions for their high potential and strong interest in pursuing careers as independent cancer researchers.
Award: Total of $800,000 over a period of 3 years

- **TREC Major Instrumentation Award (RFA R-23.2 TREC MIA):**
  Solicits applications from TREC-eligible institutions to enhance research capacity by supporting the purchase of major instrumentation for one or more Core Facilities that will support multiple cancer researchers.
  Award: Total of $1 million over a period of 1 year

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	RAMONA MAGID, CHIEF PREVENTION OFFICER
SUBJECT:	PREVENTION PROGRAM UPDATE
DATE:	NOVEMBER 8, 2022

FY 2023 Review Cycle 1 (23.1)

The Prevention Program released three RFAs on May 6, 2022. CPRIT opened the application portal June 2 to receive proposals through the August 31, 2022, deadline. Twenty-eight applications were submitted; four applications were research projects and were administratively withdrawn. The remaining twenty-four applications requesting a total of $29,628,112 will undergo peer review on December 5 by teleconference. The five applications responding to the Dissemination of CPRIT-Funded Cancer Control Interventions mechanism will be reviewed by the Prevention Review Council (PRC) on January 6 and programmatic review by the PRC will be conducted January 13. The Program Integration Committee (PIC) meets in February 2023 to consider the PRC's recommendations. Ms. Magid presents the PIC's award recommendations to the Oversight Committee on February 15, 2023.

FY 2023.1 (23.1) Application Data by Mechanism

Mechanism	Received	Funds Requested
Primary Prevention of Cancer	12	$13,965,009
Cancer Screening and Early Detection	7	$13,417,478
Dissemination of CPRIT-Funded Cancer Control Interventions	5	$2,245,625
TOTAL	**24**	**$29,628,112**

FY 2023 Review Cycle 2 (23.2)

CPRIT is recommending the release of four Requests for Applications for review cycle 23.2.

Note: Complete draft versions of the proposed RFAs can be accessed on Box.com

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I. Dissemination of CPRIT- funded Cancer Prevention and Control Interventions

Summary:
This RFA solicits applications that will describe and package strategies or approaches to introduce, modify, and implement previously funded CPRIT evidence-based cancer prevention and control interventions for dissemination to other settings and populations in the state. To be eligible, the applicant should be able to develop one or more "products" based on the results of the CPRIT-funded intervention. The proposed projects should also identify and assist others in overcoming barriers to implementation.

Award Description:
The **Dissemination of CPRIT-Funded Cancer Control Interventions** RFA solicits applications from currently or previously funded CPRIT projects that have demonstrated exemplary success and have materials, policies, and other resources that have been successfully implemented and evaluated and could be scaled up and/or applied to other systems and settings. The goal is to expand successful models for the delivery of prevention interventions all across the state through adaptation or replication.
Applicants to this RFA should outline specific implementation strategies they will utilize with targeted recipients to replicate or adapt projects to other settings or populations. Implementation strategies are described as the processes, activities, and resources that are used to integrate interventions into usual settings. Core implementation components can be staff selection, preservice and in-service training, ongoing consultation and coaching, staff and program evaluation, and systems interventions
This award will support both passive and active dissemination strategies but must include two or more active dissemination strategies. This award will also support implementation strategies in the form of technical assistance, coaching, and consultation within the grant period. Priority will be given to those projects that identify and assist potential target partners/audiences in preparing to implement the intervention and/or preparing to apply for grant funding.

Funding Amount and Duration: up to 3 years, $450K maximum

II. Primary Prevention of Cancer

Summary:
This award mechanism focuses on increasing implementation of evidence-based strategies to ensure that all Texans benefit from the cancer prevention knowledge that we currently have. CPRIT seeks to fund multilevel interventions to reduce cancer risk, disease burden, and cancer disparities. Modifiable risk behaviors include tobacco use, obesity, physical inactivity, unhealthy eating, alcohol use, sun exposure, HPV vaccination, Hepatitis B vaccination, and environmental/ occupational cancer exposures.

Applications should also assess and address social determinants that contribute to cancer burden and disparities (e.g., cultural factors, unmet needs, access barriers). Interventions and

communications should be structured to address the unique circumstances of the population to be served.

Award Description:
The **Primary Prevention of Cancer** RFA solicits applications for eligible projects up to 36 months in duration that will deliver multilevel, evidence-based interventions that improve cancer-related health behaviors. Interventions may address tobacco use, obesity, physical inactivity, unhealthy eating, alcohol use, HPV vaccination, Hepatitis B vaccination, and environmental/occupational cancer exposures. Sun safety education may be addressed if combined with another behavioral intervention to reduce risk.
The following are required components of the project:

- **Evidence-Based**: CPRIT's primary prevention grants are intended to fund culturally appropriate effective and efficient systems of delivery of preventive services based on the existing body of knowledge about and evidence for cancer prevention.
- **Multilevel Interventions:** Health behaviors have multiple levels of influences, often including individual, group, organization, and community determinants. Influences on behaviors interact across these different levels and multilevel interventions are the most effective in changing behavior.
- **Geographic Area to be Served:** Preventive service delivery to nonmetropolitan/medically underserved area (MUA) counties must be included in the defined service area. Service to urban counties that are not medically underserved is allowable if the project proposes to also serve nonmetropolitan counties that are medically underserved.
- **Community Partner Networks:** Applicants are strongly encouraged to coordinate and describe a collaboration of community partners that can deliver services to the most counties and the most people possible in a selected service region.

Funding Amount and Duration:
The amount of funding that applicants may request is dependent on the primary focus of the project and on the type of project – New, Initial Expansion or Maintenance Expansion. Use the table below to determine the maximum amount of funding and the maximum number of years that may be requested.

Project Type	Maximum Amount of Funding	Maximum Duration
New Project	$1 million	3 years
Initial Expansion	$1 million	3 years
Initial Expansion – vaccination/tobacco cessation	$1.5 million	3 years
Maintenance Expansion	$2 million	5 years
Maintenance Expansion – vaccination/tobacco cessation	$2.5 million	5 years

III. Screening and Early Detection

Program Objectives:

- Deliver comprehensive projects comprising the following: public and/or professional education, outreach, delivery of clinical services, follow-up navigation to diagnosis and cancer treatment, and system and/or policy improvements.
- Offer effective and efficient systems of delivery of screening services based on the existing body of knowledge about and evidence in ways that far exceed current performance in the proposed service area.
- Implement policy changes and/or system improvements that are sustainable over time (eg, decrease wait times between positive screen and diagnostic tests and treatment through improved navigation, reminder systems) and treatment.
- Provide tailored, culturally appropriate outreach and accurate information on early detection and prevention to the public and health care professionals that results in a health impact that can be measured.

Summary:

This award mechanism seeks to support the delivery of evidence-based clinical services to screen for cancer and pre-cancer in underserved populations who do not have adequate access to cancer early detection interventions and health care, bringing together networks of public health and community partners to carry out programs tailored for their communities. Projects should identify cancers that cause the most burden in the community, have nationally recommended screening methods, and use evidence-based methods to screen for these cancers.

Award Description:

The Screening and Early Detection RFA solicits applications for eligible projects up to 5 years in duration that will deliver evidence-based clinical services in cancer screening for breast, cervical, colorectal, liver, and lung cancers according to established and current national guidelines and criteria. Nonmetropolitan (rural) and/or medically underserved populations must be included in the defined service area.

The following are required components of the project:

- **Evidence-Based**: CPRIT's secondary prevention grants are intended to fund effective and efficient systems of delivery of early detection services based on the existing body of knowledge about and evidence for screening for both primary and secondary cancers in ways that far exceed current performance in a given service area. The provision of clinical services, including rescreening at the appropriate interval, must comply with established and current national guidelines (eg, US Preventive Services Task Force [USPSTF], American Cancer Society).
- **Comprehensive Projects:** Comprehensive projects include a continuum of services and systems and policy changes and comprise the following: Public and professional education and training, outreach, delivery of screening and diagnostic services, follow-up navigation to treatment services for those diagnosed with cancer and precancer, data collection and tracking, and systems improvement.

- **Geographic Area to be Served:** Preventive service delivery to nonmetropolitan/medically underserved area (MUA) counties must be included in the defined service area. Service to urban counties that are not medically underserved is allowable if the project proposes to also serve nonmetropolitan counties that are medically underserved.
- **Clinical Service and Community Partner Networks:** Applicants are encouraged to coordinate and describe a collaboration of clinical service providers and community partners that can deliver outreach, education, clinical, and navigation services to the most counties and the most people possible in a selected service region.

Funding Amount and Duration:
The amount of funding that applicants may request is dependent on the primary focus of the project and on the type of project – New, Initial Expansion or Maintenance Expansion. Use the table below to determine the maximum amount of funding and the maximum number of years that may be requested.

Project Type	Maximum Amount of Funding	Maximum Duration
New project	$1.5 million	3 years
Initial Expansion Project	$2 million	3 years
Maintenance Expansion Project	$2.5 million	5 years

IV. Colorectal Cancer Screening Coordinating Center - *NEW*

Summary:
Colorectal cancer (CRC) is the 3rd leading cancer diagnosis in both males and females as well as the 3rd leading cause of cancer mortality, representing 9% of all new malignant cancers diagnosed and 9.7% of cancer deaths. The mortality rate was significantly higher in non-metro versus metro areas.
The U.S. screening prevalence in 2018 was 69% while the Texas screening rate was 60%. Seven of the 30 U.S. counties with the lowest estimated percentages for being current with any type of CRC screening test were in Texas. Only 32% of uninsured Texans were current with screening in 2020.
Over 20% of colorectal cancers diagnosed were at distant stages when cancer is much more difficult to treat, and survival is lowest. The 5-year relative survival is 90% for localized CRC but drops to less than 20% at distant stage diagnosis.
To significantly reduce the burden of colorectal cancer in Texas, CPRIT seeks to support one Colorectal Cancer Screening Coordinating Center to establish and oversee a collaborative network of regional CPRIT-funded colorectal cancer screening projects, patients, communities, clinicians, and healthcare professionals. The Center will build the infrastructure necessary for a coordinated statewide evidence-based colorectal cancer screening initiative among all populations and geographic areas of Texas.

Award Description:
The Center will serve as a hub of expertise and resources, forge innovative partnerships, catalyze interactions, and enable resource and data sharing among multiple stakeholders across the state to reduce the CRC burden in the state.
The Center will be expected to do the following:

- Facilitate a statewide screening strategy to increase the reach of CRC screening among priority populations throughout the state
- Support the development of clinical networks to ensure a care pathway through CRC treatment in all regions of Texas
- Oversee a statewide steering committee to facilitate communications and interactions to promote sharing of best practices across regional screening projects and stakeholders
- Oversee pilot projects to test pragmatic approaches to implementation and dissemination and to foster evaluation of existing data
- Support advocacy for colorectal cancer screening and treatment in the state
- Convene an annual forum of stakeholders to share expertise and experiences and disseminate best practices
- Monitor the reach of CRC screening initiatives across the state and facilitate implementation in unserved areas
- Conduct a rigorous evaluation that documents successful execution of the implementation strategies and the impact on health outcomes
- Ensure successful statewide implementation activities through provision of hubs or cores of expertise in the following areas
    - Community outreach and engagement strategies
    - Awareness building and increasing the knowledge of stakeholders, including the public, patients, providers and healthcare professionals, and community partners
    - Implementation support, project coordination, technical assistance, and capacity building
    - Development and maintenance of a centralized resource for evidence-based strategies and tools and materials such as protocols and materials for outreach, education, navigation, case management, screening and diagnostic services delivery, treatment access, reporting and evaluation
    - Facilitate data collection, harmonization, analysis, sharing and coordination of data, pragmatic research design expertise and evaluation design

Funding Amount and Duration:

CPRIT plans to make one award to a single applicant in response to this RFA.
Applicants may request a maximum of $3 million in total costs over a period of 5 years.

Other Activities

- Ms. Magid participated in a panel discussion at Texas A&M Health's Health Equity Innovation Summit on October 18, 2022.
- Ms. Magid attended the Healthier Texas Summit, a collaboration between It's Time Texas and The University of Texas System, at the AT&T Conference Center on October 20 and 21.
- Mr. Carlton Allen will join CPRIT on November 15 as the Academic Research and Prevention Program Manager, reporting to Dr. Patty Moore and Ramona Magid. Carlton has most recently been the project director of multiple CPRIT projects at The University of Texas at Tyler Health Science Center.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	KEN SMITH, PH.D., CHIEF PRODUCT DEVELOPMENT OFFICER
SUBJECT:	PRODUCT DEVELOPMENT PROGRAM UPDATE
DATE:	NOVEMBER 8, 2022

Product Development Review FY 2023

CPRIT released four FY 2023 Product Development Research RFAs and opened the portal to receive preliminary applications on a rolling basis beginning August 24. As of November 2, CPRIT received 40 preliminary applications and invited 19 companies to submit full applications. The first deadline for full applications was November 1. Ten companies, requesting $149,091,114, will present their full applications to review panels the week of December 12 – 16. Following due diligence review, I will present the Product Development Review Council's (PDRC) award recommendations to the PIC and the Oversight Committee in February.

I have provided more information about each stage in the product development review process below.

Preliminary Applications

The PDRC reviews preliminary applications to determine those that demonstrate sufficient scientific merit and a compelling premise for more extensive review. This preliminary review process operates on a rolling basis and generally takes 3 – 5 weeks. Between August 24 and November 2, CPRIT received 40 preliminary applications requesting $473,588,454. Twelve companies submitting preliminary applications are currently located in states/countries outside of Texas, including California, Kansas, Massachusetts, Maryland, North Carolina, Washington, India, and Sweden.

RFA	Invited	Not Invited	Pending	Total Apps
Texas Therapeutics Company (TTC)	14	5	3	22
Texas Device and Diagnostics Company (TDDC)	1	4	0	5
Texas New Technologies Company (TNTC)	2	3	0	5
Seed Company	2	5	1	8
TOTAL	**19**	**17**	**4**	**40**

Invitation to Submit a Full Application

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CPRIT invites companies that score favorably in preliminary review to submit a full application and present their proposal to a review panel. CPRIT invited 19 companies to submit full applications. Companies invited to submit full applications may choose one of the three FY 2023 award cycles, which link to the full application submission deadlines:

	Full App Deadline	Panel Presentations	Oversight Committee Approval
Cycle 1	November 1, 2022	December 12 – 16, 2022	February 15, 2023
Cycle 2	February 1, 2023	March 13 – 17, 2023	May 17, 2023
Cycle 3	May 1, 2023	June 12 – 16, 2023	August 16, 2023

Due to scheduling and resource constraints, CPRIT notified applicants that we are limiting the number of full applications that the review panels will consider in Review Cycle 1 to the first ten applications received on or before the November 1 deadline. CPRIT received 14 applications by the deadline. The ten companies that CPRIT will review in the first cycle are requesting $149,091,114 and include four applicants that are currently located outside of Texas. CPRIT will defer the companies that submitted full applications but did not receive a panel presentation slot in December to the second review cycle.

The table below reflects the information about the preliminary and full applications CPRIT has received by November 2.

RFA	Prelim Apps	Prelim Apps $ Request	Invited Apps	Invited Apps $ Request	Full Apps	Full Apps $ Request	Full Apps Review Cycle 1	Review Cycle 1 $ Request
TTC	22	$357,139,372	14	$217,614,448	9	$150,026,040	7	$118,109,015
TDDC	5	$48,483,264	1	$3,489,000	1	$3,644,032	0	$0
TNTC	5	$46,104,376	2	$32,000,000	2	$27,982,099	2	$27,982,099
Seed	8	$21,861,442	2	$5,958,768	2	$5,983,763	1	$3,000,000
TOTAL	**40**	**$473,588,454**	**19**	**$259,062,216**	**14**	**$183,991,902**	**10**	**$149,091,114**

Due Diligence Review

Like previous years, a full application that the review panel considers exceptional after the in-person presentation review will also undergo due diligence review. At the conclusion of due diligence review, the panel will decide whether to recommend the application for funding. The PDRC will submit the recommendation(s) to the PIC and the Oversight Committee for approval.

Product Development Advisory Committee (PDAC)

The PDAC met via zoom on November 3 to discuss agenda items related to CPRIT's product development program. We provided an update on the FY 2023 review process. Overall, the PDAC members were enthusiastic about the changes CPRIT made to the review process in FY 2023. While it is too early to see the full impact of the changes, some members had suggestions for the enhancing the process for FY 2024. The PDAC also considered ways to increase prospects for external funding to help CPRIT companies fulfill their match requirement and to

drive additional investment to Texas. CPRIT and the PDAC discussed a potential RFA for regional centers that will increase product development opportunities across the state.

Product Development Outreach

- Dr. Magee attended presentations by the 2022 cohort of the TMCi Accelerator for Cancer Therapeutics in Houston on September 15. The accelerator is a 2019 CPRIT Core Facility Support Award designed to instruct and coach cancer researchers on how to move their discoveries into the early stages of commercialization. The instruction includes market research, FDA regulations, intellectual property, licensing, financing, fundraising, legal, and other critical needs for successful entrepreneurship. Graduates of the program are likely to submit product development funding applications to CPRIT. While there, she met with several companies interested in CPRIT funding.

- On October 10 Dr. Magee and I, along with several other CPRIT senior staff members, met with representatives from BrightEdge, the venture capital arm of the American Cancer Society about opportunities for CPRIT and BrightEdge to collaborate in their shared goals to advance cancer-related product development in Texas.

- Dr. Magee and I met with Dr. Ferran Prat, Senior Vice President of Research Administration and Industry Relations at The University of Texas MD Anderson Cancer Center, on October 12 to discuss CPRIT and funding opportunities in the product development research program. Dr. Magee also met with Anshuj Deva in the Office of Industry Ventures at MD Anderson. Mr. Deva and Dr. Magee discussed ways that MD Anderson could be a resource to potential companies and grantees.

- On October 25, Dr. Magee met with Dr. Moshin Khan of Fortress Biotech. Fortress Biotech, Inc. is an innovative biopharmaceutical company focused on identifying, in-licensing, and developing high-potential marketed drugs and development-stage drug candidates. They develop and commercialize products both within the company and through partner companies. Fortress is interested in working with CPRIT grantees in the future.

- Dr. Magee met with representatives with the Southwest Research Institute on October 26 to discuss potential opportunities for collaboration. The Institute is a non-profit research institute with CMC and cGMP manufacturing capabilities in San Antonio.

- Dr. Magee attended the Life Sciences Investor Showcase held at Pegasus Park in Dallas on October 27 – 28. Events included The University of Texas Southwestern Medical Center pitch competition, the VIP investor dinner, and the “Breakfast at BioLabs” quick pitches.

