

Cancer Prevention & Research Institute of Texas

# Oversight Committee Meeting

November 20, 2024



# Summary Overview of the November 20, 2024, Oversight Committee Meeting

This summary provides an overview of major agenda items and background on key issues for Committee consideration at the November 20, 2024, Oversight Committee meeting.

#### **CEO Report**

Kristen Doyle will present the CEO's report and address issues including a personnel update, grant funds available for FY 2025 and other topics.

#### **Chief Compliance Officer Report and Grant Award Certification**

Vince Burgess and Stephen Nance will report on the status of required grantee reports, financial status report reviews, desk reviews and site visits, annual compliance attestation, audit tracking, and training. They will also answer any questions regarding Mr. Burgess' certification of the proposed prevention, academic research, and product development awards and review process.

# Chief Scientific Officer Report, Grant Award Recommendations, and FY 2026 Requests for Applications

Dr. Michelle Le Beau will provide an update on the Academic Research Program and present the Program Integration Committee's (PIC) five recruitment award recommendations, totaling \$12 million. She will also present the proposed FY 2026requests for applications.

CPRIT does 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, Grant Award Recommendations, FY 2026 Requests for Applications, and the *2024 Texas Cancer Plan*

Ramona Magid will update the Oversight Committee regarding the agency's prevention activities and present the PIC's eight prevention grant award recommendations, totaling \$13.4 million. She will also present the proposed FY 2026 requests for applications. In addition, Ms. Magid will preview the *2024 Texas Cancer Plan*, which CPRIT will officially release in December as a fully integrated online resource.

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

## **Chief Product Development Officer Report and Grant Award Recommendation and FY** 2025 Requests for Applications

Dr. Ken Smith will provide an update on the Product Development Program and present the PIC's nine company award recommendations, totaling \$63.6 million. He will also present the proposed FY 2025 requests for applications.

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

# FY 2026 Program Priorities

Health and Safety Code Chapter 102 requires the Oversight Committee to establish program priorities on an annual basis. Ms. Doyle will present the proposed FY 2026 Program Priorities.

# Appointments to the Scientific Research and Prevention Programs Committee

Ms. Doyle has provisionally appointed two new members to CPRIT's Scientific Research and Prevention Programs Committees. CPRIT's statute requires the Oversight Committee to approve the CEO's recommendations before the appointments are final. CPRIT has provided biographical sketches for the appointees for the Oversight Committee's consideration.

# **Advisory Committee Presentations**

The Prevention Advisory Committee and the Geographic Diversity Advisory Committee will each present their annual reports.

# Health & Safety Code § 102.1062 Waivers

Ms. Doyle will present a FY 2025 conflict of interest waiver pursuant to Texas Health and Safety Code 102.1062 for General Counsel John Ellis.

# Proposed Amendments to 25 TAC Chapters 701

Cameron Eckel will present the three proposed changes to the agency's Chapter 703 administrative rules. If the Oversight Committee approves posting the proposed rule changes to the *Texas Register* for public comment, CPRIT staff will bring back the proposed rule amendments and any public comments in February for final approval.

# **Chief Operating Officer Report and Contract Approvals**

Heidi McConnell will discuss the operating budget, performance measures, and debt issuance history for the fourth quarter of FY 2024. Ms. McConnell will also present a recommendation to approve a contract for conference planning services to Innovation Event Management.

# **Communications Report**

Mark Loeffler will update the Oversight Committee on CPRIT's communication efforts, including coverage of the agency and grantees in earned media, digital media, and social media.

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# **Internal Auditor Report**

Weaver and Tidwell, CPRIT's internal auditor, will present an internal audit update.

# Personnel – Chief Scientific Officer

Ms. Doyle will provide a memo to Oversight Committee members separately regarding her recommendation related to a salary adjustment for the Chief Scientific Officer.



#### CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

# Oversight Committee Meeting Agenda

# November 20, 2024

8:30 a.m.

The Barbara Jordan Building 1601 Congress Avenue, Austin, TX 78701 Room 2.035A

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. If the Oversight Committee meets in closed session, it will do so in the Barbara Jordan Building, Room 2.027.

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 from August 21, 2024, and September 25, 2024, meetings	Tab 1
4.	Public Comment	
5.	Chief Executive Officer Report	Tab 2
6.	Chief Compliance Officer Report and Compliance Certification of Grant Award Process	Tab 3
7.	Chief Prevention Officer Report	Tab 4
	Grant Award Recommendations	
	• FY 2026 Requests for Applications	
	Texas Cancer Plan 2024 Presentation	
8.	Chief Scientific Officer Report	Tab 5
	Grant Award Recommendations	
	FY 2026 Requests for Applications	
9.	Chief Product Development Officer Report	Tab 6
	Grant Award Recommendations	
	FY 2025 Requests for Applications	
10.	Program Priorities for FY 2026	Tab 7
11.	Scientific Research and Prevention Program Committee Appointments	Tab 8
12.	Advisory Committee	Tab 9
	Prevention Advisory Committee Presentation	

	Geographic Diversity Advisory Committee Presentation						
13.	Health & Safety Code Section 102.1062 Waiver	Tab 10					
14.	Amendment to 25 T.A.C. Chapter 703 Tab 11						
	Proposed Amendments to Chapter 703						
15.	Chief Operating Officer Report	Tab 12					
16.	Contract Approvals	Tab 13					
	Conference Planning and Coordinating Services						
17.	State Agency Employment Level	Tab 14					
18.	Personnel – Chief Scientific Officer	Tab 15					
	Salary Adjustment						
19.	Communications Program Update	Tab 16					
20.	Internal Auditor Report	Tab 17					
21.	Subcommittee Business						
22.	Compliance Investigation Pursuant to Health & Safety Code § 102.2631						
23.	Consultation with General Counsel						
24.	Future Meeting Dates and Agenda Items						
25.	Adjourn						



#### CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

# Oversight Committee Meeting Minutes August 21, 2024

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. David Cummings announced a quorum present and called the meeting to order at 8:30 a.m.