- Throughout October Dr. Smith and/or Dr. Magee met with several companies interested in applying for CPRIT product development research awards in FY 2023, including

- In September and October, Dr. Magee and/or I met with several companies interested in applying for product development research awards in FY 2023, including Israeli-based

device company, Insightec, Inc., ScenXO, MUSIQ Bio, Cellula Therapeutics, Serene, LLC., EtiraRX, Newco (nanotechnologies for cancer imaging, gene therapy and cancer immunotherapy), Revatis (Belgium-based company developing innovative process to sample, isolate, differentiate, and culture stem cells), Volition (Belgium-based company with technology using nucleosomes as biomarkers in cancer and other diseases), Renal Care & Research (Belgium-based company specializing in the diagnosis and personalized treatment for kidney stones), XCEED Pharma (planned manufacturing facility in the Brazos Valley), and a spin out company from The University of Texas Southwestern Medical Center.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	PROGRAM PRIORITIES FOR FY 2024
DATE:	NOVEMBER 8, 2022

Summary and Recommendation

I recommend that the Oversight Committee approve the program priorities for fiscal year 2024 as presented behind this memo. Texas Health and Safety Code § 102.107 requires the Oversight Committee to set priorities for the grant programs annually. Each program officer discussed the priorities proposed for fiscal year 2024 with their respective subcommittee in meetings earlier this month. While the FY 2024 program priorities are the same as the priorities adopted by the Oversight Committee last November for fiscal year 2023, the document includes updated text regarding the background and established principles. This new text, highlighted in yellow in the attached document, better reflects CPRIT's current operations and policies.

Priorities for **FY 2024**

Legislation adopted in 2013 requires the Oversight Committee to establish program priorities on an annual basis. CPRIT uses the priorities to provide transparency in how it directs the orientation of the agency's funding portfolio between and within its three programs. The program priorities also guide CPRIT staff and the peer review panels 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 reviews its priorities annually and adjusts as circumstances change and to incorporate the latest information concerning cancer-related advances in prevention, academic research, and product development research. In January 2018, the Oversight Committee decided to approve program priorities at November meetings to provide CPRIT staff more lead time for preparing and releasing RFAs. Adopting the 2024 program priorities at the November 16, 2022, Oversight Committee meeting allows the priorities to guide the fiscal year 2024 RFA process.

Each of the program subcommittees discussed the program priorities proposed for fiscal year 2024. The Prevention, Product Development Research, and Academic Research Subcommittees recommend proposed fiscal year 2024 priorities for their respective programs unchanged from the priorities adopted for fiscal year 2023.

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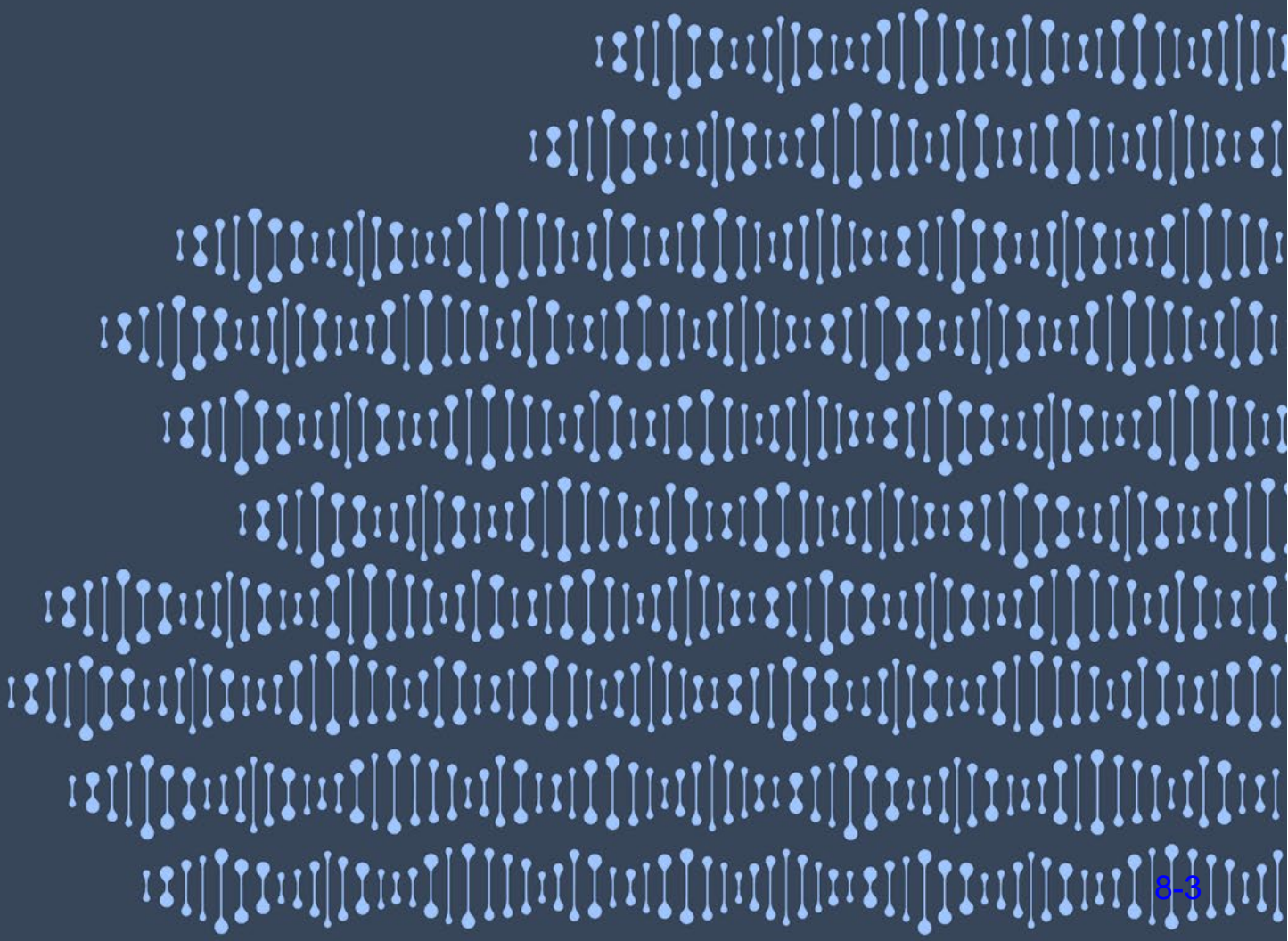
In addition to the priorities specific to each grant program, the proposed fiscal year 2024 program priorities also reflect priorities across CPRIT's three programs. These overarching priorities, which also remain the same as those adopted for fiscal year 2023, inform the Program Integration Committee on balancing the portfolio across the academic research, prevention, and product development research programs.

Although the program priorities for FY 2024 did not change, staff updated some background information and program principles included in the document to more accurately reflect CPRIT's current operations and principles. The changes are minimal but important because they convey CPRIT's commitment to reducing cancer disparities and supporting life science infrastructure across the state. For your convenience, we have marked those changes with yellow highlights in the attached document. The final document approved by the Oversight Committee and posted on our website will not include the yellow highlights.

CPRIT staff will use the newly adopted program priorities to develop RFAs for the fiscal year 2024 CPRIT grant review cycles.

Cancer Prevention & Research Institute of Texas

Program Priorities For FY 2024



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ABOUT CPRIT'S PROGRAM PRIORITIES PROJECT

Legislation adopted in 2013 modified CPRIT's governing statute, Texas Health & Safety Code Chapter 102, to include enhancements to the agency's governance and operations. One of the statutory changes adopted in 2013 requires CPRIT's Oversight Committee to establish program priorities on an annual basis. The Oversight Committee uses the priorities to provide transparency in how it directs the orientation of the agency's funding portfolio between and within its three programs as well as guide CPRIT staff and the peer review panels 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 reviews its priorities annually and adjusts as circumstances change to incorporate the latest information concerning cancer-related advances in prevention, academic research, and product development research.

CPRIT Purpose

Texas Health & 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

Texas Health & 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

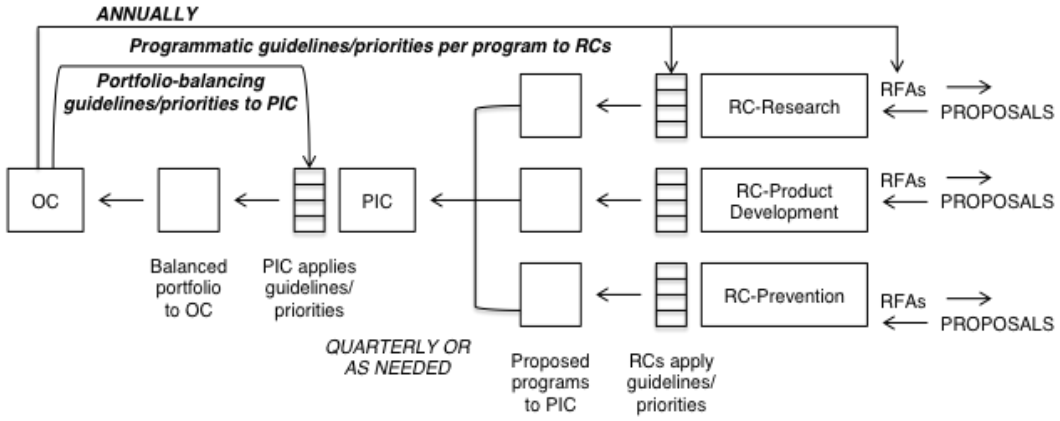
The Oversight Committee initially approved the program priorities in November 2014 after a six-month process that included public input. The fiscal year 2015 program priorities were subsequently incorporated into the RFAs released by each program. The Oversight Committee continues to annually approve priorities for each program every year, most recently adopting the program priorities for fiscal year 2023 at the November 16, 2021, meeting.

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 academic research, prevention, and product development research programs.

Priorities and CPRIT's Grant Making Process



CPRIT'S LONG TERM VISION

As the Oversight Committee established its 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;
- Informing and reducing disparities in cancer incidence and mortality (replaces "*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 because of recruiting researchers, training health care/science professionals, attracting companies and supporting investigator startups.

To accomplish CPRIT's long-term vision, the Oversight Committee has identified these priorities:

- Investing in the cancer research capacity of Texas institutions through recruitment of cancer scholars, investment in core facilities, and investment in individual investigator awards in all regions of the state;
- Building the Texas cancer life science ecosystem across Texas by bridging discovery and translational research into early-stage company products with high impact on cancer patient care and creating economic development for the State of Texas; and
- Increasing the capacity for Texas to have a significant impact on cancer prevention and early detection, ultimately decreasing cancer incidence and mortality.

PRIORITIES WITHIN EACH OF CPRIT'S PROGRAMS

Priorities within each of CPRIT's programs – academic research, prevention, and product development research– will inform staff and respective peer review councils on the development and issuance of program-specific RFAs and evaluation of applications to those RFAs.

Established key principles essential to executing CPRIT's purpose guide each of CPRIT's three programs. The main principle underlying all three programs is that each will continue to ensure only applications with scientific merit moves forward in CPRIT's peer review grant process. In addition, each program has established unique program principles. The program priorities 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.

Academic Research Program

Background

The goal of CPRIT's academic research program is to discover new insights 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. CPRIT's strategy is to support the most creative ideas and the most meritorious projects brought forward by the cancer research community in Texas. The overarching principles for awarding CPRIT funds will continue to be scientific excellence, and impact on reducing the burden of cancer across Texas.

In addition, CPRIT's academic research program will seek to fund projects in critical, but underfunded areas of cancer research. Areas of opportunity for strategic deployment of funds include prevention and early detection research; computational oncology and analytic methods; childhood cancers; and intractable cancers with emphasis on population disparities and cancers of significance in Texas such as hepatocellular cancer.

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 and the investment in core facilities. New researchers will 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. Investments in core facilities will assure that these and other cancer researchers in Texas have access to the most up-to-date technologies needed for cutting-edge cancer research. 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
- Increasing the life sciences infrastructure in all regions of the state
- Reducing cancer disparities

Academic Research Program Priorities
• Recruitment of outstanding cancer researchers to Texas • Investment in core facilities • A broad range of innovative, investigator-initiated research projects • Implementation research to accelerate adoption and deployment of evidence-based prevention, early detection, risk assessment and interventions • Computational oncology and analytic methods • Childhood and adolescent cancers • Hepatocellular cancer • Expand access to innovative clinical trials

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:

- Offer effective prevention interventions based on the existing body of knowledge about and evidence for cancer prevention ("evidence based"); and
- Deliver primary, secondary, or tertiary (includes survivor care) prevention interventions that provide 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 in all regions of the state to populations with obstacles to cancer prevention, detection, diagnostic testing, treatment, and survivorship services and serving the populations in most need including underinsured and uninsured individuals and those disproportionately affected by cancer.

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

- Potential for impact;

- Geographic distribution;
- Cancer type; and
- 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.

The prevention program reviews data on cancer incidence, mortality, and disparities (geographic, ethnic, etc.) 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 Program Priorities
• Populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence • Geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence • Populations with obstacles to cancer prevention, detection, diagnostic testing, treatment, and survivorship services • Program assessment to identify best practices, use as a quality improvement tool, and guide future program direction

Product Development Research Program

Background

The Product Development Research Program funds the commercial development of novel products in Texas that address unmet cancer diagnosis and treatment needs. CPRIT supports early stage and startup companies that are converting a one-time phenomenon discovered in a laboratory into a safe, reliable, and reproduceable product usable in a clinical setting. CPRIT invests in projects based on comprehensive scientific research developed at companies with strong management and sound business plans that will attract future private investment. These product development investments also stimulate the Texas life sciences ecosystem.

Developing novel cancer treatments, diagnostics, and devices results from a series of research and development activities. As a product moves through the development process, the risk of

failure decreases as the product successful navigates each step. Clinical research confirms the safety and efficacy of the new therapy on the target patient population.

Companies working with products that are at an earlier development stage (preclinical, Phase I and Phase II clinical trials) are a higher investment risk and have a harder time attracting private capital. CPRIT invests in these early stage companies where private capital is hardest to obtain, typically referred to as the technology "valley of death," where promising ideas die for lack of funding. Subject matter experts review company proposals to identify the most promising projects. CPRIT's investment in early stage companies increases the number of cancer therapies in development in Texas, which stimulates the Texas life sciences ecosystem.

CPRIT uses its limited resources to maximize clinical benefits, including curing disease, slowing cancer progression, detecting malignancies earlier, mitigating side effects, and/or reducing cost of care. More scientifically and commercially attractive product development opportunities exist than CPRIT can fund.

Established Principles

To invest strategically the Product Development Research Program focuses on the funding novel projects, including those that:

- Offer therapeutic or diagnostic benefits not currently available; i.e., disruptive technologies;
- Address large or challenging unmet medical needs;
- Support early stage projects with sound scientific research, strong management and compelling business plans when private capital is most difficult to obtain.

CPRIT's Product Development Research Program also catalyzes the Texas life science ecosystem by:

- Supporting new company startups in Texas and attracting promising companies to Texas;
- Identifying companies that will recruit staff with life science industry expertise; especially experienced C-level staff to seed clusters of life science expertise at various Texas locations;
- Commercializing technologies developed at Texas institutions; and
- Promoting company formation.

Product Development Research Program Priorities
• Funding novel projects that offer therapeutic or diagnostic benefits; i.e., disruptive technologies • Funding projects addressing large or challenging unmet medical needs • Investing in early stage projects when private capital is least available • Stimulating commercialization of technologies developed at Texas research entities • Supporting new company formation in Texas or attracting promising companies to Texas that will recruit staff with life science expertise, especially C-level executives • Providing appropriate return on Texas taxpayer investment

PRIORITIES ACROSS CPRIT'S THREE PROGRAMS

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

CPRIT's structure, which includes programs in academic research, prevention, and product development research, 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 may have an impact distinguishing it from other funding sources provides a basis for focusing resources and guiding decisions for limited resources. 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, the ability of cancer cells to develop resistance to chemotherapy, radiation, and even targeted therapy has thwarted attempts to control cancer by these treatment modalities. Detecting cancer early in its development is a more desirable approach to cancer control. Despite 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, academic research will create the evidence base for novel approaches to prevention and early detection. Product development research will provide new methods, diagnostics, imaging, or devices, for early cancer detection. The prevention program will implement interventions to put these innovative approaches into practice once a solid evidence base of effectiveness exists.

Strategies include each program issuing either a targeted RFA or listing prevention or 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. Funds for research and development are needed between the stages of discovery science, which is funded traditionally by grants from federal sources and foundations, and late term development and commercialization of drugs, devices, diagnostic tests, and biologicals, which is funded often by private sector industries. Data indicate that 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 innovative technologies for early detection and 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 across Texas.

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 that educate pre- and post-doctoral fellows 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 takes time, the process generates jobs and economic activity. 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

This table illustrates how each of CPRIT's three programs may implement the recommended areas of emphasis outlined above.

	Prevention and Early Detection Initiatives	Early Translational Research	Enhance Texas' Research Capacity and Life Science Infrastructure
Academic Research Program Implementation	Create the evidence base for novel approaches to risk assessment, prevention, early detection and interventions that could translate into implementation prevention research.	Fund the continuum of cancer research - population, basic, translational, and clinical research - that could develop new discoveries into practical advances	Increase the cancer research infrastructure across Texas by investing in researcher recruitment, training grants and core facilities.
Prevention Program Implementation	Implement programs that place innovative, evidence-based approaches into practice and continue to fund effective approaches	Harness emerging technologies that expedite the development of early cancer detection, risk assessment, and interception to implement novel prevention services	Implementing systems change, developing partnerships and collaborations, training of community and healthcare providers, and creating new jobs.
Product Development Research Program Implementation	Fund new technologies and methods for early cancer detection and prevention.	Fund early-stage companies that are bridging the gap between basic research and product development.	Grow the life sciences industry and infrastructure in Texas while creating new employment opportunities.

November 2022 Oversight Committee
Internal Audit Status Report
As of October 31, 2022

Weaver and Tidwell, LLP (Weaver) is the outsourced internal auditor of the Cancer Prevention Research Institute of Texas (CPRIT). The Weaver engagement team is led by Daniel Graves, Partner.

2022 Internal Audit Plan and Schedule

Based on the approved 2022 Internal Audit Plan by the Oversight Committee, we have completed the internal audits and follow-up procedures for the 2022 Internal Audit Plan.

2022 INTERNAL AUDITS		
Internal Audit	**Description**	**Status**
IT General Computer Controls Remediation Assistance	The advisory audit was planned to provide CPRIT assistance in designing control procedures and templates to implement in order to remediate the findings identified in the FY 2021 IT General Computer Controls Internal Audit. We have assisted CPRIT in updating all 25 separate policies and consolidating them into one global IT policy. The 25 revised policies have been reviewed with the IT Governance Committee, and the final global IT policy is in their review. We provided templates for CPRIT IT to use in documentation of their performance of controls and procedures. A template for a Statement of IT Integrity has also been provided to CPRIT IT to facilitate their self-assessment and reporting of compliance with IT policies and procedures to CPRIT management every six months.	Complete
Vendor Contract Compliance	Internal Audit evaluated the risk of significant vendor contracts in place at CPRIT. The audit received a rating of **Strong**, with 2 **Low** risk findings. Audit follow-up procedures will be performed in fiscal year 2023.	Complete
Records Management – Grantee Compliance Records Advisory Audit	Internal Audit will provide audit advisory services to evaluate the grantee compliance record migration from a third-party designed system to the integrated CPRIT system. Consulting services will include the validation of the system configuration, verification of the completeness of the data migration and testing the accuracy of data classification and mapping.	Cancelled

Procurement	Internal Audit will validate CPRIT's compliance with the requirements for procurements specified in the State of Texas Procurement and Contract Management Guide.	Rescheduled for FY 2023

2022 INTERNAL AUDIT FOLLOW-UPS		
Information Technology General Computer Controls and Information Security Follow-Up	Internal Audit will perform possible follow-up procedures on the findings from the 2021 internal audit to ensure corrective action has been taken.	Cancelled
Communications Follow-Up • 1 High Finding • 2 Moderate Findings	Internal Audit completed follow-up procedures on the findings from the 2021 internal audit to ensure corrective action has been taken. Both Moderate findings were remediated, and the High finding remains partially remediated. Additional follow-up procedures will be performed in FY 2023.	Complete
Governance Follow-up • 1 Moderate Finding	Internal Audit completed follow-up procedures on the findings from the 2021 internal audit to ensure corrective action has been taken. The one, Moderate finding was remediated.	Complete
Disaster Recovery and Business Continuity Planning Advisory Follow-up • 5 recommendations	Internal Audit completed follow-up procedures on the remaining open recommendations from the 2021 audit advisory work. All 5 recommendations remain partially remediated. Additional follow-up procedures will be performed in FY 2023.	Complete

We have prepared a summary schedule of audits, their status and a summary of the findings by risk rating. The schedule maps out the internal audit and follow-up procedures performed, by year, the report date, report rating, and the findings by risk rating. The summary schedule is attached.

We also prepared the FY 2022 Annual Internal Audit Report, as required by the Texas Internal Audit Act. Once approved by the Oversight Committee, the audit plan will be submitted to the State Auditor's Office, LBB, and Governor's Office.

Daniel Graves, CPA, Internal Auditor
Partner
Weaver and Tidwell L.L.P.

Cancer Prevention and Research Institute of Texas
Schedule of Audits, Status, and Findings Summary
As of October 31, 2022

					Open Findings				Closed Findings				Total Findings			
Audit	**Fiscal Year**	**Status/Timing**	**Report Date**	**Report Rating**	**High**	**Mod**	**Low**	**Total**	**High**	**Mod**	**Low**	**Total**	**High**	**Mod**	**Low**	**Total**
Fiscal Year 2017																
2016 Information Security Follow-Up	2017	Complete	May 30, 2017													
Fiscal Year 2017 Subtotal					**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Fiscal Year 2018																
Communications Internal Audit	2018	Complete	April 30, 2018	Satisfactory	1	4	-	5	-	-	-	-	1	4	-	5
2016 Information Security Follow-Up	2018	Complete	July 17, 2018													
Fiscal Year 2018 Subtotal					**1**	**4**	**-**	**5**	**-**	**-**	**-**	**-**	**1**	**4**	**-**	**5**
Fiscal Year 2019																
2016 Information Security Follow-Up	2019	Cancelled	N/A													
2018 Communications Follow-Up	2019	Complete	August 30, 2019	Satisfactory	1	4	-	5	-	2	-	2	1	2	-	3
Fiscal Year 2019 Subtotal					**1**	**4**	**-**	**5**	**-**	**2**	**-**	**2**	**1**	**2**	**-**	**3**
Fiscal Year 2020																
Governance	2020	Complete	October 30, 2020	Strong	-	1	-	1	-	-	-	-	-	1	-	1
2016 Information Security Follow-Up	2020	Complete	N/A													
2018 Communications Follow-Up	2020	Complete	N/A	N/A	1	4	-	5	-	2	-	2	1	2	-	3
Fiscal Year 2020 Subtotal					**1**	**5**	**-**	**6**	**-**	**2**	**-**	**2**	**1**	**3**	**-**	**4**
Fiscal Year 2021																
Sunset Self-Assessment Advisory	2021	Cancelled	N/A	N/A	-	-	-	-	-	-	-	-	-	-	-	-
Information Technology General Computer Controls	2021	Complete	September 24, 2022													
Grantee Compliance Records Management	2021	Rescheduled	FY 2022	N/A	-	-	-	-	-	-	-	-	-	-	-	-
2016 Information Security Follow-Up	2021	Rescheduled	FY 2022													
2018 Communications Follow-Up	2021	Rescheduled	FY 2022	N/A	1	4	-	5	-	2	-	2	1	2	-	3
2020 Governance Follow-up	2021	Rescheduled	FY 2022	Strong	-	1	-	1	-	-	-	-	-	-	-	1
2020 Disaster Recovery and Business Continuity Follow-up	2021	Complete	September 28, 2021	N/A	-	-	-	30	-	-	-	25	-	-	-	5
Fiscal Year 2021 Subtotal					**1**	**5**	**-**	**36**	**-**	**2**	**-**	**27**	**1**	**2**	**-**	**9**
Fiscal Year 2022																
Vendor Contract Compliance	2022	Complete	October 25, 2022	Strong	-	-	2	2	-	-	-	-	-	-	2	2
Information Technology General Computer Controls	2021	Cancelled	NA													
2016 Information Security Follow-Up	2021	Cancelled	NA													
2018 Communications Follow-Up	2021	Rescheduled	October 28, 2022	Satisfactory	1	4	-	5	-	4	-	4	1	-	-	1
2020 Governance Follow-up	2021	Rescheduled	October 28, 2022	Strong	-	1	-	1		1	-	1	-	-	-	-
2020 Disaster Recovery and Business Continuity Follow-up	2021	Rescheduled	October 28, 2022	Satisfactory	-	-	-	30	-	-	-	25	-	-	-	5
Fiscal Year 202 Subtotal					**1**	**5**	**2**	**38**	**-**	**5**	**-**	**30**	**1**	**-**	**2**	**8**

Open Items Summary																	
Audit	**Fiscal Year**	**Status/Timing**	**Report Date**	**Report Rating**	**Findings**				**Closed Findings**				**Total Open Findings**				**Timing of Follow-Up Procedures by IA**
					High	**Mod**	**Low**	**Total**	**High**	**Mod**	**Low**	**Total**	**High**	**Mod**	**Low**	**Total**	
Vendor Contract Compliance	2022	Complete	October 25, 2022	Strong	-	-	2	2	-	-	-	-	-	-	2	2	**FY 2023**
Information Technology General Computer Controls	2021	September 2021	September 24, 2022														
2020 Governance	2020	July 2020	October 28, 2022	Strong	-	1	-	1	-	1	-	1	-	-	-	-	
2016 Information Security Follow-Up	2020	August 2020	October 28, 2022														
2018 Communications Follow-Up	2020	November 2020	October 28, 2022	Satisfactory	1	4	-	5	-	4	-	4	1	-	-	1	**FY 2023**
2020 Disaster Recovery and Business Continuity Follow-up	2020	September 2021	September 28, 2021	Satisfactory	-	-	-	30	-	-	-	25	-	-	-	5	**FY 2023**
Total Findings For Internal Audit Follow-Up					**1**	**5**	**-**	**36**	**-**	**5**	**-**	**30**	**1**	**-**	**2**	**8**	

NOTE: The 2020 Disaster Recovery and Business Continuity findings are recommendations for improvement of the DR/BCP documentation. Therefore, they do not have a risk rating associated with them.

Cancer Prevention & Research Institute of Texas

IA #2022-01 Internal Audit Report over Vendor Contract Compliance
Report Date: October 25, 2022
Issued: October 31, 2022

weaver
Assurance • Tax • Advisory

CONTENTS

The Oversight Committee
Cancer Prevention & Research Institute of Texas
1701 North Congress Avenue, Suite 6-127
Austin, Texas 78701

This report presents the results of the internal audit procedures performed for the Cancer Prevention and Research Institute of Texas (CPRIT) during the period August 16, 2022, through October 24, 2022 relating to the vendor contract compliance processes.

The objective of the internal audit was to determine compliance with the terms and conditions of their contract for key vendors of CPRIT. We reviewed the performance of the vendors who have contracts with CPRIT for services that are key to CPRIT's core operations for compliance with key terms and conditions in their respective contract.

To accomplish the objective, we conducted interviews and walkthroughs with key personnel involved in the vendor contract compliance processes to gain an understanding of the key contracts and the compliance provisions within each contract. Our coverage period was from January 1, 2021 through June 30, 2022.

The following report summarizes the findings identified, risks to the organization, recommendations for improvement and management's responses.

Weaver and Tidwell, L.L.P.

WEAVER AND TIDWELL, L.L.P.

Austin, Texas
October 25, 2022

Cancer Prevention & Research Institute of Texas

IA #2022-01 Internal Audit Report over Vendor Contract Compliance
October 25, 2022
Issued: October 31, 2022

Background

CPRIT is the state agency established to create and expedite innovation in academic and product development cancer research, and to enhance access to evidence-based innovation prevention programs throughout the state. As a state agency, CPRIT must periodically report on the agency's operational and financial activities to the Governor, Texas Legislature, and other state oversight agencies.

To accomplish its mission to award cancer prevention and research grants, CPRIT depends on vendors to provide services which augment the agency's staff resources and capabilities to execute core operational functions and activities.

General Dynamics Information Technology (GDIT), Business and Financial Management Solutions (BFS), Baker Botts LLP (BB), Norton Rose Fulbright US LLP (NRF), and ICON Clinical Research Limited (ICON) are five of the primary vendors providing grant management support and professional services to CPRIT. GDIT is CPRIT's primary provider of grant management support services. While GDIT has provided pre-award and post-award grant management-related services to CPRIT for several years, GDIT recently won the contract rebid that went into effect on September 1, 2021. As part of the contract, GDIT provides the online grant application receipt system and peer review evaluation system to process all CPRIT applications as well as the online post-award grant management system to manage the submission and review of required reports from grantees. Additionally, GDIT manages the peer review panel meetings and provides scientific expertise to review academic research grant program reports.

Business and Financial Management Solutions (BFS) provides peer review monitoring services to CPRIT. These services fulfill CPRIT's requirement that a neutral party observe meetings of the peer review panels when peer reviewers discuss applications and report to the Chief Compliance Officer regarding issues, if any, that are inconsistent with CPRIT's requirements. (See T.A.C. 703.6(g)(3)) BFS's most recent contract with CPRIT started on September 1, 2020, and is currently in the second annual renewal option. BFS observes every prevention review panel, product development research review panel, and academic research review panel meeting for CPRIT. After the meetings occur, BFS provides reports about the conduct of each meeting to CPRIT.

ICON Clinical Research Limited (ICON) provides due diligence review services to CPRIT. ICON's contract was active from September 1, 2018, through August 31, 2022, when the third and final contract renewal ended. In the last year of the contract, ICON provided CPRIT with due diligence evaluation reports of approximately 17 early stage companies that submitted product development research grant applications.

Baker Botts LLP (BB) and Norton Rose Fulbright US LLP (NRF) provide outside counsel services to CPRIT. The most recent contracts for BB and NRF began on September 1, 2021. Both law firms provide intellectual property due diligence reports that cover the strengths and weaknesses of a product development research grant applicant's intellectual property strategy and intellectual property estate including patent applications and related patents. The Product Development Review Council considers these reports before making their final recommendations for product development research awards.

Cancer Prevention & Research Institute of Texas

IA #2022-01 Internal Audit Report over Vendor Contract Compliance
October 25, 2022
Issued: October 31, 2022

Audit Objective and Scope

The audit focused on vendor compliance with contract terms and conditions. We reviewed the performance of the vendors who have contracts with CPRIT for services that are key to CPRIT's core operations for compliance with key terms and conditions in their respective contract. Vendors with key contracts include the following:

- General Dynamics Information Technology (GDIT)
- ICON Clinical Research Limited (ICON)
- Norton Rose Fulbright US LLP(NRF)
- Baker Botts LLP (BB)
- Business and Financial Management Solutions (BFS)

The objective of the internal audit was to determine the compliance with the terms and conditions of their contract for key vendors of CPRIT.

Our procedures included interviewing key personnel involved in the vendor contract compliance processes to gain an understanding of the key contracts and the compliance provisions within each contract. Our coverage period was from January 1, 2021 through June 30, 2022.

Executive Summary

Through our interviews, evaluation of internal control design and testing of transactions, we identified two findings. The listing of findings include those items that have been identified and are considered to be non-compliance issues with the terms and conditions in the vendors contract with the Cancer Prevention & Research Institute of Texas. These issues could have significant financial or operational implications.

A summary of our results, by audit objective, is provided in the table below. *See the Appendix for an overview of the Assessment and Risk Ratings*.

OVERALL ASSESSMENT	Strong

SCOPE AREA	RESULT	RATING
Objective: Determine compliance with the terms and conditions of their contract for key vendors of CPRIT.	We identified 43 contract deliverables in the Vendor Contract Compliance process. However, there are opportunities to strengthen the processes and control environment including: • Develop a process to ensure that all contract deliverables are received • Develop a process to periodically review and update vendor contracts for any changes in deliverables	**Strong**

Conclusion

Based on our evaluation, the vendors who have contracts with CPRIT to provide key services as part of CPRIT's operations are in compliance with the terms and conditions of their contract. We identified some instances of non-compliance with specific items in the contract. However, these instances were inconsequential to the service provided to CPRIT and did not impact CPRIT operations. Several of the instances of non-compliance were delays in delivering information to CPRIT and were known and authorized by agency personnel.

Additionally, CPRIT has designed processes such that delays in receiving information from vendors will not slow agency processes or delay agency actions for key processes, such as the grant award process.

Opportunities to strengthen vendor compliance processes include implementing a process to verify that CPRIT receives all deliverables from vendors that are included within CPRIT contracts, and periodically review contracts to ensure that the deliverables included in contract terms and conditions are appropriate.

Follow-up procedures will be performed in Fiscal Year 2023 to evaluate the completion of remediation efforts to address the findings identified.

Detailed Procedures Performed, Findings, Recommendations and Management Response

Cancer Prevention & Research Institute of Texas

IA #2022-01 Internal Audit Report over Vendor Contract Compliance
October 25, 2022
Issued: October 31, 2022

Detailed Procedures Performed, Findings, Recommendations and Management Response

Our procedures included interviewing key personnel involved in the vendor contract compliance processes to gain an understanding of the key contracts and the compliance provisions within each contract.

Objective: Design of and Effectiveness of Vendor Contract Compliance

Determine the compliance with the terms and conditions of their contract for key vendors of CPRIT.

1. **Procedures Performed:** We reviewed the five key vendor contracts in our scope and identified the key terms and conditions in their contract that included deliverables and objective performance measurements. We confirmed with CPRIT management that the identified deliverables and performance measures were appropriate.

   Results: We determined that 43 deliverables were testable, see table below.

Contract	Deliverable Coverage	Findings / Observations
General Dynamics Information Technology (GDIT)	19	
Business and Financial Management Solutions (BFS)	3	**Finding 1**
Baker Botts LLP(BB)	2	
Norton Rose Fulbright US LLP (NRF)	1	
ICON Clinical Research Limited	18	**Finding 2**
Total:	**43**	**2**

For the selected vendors, we selected a sample of deliverables for testing to verify that CPRIT received the deliverable.

General Dynamics Information Technology

Procedures Performed: We obtained and reviewed the current contract with GDIT and identified 19 deliverables. We selected the following samples and verified the following deliverables:

- For the selected months of January 2021, December 2021, and January 2022, we verified:
  - Help desk access was available from 8:00 am to 6:00 pm,
  - Help desk requests submission history reports are indefinitely maintained
- We reviewed the user access logs for the period of May 31, 2022 through August 31, 2022 and verified that all users that accessed the help desk system were approved employees.
- For the 15 out of 162 total help desk tickets submitted by CPRIT personnel during our coverage period, we verified that communication occurred with the requester if more than one day was needed to fulfill the help desk request.

- For the 10 selected Requests for Applications (RFA) out of 41 total RFA's, we tested that GDIT:
    - Provided administrative support including editing of RFA release that does not alter the intent of any RFA,
    - Conducted administrative reviews of each group of grant application submissions for compliance with the requirements of the RFA,
    - Provided training to peer reviewers to use the online application review information technology platform appropriately to submit non-disclosure agreements as well as to document conflicts of interest and to record critiques and scores for each grant application.
    - Arranged logistics for all CPRIT peer review panel and Review Council meetings for each program, including collecting conflict of interest (COI) statements, and providing meeting summaries.
    - Completed category sections one through five of the Application Pedigree form verifying compliance with steps in the pre-award grants management process and sent the completed pedigree documents to the designated CPRIT staff a minimum of 15 business days prior to a PIC meeting.
    - Delivered to CPRIT the grant applications, summary statements and score reports for each grant proposal to be discussed at a Review Council meeting a minimum of 10 calendar days prior to a scheduled Review Council meeting.
- For all patient reviewer applicants, we verified that the applicant was notified of approval or denial timely.
- We obtained the Service Organization Control 2 (SOC) reports for fiscal year 2021 and fiscal year 2022 and verified that CPRIT's data is stored in the continental United States and the SOC 2 reports are maintained.
- We requested a listing of all transfer dates for the data maintained in the Post-award grants management database in a Microsoft SQL server for January 1, 2021 through June 30, 2022 and verified there was a daily data transfer occurred.
- For January 2021, December 2021 and June 2022, and verified security access control processes and logged data was maintained.
- We requested the third quarter 2021 and first quarter 2022 quarterly executive summary reports of CPRIT's overall data inventory to ensure the reporting occurred.
- We verified that all system updated ERD's and data dictionaries were provided to CPRIT.
- We verified that GDIT could provide a WCAG 2.0 compliance statement.

Results: No findings identified.