#### Roll Call/Excused Absences – Agenda Item 2

Committee Members Present David Cummings, M.D. Ambrosio Hernandez, M.D. Donald (Dee) Margo Will Montgomery (via video) Mahendra Patel, M.D., P.A. Cindy Barberio Payne Bill Rice, M.D. Craig Rosenfeld, M.D. Thomas (Tommy) Taylor

Committee Members Absent None

#### Oath of Office – Agenda Item 3

Presiding Officer Dr. Cummings welcomed the Oversight Committee's newest member, Thomas A. Taylor, appointed in June by Lieutenant Governor Dan Patrick. Presiding Officer Dr. Cummings administered the Oath of Office to Mr. Taylor.

# Adoption of Minutes from the May 15, 2024, Meetings – Agenda Item 4, Tab 1

#### **MOTION:**

On a motion by Dr. Rice and seconded by Dr. Hernandez, the Oversight Committee voted unanimously to approve the minutes of the May 15 Oversight Committee meeting as presented.

## Public Comment – Agenda Item 5

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

# Chief Executive Officer Report – Agenda Item 6, Tab 2

Presiding Officer Dr. Cummings recognized Chief Executive Officer Kristen Doyle to present her report.

#### Chief Compliance Officer Report and Compliance Certification for the Proposed Grant Awards – Agenda Item 7, Tab 3

Presiding Officer Dr. Cummings recognized Chief Compliance Officer Vince Burgess and Compliance Program Manager Stephen Nance to present the compliance report. Mr. Nance presented the compliance report for the past quarter's activities.

There were no questions for Mr. Nance following his presentation.

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 – Agenda Item 8, Tab 4

Presiding Officer Dr. Cummings recognized Chief Scientific Officer Dr. Michelle Le Beau to provide the Academic Research Program update and introduce the Program Integration Committee's Grant Award recommendations.

As part of her program update, Dr. Le Beau presented the six FY 2024 Cycle 2 requests for applications (RFAs) for the committee's consideration: Core Facility Support Awards, High-Impact/High-Risk Research Awards, Early Clinical Investigator Awards, TREC: Core Facility Support Awards, TREC: Advancing Innovative Individual Research Awards at TREC-Eligible Institutions, and TREC: Pilot Study Award.

Following her program update, Dr. Le Beau presented the Scientific Review Council and Program Integration Committee (PIC) award recommendations for the FY2024 Cycle 2 and Recruitment Cycle 24.12. The five award slates include 36 recommended grants totaling \$60.6 million.

Rank	ID	RFA	Score	Application Title	PI	PI Org.	Budget
1	RP240545	CFSA	1.0	Renewal of CPRIT GMP Core	Lapteva, Natalia	Baylor College of Medicine	\$2,000,000
2	RR240070	RFTTFM	1.0	Expanding the Accessibility and Efficacy of CAR-T Cells Throug In Vivo Engineering	Labanieh, Louai	Baylor College of Medicine	\$2,000,000

Rank	ID	RFA	Score	Application Title	PI	PI Org.	Budget
3	RR240076	RFTTFM	1.0	Discovery of Molecular Glue Degraders Targeting the Undruggable Cancer Proteome	Yoon, Hojong	The University of Texas M. D. Anderson Cancer Center	\$2,000,000
4	RR240082	RFTTFM	1.2	Identification of Neural Mechanisms Contributing to Chemotherapy- Associated Cognitive Impairments	Sun, Yanjun	The University of Texas Health Science Center at Houston	\$2,000,000
5	RP240610	CFSA	1.4	UTHealth Cancer Genomics Cord (UTHealth CGC)	Zhao, Zhongming	The University of Texas Health Science Center at Houston	\$2,000,000
6	RP240478	CIA	1.4	Advancing immunotherapy for high-risk cancers in children and adolescents	Hegde, Meenakshi	Baylor College of Medicine	\$1,030,892
7	RP240473	CIA	1.6	Signal-Augmented Cancer Cell Therapies: Integrating Advanced Correlatory Studies and Mentorship	Omer, Bilal	Baylor College of Medicine	\$1,046,414
8	RP240494	CFSA	1.7	Children's Research Institute Metabolomics Core: Advanced Methodologies in Cancer Metabolism	DeBerardinis, Ralph	The University of Texas Southwestern Medical Center	\$2,601,616
9	RP240497	CFSA	1.7	Advanced Spatial Genomics Core Facility	Navin, Nicholas	The University of Texas M. D. Anderson Cancer Center	\$2,999,993
10	RR240079	RFTTFM	1.7	Immune surveillance and elimination of aneuploid cells in vivo	Trakala, Marianna	The University of Texas M. D. Anderson Cancer Center	\$2,000,000
11	RP240432	CFSA	1.8	Advanced Multiparameter Cytometry and Cell Sorting Core	Beeton, Christine	Baylor College of Medicine	\$1,999,882
12	RP240440	MIRA2	1.8	Novel Therapies for Osteosarcoma	Gorlick, Richard	The University of Texas M. D. Anderson Cancer Center	\$4,498,684
13	RP240557	CIA	1.8	Dietary intervention to modulate the microbiome and immune response	McQuade, Jennifer	The University of Texas M. D. Anderson Cancer Center	\$1,074,727
14	RP240430	CFSA	1.9	GCC Center for Comprehensive PK/PD & Formulation	Liang, Dong	Texas Southern University	\$2,000,000
15	RP240590	HIHRRA	2.0	Bidentate ERK Traps: Revolutionizing Combination Cancer Therapy Strategies	Dalby, Kevin	The University of Texas at Austin	\$249,996