Business and Financial Management Services

Procedures Performed: We obtained the BFS contract and identified three deliverables for testing. We selected a sample of 10 out of the 50 peer review meeting reports and verified:

- By the seventh business day after each peer review panel meeting, a written report that documents the results of the observations and the procedures was provided,
- A copy of the report is provided electronically to the Chief Compliance Officer (CCO) to address compliance issues, and

- The report documents all required information:
  - Report Title
  - Name of Panel Observed
  - Date of Panel Meeting
  - Date of Report
  - Explanation of the purpose of the report
  - Scope and objectives of the third-party peer review monitoring
  - Explanation of the purpose of the panel meeting, including the name of panel chair and the meeting method
  - Summary of the observations made during the meeting

Results: Finding identified. BFS complied with most of contract deliverable requirements. BFS provided CPRIT's CCO electronic versions of the reports and the reports contained the required information.

Finding 1 – Low – Peer Review Panel Meeting Reports
While BFS completed and submitted reports for every peer review panel meeting that occurred, CPRIT did not always receive the peer review panel meeting reports within seven business days of the conclusion of a meeting, the timeframe required in the contract. For four out of the 10 meeting samples that we selected for testing, BFS did not meet the seven-business day requirement. Of the four exceptions, one was nine days late, two were two days late, and one was one day late.

Recommendation: CPRIT should develop a process to ensure that BFS complies with the contract requirement to provide the peer review panel meeting reports within seven business days, as contractually required, or review and amend the contract if this requirement is no longer necessary.

Management Response: Management agrees with the finding and accepts the risk of the minor delays in the deliverables by BFS. The delays in providing the summary reports by BFS are not a significant concern, and it does not delay the process of considering grants for award. BFS and CPRIT often communicate during the reporting time frame.

Baker Botts LLP

Procedures Performed: We obtained the Baker Botts LLP contract and identified two deliverables for testing. We tested all six intellectual due diligence reports performed and verified that the review included the grant applicant's intellectual property strategy, patent applications and related patents and, as appropriate, advising on the strengths and weakness of such strategy and submissions.

We verified that outside council submitted a written disclosure statement identifying every matter in which the firm represents, or has represented, within the past calendar year, any entity or individual in any litigation matter in which the entity or individual is directly adverse to the State of Texas or any of its boards, agencies, commissions, universities, or elected or appointed state agency officials in connection with their official job duties and responsibilities.

Results: No findings identified. 9-13

Norton Rose Fulbright US LLP

1. **Procedures Performed:** We obtained the Norton Rose Fulbright contract and identified one deliverable for testing. We tested all four intellectual due diligence reports performed during our coverage period, and verified that the review included the grant applicant's intellectual property strategy, patent applications and related patents and, as appropriate, advising on the strengths and weakness of such strategy and submissions.

   Results: No findings identified.

ICON Clinical Research Limited

1. **Procedures Performed:** We obtained and reviewed the current contract with ICON and identified 18 deliverables. We selected all eleven applications for the 22.2 testing cycle and verified the following:
   - Questions were provided for the selected applications to be addressed at an in-person presentation to the peer review panel should an applicant be invited to present
   - Conferences are held with applicants, ICON, and CPRIT to discuss outstanding issues and to discuss any clarifications of applicant responses
   - Draft Due Diligence Report was provided to CPRIT and the applicant within 30 business days following the application receipt
   - Final Due Diligence Report was provided to CPRIT and the applicant within five business days of receiving the applicant's responses to questions.
   - Draft and final due diligence reports contained the correct information, which includes:
     - Executive summary (1-2 pages) describing due diligence analysis conducted.
     - Detailed review and evaluation of the applicant's product development plan,
     - Numerical score summarizing ICON's judgement regarding how the application ranks relative to similar applications for each subject area above and provide detailed information/comments explaining and supplementing the scores.
     - An assessment of whether:
       - The product is on a path to be produced/manufactured commercially
       - The work undertaken or proposed by the applicant supports advancement of the product/service/technology, and
       - Any missed steps during the application process may be omitted
     - An assessment of the applicant's ability to execute the proposal, including:
       - Business projections
       - Financial analysis
       - Risk projections, and
       - Company management experience
     - Evaluation of specific concerns described by CPRIT's peer review panel in scoring summaries/written critiques.
     - Specific recommendations to include suggestions about:
       - Regulatory path, including changes to maximize approval chances and commercial development
       - Risk reduction milestones in the milestone timeline, including any tranche funding adjustments
       - Additional organizational or personnel resources necessary to perform development tasks
     - Overall evaluation provided a numbered list of key strengths and weaknesses

- An appendix containing the applicant's response to the draft report and a summary of the discussions held with the applicant. This appendix is only included on the Final Due Diligence Report
- An appendix describing whether the applicant has provided as satisfactory response to all questions/concerns brought by CPRIT's Peer Review Panel. This appendix is only included in the Final Due Diligence Report
- List sources of information used to form application recommendations. This is only included in the Final Due Diligence Report.

Results: Finding identified. ICON complied with most of the contract deliverables. Minor exceptions were identified between the deliverables ICON provided to CPRIT. CPRIT received the final due diligence reports for the selected application period. For most exceptions, there was communication between ICON and CPRIT that indicated that CPRIT accepted the differences.

Finding 2 – Low – Due Diligence Reports
While every requested due diligence report was provided to CPRIT for use in the evaluation of product development research grant applications, ICON did not provide the due diligence reports within the timeframes outlined in the terms of the contract. Additionally, the due diligence reports excluded minor requirements that, according to the contract, should have been included in the due diligence reports.

Recommendation: CPRIT should develop a process to ensure that ICON complies with the contract and providing the due diligence reports within the required contract terms or review and amend the contract if this requirement is no longer necessary.

Management Response: Management agrees with the finding. The exceptions identified are minor in nature and although the information may not have been included in the reports, it was provided by ICON in a timely manner. CPRIT is going through a re-bid and contracting phase for this contract, as part of the normal contracting cycle and we will include the considerations for modifying the terms and conditions in the contract to remove items that are required deliverables, and adjust timelines, as necessary.

Responsible Party: Chief Product Development Officer
Implementation Date: January 31, 2023

Appendix

Cancer Prevention & Research Institute of Texas

IA #2022-01 Internal Audit Report over Vendor Contract Compliance
October 25, 2022
Issued: October 31, 2022

The appendix defines the approach and classifications utilized by Internal Audit to assess the residual risk of the area under review, the priority of the findings identified, and the overall assessment of the procedures performed.

Report Ratings

The report rating encompasses the entire scope of the engagement and expresses the aggregate impact of the exceptions identified during our test work on one or more of the following objectives:

- Operating or program objectives and goals conform with those of the agency
- Agency objectives and goals are being met
- The activity under review is functioning in a manner which ensures:
    - Reliability and integrity of financial and operational information
    - Effectiveness and efficiency of operations and programs
    - Safeguarding of assets
    - Compliance with laws, regulations, policies, procedures and contracts

The following ratings are used to articulate the overall magnitude of the impact on the established criteria:

Strong	The area under review meets the expected level. No high risk rated findings and only a few moderate or low findings were identified.
Satisfactory	The area under review does not consistently meet the expected level. Several findings were identified and require routine efforts to correct, but do not significantly impair the control environment.
Unsatisfactory	The area under review is weak and frequently falls below expected levels. Numerous findings were identified that require substantial effort to correct.

Cancer Prevention & Research Institute of Texas

IA #2022-01 Internal Audit Report over Vendor Contract Compliance
October 25, 2022
Issued: October 31, 2022

Risk Ratings

Residual risk is the risk derived from the environment after considering the mitigating effect of internal controls. The area under audit has been assessed from a residual risk level utilizing the following risk management classification system.

High

High risk findings have qualitative factors that include, but are not limited to:

- Events that threaten the agency's achievement of strategic objectives or continued existence
- Impact of the finding could be felt outside of the agency or beyond a single function or department
- Potential material impact to operations or the agency's finances
- Remediation requires significant involvement from senior agency management

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Moderate

Moderate risk findings have qualitative factors that include, but are not limited to:

- Events that could threaten financial or operational objectives of the agency
- Impact could be felt outside of the agency or across more than one function of the agency
- Noticeable and possibly material impact to the operations or finances of the agency
- Remediation efforts that will require the direct involvement of functional leader(s)
- May require senior agency management to be updated

Low

Low risk findings have qualitative factors that include, but are not limited to:

- Events that do not directly threaten the agency's strategic priorities
- Impact is limited to a single function within the agency
- Minimal financial or operational impact to the agency
- Require functional leader(s) to be kept updated, or have other controls that help to mitigate the related risk

Cancer Prevention and Research Institute of Texas

IA #2022-02 Internal Audit Follow-Up Procedures Report over Communications

Report Date: October 28, 2022

Issued: October 31, 2022

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CONTENTS

The Oversight Committee
Cancer Prevention and Research Institute of Texas
1701 North Congress Avenue, Suite 6-127
Austin, Texas 78701

This report presents the results of the internal audit follow-up procedures performed for the Cancer Prevention and Research Institute of Texas (CPRIT) during the period October 24, 2022 through October 28, 2022 related to the findings from the Internal Audit Report over Communications dated April 30, 2018.

The objective of these follow-up procedures was to validate that adequate corrective action has been taken to mediate the issues identified in the 2018 Internal Audit Report over Communications.

To accomplish this objective, we conducted interviews with CPRIT personnel responsible for the communication process. We also reviewed documentation and performed specific testing procedures to validate actions taken. Procedures were performed remotely, and completed on October 28, 2022.

The following report summarizes the findings identified, risks to the organization, recommendations for improvement and management's responses.

Weaver and Tidwell, L.L.P.

WEAVER AND TIDWELL, L.L.P.

Austin, Texas
October 28, 2022

Weaver and Tidwell, L.L.P.
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CPAs AND ADVISORS | WEAVER.COM

Cancer Prevention and Research Institute of Texas

IA #2022-02 Internal Audit Follow-Up Procedures Report over Communications
October 28, 2022
Issued: October 31, 2022

Background

In fiscal year 2018, an internal audit over CPRIT's communication process was completed. The internal audit report identified five areas of improvement within the communication process. Opportunities for improvement included documenting the timeliness and approval requirements of website content updates, the review and approval of social media posts, and ensuring Momentum (formerly Achievement) Reports are accurate and approved timely. The report also identified areas of improvement related to ensuring compliance with state website requirements and maintaining appropriate user access to MailChimp software. The 2019 Internal Audit Plan included performing follow-up procedures to validate that CPRIT management has taken steps to address the five internal audit findings. The 2019 follow-up results showed that two out of the five findings were remediated.

The 2022 Internal Audit Plan included performing follow-up procedures to validate that CPRIT management has taken steps to address the remaining three internal audit findings.

Follow-Up Objective and Scope

The follow-up procedures focused on the remediation efforts taken by CPRIT management to address the remaining three findings included in the 2018 Internal Audit Report over Communications, and to validate that appropriate corrective action had been taken.

We evaluated the corrective action for the three remaining internal audit findings identified in the 2018 Internal Audit Report over Communications.

Executive Summary

The findings from the 2018 Internal Audit Report over Communications include those items that were identified and are considered to be non-compliance issues with CPRIT's policies and procedures, rules and regulations required by law, or where there is a lack of procedures or internal controls in place to cover risks to CPRIT. These issues could have significant financial or operational implications.

Through our interviews, review of documentation, observations and testing, we determined that of the three remaining findings where corrective action was evaluated, two were fully remediated while one was partially remediated.

A summary of our results is provided in the table below.

Risk Rating	Total Findings	Previously Remediated	Remediated	Partially Remediated
High	1	-	-	1
Moderate	4	2	2	-
Low	-	-	-	-
Total	**5**	**2**	**2**	**1**

Cancer Prevention and Research Institute of Texas
IA #2022-02 Internal Audit Follow-Up Procedures Report over Communications
October 28, 2022
Issued: October 31, 2022

A summary of our results is provided in the table below. *See the Appendix for an overview of the Assessment and Risk Ratings*.

OVERALL ASSESSMENT	Satisfactory

SCOPE AREA	RESULT	RATING
Communications: Validate that adequate corrective action has been taken to remediate the issues identified in the 2018 Internal Audit Report over Communications.	We determined that CPRIT management made efforts to remediate the findings from the 2018 Internal Audit Report over Communications. However, management should continue their efforts to remediate the remaining open findings: • Ensure compliance with state website requirements	Satisfactory

Conclusion

Based on our evaluation, CPRIT has made satisfactory progress to remediate the findings from the 2018 Internal Audit Report over Communications. However, additional efforts should be made to remediate the remaining open findings. Specifically, CPRIT should ensure that the agency's website is in compliance with all state requirements.

Follow-up procedures should be conducted in Fiscal Year 2023 to validate the effectiveness of the remediation efforts taken to address the remaining open findings.

Detailed Follow-Up Results, Findings, Recommendations and Management Response

Detailed Follow-Up Results, Recommendations and Management Response

Our procedures included interviewing key CPRIT personnel responsible for the communication process to gain an understanding of the corrective actions taken in order to address the open findings identified in the 2018 Internal Audit Report over Communications, as well as examining existing documentation and communications and performing testing in order to validate those corrective actions. We evaluated the existing policies, procedures, and processes in their current state.

Finding 1 – Moderate – Website Content Updates: While CPRIT utilizes a ticketing system to track and monitor updates to website content, the protocols and workflow lack definition to include the required review of postings and the timing of the completion of the updates.

The existing workflow does not have criteria identified to define which updates to website content require a review by communications prior to posting or procedures to document the review and approval of website content updates. Currently, website content updates are requested by CPRIT personnel via the IT ticketing system. All website updates are completed by the Information Technology Manager and the completion is documented within the ticketing system. Although the Information Specialist is notified of all tickets requesting website updates, the updates are not consistently reviewed and approved by communications prior to posting.

Additionally, the requirements to post updates in a specific timeframe are inconsistently defined. Only when individuals include a posting deadline in the update request ticket are posting deadlines established.

We reviewed 50 out of 351 website updates that were completed during the period of September 1, 2016, through February 28, 2018, and identified the following:

- 5 out of 50 sample items tested had no documentation to demonstrate that the website content updates were completed timely. Timing of completion dates recorded in the ticketing system range from 78 to 418 days after requests were submitted. Additionally, 1 of the 5 changes was not completed accurately
- 2 out of 50 sample items tested were posted 1 and 6 days after the deadline indicated in the ticket.

Results: Finding remediated

We obtained a list of all website update tickets and selected a sample of 10 out of the 82 website update tickets. We determined that CPRIT performed the requested website updates within the required timeline in accordance with CPRIT guidelines.

Finding 3 – Moderate – Accuracy and Timeliness of Momentum (formerly Achievement) Reports: Through the preparation of the Achievement Report, CPRIT has identified that the agency inconsistently meets their internally established deadlines and requirements to draft, review, approve, and publish the report. Therefore, new procedures were implemented in February 2018 to address the preparation of the report. Through the dynamic process to draft, review and edit the report, the final review and approval of Achievement Reports is not consistently documented as part of the established workflow. Additionally, information included in Achievement Reports is not consistently accurate.

9-25

According to CPRIT's recently implemented internal timeline, Achievement Reports should be completed and approved before an Oversight Committee meeting. Prior to February 2018, the internal timeline for completion and approval of Achievement Reports was one week after the Oversight Committee meeting. We selected a sample of 3 out of 6 Achievement Reports that were posted during the period of September 1, 2016, through February 28, 2018, and identified the following exceptions:

- All 3 reports were not approved prior to CPRIT's internal deadline
- 2 reports contained inaccurate information, totaling 5 errors in the reports

Results: Finding remediated

We met with CPRIT management and determined that the Momentum Report process has changed. The Oversight Committee now starts the Momentum Report process and approvals from the Executive Director and General Counsel are required prior to posting the Momentum Reports. We reviewed email approvals to determine whether the most recent Momentum Reports were reviewed and approved prior to posting. We determined that the Momentum Report was approved prior to CPRIT's requirements.

Finding 4 – HIGH – CPRIT Website Compliance: In February 2018 CPRIT's Senior Program Manager for Prevention, Staff Attorney and Information Specialist conducted an annual website review to assess compliance with applicable state requirements and identified that CPRIT is not in compliance with the following requirements:

- 1 TAC 206.54(a) - Requirement to include meta data tags on all publications
- 1 TAC 206.54(b) - Requirement to include TRAIL meta data on the homepage
- 13 TAC 3.4(2)(a) - Requirement for accessibility of publications
- 13 TAC 3.2(b) - Requirement for posting the date that each publication is produced or distributed
- 1 TAC 206.51 - Requirement for translation of the website
- 1 TAC 206.55(d) - Requirement for address of the web page with high-value data set.

CPRIT personnel identified the non-compliance prior to this audit and are actively working on addressing these issues with the ongoing implementation of the new agency website.

Results: Finding partially remediated

We obtained supporting documentation that 1 TAC 206.54(b) and 1 TAC 3.2(b) were implemented. We verified that the home page of CPRIT's website included the TRAIL metadata link. We clicked the link to ensure that the user is directed to the appropriate website. We reviewed five publications listed in the reports section and verified that the publication had a date that was either the production or distribution date included.

We also obtained CPRIT's internal review of their website compliance and identified that the steps to address the following compliance requirements are still in progress:

- 1 TAC 206.54(a) - Requirement to include meta data tags on all publications
- 13 TAC 3.4(2)(a) - Requirement for accessibility of publications
- 1 TAC 206.51 - Requirement for translation of the website
- 1 TAC 206.55(d) - Requirement for address of the web page with high-value data set.

9-26

Management Response: CPRIT management agrees that actions to complete the remediation of the compliance items should be completed. The agency has drafted procedures that will be submitted and approved in FY 2023. CPRIT also has entered into contracts with service providers to complete the implementation of changes that will address the outstanding compliance items though FY 2023.

Responsible Party: Information Resources Manager
Implementation Date: December 2022

Appendix

Cancer Prevention and Research Institute of Texas
IA #2022-02 Internal Audit Follow-Up Procedures Report
over Communications
October 28, 2022
Issued: October 31, 2022

The appendix defines the approach and classifications utilized by Internal Audit to assess the residual risk of the area under review, the priority of the findings identified, and the overall assessment of the procedures performed.

Report Ratings

The report rating encompasses the entire scope of the engagement and expresses the aggregate impact of the exceptions identified during our test work on one or more of the following objectives:

- Operating or program objectives and goals conform with those of the agency
- Agency objectives and goals are being met
- The activity under review is functioning in a manner which ensures:
    - Reliability and integrity of financial and operational information
    - Effectiveness and efficiency of operations and programs
    - Safeguarding of assets
    - Compliance with laws, regulations, policies, procedures and contracts

The following ratings are used to articulate the overall magnitude of the impact on the established criteria:

Strong	The area under review meets the expected level. No high risk rated findings and only a few moderate or low findings were identified.
Satisfactory	The area under review does not consistently meet the expected level. Several findings were identified and require routine efforts to correct, but do not significantly impair the control environment.
Unsatisfactory	The area under review is weak and frequently falls below expected levels. Numerous findings were identified that require substantial effort to correct.

The appendix defines the approach and classifications utilized by Internal Audit to assess the residual risk of the area under review, the priority of the findings identified, and the overall assessment of the procedures performed.

Cancer Prevention and Research Institute of Texas

IA #2022-02 Internal Audit Follow-Up Procedures Report
over Communications
October 28, 2022
Issued: October 31, 2022

Risk Ratings

Residual risk is the risk derived from the environment after considering the mitigating effect of internal controls. The area under audit has been assessed from a residual risk level utilizing the following risk management classification system.

High

High risk findings have qualitative factors that include, but are not limited to:

- Events that threaten the agency's achievement of strategic objectives or continued existence
- Impact of the finding could be felt outside of the agency or beyond a single function or department
- Potential material impact to operations or the agency's finances
- Remediation requires significant involvement from senior agency management

Moderate

Moderate risk findings have qualitative factors that include, but are not limited to:

- Events that could threaten financial or operational objectives of the agency
- Impact could be felt outside of the agency or across more than one function of the agency
- Noticeable and possibly material impact to the operations or finances of the agency
- Remediation efforts that will require the direct involvement of functional leader(s)
- May require senior agency management to be updated

Low

Low risk findings have qualitative factors that include, but are not limited to:

- Events that do not directly threaten the agency's strategic priorities
- Impact is limited to a single function within the agency
- Minimal financial or operational impact to the organization
- Require functional leader(s) to be kept updated, or have other controls that help to mitigate the related risk

Cancer Prevention and Research Institute of Texas

IA #2022-04 Report over Disaster Recovery and Business Continuity Planning Advisory Audit Follow-Up Procedures

Report Date: October 28, 2021

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Assurance • Tax • Advisory

CONTENTS

The Oversight Committee
Cancer Prevention and Research Institute of Texas
1701 North Congress Avenue, Suite 6-127
Austin, Texas 78701

This report presents the results of the internal audit follow-up procedures performed for the Cancer Prevention and Research Institute of Texas (CPRIT) during October 2022 relating to the recommendations for improvement from the Advisory Audit Report over Disaster Recovery and Business Continuity Planning (September 2020).

The objective of these follow-up procedures was to validate that corrective actions have been taken to remediate the recommendations identified in the 2020 Advisory Audit Report over Disaster Recovery and Business Continuity Planning (DR/BCP).

To accomplish this objective, we obtained updated disaster recovery and business continuity planning documentation from CPRIT personnel responsible for their maintenance. This documentation was reviewed to verify that the advisory audit improvement opportunities were addressed. Procedures were performed remotely and completed on October 28, 2022.

The following report summarizes the findings identified, risks to the organization, recommendations for improvement and management's responses.

Weaver and Tidwell, L.L.P.

WEAVER AND TIDWELL, L.L.P.

Austin, Texas
October 28, 2022

Cancer Prevention and Research Institute of Texas

IA #2022-04 Report over Disaster Recovery and Business Continuity Planning
Advisory Audit Follow-Up Procedures
October 28, 2022

Background

In fiscal year 2020, Weaver performed advisory audit procedures over CPRIT's disaster recovery and business continuity planning (DR/BCP) processes. The advisory audit report identified one recommendation for improvement (including reviewing proposed revisions, modifying and finalizing DR/BCP documentation) to better align procedures with criteria required by the State Office of Risk Management (SORM).

In the 2020 audit advisor report, 30 items were identified to improve and better align CPRIT's planned processes and procedures. In 2021, follow-up procedures were performed and identified 25 of the 30 items had been addressed, and the remaining five items were partially addressed.

The 2022 Internal Audit Plan included performing follow-up procedures to validate that CPRIT management has taken steps to address the five remaining advisory audit improvement opportunities.

Follow-Up Objective and Scope

The follow-up procedures focused on the remediation efforts taken by CPRIT management to address the five open recommendations included in the 2020 Disaster Recovery and Business Continuity Planning Advisory Audit Report and to validate that appropriate corrective action had been taken.

We evaluated the corrective action taken for the improvement opportunity identified in the 2020 Disaster Recovery and Business Continuity Planning Advisory Audit Report.

Executive Summary

Through our review of updated DR/BCP documentation, we determined that the five recommendations that were partially remediated as part of the fiscal year 2021 follow-up procedures remain partially remediated. Due to staffing changes within Information Technology personnel at CPRIT in the 2022 fiscal year, remediation efforts were slower than CPRIT anticipated.

A summary of our results is provided in the table below. *See the Appendix for an overview of the Assessment and Risk Ratings*.

SCOPE AREA	RESULT
DR/BCP: Validate that adequate corrective action has been taken to address improvement opportunities identified in the 2020 Disaster Recovery and Business Continuity Planning Advisory Audit Report.	We determined that CPRIT has made progress in addressing the recommendations from the 2020 Advisory Audit Report over DR/BCP. However, CPRIT should continue its efforts to address the remaining open improvement opportunities relating to disaster recovery planning.

Cancer Prevention and Research Institute of Texas

IA #2022-04 Report over Disaster Recovery and Business Continuity Planning
Advisory Audit Follow-Up Procedures
October 28, 2022

Conclusion

Based on our evaluation, CPRIT has made progress to remediate the recommendations from the 2020 Advisory Audit Report over DR/BCP. However, additional efforts should be made to address the remaining improvement opportunities. Specifically, CPRIT should ensure its Disaster Recovery plans and procedures are updated and consistent with SORM requirements.

Additionally, CPRIT should ensure regular maintenance and testing of Disaster Recovery and Business Continuity Planning and Procedures to better facilitate timely and appropriate responses in the event of a business disruption.

Follow-up procedures should be conducted in Fiscal Year 2023 to validate the implementation of the remaining remediation efforts taken to address the open items in the recommendations.

Detailed Follow-Up Results, Findings, Recommendations and Management Response

Cancer Prevention and Research Institute of Texas

IA #2022-04 Report over Disaster Recovery and Business Continuity Planning
Advisory Audit Follow-Up Procedures
October 28, 2022

Detailed Follow-Up Results, Recommendations and Management Response

Our procedures included reviewing CPRIT's current disaster recovery and business continuity planning documentation to gain an understanding of the corrective actions taken in order to address improvement opportunities identified in the 2020 Disaster Recovery and Business Continuity Planning Advisory Audit Report.

FY 2020 Recommendation – Revisions to DR/BCP documentation: Management should review proposed revisions to the DR/BC planning documentation, modify as appropriate, and finalize the DR/BC plans. Upon finalization, CPRIT should test the plans and develop and implement a strategy to review and update the documentation periodically based on changes in CPRIT's IT infrastructure or operations as well as conduct periodic testing of the plans.

Our review identified that 25 of 30 revisions recommended were completed since the 2020 Disaster Recovery and Business Continuity Planning Advisory Audit Report was issued. The remaining five recommended revisions were determined to be in progress.

DR/BC Component	Total Criteria	Open Improvement Opportunities		Partially Remediated
		Count	Type	Content Addition
Incident Evaluation	31	2	R	2
Incident Management	30	1	OA	1
Disaster Recovery	37	1	R	1
Business Resumption	23	1	R	1
Total	**121**	***5***		***5***

R – Required elements by SORM or DIR
OA – Other authoritative guidance

Results: **Recommendations are partially addressed**

Management Response: CPRIT will continue to address the open advisory audit recommendations.

Responsible Party: Chief Operating Officer, Information Resources Manager, Chief Compliance Officer, Information Security Officer, Operations Manager

Implementation Date: March 1, 2023

Cancer Prevention and Research Institute of Texas

IA #2022-03 Internal Audit Follow-Up Procedures Report Over Governance

Report Date: October 28, 2022

Issued: October 31, 2022

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The Oversight Committee
Cancer Prevention and Research Institute of Texas
1701 North Congress Avenue, Suite 6-127
Austin, Texas 78701

This report presents the results of the internal audit follow-up procedures performed for the Cancer Prevention and Research Institute of Texas (CPRIT) during the period October 24, 2022 through October 28, 2022 related to the findings from the Internal Audit Report over Governance dated October 16, 2020.

The objective of these follow-up procedures was to validate that adequate corrective action has been taken to remediate the issues identified in the 2020 Internal Audit Report over Governance.

To accomplish this objective, we conducted interviews with CPRIT personnel responsible for the governance process. We also reviewed documentation and performed specific testing procedures to validate actions taken. Procedures were performed at CPRIT's office, and completed on October 28, 2022.

The following report summarizes the findings identified, risks to the organization, recommendations for improvement and management's responses.

Weaver and Tidwell, L.L.P.

WEAVER AND TIDWELL, L.L.P.

Austin, Texas
October 28, 2022

Weaver and Tidwell, L.L.P.
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Cancer Prevention and Research Institute of Texas

IA #2022-03 Internal Audit Follow-Up Procedures Report over Governance

October 28, 2022

Issued: October 31, 2022

Background

In fiscal year 2020, an internal audit over CPRIT's governance process was completed. The internal audit report identified one area of improvement within the governance process. Opportunities for improvement included implementing procedures to review the internal controls and reports of internal controls of vendors who provide key outsourced services of the agency.

The 2022 Internal Audit Plan included performing follow-up procedures to validate that CPRIT management has taken steps to address the one internal audit finding.

Follow-Up Objective and Scope

The follow-up procedures focused on the remediation efforts taken by CPRIT management to address the finding included in the 2020 Internal Audit Report over Governance, and to validate that appropriate corrective action had been taken.

We evaluated the corrective action for the one internal audit finding identified in the 2020 Internal Audit Report over Governance.

Executive Summary

The findings from the 2020 Internal Audit Report over Governance include those items that were identified and are considered to be non-compliance issues with CPRIT's policies and procedures, rules and regulations required by law, or where there is a lack of procedures or internal controls in place to cover risks to CPRIT. These issues could have significant financial or operational implications.

Through our interviews, review of documentation, observations and testing, we determined that of the three remaining findings where corrective action was evaluated, two were fully remediated while one was partially remediated.

A summary of our results is provided in the table below.

Risk Rating	Total Open Findings	Remediated	Open
High	-	-	-
Moderate	1	1	-
Low	-	-	-
Total	**1**	**1**	**-**

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A summary of our results is provided in the table below. *See the Appendix for an overview of the Assessment and Risk Ratings*.

OVERALL ASSESSMENT	Strong

SCOPE AREA	RESULT	RATING
Communications: Validate that adequate corrective action has been taken to remediate the issues identified in the 2020 Internal Audit Report over Governance.	We determined that CPRIT management fully remediated the finding from the 2020 Internal Audit Report over Governance.	**Strong**

Conclusion

Based on our evaluation, key personnel in each of their respective program areas made efforts to remediate the finding from the 2020 Internal Audit over Governance report. The prior year finding has been remediated.

Detailed Follow-Up Results, Findings, Recommendations and Management Response

Cancer Prevention and Research Institute of Texas

IA #2022-03 Internal Audit Follow-Up Procedures Report over Governance
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Detailed Follow-Up Results, Recommendations and Management Response

Our procedures included interviewing key CPRIT personnel responsible for the governance process to gain an understanding of the corrective actions taken in order to address the open findings identified in the 2020 Internal Audit Report over Governance, as well as examining existing documentation and communications and performing testing in order to validate those corrective actions. We evaluated the existing policies, procedures, and processes in their current state.

Finding 1 – Moderate – Outsourced Service Provider Controls Review: Of the two service providers selected for testing from the 24 outsourced services providers, CPRIT did not review one of the reports to ensure that the service provider did not have any internal control weaknesses that could impact CPRIT operations. This was also identified in a prior internal audit.

Results: Finding remediated

We verified that CPRIT has implemented a process to review Service Organization Controls (SOC) reports for outsourced service providers. We reviewed the SOC review template was used to evaluate SOC reports for Okta, Box, and GDIT.

Appendix

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The appendix defines the approach and classifications utilized by Internal Audit to assess the residual risk of the area under review, the priority of the findings identified, and the overall assessment of the procedures performed.

Report Ratings

The report rating encompasses the entire scope of the engagement and expresses the aggregate impact of the exceptions identified during our test work on one or more of the following objectives:

- Operating or program objectives and goals conform with those of the agency
- Agency objectives and goals are being met
- The activity under review is functioning in a manner which ensures:
    - Reliability and integrity of financial and operational information
    - Effectiveness and efficiency of operations and programs
    - Safeguarding of assets
    - Compliance with laws, regulations, policies, procedures and contracts

The following ratings are used to articulate the overall magnitude of the impact on the established criteria:

Strong	The area under review meets the expected level. No high risk rated findings and only a few moderate or low findings were identified.
Satisfactory	The area under review does not consistently meet the expected level. Several findings were identified and require routine efforts to correct, but do not significantly impair the control environment.
Unsatisfactory	The area under review is weak and frequently falls below expected levels. Numerous findings were identified that require substantial effort to correct.

The appendix defines the approach and classifications utilized by Internal Audit to assess the residual risk of the area under review, the priority of the findings identified, and the overall assessment of the procedures performed.

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Risk Ratings

Residual risk is the risk derived from the environment after considering the mitigating effect of internal controls. The area under audit has been assessed from a residual risk level utilizing the following risk management classification system.

High

High risk findings have qualitative factors that include, but are not limited to:

- Events that threaten the agency's achievement of strategic objectives or continued existence
- Impact of the finding could be felt outside of the agency or beyond a single function or department
- Potential material impact to operations or the agency's finances
- Remediation requires significant involvement from senior agency management

Moderate

Moderate risk findings have qualitative factors that include, but are not limited to:

- Events that could threaten financial or operational objectives of the agency
- Impact could be felt outside of the agency or across more than one function of the agency
- Noticeable and possibly material impact to the operations or finances of the agency
- Remediation efforts that will require the direct involvement of functional leader(s)
- May require senior agency management to be updated

Low

Low risk findings have qualitative factors that include, but are not limited to:

- Events that do not directly threaten the agency's strategic priorities
- Impact is limited to a single function within the agency
- Minimal financial or operational impact to the organization
- Require functional leader(s) to be kept updated, or have other controls that help to mitigate the related risk

Cancer Prevention and Research Institute of Texas

Fiscal Year 2022 Annual Internal Audit Report

August 31, 2022

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Cancer Prevention and Research Institute of Texas

Fiscal Year 2022 Annual Internal Audit Report
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I. Compliance with Texas Government Code, Section 2102.015: Posting the Internal Audit Plan, Internal Audit Annual Report, and Other Audit information on Internet Web site

Texas Government Code, Section 2102.015 requires state agencies and higher education institutions, as defined in the statute, to post their Internal Audit Plan, Internal Audit Annual Report, and other audit information on the Internet.

The Cancer Prevention and Research Institute of Texas (CPRIT or the agency) will post this report which includes the Fiscal Year 2022 Internal Audit Plan on its website at www.cprit.texas.gov. CPRIT's Oversight Committee reviewed and approved the Annual Internal Audit Report as part of their regular meeting held on November 16, 2022. In accordance with Texas Government Code, Section 2102.015, CPRIT will post this report on its website within 30 days of the Oversight Committee's approval.

The table in Section II below provides a detailed summary of the weaknesses, deficiencies, wrongdoings or other concerns raised by performance of the audit plan and the actions taken by the agency to address any of those issues identified.

II. Internal Audit Plan for Fiscal Year 2022

The internal audits planned and performed for fiscal year 2022 were selected to address the agency's highest risk areas, based on the risk assessment update conducted in 2020, which included input from CPRIT management. The audits conducted during fiscal year 2022 are listed below.

Internal Audit	Report Date	Current Status
Vendor Contract Compliance Audit	October 26, 2022	The report was issued October 26, 2022. Follow-up procedures to verify that recommendations have been addressed are included in the proposed 2023 Internal Audit Plan.
Purchasing	NA	The audit was re-scheduled to fiscal year 2023.
Information Technology General Computer Controls Follow-Up	NA	Due to CPRIT staffing considerations with Oversight Committee approval, follow-up procedures were cancelled.
Information Security Follow-Up	NA	Due to CPRIT staffing considerations with Oversight Committee approval, follow-up procedures were cancelled.
Communications Follow-Up	October 28, 2022	This audit is complete. Follow-up Procedures to address the remaining outstanding findings is included in the FY 2023 Internal Audit Plan.
Governance Follow-Up	October 28, 2022	This audit is complete and all open internal audit findings were remediated.

Cancer Prevention and Research Institute of Texas

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III. Consulting Services and Non-audit Services Completed

Weaver, as the agency's Internal Auditor, provided audit consulting services in one area, as defined in the Institute of Internal Audit Auditors' International Standards for the Professional Practice of Internal Auditing. The area, the report date and status of those services are provided in the table below.

Audit	Report Date	Current Status
IT General Computer Controls Remediation Assistance	NA	Advisory procedures are complete. The procedures included providing templates for the performance of internal controls and policy documents for CPRIT's Management to adopt and implement.
Disaster Recovery and Business Continuity Planning Advisory Follow-Up	October 28, 2022	This advisory follow-up audit is complete. Follow-up procedures to verify that corrective action has been performed on the remaining open findings are included in the proposed 2023 Internal Audit Plan.

IV. External Quality Assurance 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. Weaver's review was issued in October 2019.

EideBailly
CPAs & BUSINESS ADVISORS

Report on Firm's System of Quality Control

October 16, 2019

To the Partners of Weaver and Tidwell, L.L.P.
and the National Peer Review Committee

We have reviewed the system of quality control for the accounting and auditing practice of Weaver and Tidwell, L.L.P. (the firm) applicable to engagements not subject to PCAOB permanent inspection in effect for the year ended May 31, 2019. Our peer review was conducted in accordance with the Standards for Performing and Reporting on Peer Reviews established by the Peer Review Board of the American Institute of Certified Public Accountants (Standards).

A summary of the nature, objectives, scope, limitations of, and the procedures performed in a System Review as described in the Standards may be found at www.aicpa.org/prsummary. The summary also includes an explanation of how engagements identified as not performed or reported in conformity with applicable professional standards, if any, are evaluated by a peer reviewer to determine a peer review rating.

Firm's Responsibility

The firm is responsible for designing a system of quality control and complying with it to provide the firm with reasonable assurance of performing and reporting in conformity with applicable professional standards in all material respects. The firm is also responsible for evaluating actions to promptly remediate engagements deemed as not performed or reported in conformity with professional standards, when appropriate, and for remediating weaknesses in its system of quality control, if any.