Rank	ID	RFA	Score	Application Title	PI	PI Org.	Budget
16	RP240539	HIHRRA	2.0	Spectroscopy for quantitative real-time imaging of radical formation in ultra-high dose rate radiation therapy	Gustavsson, Anna- Karin	Rice University	\$250,000
17	RP240508	CFSA	2.1	The Texas Decision Science Corr Facility: A CPRIT Population Science Core	Volk, Robert	The University of Texas M. D. Anderson Cancer Center	\$2,995,778
18	RP240446	HIHRRA	2.1	Regulation of Transcription Factor Function by Local Chromatin Context	Soshnev, Alexey	The University of Texas at San Antonio	\$249,561
19	RP240442	CIA	2.1	Identifying and exploiting novel metabolic vulnerabilities in the treatment of kidney cancer	Courtney, Kevin	The University of Texas Southwestern Medical Center	\$913,682
20	RP240559	CFSA	2.1	High Performance Mass Spectrometry Imaging Core Facility	Brodbelt, Jennifer	The University of Texas at Austin	\$1,998,763
21	RP240441	CIA	2.2	Precision Lung Cancer Interception by Targeting High- Risk Lung Nodules	Zhang, Jianjun	The University of Texas M. D. Anderson Cancer Center	\$1,098,945
22	RP240438	MIRA2	2.2	Overcoming major barriers to the delivery of successful T-cell immunotherapies	Rooney, Cliona	Baylor College of Medicine	\$4,500,000
23	RP240579	HIHRRA	2.3	Renal Clearable Nano Delivery Systems for Maximizing Anti- tumor Immunity in Breast Cancer Brain Metastasis Treatment	Zheng, Jie	The University of Texas at Dallas	\$250,000
24	RP240521	CFSA	2.3	Pediatric Cancer Data Core	Xie, Yang	The University of Texas Southwestern Medical Center	\$1,999,760
25	RP240518	CIA	2.4	Adapting radiotherapy clinical trials to treatment response and artificial intelligence innovations	Desai, Neil	The University of Texas Southwestern Medical Center	\$1,460,229
26	RP240462	HIHRRA	2.5	Development of an Endoscopic Nuclear Imaging Capsule for Radio-Guided Cancer Surgery	Zannoni, Elena Maria	The University of Texas at Austin	\$250,000
27	RP240501	HIHRRA	2.6	Delivering Immunotherapy more effectively to glioblastoma with a "magnetic switch"	Qin, Zhenpeng	The University of Texas at Dallas	\$250,000
28	RP240542	HIHRRA	2.6	Digital Twin Augmented Reality for Prostate Laparoscopic Surgery	Fei, Baowei	The University of Texas at Dallas	\$250,000

Rank	ID	RFA	Score	Application Title	PI	PI Org.	Budget
29	RP240454	HIHRRA	2.7	Reversing Tumor Immune Exclusion with Sphingosine- 1- Phosphate Depleting Therapeutics	Stone, Everett	The University of Texas at Austin	\$249,998
30	RP240498	HIHRRA	2.7	Improving the management of gastric peritoneal carcinomatosis with Photo- Betabody Immunotherapy	Obaid, Girgis	The University of Texas at Dallas	\$248,991
31	RP240493	HIHRRA	2.8	Engineering in vivo chimeric antigen receptor (CAR) macrophages for diffuse midline glioma	Jiang, Wen	The University of Texas M. D. Anderson Cancer Center	\$250,000
32	RP240516	HIHRRA	2.9	Mapping multivalent Chromatin interactions to define the 3D genome of Clear cell renal cell carcinoma	Mani, Ram	The University of Texas Southwestern Medical Center	\$250,000
33	RP240605	HIHRRA	3.1	Stimulate Mucosal- associated Invariant T cells to Kill Cancer Cells	Huang, Shouxiong	Texas Biomedical Research Institute	\$249,484
34	RP240439	MIRA2	3.1	Innovative cell therapy approaches for hematological and solid malignancies	Neelapu, Sattva	The University of Texas M. D. Anderson Cancer Center	\$4,500,000
35	RP240489	MIRA2	3.2	Neural Regulation of Childhood Cancers	Morrison, Sean	The University of Texas Southwestern Medical Center	\$4,362,563
36	RP240474	MIRA2	3.6	Cellular Immunotherapies for Pediatric Solid Tumors	Metelitsa, Leonid	Baylor College of Medicine	\$4,497,964

Clinical Investigator Award (CIA) Core Facility Support Awards (CFSA) High-Impact/High Risk Awards (HIHRRA) Multi-Investigator Research Awards (MIRA2) Recruitment of First-Time, Tenure Track Faculty Members (RFTTFM)

In response to an Oversight Committee member's question about whether CPRIT limited the number of nominees an institution may submit for each cycle of the First-Time Tenure-Track award, Dr. Le Beau explained that CPRIT does not have a limit. Since CPRIT has received an increasing number of applications, she has discussed potential limits with the University Advisory Committee.

An Oversight Committee member commented that some of the same applicants receive the awards. Dr. Le Beau agreed that the largest institutions have the most robust recruitment programs and submit the most applications.

An Oversight Committee member responded that there are other areas that need to grow as well, noting that since some of the institutions have all the tools, they are at an advantage. The

member indicated that it is up to the board to address this, as there are ways to offset the balance. Dr. Le Beau explained that CPRIT shares the goal of expanding opportunities across the state of Texas. She noted that the Geographic Diversity Advisory Committee (GDAC) provided feedback on awards could make the most impact, including a recruitment award for the institutions eligible for Texas Regional Excellence in Cancer (TREC) awards.

An Oversight Committee member agreed that CPRIT should look at areas outside of the major research pipeline to support the best and move forward with the goal of curing cancer. The member recommended continuing to support the GDAC considerations to address issues like these.

An Oversight Committee member referenced two core facility projects proposed for awards and asked if CPRIT ensures rural access to the core facilities mentioned and how to bring these resources out to the rural areas. Dr. Le Beau responded that CPRIT encourages core facility applicants to include a plan for regional accessibility in their applications. She reports that an increasing number of applicants incorporate plans for providing services around the state. She noted that CPRIT can monitor this through evaluation of the annual progress reports. CPRIT may consider emphasizing the need for regional expansion in renewal applications.

An Oversight Committee member reiterated that CPRIT should ensure that oncologists and TREC institutions have access to these resources and that the goal of TREC grants is to assist institutions in becoming valuable, viable research institutions that are competitive for grant awards.

# Approval for Academic Research Awards

Presiding Officer Dr. Cummings noted that no Oversight Committee member had reported a conflict with the 36 award recommendations presented today.

# **MOTION:**

On a motion made by Mr. Montgomery and seconded by Dr. Rosenfeld, the Oversight Committee voted unanimously to approve the PIC's 36 recommendations for the following academic research grant award mechanisms:

- Clinical Investigator Awards;
- Core Facility Support Awards;
- High-Impact/High-Risk Research Awards;
- Multi-Investigator Research Awards; and
- Recruitment of First-Time, Tenure Track Faculty Members.

# Delegation of Contract Negotiation and Execution Authority

# **MOTION:**

On a motion made by Dr. Rice and seconded by Mr. Montgomery, the Oversight Committee voted unanimously to approve delegating contract negotiation authority to the CEO and CPRIT staff and to authorize the CEO to sign the contracts on behalf of CPRIT.

#### Approval for Proposed Budget Increase

Ms. Doyle presented a proposed budget increase of \$49,157 for the Texas A&M Health Science Center Research Training Award grant (RP210043). She explained that the increase allows the institution to bring the CPRIT post doc stipend on parity with the NIH stipend and noted that the Oversight Committee previously approved supplemental funds for six other Research Training Awards at the May meeting.

## **MOTION:**

On a motion made by Dr. Hernandez and seconded by Mr. Montgomery, the Oversight Committee voted unanimously to approve Ms. Doyle's recommendation to increase the approved budget for RP210043 by \$49,157.

#### Approval for Proposed FY 2025 RFAs

#### **MOTION:**

On a motion made by Dr. Hernandez and seconded by Dr. Rosenfeld, the Oversight Committee voted unanimously to approve the six proposed FY2025 Cycle 2 RFAs as presented by Dr. Le Beau.

#### Chief Prevention Officer Report and Grant Recommendations – Agenda Item 9, Tab 5

Presiding Officer Dr. Cummings recognized Chief Prevention Officer Ramona Magid to provide the Prevention program update.

There were no questions for Ms. Magid following her presentation.

# Chief Product Development Officer Report and Grant Recommendations – Agenda Item 10, Tab 6

Presiding Officer Dr. Cummings recognized Chief Product Development Officer Dr. Ken Smith and Senior Product Development Program Manager Dr. Abria Magee to present the product development program update.

Following Dr. Magee's presentation, an Oversight Committee member asked her whether the Texas New Technology Company award funds technologies other than artificial technology. Dr Magee explained that the RFA seeks proposals from companies developing novel technologies including machine learning, AI, and other breakthroughs outside of traditional therapeutics or devices.

There were no other questions.

# Scientific Research and Prevention Program Committee Appointments & FY 2025 Honoraria Policy - Agenda Item 11, Tab 7

Presiding Officer Dr. Cummings recognized Ms. Doyle to present the CEO's peer review appointments and the proposed FY 2025 honoraria policy. Ms. Doyle introduced the 28 new members of the Scientific Research and Prevention Program Committee (also called peer reviewers) and explained the FY 2025 Honoraria Policy.

# **MOTION:**

On a motion made by Dr. Hernandez, and seconded by Mr. Montgomery, the Oversight Committee voted unanimously to approve the CEO's 28 appointments to the Scientific Research and Prevention Program Committees.

# **MOTION:**

On a motion made by Dr. Rosenfeld, and seconded by Mr. Montgomery, the Oversight Committee voted unanimously to approve the FY 2025 Honoraria Policy.

# Advisory Committees – Item 12, Tab 9

Presiding Officer Dr. Cummings noted that two Oversight Committee advisory committees would present their annual reports and recommendations to the board. He recognized Dr. Le Beau to introduce David Gerber, M.D., Chair of the Clinical Trials Advisory Committee.

# Clinical Trials Advisory Committee Presentation

Dr. Le Beau introduced Dr. Gerber, co-director of the Office of Education and Training for the Simmons Comprehensive Cancer Center and professor in the Department of Internal Medicine at The University of Texas Southwestern Medical Center. He presented the Clinical Trials Advisory Committee (CTAC) Annual Report.

Following Dr. Gerber's report, an Oversight Committee member asked about patient eligibility for the CPRIT Clinical Trials Participation Award and whether the funds provided to the patients are tax-exempt. Dr. Gerber explained patient eligibility requirements and responded that he would look into the tax-exempt issue.