Peer Reviewer's Responsibility

Our responsibility is to express an opinion on the design of the system of quality control and the firm's compliance therewith based on our review.

Required Selections and Considerations

Engagements selected for review included engagements performed under Government Auditing Standards, including compliance audits under the Single Audit Act; audits of employee benefit plans, an audit performed under FDICIA, an audit of a broker-dealer, and examinations of service organizations [SOC 1 and SOC 2 engagements].)

As a part of our peer review, we considered reviews by regulatory entities as communicated by the firm, if applicable, in determining the nature and extent of our procedures.

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Opinion

In our opinion, the system of quality control for the accounting and auditing practice of Weaver and Tidwell, L.L.P. applicable to engagements not subject to PCAOB permanent inspection in effect for the year ended May 31, 2019, has been suitably designed and complied with to provide the firm with reasonable assurance of performing and reporting in conformity with applicable professional standards in all material respects. Firms can receive a rating of pass, pass with deficiency(ies) or fail. Weaver and Tidwell, L.L.P. has received a peer review rating of pass.

Eide Bailly LLP

Eide Bailly LLP

V. Internal Audit Plan for Fiscal Year 2023

The Internal Audit Plan was submitted to the Audit Subcommittee of the CPRIT Oversight Committee. The Audit Subcommittee approved the plan on August 8, 2022, and the Oversight Committee subsequently approved the plan on August 17, 2022. Below is the Fiscal Year 2022 Internal Audit Plan submitted to the agency's Oversight Committee based on the results of the 2022 Internal Audit Risk Assessment Update. The approved internal audit plan was submitted to the State Auditor's Office prior to November 1,2022.

Fiscal Year 2023 Internal Audit Plan		
Audit Area	**2022 Risk Rating**	**Estimated Hours**
Contract Risk Assessment	**High**	280
Post-Award Compliance Program	**High**	180
Purchasing	**High**	150
IT General Controls	**High**	320

Planned follow-up procedures for fiscal year 2023 to verify and communicate with Management the remediation efforts of prior Internal Audit Recommendations.

Fiscal Year 2023 Follow-up Procedures		
Audit Area	**2022 Risk Rating**	**Estimated Hours**
Vendor Contract Compliance	**High**	60
Communications	**Moderate**	40
Disaster Recovery and Business Continuity Advisory	**High**	40
IT Security Follow-up	**High**	100

As part of the risk assessment, CPRIT assesses the probability and impact of the following risk categories across all significant activities of the agency, which include the information technology risks and considerations related to Title 1, Texas Administrative Code, Chapter 202:

- financial and fraud risk
- operations, complexity, and human capital risk
- information technology risk
- regulatory compliance and public policy risk, and
- reputational risk

Taking into consideration the input from the CPRIT management, all significant activities are assigned a risk score for probability and impact related to each risk category. The overall risk rating (High, Moderate or Low) is assigned to each significant activity based on the activity's average risk rating.

The internal audit plan is developed by considering risk ratings for each significant activity and prioritizing "High" risk activities.

The 2022 Internal Audit Risk Assessment Update resulted in ten (10) Significant Activities rated as "High" risk. Six (6) of the ten (10) Significant Activities are not included in the Fiscal Year 2023 Internal Audit Plan. Those activities are as follows:

1. Pre-Award Grant Management
2. Post-Award Grant Monitoring
3. Commodity and Service Contracts
4. Procurement and P-Cards
5. Internal Agency Compliance
6. Application Development and Management

VI. External Audit Services Procured in FY 2022

CPRIT engaged McConnell & Jones, LLP, a certified public accounting and consulting firm, as their external auditors for FY 2022.

VII. Reporting Suspected Fraud, Waste and Abuse

- CPRIT contracts with Red Flag Reporting to provide a confidential hotline for reporting fraud, waste and abuse. The agency has posted a link on its home page at www.cprit.texas.gov and also has a dedicated page to fraud prevention and reporting on its website at https://www.cprit.texas.gov/about-us/fraud-reporting.

- 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 Chief 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:	OVERSIGHT COMMITTEE MEMBERS
FROM:	CAMERON ECKEL, ASSISTANT GENERAL COUNSEL
SUBJECT:	APPOINTMENT TO THE SCIENTIFIC RESEARCH AND PREVENTION PROGRAMS COMMITTEE
DATE:	NOVEMBER 3, 2022

Summary and Recommendation

The Chief Executive Officer has appointed eight experts to CPRIT's Scientific Research and Prevention Programs Committee. CPRIT's statute requires Oversight Committee approval for the appointments. At their November 3 meeting, the Board Governance subcommittee reviewed the appointees and recommends approval by the Oversight Committee.

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 research. Peer reviewers perform a significant role for the state; all CPRIT grant awards must first be recommended by a Scientific Research and Prevention Programs committee. 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 research, 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 Board Governance 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."

The Board Governance Subcommittee reviewed the appointees at its November 3 meeting and recommends their approval by the Oversight Committee.

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CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	KRISTEN PAULING DOYLE, DEPUTY EXECUTIVE OFFICER & GENERAL COUNSEL CAMERON L. ECKEL, ASSISTANT GENERAL COUNSEL
SUBJECT:	CHAPTER 703 RULE CHANGE PROPOSED FOR FINAL ADOPTION
DATE:	NOVEMBER 3, 2022

Summary and Recommendation

The Board Governance Subcommittee convened on November 3 to review the final order adopting rule amendments to Chapter 703. Once the Oversight Committee approves the final order adopting the changes to T.A.C. §§ 703.10, 703.11, 703.15, 703.24 and 703.26, CPRIT will submit the amendment to the Secretary of State and the change will be effective 20 days later.

Discussion

State law requires an agency to set policy using a rulemaking process, which includes an opportunity for public comment on proposed rules and rule changes before the agency formally adopts the policy. CPRIT published the proposed amendments in the September 2, 2022, edition of the *Texas Register*. CPRIT received no public comments regarding the proposed rule changes that affect five sections in Chapter 703.

First, the amendment to § 703.11(c) adds a new paragraph (7) allowing a grant recipient to count expenditures the grant recipient incurs for relocating its operations and personnel to Texas toward the grant recipient's matching funds obligation.

Next, the amendment to § 703.24(a)(5) requires a grant recipient to provide information necessary to correct a deficiency in the supporting documentation of a Financial Status Report (FSR) within five (5) business days of a request from the Institute. If the grant recipient fails to provide the requested information, the Institute may disapprove the FSR.

Lastly, the amendments to §§ 703.10(c)(11), 703.15(b)(3), and 703.26(b) update outdated references to Uniform Grant Management Standards (UGMS) in the Institute's administrative rules with the new Texas Grant Management Standards (TxGMS) reference

The Board Governance Subcommittee met on November 3 to discuss adoption of the proposed rule changes to Chapter 703 with CPRIT staff. The subcommittee voted to recommend that the Oversight Committee approve adoption of the rule change.

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Next Steps

After the Oversight Committee adopts the proposed rule change, CPRIT will submit the final order to the Secretary of State. The rule change becomes effective 20 days after the date CPRIT files the order with the Secretary of State.

The Cancer Prevention and Research Institute of Texas ("CPRIT" or "the Institute") adopts the amendments to 25 Tex. Admin. Code §§ 703.10, 703.11, 703.15, 703.24 and 703.26 without changes to the proposed amendments as published in the September 2, 2022, issue of the Texas Register (47 TexReg 5229); therefore, the rules will not be republished. The amendments relate to eligible matching funds, deadlines for corrections to Financial Status Report supporting documentation, and references to Texas Grant Management Standards.

Reasoned Justification

The amendment to § 703.11(c) adds a new paragraph (7) to allow a grant recipient to use relocation costs to Texas as a source matching grant funds. The proposed amendment to § 703.24(a)(5) requires a grant recipient to provide more information to or correct a deficiency in the supporting documentation of a Financial Status Report (FSR) within five (5) business days of a request from the Institute. The amendments to §§ 703.10, 703.15, and 703.26 replace references to Uniform Grant Management Standards with Texas Grant Management Standards.

Summary of Public Comments and Staff Recommendation

CPRIT received no public comments regarding the proposed amendments to Chapter 703; CPRIT staff recommends moving forward with adoption of the amendments.

The rule changes are adopted under the authority of the Texas Health and Safety Code Annotated, § 102.108, which provides the Institute with broad rule-making authority to administer the chapter.

Certification

The Institute hereby certifies that Kristen Pauling Doyle, General Counsel, reviewed the adoption of the rules and found it to be a valid exercise of the agency's legal authority.

To be filed with the Office of Secretary of State on November 18, 2022.

<rule>

§703.10.Awarding Grants by Contract.

(a) The Oversight Committee shall negotiate on behalf of the state regarding the awarding of grant funds and enter into a written contract with the Grant Recipient.

(b) The Oversight Committee may delegate Grant Contract negotiation duties to the Chief Executive Officer and the General Counsel for the Institute. The Chief Executive Officer may enter into a written contract with the Grant Recipient on behalf of the Oversight Committee.

(c) The Grant Contract shall include the following provisions:

(1) If any portion of the Grant Contract has been approved by the Oversight Committee to be used to build a capital improvement, the Grant Contract shall specify that:

(A) The state retains a lien or other interest in the capital improvement in proportion to the percentage of the Grant Award amount used to pay for the capital improvement; and

(B) If the capital improvement is sold, then the Grant Recipient agrees to repay to the state the Grant Award used to pay for the capital improvement, with interest, and share with the state a proportionate amount of any profit realized from the sale;

(2) Terms relating to Intellectual Property Rights and the sharing with the Institute of revenues generated by the sale, license, or other conveyance of such Project Results consistent with the standards established by this chapter;

(3) Terms relating to publication of materials created with Grant Award funds or related to the Cancer Research or Cancer Prevention project that is the subject of the Grant Award, including an acknowledgement of Institute funding and copyright ownership, if applicable:

(A) Acknowledgment of Institute funding must include the grant number of every Institute-funded grant contributing to the work memorialized in the publication; and

(B) Subparagraph (A) of this paragraph is effective beginning September 1, 2021;

(4) Repayment terms, including interest rates, to be enforced if the Grant Recipient has not used Grant Award funds for the purposes for which the Grant Award was intended;

(5) A statement that the Institute does not assume responsibility for the conduct of the Cancer Research or Cancer Prevention project, and that the conduct of the project and activities of all investigators are under the scope and direction of the Grant Recipient;

(6) A statement that the Cancer Research or Cancer Prevention project is conducted with full consideration for the ethical and medical implications of the project and that the project will comply with all federal and state laws regarding the conduct of the Cancer Research or Prevention project;

(7) Terms related to the Standards established by the Oversight Committee in Chapter 701 of this title (relating to Policies and Procedures) to ensure that Grant Recipients, to the extent reasonably possible, demonstrate good faith effort to purchase goods and services for the Grant Award project from suppliers in this state and from historically underutilized businesses as defined by Chapter 2161, Texas Government Code, and any other state law;

(8) An agreement by the Grant Recipient to submit to regular inspection reviews of the Grant Award project by Institute staff during normal business hours and upon reasonable notice to ensure compliance with the terms of the Grant Contract and continued merit of the project;

(9) An agreement by the Grant Recipient to submit Grant Progress Reports to the Institute on a schedule specified by the Grant Contract that includes information on a grant-by-grant basis quantifying the amount of additional research funding, if any, secured as a result of Institute funding;

(10) An agreement that, to the extent possible, the Grant Recipient will evaluate whether any new or expanded preclinical testing, clinical trials, Product Development, or manufacturing of any real or intellectual property resulting from the award can be conducted in this state, including the establishment of facilities to meet this purpose;

(11) An agreement that the Grant Recipient will abide by the Texas [~~Uniform~~] Grant Management Standards (TxGMS) [~~(UGMS)~~] published [~~adopted~~] by the Comptroller of Public Accounts Statewide Procurement Division [~~Governor's Office~~], if applicable, unless one or more standards conflicts with a provision of the Grant Contract, Chapter 102, Texas Health and Safety Code, or the Institute's administrative rules. Such interpretation of the Institute rules and TxGMS [~~UGMS~~] shall be made by the Institute;

(12) An agreement that the Grant Recipient is under a continuing obligation to notify the Institute of any adverse conditions that materially impact milestones and objectives included in the Grant Contract;

(13) An agreement that the design, conduct, and reporting of the Cancer Research or Prevention project will not be biased by conflicting financial interest of the Grant Recipient or any individuals associated with the Grant Award. This duty is fulfilled by certifying that an appropriate written, enforced Conflict of Interest policy governs the Grant Recipient;

(14) An agreement regarding the amount, schedule, and requirements for payment of Grant Award funds, if such advance payments are approved by the Oversight Committee in accordance with this chapter. Notwithstanding the foregoing, the Institute may require that up to ten percent of the final tranche of funds approved for the Grant Award must be expended on a reimbursement basis. Such reimbursement payment shall not be made until close out documents described in this section and required by the Grant Contract have been submitted and approved by the Institute;

(15) An agreement to provide quarterly Financial Status Reports and supporting documentation for expenses submitted for reimbursement or, if appropriate, to demonstrate how advanced funds were expended;

(16) A statement certifying that, as of June 14, 2013, the Grant Recipient has not made and will not make a contribution, during the term of the Grant Contract, to the Institute or to any foundation established specifically to support the Institute;

(17) A statement specifying the agreed effective date of the Grant Contract and the period in which the Grant Award funds must be spent. If the effective date specified in the Grant Contract is different from the date the Grant Contract is signed by both parties, then the effective date shall control;

(18) A statement providing for reimbursement with Grant Award funds of expenses made prior to the effective date of the Grant Contract at the discretion of the Institute. Pre-contract reimbursement shall be made only in the event that:

(A) The expenses are allowable pursuant to the terms of the Grant Contract;

(B) The request is made in writing by the Grant Recipient and approved by the Chief Executive Officer; and

(C) The expenses to be reimbursed were incurred on or after the date the Grant Award recommendation was approved by the Oversight Committee;

(19) Requirements for closing out the Grant Contract at the termination date, including the submission of a Financial Status Report, a final Grant Progress Report, an equipment inventory, a HUB and Texas Business report, a revenue sharing form, a single audit determination report form and a list of contractual terms that extend beyond the termination date;

(20) A certification of dedicated Matching Funds equal to one-half of the amount of the Research Grant Award that includes the name of the Research Grant Award to which the matching funds are to be dedicated, as specified in Section §703.11 of this chapter (relating to Requirement to Demonstrate Available Funds for Cancer Research Grants);

(21) The project deliverables as described by the Grant Application and stated in the Scope of Work for the Grant Contract reflecting modifications, if any, approved during the Peer Review process or during Grant Contract negotiation;

(22) An agreement that the Grant Recipient shall notify the Institute and seek approval for a change in effort for any of the Senior Members or Key Personnel of the research or prevention team listed on the Grant Application, including any proposed temporary leave of absence of a Principal Investigator, Program Director, or Company Representative;

(23) An agreement that the Grant Recipient is legally responsible for the integrity of the fiscal and programmatic management of the organization; and

(24) An agreement that the Grant Recipient is responsible for the actions of its employees and other research collaborators, including third parties, involved in the project. The Grant Recipient is responsible for enforcing its standards of conduct, taking appropriate action on individual infractions, and, in the case of financial conflict of interest, informing the Institute if the infraction is related to a Grant Award.

(d) The Grant Recipient's failure to comply with the terms and conditions of the Grant Contract may result in termination of the Grant Contract, pursuant to the process prescribed in the Grant Contract, and trigger repayment of the Grant Award funds.

§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 at least 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.

(1) The Grant Recipient's written certification of Matching Funds, as described in this section, shall be included in the Grant Contract.

(2) 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.

(3) A Grant Recipient receiving multiple Grant Awards may provide certification at the institutional level.

(4) Nothing herein restricts the Institute from requiring the Grant Recipient to demonstrate an amount of Encumbered Funds greater than 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. To the extent that a greater Matching Funds amount will be required, the Institute shall include the requirement in the Request for Applications and in the Grant Contract.

(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;

(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 six months or less 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 must be spent directly on the Grant Project or spent on closely related work that supports, extends, or facilitates the Grant Project and 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;

(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; and

(C) 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.

(7) Costs incurred by the Grant Recipient to relocate the Grant Recipient's operations and/or personnel to Texas.

(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 Project Year basis, the failure to provide certification of Encumbered Funds at the appropriate time for each Project Year may serve as grounds for suspending reimbursement or advancement of Grant Funds for project costs or 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 thirty (30) days following the due date of the FSR reflecting expenses incurred during the last quarter of the Grant Recipient's Project Year, the Grant Recipient shall file a form with the Institute reporting the amount of Matching Funds spent for the preceding Project Year.

(1) The Grant Recipient must provide all documentation, including proof of payment, showing that the Grant Recipient expended the required amount of Matching Funds on the CPRIT project for the preceding Project Year. The Institute will accept a general ledger from public or private institutions of higher education as proof of payment.

(2) The Institute will not review or approve the Grant Recipient's Matching Funds form until the Grant Recipient submits the form and all required documentation.

(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 Project Year 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.

(k) If a deadline set by this rule falls on a Saturday, Sunday, or federal holiday as designated by the U.S. Office of Personnel Management, the required filing may be submitted on the next business day. The Institute will not consider a required filing delinquent if the Grant Recipient complies with this subsection.

§703.15.Financial Policies Applicable to Grant Awards.

(a) The Grant Recipient is responsible for managing the day-to-day operations of the activities supported by the Grant Award and is accountable to Institute for the performance of the Grant Award, including the appropriate expenditure of Grant Award funds by all parties and all other obligations of the Grant Recipient.

(b) The Grant Recipient must maintain a sound financial management system that provides appropriate fiscal controls and accounting procedures to ensure accurate preparation of reports by the Grant Contract and adequate identification of the source and application of Grant Award funds.

(1) The Grant Recipient may use its established controls and policies, as long as the controls and policies are consistent with requirements described in the Institute's administrative rules, the Grant Contract, and other applicable standards.

(2) The Grant Recipient's system of internal controls should encompass segregation of functions, proper authorization of transactions, proper recording of transactions, limited access to assets, and monitoring of internal controls. The extent to which internal controls are established is dependent upon the nature and size of the organization involved.

(3) The Grant Recipient's accounting system must conform to Generally Accepted Accounting Principles applicable to state and federal grant funds and conform to the standards for financial management set forth in the Texas [~~Uniform~~] Grant Management Standards (TxGMS).

(4) The Institute may review the adequacy of the financial management system of any Grant Recipient to ensure that the system is appropriate to fulfill the Institute's administrative rules, the Grant Contract, and other applicable standards.