Dr Gerber responded to a member's question about whether the CTAC had considered recommending a central IRB like the one used by Children's Oncology Group, a clinical trials group supported by the National Cancer Institute, which cuts through local IRBs and allows trials to move more quickly. He noted that there is an NCI Central IRB for the cancer centers participating in NCI trials. Although industry sponsored trials do not use a central IRB nationally, they try to create a model for sites to rely on each other's IRBs. Dr. Gerber agreed that this would significantly streamline the process of initiating clinical trials.

An Oversight Committee member asked Dr. Gerber about the number of people in CPRITsponsored clinical trials. Dr. Gerber explained that CPRIT-sponsored clinical trials enrolled more than 57,000 patients in multiple types of trials, including observational trials with many patients.

On behalf of the Oversight Committee, Presiding Officer Dr. Cummings thanked Dr. Gerber for his presentation and the advisory committee's work.

He asked Dr. Magee to introduce the Product Development Advisory Committee (PDAC) presenters.

#### Product Development Advisory Committee Presentation

Dr. Magee introduced the PDAC chair and vice chair, Andrew Strong, and Dr. Michele Park, to present the PDAC report.

An Oversight Committee member asked whether previous funding is necessary for a company to receive a CPRIT award. Mr. Strong responded that an awardee must verify that the company has the required matching funds to receive CPRIT funding.

An Oversight Committee member asked whether CPRIT should prioritize funding more new companies or more follow-ups. Dr. Park answered that both are important, so more dollars invested in more companies is the preferred strategy. Mr. Strong added that it is CPRIT's strategy to balance the portfolio for successful investments.

An Oversight Committee member asked whether PDAC recommended CPRIT add more product development research program staff. Mr. Strong agreed, particularly for post award management.

An Oversight Committee member asked about distribution of product development awardees across the state, and whether companies are receiving awards in the areas of the state with TREC eligible institutions. Mr. Strong responded that the CPRIT-funded companies are mostly in Houston, Dallas, and San Antonio areas. He pointed out that there are growing inter-area connections and collaboration projects.

# Health & Safety Code § 102.1062 Waivers – Agenda Item 13, Tab 9

Presiding Officer Dr. Cummings recognized Ms. Doyle to present the four FY 2025 conflict of interest waivers. Ms. Doyle presented the waivers for CPRIT Program Manager for Prevention Carlton Allen, CPRIT Contract Specialist Donald Brandy, CPRIT Program Manager for Product Development Dr. Michelle Leeuwon, and a standing waiver for Review Council Members.

# **MOTION:**

On a motion by Dr. Rosenfeld and seconded by Dr. Hernandez, the Oversight Committee voted unanimously to approve the four proposed Health and Safety Code Section 102.1062 waivers for FY 2025.

# Amendments to 25 T.A.C. Chapter 701 – Agenda Item 14, Tab 10

Presiding Officer Dr. David Cummings recognized Assistant General Counsel Cameron Eckel to present the proposed final order approving a rule change to Chapter 701.

There were no questions for Ms. Eckel following her presentation.

# **MOTION**:

On a motion made by Mr. Margo, and seconded by Mr. Montgomery, the Oversight Committee voted unanimously to approve the final order adopting the rule change to Texas Administrative Code Chapter 701.

# Chief Operating Officer Report – Agenda Item 15, Tab 11 Contract Approvals - Agenda Item 16, Tab 12 Legislative Appropriations Request for the 2026-2027 Biennium – Agenda Item 17, Tab 13

Presiding Officer Dr. Cummings recognized Deputy Executive and Chief Operating Officer Heidi McConnell to present agenda items 15-17.

An Oversight Committee member asked if the royalty payment from Merck came from a prior product development grant and how long it has been since the initiation of that grant. Ms. McConnell responded that the Merck royalty payments are associated with the grant CPRIT made to Peloton in 2010. Merck acquired Peloton several years ago and has put Welireg on the market.

# Contract Approvals and Extensions

Ms. McConnell presented the following contracts and contract renewals for Oversight Committee approval:

- The Perryman Group for the economic Assessment of the Cost of Cancer in Texas,
- Alan Boyds Consultants for due Diligence Services,
- Weaver and Tidwell for Internal Audit Services,
- Norton Rose Fulbright and McDermott Will & Emery as outside counsel,
- Wellspring intellectual property database.

Ms. McConnell also presented her recommendation to extend the FY 2024 Business and Financial Management Solutions contract through October 15.

# **MOTION:**

On a motion by Dr. Rice and seconded by Mr. Montgomery, the Oversight Committee voted unanimously to approve the FY 2025 contract renewals and contract extension as laid out by Ms. McConnell with The Perryman Group, Alan Boyds Consultants, Weaver and Tidwell, Norton Rose Fulbright, McDermott Will & Emery, Wellspring, and Business and Financial Management Solutions.

#### Legislative Appropriations Request for the 2026-2027 Biennium

Following the contract approvals, Ms. McConnell laid out CPRIT's proposed legislative appropriations request (LAR) for the 2026-2027 biennium for the Oversight Committee's consideration.

There were no questions for Ms. McConnell following her presentation.

#### **MOTION:**

On a motion made by Mr. Margo, and seconded by Mr. Montgomery, the Oversight Committee voted unanimously to approve CPRIT's Legislative Appropriations Request for the 2026 – 2027 biennium.

#### Communication Report – Agenda Item 19, Tab 15

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

There were no questions for Mr. Loeffler following his presentation.

An Oversight Committee member thanked the communications team for the daily emails.

#### Subcommittee Business – Agenda Item 20, Tab 16

Presiding Officer Dr. Cummings proposed that Mr. Taylor join the Prevention, Product Development, and Scientific Research Subcommittees.

#### **MOTION:**

On a motion by Dr. Hernandez and seconded by Mr. Montgomery, the Oversight Committee voted unanimously to approve the new subcommittee appointments for Mr. Taylor.

#### Internal Audit Report – Agenda Item 18, Tab 14 Compliance Investigation Pursuant to Health & Safety Code § 102.26 – Agenda Item 21 Consultation with General Counsel – Agenda Item 22

Presiding Officer Dr. Cummings recognized Daniel Graves, representing CPRIT's internal auditor Weaver & Tidwell, to give the Internal Auditor's Report, the fiscal year 2024 Annual Internal Audit Report, and three internal audit reports. Presiding Officer Dr. Cummings noted for the board that at the conclusion of Mr. Graves report and a board vote, the Oversight Committee will move into closed session to receive the Internal Audit Follow-Up Procedures Report over Information Technology General Controls.

Mr. Graves provided the internal auditor update and presented the FY 2025 Internal Audit Plan, the FY 2024 annual internal audit report, and three internal audit reports.

There were no questions for Mr. Graves following his presentation.

# **MOTION:**

On a motion by Mr. Montgomery and seconded by Dr. Rosenfeld, the Oversight Committee voted unanimously to approve the internal audit reports regarding Oversight Committee Compliance, Records Management, and Communications, the FY 2025 Internal Audit Plan, and the FY 2024 Annual Internal Audit Report.

Following the vote, Presiding Officer Dr. Cummings announced the committee would go into closed session at 11:25 a.m. pursuant to Texas Government Code § 551.076 and Texas Health & Safety Code § 102.2631 to discuss the internal audit addressing information technology general controls and to consult with CPRIT's counsel and the Chief Compliance Officer regarding an ongoing compliance investigation. He asked Ms. Doyle, Ms. McConnell, Mr. Burgess, Mr. Nance, Ms. Eckel, Ms. Cusick, Mr. Emenike, and Mr. Graves to join the Oversight Committee in the closed session.

After the closed session discussion, the Oversight Committee reconvened in open session at 11:50 a.m.

Presiding Officer Dr. Cummings noted for the record that Ms. Cusick, Mr. Emenike, and Mr. Graves left the closed session before the board discussed the ongoing compliance investigation.

# **MOTION:**

On a motion by Mr. Montgomery and seconded by Dr. Rosenfeld, the Oversight Committee voted unanimously to approve the Internal Audit Follow-Up Procedures Report over Information Technology General Controls.

# Future Meeting Dates and Agenda Items – Agenda Item 23

Presiding Officer Dr. Cummings directed members to the FY 2025 schedule for Oversight Committee and standing subcommittee meetings behind tab 17 and reminded members that the next regular Oversight Committee meeting will take place on November 20, 2024.

# Adjournment – Agenda Item 24

# **MOTION:**

There being no further business, the Oversight Committee voted unanimously to approve Presiding Officer Dr. Cummings's motion to adjourn, which Dr. Hernandez seconded.

Presiding Officer Dr. Cummings adjourned the meeting at 11:54 a.m.

Signature

Date



#### CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

# Oversight Committee Meeting Minutes September 25, 2024

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. David Cummings announced that a quorum was present and called the meeting to order at 8:02 a.m. He explained that all Oversight Committee members except Dr. Bill Rice joined the meeting via video conference; the Texas Open Meetings Act allows this if the public guests attending the meeting in the posted location can see and hear those attending remotely. He thanked CPRIT's IT team for assisting the remote members' participation in the meeting.

Dr. Cummings announced that Oversight Committee member Dr. Bill Rice will serve as the Presiding Officer for this meeting in accordance with the Open Meetings Act and with the Oversight Committee Bylaws

Presiding Officer Dr. Rice proceeded with the roll call.

# Roll Call/Excused Absences – Agenda Item 2

Committee Members Present David Cummings, M.D. Will Montgomery Mahendra Patel, M.D., P.A. Cindy Barberio Payne Craig Rosenfeld, M.D. Thomas (Tommy) Taylor

Presiding Officer Dr. Rice announced a quorum.

# **Contract Approvals – Agenda Item 3**

Presiding Officer Dr. Rice recognized Chief Operating Officer Heidi McConnell to address agenda item 3.

Ms. McConnell presented the proposed FY 2025 contract approval for Business and Financial Management Solutions in the amount of \$118,000. She also presented the request for approval to execute a contract with a to-be-determined professional search firm for an amount not to exceed \$225,000.

An Oversight Committee asked whether the contract for the third-party peer review observer services followed a competitively bid process and how many responses CPRIT received. Ms. McConnell explained that CPRIT issued a request for proposals for the third-party peer review observer services and received one response.

#### **MOTION:**

On a motion by Mr. Montgomery and seconded by Dr. Rosenfeld, the Oversight Committee voted unanimously to approve the FY 2025 contract as laid out by Ms. McConnell with Business and Financial Management Solutions and the contract with a tobe-determined search firm for an amount not to exceed \$225,000.

#### Adjournment – Agenda Item 4

#### **MOTION:**

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

Presiding Officer Dr. Rice adjourned the meeting at 8:07 a.m.

Signature

Date



#### CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

# MEMORANDUM

TO:OVERSIGHT COMMITTEE MEMBERSFROM:KRISTEN DOYLE, CHIEF EXECUTIVE OFFICERSUBJECT:CHIEF EXECUTIVE OFFICER REPORTDATE:NOVEMBER 13, 2024

The Chief Executive Officer Report presented at the November 20 Oversight Committee meeting will include a brief update on grant funds available, personnel, and the 89<sup>th</sup> Texas Legislative session. I may add other items as warranted. For your reference, I have included copies of the August/September 2024 and October 2024 CPRIT Activities Updates behind this memo.