(c) The Grant Recipient shall use cash basis accounting when reporting expenses to be reimbursed with Grant Award funds.

(1) A Grant Recipient utilizing an accrual basis of accounting in its normal operations must present expenses on a cash basis and reflect actual costs incurred during the payment period.

(2) A subcontractor is not required to record the adjustment in the general ledger; the adjustment should be documented by memo entries along with a reconciliation of the expense reported to the Institute and the expense recorded to the general ledger.

§703.24.Financial Status Reports.

(a) The Grant Recipient shall report expenditures to be reimbursed with Grant Award funds on the quarterly Financial Status Report form. The Grant Recipient must report all expenses for which it seeks reimbursement that the Grant Recipient paid during the fiscal quarter indicated on the quarterly Financial Status Report form.

(1) Expenditures shall be reported by budget category consistent with the Grant Recipient's Approved Budget.

(2) If the Grant Recipient seeks reimbursement for an expense it paid prior to the period covered by the current quarterly Financial Status Report but did not previously report to the Institute, the Grant Recipient must provide a written explanation for failing to claim the prior payment in the appropriate period.

(A) The Grant Recipient must submit the written explanation with any supporting documentation at the time that the Grant Recipient files its current Financial Status Report.

(B) The Institute shall consider the explanation and may approve reimbursement for the otherwise eligible expense. The Institute's decision whether to reimburse the expense is final.

(3) All expenditures must be supported with appropriate documentation showing that the costs were incurred and paid. A Grant Recipient that is a public or private institution of higher education as defined by §61.003, Texas Education Code is not required to submit supporting documentation for an individual expense totaling less than $750 in the "supplies" or "other" budget categories.

(4) The Financial Status Report and supporting documentation must be submitted via the Grant Management System, unless the Grant Recipient is specifically directed in writing by the Institute to submit or provide it in another manner.

(5) The Institute may request in writing that a Grant Recipient provide more information or correct a deficiency in the supporting documentation for a Financial Status Report. If a Grant Recipient does not submit the requested information within five (5) business [~~21~~] days after the request is submitted, the Financial Status Report may [~~will~~] be disapproved by the Institute.

(A) Nothing herein restricts the Institute from disapproving the FSR without asking for additional information or prior to the submission of additional information.

(B) Nothing herein extends the FSR due date.

(6) The requirement to report and timely submit quarterly Financial Status Reports applies to all Grant Recipients, regardless of whether Grant Award funds are disbursed by reimbursement or in advance of incurring costs.

(b) Quarterly Financial Status Reports shall be submitted to the Institute within ninety (90) days of the end of the state fiscal quarter (based upon a September 1 - August 31 fiscal year). The Institute shall review expenditures and supporting documents to determine whether expenses charged to the Grant Award are:

(1) Allowable, allocable, reasonable, necessary, and consistently applied regardless of the source of funds; and

(2) Adequately supported with documentation such as cost reports, receipts, third party invoices for expenses, or payroll information.

(c) A Grant Award with a Grant Contract effective date within the last quarter of a state fiscal year (June 1 - August 31) will have an initial financial reporting period beginning September 1 of the following state fiscal year.

(1) A Grant Recipient that incurs Authorized Expenses after the Grant Contract effective date but before the beginning of the next state fiscal year may request reimbursement for those Authorized Expenses.

(2) The Authorized Expenses described in paragraph (1) of this subsection must be reported in the Financial Status Report reflecting Authorized Expenses for the initial financial reporting period beginning September 1.

(d) Except as provided herein, the Grant Recipient waives the right to reimbursement of project costs incurred during the reporting period if the Financial Status Report for that quarter is not submitted to the Institute within thirty (30) days of the Financial Status Report due date. Waiver of reimbursement of project costs incurred during the reporting period also applies to Grant Recipients that have received advancement of Grant Award funds.

(1) For purposes of this rule, the "Financial Status Report due date" is ninety (90) days following the end of the state fiscal quarter.

(2) The Chief Executive Officer may approve a Grant Recipient's request to defer submission of the reimbursement request for the current fiscal quarter until the next fiscal quarter if, on or before the original Financial Status Report due date, the Grant Recipient submits a written explanation for the Grant Recipient's inability to complete a timely submission of the Financial Status Report.

(3) A Grant Recipient may appeal the waiver of its right to reimbursement of project costs.

(A) The appeal shall be in writing, provide good cause for failing to submit the Financial Status Report within thirty (30) days of the Financial Status Report due date, and be submitted via the Grant Management System.

(B) The Chief Executive Officer may approve the appeal for good cause. The decision by the Chief Executive Officer to approve or deny the grant recipient's appeal shall be in writing and available to the Grant Recipient via the Grant Management System.

(C) The Chief Executive Officer's decision to approve or deny the Grant Recipient's appeal is final, unless the Grant Recipient timely seeks reconsideration of the Chief Executive Officer's decision by the Oversight Committee.

(D) The Grant Recipient may request that the Oversight Committee reconsider the Chief Executive Officer's decision regarding the Grant Recipient's appeal. The request for reconsideration shall be in writing and submitted to the Chief Executive Officer within 10 days of the date that the Chief Executive Officer notifies the Grant Recipient of the decision regarding the appeal as noted in subparagraph (C) of this paragraph.

(E) The Chief Executive Officer shall notify the Oversight Committee in writing of the decision to approve or deny the Grant Recipient's appeal. The notice should provide justification for the Chief Executive Officer's decision. In the event that the Grant Recipient timely seeks reconsideration of the Chief Executive Officer's decision, the Chief Executive Officer shall provide the Grant Recipient's written request to the Oversight Committee at the same time.

(F) The Grant Recipient's request for reconsideration is deemed denied unless three or more Oversight Committee members request that the Chief Executive Officer add the Grant Recipient's request for reconsideration to the agenda for action at the next regular Oversight Committee meeting. The decision made by the Oversight Committee is final.

(G) If the Grant Recipient's appeal is approved by the Chief Executive Officer or the Oversight Committee, the Grant Recipient shall report the project costs and provide supporting documentation for the costs incurred during the reporting period covered by the appeal on the next available financial status report to be filed by the Grant Recipient.

(H) Approval of the waiver appeal does not connote approval of the expenditures; the expenditures and supporting documentation shall be reviewed according to subsection (b) of this section.

(I) This subsection applies to any waivers of the Grant Recipient's reimbursement decided by the Institute on or after September 1, 2015.

(4) Notwithstanding subsection (c) of this section, in the event that the Grant Recipient and Institute execute the Grant Contract after the effective date of the Grant Contract, the Chief Program Officer may approve additional time for the Grant Recipient to prepare and submit the outstanding Financial Status Report(s). The approval shall be in writing and maintained in the Grants Management System. The Chief Program Officer's approval may cover more than one Financial Status Report and more than one fiscal quarter.

(5) In order to receive disbursement of grant funds, the most recently due Financial Status Report must be approved by the Institute.

(e) If a deadline set by this rule falls on a Saturday, Sunday, or federal holiday as designated by the U.S. Office of Personnel Management, the required filing may be submitted on the next business day. The Institute will not consider a required filing delinquent if the Grant Recipient complies with this subsection.

§703.26.Allowable Costs.

(a) A cost is an Allowable Cost and may be charged to the Grant Award if it is reasonable, allocable, and adequately documented.

(1) A cost is reasonable if the cost does not exceed that which would be incurred by a prudent individual or organization under the circumstances prevailing at the time the decision was made to incur the cost; and is necessary for the performance of the Grant Award defined in the Scope of Work in the Grant Contract.

(2) A cost is allocable if the cost:

(A) Benefits the Grant Award either directly or indirectly, subject to Indirect Cost limits stated in the Grant Contract;

(B) Is assigned the Grant Award in accordance with the relative benefit received;

(C) Is allowed or not prohibited by state laws, administrative rules, contractual terms, or applicable regulations;

(D) Is not included as a cost or used to meet Matching Fund requirements for any other Grant Award in either the current or a prior period; and

(E) Conforms to any limitations or exclusions set forth in the applicable cost principles, administrative rules, state laws, and terms of the Grant Contract.

(3) A cost is adequately documented if the cost is supported by the organization's accounting records and documented consistent with §703.24 of this title (relating to Financial Status Reports).

(b) Grant Award funds must be used for Allowable Costs as provided by the terms of the Grant Contract, Chapter 102, Texas Health and Safety Code, the Institute's administrative rules, and the Texas [~~Uniform~~] Grant Management Standards (TxGMS) [~~(UGMS)~~] adopted by the Comptroller's Office. If guidance from the Uniform Grant Management Standards on a particular issue conflicts with a specific provision of the Grant Contract, Chapter 102, Texas Health and Safety Code or the Institute's administrative rules, then the Grant Contract, statute, or Institute administrative rule shall prevail.

(c) An otherwise Allowable Cost will not be eligible for reimbursement if the Grant Recipient incurred the expense outside of the Grant Contract term, unless the Grant Recipient has received written approval from the Institute's Chief Executive Officer to receive reimbursement for expenses incurred prior to the effective date of the Grant Contract.

(d) An otherwise Allowable Cost will not be eligible for reimbursement if the benefit from the cost of goods or services charged to the Grant Award is not realized within the applicable term of the Grant Award. The Grant Award should not be charged for the cost of goods or services that benefit another Grant Award or benefit a period prior to the Grant Contract effective date or after the termination of the Grant Contract.

(e) Grant Award funds shall not be used to reimburse unallowable expenses, including, but not limited to:

(1) Bad debt, such as losses arising from uncollectible accounts and other claims and related costs.

(2) Contributions to a contingency reserve or any similar provision for unforeseen events.

(3) Contributions and donations made to any individual or organization.

(4) Costs of entertainment, amusements, social activities, and incidental costs relating thereto, including tickets to shows or sports events, meals, alcoholic beverages, lodging, rentals, transportation and gratuities.

(5) Costs relating to food and beverage items, unless the food item is related to the issue studied by the project that is the subject of the Grant Award.

(6) Fines, penalties, or other costs resulting from violations of or failure to comply with federal, state, local or Indian tribal laws and regulations.

(7) An honorary gift or a gratuitous payment.

(8) Interest and other financial costs related to borrowing and the cost of financing.

(9) Legislative expenses such as salaries and other expenses associated with lobbying the state or federal legislature or similar local governmental bodies, whether incurred for purposes of legislation or executive direction.

(10) Liability insurance coverage.

(11) Benefit replacement pay or legislatively-mandated pay increases for eligible general revenue-funded state employees at Grant Recipient state agencies or universities.

(12) Professional association fees or dues for an individual employed by the Grant Recipient. Professional association fees or dues for the Grant Recipient's membership in business, technical, and professional organizations may be allowed, with prior approval from the Institute, if:

(A) the professional association is not involved in lobbying efforts; and

(B) the Grant Recipient demonstrates how membership in the professional association benefits the Grant Award project(s).

(13) Promotional items and costs relating to items such as T-shirts, coffee mugs, buttons, pencils, and candy that advertise or promote the project or Grant Recipient.

(14) Fees for visa services.

(15) Payments to a subcontractor if the subcontractor working on a Grant Award project employs an individual who is a Relative of the Principal Investigator, Program Director, Company Representative, Authorized Signing Official, or any person designated as Key Personnel for the same Grant Award project (collectively referred to as "affected Relative"), and the Grant Recipient will be paying the subcontractor with Grant Award funds for any portion of the affected Relative's salary or the Relative submits payment requests on behalf of the subcontractor to the Grant Recipient for payment with Grant Award funds.

(A) For exceptional circumstances, the Institute's Chief Executive Office may grant an exception to allow payment of Grant Award funds if the Grant Recipient notifies the Institute prior to finalizing the subcontract. The Chief Executive Officer must notify the Oversight Committee in writing of the decision to allow reimbursement for the otherwise unallowable expense.

(B) Nothing herein is intended to supersede a Grant Recipient's internal policies, to the extent that such policies are stricter.

(16) Fundraising.

(17) Tips or gratuities.

(f) Pursuant to Texas Health and Safety Code Section 102.203(b) the Institute may authorize reimbursement for one or more of the following expenses incurred by a cancer clinical trial participant that are associated with participating in a clinical trial and included in the Grant Recipient's Approved Budget:

(1) transportation, including car mileage, parking, bus fare, taxi or ride hailing fare exclusive of tips, and commercial economy class airfare within the borders of the State of Texas;

(2) lodging; and

(3) any cost reimbursed under a cancer clinical trial participation program established pursuant to Texas Health and Safety Code Chapter 51 (relating to Cancer Clinical Trial Participation Program).

(g) The Institute is responsible for making the final determination regarding whether an expense shall be considered an Allowable Cost.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: HEIDI MCCONNELL, CHIEF OPERATING OFFICER

SUBJECT: CHIEF OPERATING OFFICER REPORT

DATE: NOVEMBER 7, 2022

CPRIT Financial Overview for FY 2022, Quarter 4

FY 2022, Quarter 4 Operating Budget

In FY 2022, CPRIT had a budget of $4.9 million in Indirect Administration and approximately $16.1 million budgeted in Grant Review and Award Operations. The Grant Review and Award Operations budget includes the majority of the agency's vendor contracts which support grant award and administration, including the $9.6 million contract for grant management support services with GDIT.

Approximately 82 percent of the $4.9 million budget for Indirect Administration had been expended. Of the $16.1 million budget for Grant Review and Award Operations, approximately 97 percent had been expended. The final expended amounts in each area of the budget will increase slightly as FY 2022 invoices for goods and services are paid in the first few months of FY 2023.

CPRIT received $101,264 in revenue sharing payments during the fourth quarter. This amount includes the receipt of a quarterly royalty payment for $40,033 from Merck & Co., Inc. from the sales revenue of WELIREG™ (belzutifan).

Revenue sharing payment deposits from CPRIT's inception total approximately $7.7 million through the end of August 2022.

FY 2022, Quarter 4 Performance Measure Report

CPRIT completed reporting on the two quarterly and three annual key performance measures to the Legislative Budget Board for FY 2022. The results are:

- A total of 834,962 people served through CPRIT prevention and control grants, exceeding the 700,000-person served goal;
- No company relocations;
- Being within range of the 143.0 annual age-adjusted mortality rate at 139.9;
- A total of 1,121 published articles on CPRIT-funded research, exceeding the 1,000-article target; and
- A total of 3,497 jobs created or maintained, exceeding the 3,000-job target.

PO Box 12097 | Austin, Texas 78711 | PH: 512-463-3190 | F: 512-475-2563 | cprit.texas.gov

Debt Issuance History

The Texas Public Finance Authority (TPFA) issued $66.3 million in commercial paper notes on CPRIT's behalf in July 2022. This brought the total general obligation debt transactions to $298.1 million for FY 2022.

2023 CPRIT Innovations VI Conference Update

CPRIT program staff are finalizing the plenary and breakout session topics and conducting outreach to possible keynote and breakout speakers and panelists. As soon as the schedule is finalized, Ms. Shannon Cusick, the Information Resources Manager, will be able to complete the conference website which is already being updated for registration and abstract submission capabilities.

Cancer Prevention and Research Institute of Texas
Quarterly Financial Report
As of August 31, 2022

Indirect Administration (B.1.1.)

		2022 Appropriated	2022 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
1001	Salaries and Wages	$ 1,847,425	$ 1,839,031		$ 1,308,457	530,574	71%	$ 1,308,457	$ 530,574
1002	Other Personnel Costs	38,785	47,179		47,179	(0)	100%	47,179	(0)
2001	Professional Fees and Services	1,808,662	1,953,603		1,754,422	199,181	90%	1,754,422	199,181
2003	Consumable Supplies	24,000	24,000		4,895	19,105	20%	4,895	19,105
2004	Utilities	58,600	58,600		33,428	25,172	57%	33,428	25,172
2005	Travel	45,000	46,511		46,511	0	100%	46,511	0
2006	Rent-Building	11,000	11,000		9,833	1,167	0%	9,833	1,167
2007	Rent-Machine and Other	32,172	32,172		21,411	10,761	67%	21,411	10,761
2009	Other Operating Expenses	1,062,737	1,055,750		920,572	135,178	87%	920,572	135,178
	Subtotal - Indirect Administration (B.1.1.)	**$ 4,928,381**	**$ 5,067,846**	**1.70%**	**$ 4,146,709**	**$ 921,137**	**82%**	**$ 4,146,709**	**$ 921,137**

Grant Review and Award Operations (A.1.3.)

		2022 Appropriated	2022 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
1001	Salaries and Wages	$ 3,505,873	3,904,283		$ 3,904,283	$ (0)	100%	$ 3,904,283	$ (0)
1002	Other Personnel Costs	45,000	183,027		183,027	(0)	0%	183,027	(0)
2001	Professional Fees and Services	12,419,373	12,243,663		11,910,438	333,225	97%	11,910,438	333,225
2003	Consumable Supplies	-	-		-	-	0%	-	-
2004	Utilities	12,000	19,042		19,042	0	100%	19,042	0
2005	Travel	45,000	45,000		12,209	32,791	27%	12,209	32,791
2009	Other Operating Expenses	71,649	64,607		15,995	48,612	25%	15,995	48,612
	Subtotal - Grant Operations (A.1.3.)	**$ 16,098,895**	**$ 16,459,622**	**5.53%**	**$ 16,044,995**	**$ 414,627**	**97%**	**$ 16,044,995**	**$ 414,627**

Grants

		2022 Appropriated	2022 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
4000	Grants - Prevention (A.1.2)	$ 27,670,031	$ 27,709,943		$ 27,633,765	$ 76,178	100%	$ 27,633,765	$ 76,178
4000	Grants - Research (A.1.1.)	251,353,693	$ 248,235,661		244,768,282	$ 3,467,379	99%	244,768,282	3,467,379
	Subtotal - Grants	**$ 279,023,724**	**$ 275,945,604**	**92.76%**	**$ 272,402,047**	**$ 3,543,557**	**99%**	**$ 272,402,047**	**$ 3,543,557**
	Grand Totals	**$ 300,051,000**	**$ 297,473,072**	**100.00%**	**$ 292,593,751**	**$ 4,879,321**	**98%**	**$ 292,593,751**	**$ 4,879,321**

Cancer Prevention and Research Institute of Texas
Cancer Prevention and Research Institute Fund Account - 5136
As of August 31, 2022

	8/01/2022-8/31/2022	AY 21 Year to Date as of 8/31/2022
Beginning Balance : 9/01/2021		**$ 600,506**
Increases:		
(1)	$ -	$ -
(2)	-	
Total Increases	**$ -**	**$ 600,506.00**
Reductions:		
Expenditures - Appropriated	$ -	$ -
	$ -	$ -
	$ -	$ -
Total Reductions	**$ -**	**$ -**
Ending Balance: 8/31/2022		**$ 600,506.00**

Note: (1) The Institute received a settlement from the Texas Cancer Coalition (TCC). This amount represents the final distribution and transfer of all funds ($303,877) from the TCC which ceased operations in May 2013. These funds are in the State Treasury but are not appropriated to CPRIT. The beginning balance reflects the transfer of all TCC funds.