#### FY 2025 Grant Awards Funds Available and CPRIT Dashboard

As shown in the attached "FY 2025 Grant Funds Available" document, if the Oversight Committee approves the Academic Research awards, Product Development Research awards, and Prevention awards at the Program Integration Committee's recommended level of \$89.0 million, we will have \$181.8 million remaining for grant awards in FY 2025.

I have also attached CPRIT's dashboard of metrics that we track on a regular basis.

# Personnel

CPRIT has filled 52 full-time equivalent positions, including eight long-term contract employees. Since our last quarterly meeting, Glenda Bearden joined CPRIT as a full-time grant accountant on August 30. She started working with CPRIT earlier this year as a contract employee and has years of accounting experience with Texas agencies and other public and private sector entities. In October, CPRIT welcomed two new members of our senior staff, John Ellis and Grant Weaver.

• Mr. Ellis joined CPRIT as our new general counsel on October 14. He most recently served as the Chief Compliance and Risk Officer for the Texas Department of Information Resources, where he oversaw programs to manage risk and operationalize compliance with legal and ethical standards. Mr. Ellis also worked for the Office of the Attorney General, successively as Chief of the General Counsel Division, Special Counsel to the First Assistant Attorney General, and Associate Deputy Attorney General for Policy and Communications. Before joining state government, he served as legal counsel in the United States Senate.

• Mr. Weaver is CPRIT's first Chief Financial Officer, joining CPRIT on October 21. He has two decades of fiscal management experience, with a background in bond finance. He has served in various capacities at state agencies and institutions of higher education, including the Texas Department of Transportation, The University of Texas System, the Office of Attorney General, and the Commission on the Arts, where he served as Chief Financial Officer.

# Legislative Update

Since the August Oversight Committee meeting, I have met with several Texas state senators and members of their staff, including Sen. César Blanco, Sen. Bob Hall, Sen. Kelly Hancock, Sen. Juan "Chuy" Hinojosa, Sen. Bryan Hughes, Sen. Nathan Johnson, Sen. Tan Parker, Sen. Charles Perry, Sen. Royce West, and Dean Sen. Judith Zaffirini. I have meetings scheduled with Sen. Pete Flores (November 20) and Sen. Sarah Eckhardt (December 4). Chief Operating Officer Heidi McConnell, Chief Scientific Officer Dr. Michelle Le Beau, and Presiding Officer Dr. David Cummings accompanied me on some of these meetings. In addition to meetings with state senators, Dr. Cummings, Ms. McConnell, and I also met with Rep. Drew Darby. Now that the election is behind us, I will accelerate my outreach activities and start scheduling meetings with House of Representatives members.

November 12 was the first day that Texas state legislators could begin filing bills for consideration during the 89<sup>th</sup> Legislative Session, which will convene January 14. By the end of the first day, lawmakers filed 1,511 bills. Legislators will submit thousands more bills by the March 14, 2025, bill-filing deadline.

It appears that legislators did not file any bills the first day that directly affect CPRIT or CPRIT's enabling statute, Texas Health & Safety Code Chapter 102.

Other notable legislation includes:

# <u>SB 124</u>

Senator Bob Hall filed legislation relating to hospital patients' rights and hospital policies and procedures. The proposed legislation requires the hospital to adopt and implement a written policy ensuring a hospital patient's rights. Included in several enumerated rights proposed in the legislation is the right of a terminally ill patient to access and use certain investigational drugs, biological products, and devices that are in clinical trials in accordance with Texas' Right to Try Act (Texas Health & Safety Code Chapter 489).

# <u>HB 185/HJR 24</u>

Representative Senfronia Thompson filed legislation to establish the Mental Health and Brain Research Institute of Texas (MBRIT), modeled on CPRIT. This proposed bill is the same or similar to CPRIT's enabling statute and appears to be the same as the proposed legislation filed last session and passed by the House of Representatives. There is not a Senate bill companion filed at this time. Rep. Thompson also filed a house joint resolution to amend the Texas Constitution authorizing the Texas Comptroller to transfer \$3 billion from the general revenue fund to the MBRIT fund. This transfer would serve as the source of funding for MBRIT's grants and operations.

# <u>HB 975</u>

Representative Brian Harrison filed legislation relating to the right to try cutting-edge treatments for patients with life-threatening or severely debilitating illnesses.

# <u>HB1302/HJR 90</u>

Representative Richard Raymond filed legislation to create the Alzheimer Prevention and Research Institute of Texas, modeled on CPRIT. This proposed bill is the same or similar to CPRIT's enabling statute. There is not a Senate bill companion filed at this time. Rep. Raymond also filed a house joint resolution to amend the Texas Constitution authorizing the Texas Comptroller to transfer \$3 billion from the general revenue fund to the Alzheimer Prevention and Research Institute of Texas to serve as the source of funding for the agency's grants and operations.

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# CPRIT has awarded **2,017** grants totaling **\$3.65 billion**.

- 303 prevention awards totaling \$380.7 million
- 1,714 academic research and product development research awards totaling \$3.27 billion

Of the \$3.27 billion in academic research and product development research awards,

- 32.5% of the funding (\$1.06 billion) supports clinical research projects
- 23.2% of the funding (\$757.2 million) supports translational research projects
- 29.4% of funding (\$961.4 million) supports recruitment awards
- 12.1% of the funding (\$397.2 million) supports discovery stage research projects
- 2.8% of funding (\$90.4 million) supports training programs.