Cancer Prevention and Research Institute of Texas

License Plate Trust Fund Account - 0802

As of August 31, 2022

		8/01/2022-8/31/2022	AY 21 Year to Date as of 8/31/2022
Beginning Balance : 9/01/2021			**$ 39,573.54**
Increases:			
(1)	License Plate Revenue Received	$ 799.32	$ 6,864.15
	Interest	$ 57.22	$ 184.08
Total Increases		**$ 856.54**	**$ 46,621.77**
Reductions:			
	Expenditures - Appropriated	$ -	$ -
		-	-
Total Reductions		**$ -**	**$ -**
Ending Balance: 8/31/2022			**$ 46,621.77**

Note:

Balance forward from 2021 License Plate $39,573.54

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Cancer Prevention and Research Institute of Texas

Appropriated Receipts - 666

As of August 31, 2022

		8/01/2022-8/31/2022	AY 21 Year to Date as of 8/31/2022
Beginning Balance : 9/01/2021			**$ 11,246.90**
Increases:			
(1)	Product Development Application Fees Received	$ -	$ 23,000.00
(2)	Conference Registration Fees	$ -	$ -
(3)	Conference Registration Fees-Credit Card	$ -	$ -
Total Increases		**$ -**	**$ 23,000.00**
Reductions:			
	Conference Expenditures - Appropriated	$ -	$ -
	Credit Card Fees Expended	$ -	$ -
	Refund-Application Fees	$ -	$ -
	Legal Services Expenses (Application Fees)	$ -	$ -
Total Reductions		**$ -**	**$ -**
Ending Balance: 8/31/2022			**$ 34,246.90**

Forward balance for FY 2021 is $11,246.90
Application Fees

Cancer Prevention and Research Institute of Texas

Interest & Sinking Fund Account - 5168

As of August 31, 2022

		8/01/2022-8/31/2022	AY 21 Year to Date as of 8/31/2022
Beginning Balance : 9/01/2021			**$ 2,525,531.25**
Increases:			
(1)	Revenue Sharing / Royalties	$ 62,467.86	$ 2,785,921.35
(2)	Reconciled previous FY for double entry	$ -	$ (781,435.16)
Total Increases		**$ 62,467.86**	**$ 4,530,017.44**
Reductions:			
	Expenditures - Appropriated	$ -	$ -
		$ -	
		$ -	$ -
Total Reductions		**$ -**	**$ -**
Ending Balance: 8/31/2022			**$ 4,530,017.44**

Balance forward from FY 2021 is $2,525,531.25

(2) Reconciled previous for double entry FY 2018 ($734.53) FY 2019 ($236,024.48) 2020 ($531,764.33) FY 2021 ($12,911.82) = ($781,435.16)

Cancer Prevention and Research Institute of Texas
FY 2022, Quarter 4 Performance Measure Report

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	700,000	203,604	195,926	204,599	230,833	834,962	119.28%
Number of Entities Relocating to TX for Cancer Research Related Projects	1	0	0	0	0	0	0.00%
Annual Age-adjusted Cancer Mortality Rate	143.0	N/A	N/A	N/A	N/A	139.9	97.83%
Number of Published Articles on CPRIT-Funded Research Projects	1,000	N/A	N/A	N/A	N/A	1,121	112.10%
Number of New Jobs Created and Maintained	3,000	N/A	N/A	N/A	N/A	3,497	116.57%

Variance Explanations

Number of People Served by Institute Funded Prevention and Control Activities
CPRIT prevention grantees have continued to be successful at delivering cancer prevention education and clinical services to more people than they anticipated, stretching their CPRIT-grant funds further to serve Texans. They have resumed providing cancer prevention clinical services, such as mammograms and colonoscopies, following COVID-19 precautions which include the use of COVID-19 tests and extra safety
Number of Entities Relocating to TX for Cancer Research Related Projects
This output is dependent on the number of companies applying for CPRIT Company Awards that can successfully advance through CPRIT's rigorous review and evaluation process, receive an award and actually relocate operations to Texas. Therefore, the results vary. A company must meet 4 of CPRIT's 7 criteria for a relocation to be considered complete.
Number of Published Articles on CPRIT- Funded Research Projects
The number reflects that CPRIT-funded research projects have yielded numerous results and breakthroughs which grantees have been successful in reporting through scientific publications.
Number of New Jobs Created and Maintained
The number of new jobs created and maintained reported by academic and product development research grantees exceeded the projection because CPRIT has a portfolio with more than 500 active grants and several scientific staff are required for each project. In addition, the measure includes jobs maintained which is proportionally double the number of new jobs created in a given year. Grantees conduct CPRIT-funded research projects over multiple years and must maintain the scientific expertise to do so.

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	Refunded as G.O. Bonds	
2010		September 9, 2009	$ 3,600,000		Commercial Paper Notes	Series B, Tax-Exempt	Defeased with cash July 2011	
2010		March 12, 2010	$ 63,800,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2010		August 26, 2010	$ 148,500,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
				$ 225,000,000				
2011	$ 225,000,000	September 7, 2010	$ 11,800,000		Commercial Paper Notes	Series A, Taxable		
2011		August 10, 2011	$ 51,000,000		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%
				$ 62,800,000				
2012	$ 300,000,000	September 7, 2011	$ 3,200,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2012		December 8, 2011	$ 3,200,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2012		March 2, 2012	$ 12,300,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2012		June 21, 2012	$ 15,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2012		August 16, 2012	$ 42,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
				$ 75,700,000				
2013	$ 300,000,000	September 6, 2012	$ 9,600,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2013		May 16,2013	$ 13,400,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
				$ 23,000,000				
2014	$ 300,000,000	November 25, 2013	$ 55,200,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2014		March 13, 2014	$ 47,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2014		June 17, 2014	$ 60,300,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2014		July 8, 2014	$ 233,280,000		G.O. Bonds (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	Refunded as G.O. Bonds	
2015		April 29, 2014	$ 112,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2015		June 26, 2015	$ 75,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
				$ 244,600,000				

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
2016	$ 300,000,000	September 22, 2015	$ 55,400,000		Commercial Paper Notes	Series A, Taxable		
2016		October 29, 2015	$ 300,000,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2015C	Par amount of refunding; Refunded $300M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 3.299867%
2016		October 29, 2015	$ 69,800,000		G.O. Bonds	Taxable Series 2015C	Par amount of new money: Disbursed to CPRIT January 2016	Fixed Rate Bonds All-In-True Interest Cost 3.299867%
2016		May 16, 2016	$ 92,100,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2016		August 29, 2016	$ 60,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
				$ 277,300,000				
2017	$300,000,000	October 19, 2016	$ 58,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2017		January 5, 2017	$ 58,900,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2017		February 8, 2017	$ 269,000,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2017	Par amount of refunding: Refunded $269M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 3.4622%
2017		February 8, 2017	$ 106,000,000		G.O. Bonds	Taxable Series 2017	Par amount of new money	Fixed Rate Bonds All-In-True Interest Cost 3.4622 %
				$ 222,900,000				
2018	$300,000,000	September 29, 2017	$ 68,200,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2018		March 8, 2018	$ 99,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2018		July 11, 2018	$ 55,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
				$ 222,200,000				
2019		September 21, 2018	$ 222,200,000		G.O. Bond (Refunding Bonds)	Taxable Series 2018	Par amount of refunding: Refunded $222.2M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 3.720632%
2019	$300,000,000	September 21, 2018	$ 75,975,000		G.O. Bonds	Taxable Series 2018	Par amount of new money	Fixed Rate Bonds All-In-True Interest Cost 3.720544%
2019		March 28, 2019	$ 77,725,000		Commercial Paper Notes	Series A, Taxable		Interest rates between 1.90% - 2.55%
2019		July 12, 2019	$ 54,000,000		Commercial Paper Notes	Series A, Taxable		Interest rates between 1.95% - 2.35%
				$ 207,700,000				

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
2020		September 16, 2019	$ 64,300,000		Commercial Paper Notes	Series A, Taxable		Interest rate of 2.10%
2020		January 9, 2020	$ 52,000,000		Commercial Paper Notes	Series A, Taxable		
2020		April 23, 2020	$ 237,720,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2020	Par amount of refunding: Refunded $248.025M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 2.644360%
2020		April 23, 2020	$ 115,000,000		G.O. Bonds	Taxable Series 2020	Par amount of new money	Fixed Rate Bonds All-In-True Interest Cost 2.644360%
2020		April 23, 2020	$ 119,750,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2020	Par amount of refunding. Refunded $120.525M of Taxable Series 2011	
				$ 231,300,000				
2021	$300,000,000	September 11, 2020	$ 75,000,000		Commercial Paper Notes	Series A, Taxable		
2021		January 14, 2021	$ 59,000,000		Commercial Paper Notes	Series A, Taxable		
2021		April 29, 2021	$ 68,900,000		Commercial Paper Notes	Series A, Taxable		
2021		August 12, 2021	$ 57,400,000		Commercial Paper Notes	Series A, Taxable		
				$ 260,300,000				
2022	$300,000,000	September 28, 2021	$ 87,000,000		Commercial Paper Notes	Series A, Taxable		
2022		November 18, 2021	$ 334,745,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2021B	Par amount of refunding: Refunded $347.300M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 2.191715%
2022		November 18, 2021	$ 139,565,000		G.O. Bonds	Taxable Series 2021B	New money proceeds of $144.800M	Fixed Rate Bonds All-In-True Interest Cost 2.191715%
2022		November 18, 2021	$ 108,005,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2021B	Par amount of refunding: Refunded $108.660M of Taxable Series 2014B	Fixed Rate Bonds All-In-True Interest Cost 2.191715%
2022		July 14, 2022	$ 66,300,000		Commercial Paper Notes	Series A, Taxable		
				$ 298,100,000				
TOTAL ISSUED TO DATE				**$ 2,513,400,000**				

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

To:	OVERSIGHT COMMITTEE MEMBERS
From:	KEN SMITH, PH.D., CHIEF PRODUCT DEVELOPMENT OFFICER
Subject:	FY 2023 DUE DILIGENCE SERVICES CONTRACT
Date:	NOVEMBER 13, 2022

Recommendation

CPRIT staff recommends that the agency award a contract to Alan Boyd Consultants, Inc. (Boyd Consultants) for due diligence services for a not-to-exceed amount of $300,000 in FY 2023. The contract cost is based on the estimated diligence evaluations completed by Boyd Consultants during the year. Payment is for the delivery of actual services based upon negotiated hourly rates. The contract includes three optional extension periods.

CPRIT staff discussed the proposed contract with the Audit Subcommittee on November 11. The subcommittee provisionally recommended approval of the FY 2023 due diligence services contract pursuant to the terms proposed by CPRIT and reflected in the final agreement.

Background

CPRIT has incorporated due diligence review as the final step in the multi-stage product development research review process. Due diligence is a comprehensive assessment of the company prior to investment, which may include issues including manufacturing, the clinical research plan, the regulatory pathway, management, commercial viability, and budget review. CPRIT contracts separately with outside counsel to perform an intellectual property assessment during the due diligence phase.

As of November 10, CPRIT has received 47 preliminary applications and invited 19 companies to submit full applications for product development grants in the FY 2023 award cycle. Up to three times in FY 2023, applicants invited to submit full applications will present their applications to product development review panels. A subset of these applications will undergo due diligence based upon a positive evaluation by the peer review panels.

With information from the due diligence process, the peer review panel will decide whether to recommend an application to the Product Development Review Council (PDRC) for a grant award. The PDRC provides a final list of product development research applications recommended for CPRIT awards to CPRIT's Program Integration Committee and the Oversight Committee.

The selected vendor, Boyd Consultants, has the expertise to perform the necessary services at the negotiated rates.

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CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	KRISTEN DOYLE, DEPUTY EXECUTIVE OFFICER AND GENERAL COUNSEL
	CAMERON ECKEL, ASSISTANT GENERAL COUNSEL
SUBJECT:	FY 2023 OUTSIDE COUNSEL CONTRACTS
DATE:	NOVEMBER 8, 2022

Recommendation

CPRIT staff recommends approval of an outside counsel contract for FY 2023 with the firm McDermott Will & Emery (amount not to exceed $185,000) and an increase to the FY 2023 outside counsel contract with the firm Norton Rose Fulbright to an amount not to exceed $185,000. These firms will provide CPRIT legal advice and evaluation services regarding the intellectual property (IP) and revenue sharing agreements associated with CPRIT grants during FY 2023. The Audit Subcommittee discussed staff's recommendation at its meeting on November 7 and encourages the Oversight Committee to approve the outside counsel contracts as proposed. The Office of the Attorney General must approve all outside counsel agreements prior to contract execution.

Although CPRIT seeks contract approval for FY 2023, CPRIT has an option to renew the outside counsel contracts for up to four additional one-year periods. If CPRIT decides to exercise its option to extend the contract(s), CPRIT staff will seek approval from the Oversight Committee and the Office of the Attorney General at the appropriate time.

Background and Proposal Evaluation

CPRIT relies on outside legal counsel with expertise in intellectual property to conduct a review of companies' IP estate as part of the due diligence process. The IP due diligence review is not a re-evaluation of the grant application but serves as an independent analysis of the IP and associated licenses underlying the company's planned drug, device, diagnostic, technology, or service proposed for CPRIT funding. The Product Development Research review panels use information gained through the IP due diligence process to finalize their grant award recommendations.

Pursuant to a request for proposals (RFP) issued in FY 2022, the firm Norton Rose Fulbright currently serves as CPRIT's outside counsel. A second firm also provided outside counsel services in FY 2022. However, the lead partner and many of the IP lawyers that performed

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CPRIT's work at the second law firm left that firm this summer. As a result, CPRIT did not execute a contract renewal with the second firm for FY 2023.

CPRIT prefers contracting with multiple firms. The practice allows the agency to balance the workload and avoid potential conflicts of interest between the firms and the companies under review. In September CPRIT issued an RFP seeking additional firms to provide outside counsel services in FY 2023.

CPRIT's contract team evaluated the proposal submitted to the agency in response to the RFP. Based upon the evaluation, we recommend approving an outside counsel contract with McDermott Will & Emery for an amount not to exceed $185,000. The initial term the contract is for FY 2023. At CPRIT's sole option, we may renew the contract for up to four additional one-year periods. The option to extend the contract provides service continuity, particularly when review cycles cross fiscal years. We will seek Oversight Committee approval at the appropriate time if CPRIT elects to extend the contract beyond FY 2023. The Office of the Attorney General must also approve outside counsel contracts and contract amendments, including extensions.

The current budget for Norton Rose Fulbright's FY 2023 outside contract is $95,000. Considering the growing amount of IP work expected in FY 2023, we recommend increasing the FY 2023 budget for the Norton Rose Fulbright budget to an amount not to exceed $185,000. The overall budget for legal services in FY 2023 is consistent with the amounts approved in past years.

The outside counsel contracts are based on an hourly rate. CPRIT pays the firms based solely on the number of hours worked; there is no guaranteed minimum payment. The cost of each assessment varies based upon the complexity of the IP information and issues presented, as well as the volume of documents reviewed. Generally, the price per IP due diligence company project ranges from $10,000 - $25,000.

The Audit Subcommittee voted at its November 7, 2022, meeting to recommend that the Oversight Committee approve the outside counsel contracts for FY 2023.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	MARK DALLAS LOEFFLER
SUBJECT:	COMMUNICATIONS UPDATE
DATE:	NOVEMBER 7, 2022

These are the highlights of CPRIT Communications efforts since the most recent quarterly Oversight Committee meeting in August.

MEDIA RELATIONS

- Conducted LIVE in-studio interview with KXAN TV 36 – Austin re: August OC award slate
- Facilitated follow up KXAN interview with Dr. Patel for airing on Nexstar network
- Facilitated interview with Dr. Le Beau and *Dallas Morning News* re: August UTSW grant
- Responded to inquiry from *Houston Chronicle* re: August CPRIT grants
- Conducted LIVE in-studio interview with KXAN TV 36 – Austin re: September OC award slate
- Facilitated interview between Michelle Le Beau and KXAN Nexstar Correspondent
- Facilitated interview with Dr. Le Beau and *Dallas Morning News* Breaking News reporter re: September awards
- Facilitated interview for Wayne Roberts and Tracey Davies with *Bloomberg Government* reporter Alex Ruoff re: ARPA-H
- Interviewed by Texas A&M student newspaper, *The Battalion*, about CPRIT grant
- Posted and distributed media advisories and press releases related to CPRIT programs and news:
    - PRESS RELEASE: State cancer agency approves $49 million in new research grants (Sent: Sep 14, 2022)
    - MEDIA ADVISORY: CPRIT to consider more than $52 million in cancer grants on September 14 (Sent: Sep 9, 2022)
    - PRESS RELEASE: CPRIT Oversight Committee approves $89 Million in grants (Sent: August 17, 2022)

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DIRECT COMMUNICATION

- Drafted and uploaded messages to CPRIT's listserv (6,401 contacts) regarding new Product Development RFAs, agency rules updates, various reminders and Save-The-Dates for CPRIT and partner events.
- Helped release a CPRIT statement on the importance of colonoscopies in preventing colorectal cancer

SOCIAL MEDIA

- Created posts to spotlight CPRIT grantees, programs and outreach

OTHER

- Onboarded new Digital Communications Specialist Justin Rand. Justin will be assisting with all communications goals with a special emphasis on creating new digital media for CPRIT use.

STATISTICS

Social Media from May 19, 2022 to August 4, 2022

Facebook	Twitter	LinkedIn
6.78% post engagement rate	**3.27%** engagement rate	**6.01%** engagement rate
1,122 Fans	**3,326** followers	**1,884** followers
Top Post: **100%** engagement (5/24)	Top Tweet: **9,811** impressions (5/25)	Top Post: **2,855** impressions (5/27)

Social Media from August 5 to November 6

Facebook	Twitter	LinkedIn
18.45% post engagement rate	**3.34%** engagement rate	**4.97%** post engagement rate
1,204 Fans	**3,406** followers	**2,304** followers
Top Post: **7.21%** engagement (9/28)	Top Tweet: **6,007** impressions (4/4)	Top Post: **10,762** impressions (8/31)

Website Hits and Visitors August 18 to November 7

Users	New Users	Sessions (Visits)	Pageviews	Pages / Session
20,375	**19,093**	**28,190**	**59,234**	**2.10**