# CPRIT has 12 open Requests for Applications (RFAs)

- 3 Academic Research Recruitment RFAs
- 6 Academic Research RFAs
- 3 Prevention RFAs

#### FY 2025 GRANT AWARD FUNDS AVAILABLE

General Obligation Bond Proceeds

	F	Prevention	A	Academic / Product Development Research			1% Grant Funding Buffer		Operating Budget		Ap	Total Appropriations	
Available Appropriated Funds Approved Adjustment to Operating Costs Appropriations Transfer to DSHS	\$	27,286,961	\$	251,369,432 (1,990,411) (3,118,032)					\$	21,343,607 1,990,411 3,118,032	\$	300,000,000	
Adjusted Appropriations	Ś	27.286.961	Ś	246.260.989					Ś	26.452.050	Ś	300.000.000	
Total Available for All Grants	Ť	21,200,012	Ť.	,			Ś	273.547.950	Ŧ	20, 102,022	Ŧ	000,000,000	
1% of Total Available Grant Funding								2,735,480					
Adjusted Grant Award Funding	\$	27,286,961	\$	243,525,510							\$	270,812,471	
		Prevention Grants	A	cademic Research Grants		PD Research Grants							
Total Available for Grant Awards (Total GO Bond Proceeds Less Operating Budget)	\$	27,286,961	\$	172,382,692	\$	73,878,297					\$	273,547,950	
Total Available for Grant Awards Incorporating 1% Grant Funding Buffer	\$	27,286,961	\$	170,467,857	\$	73,057,653					\$	270,812,471	
Announced Grant Awards	\$	-	\$	-	\$	-							
Announced Grant Award Subtotal	\$	-	\$	-	\$	-	\$	-			\$	-	
Available Funds as of September 1, 2024	\$	27,286,961	\$	170,467,857	\$	73,057,653					\$	270,812,471	
Pending Grants-PIC Recommendations Prevention Grant Awards (8) ACR Recruitment Awards (5) PDR Company Grant Awards (9)	\$	13,446,501 - -	\$	- 12,000,000 -	\$	- - 63,566,376							
Pending Award Subtotal	Ś	13.446.501	Ś	12.000.000	Ś	63.566.376					Ś	89.012.877	
Total Potential Grant Funding Committed	\$	13,446,501	\$	12,000,000	\$	63,566,376					\$	89,012,877	
Available Funds as of November 21, 2024	Ś	13 840 460	Ś	158 467 857	Ś	9 491 277					Ś	181 799 594	
1% Grant Funding Buffer	\$	-	\$	1,914,836	\$	820,644					\$	2,735,480	
Total Remaining Funds	\$	13,840,460	\$	160,382,692	\$	10,311,921					\$	184,535,073	
Operating Budget Detail			—										
Indirect Administration									\$	4,910,893			
Grant Review & Award Operations										16,058,895			
Adjustment to Grant Review & Award Operations										1,990,411			
Subtotal CPPIT Operating Costs									ć	22 224 018			
Cancer Registry Operating Cost Transfer								ڔ	3 118 032				
Total. Operating Costs									Ś	26 452 050			

#### CPRIT MANAGEMENT DASHBOARD FISCAL YEAR 2024

	SEPT	ОСТ	NOV	DEC	JAN	FEB	MAR	APR	МАҮ	JUN	JUL	AUG	CUMULATIVE (ANNUAL)	CUMULATIV E (TO DATE)
ACCOUNTABILITY														L(IO DIIIL)
Announced Grant Awards	0		8			58			17			36	119	
New Grant Contracts Signed	7	11	3	3	3	1	7	33	10	8	9	6	101	
New Grant Contracts In Negotiation			12			26			12			20	70	
Grant Reimbursements Processed (#)	158	169	150	180	151	155	175	163	173	195	176	184	2029	
Grant Reimbursements Processed (\$)	\$ 21,014,507	\$ 20,145,254	\$ 12,238,992	\$ 21,326,886	\$ 24,511,438	\$ 17,776,613	\$ 20,891,726	\$ 29,758,929	\$ 13,836,090	\$ 30,261,680	\$ 27,737,710	\$ 19,044,645	\$ 258,544,469	
Revenue Sharing Payments Received	\$ 3,250	\$ 33,193	\$ 104,746	\$ 4,991	\$ 9,041	\$ 139,291	\$ 107,094	\$ 17,331	\$ 157,027	\$ 2,000	\$ 1,250	\$ 263,235	\$ 842,448	\$ 10,491,044
Grants Awarded (#)/ Applications Rec'd	19%	19%	19%	19%	19%	19%	19%	19%	19%	19%	19%	19%		
Grantee Compliance Trainings	2	3	1	5	0	3	3	3	2	3	5	6	36	
Grantee Compliance Monitoring Visits	0	0	3	3	4	3	4	4	5	4	5	0	35	
Awards with Delinquent Reimbursement Submission (FSR)			0			5			2			3		
Awards with Delinquent Matching Funds Verification			1			9			3			6		
Awards with Delinquent Progress Report			4			1			2			0		
MISSION														
Open RFAs	3	7	7	11	11	7	13	14	15	14	7	3		
Prevention Applications Received	0	0	0	0	0	0	0	0	0	24	0	0	24	1,041
Product Development Preliminary Applications Received	0	0	0	63	0	0	0	0	94	0	0	0	157	293
Product Development Full Applications Received	0	0	0	0	0	15	0	0	0	0	22	0	37	712
Academic Research Applications	4	5	4	5	3	4	17	0	0	357	0	3	402	9,458
Help Desk Calls/Emails	122	67	105	201	124	135	127	172	225	135	141	142	1,696	
Number of Research Grants Announced (Annual)	0		2			46			11			36	95	
Recruited Scientists Contracted														314
Number of Product Development Grants Announced (Annual)	0		6			0			6			0	12	
Life Science Companies Recruited (in														17
Number of Product Development Jobs Created & Maintained														1,866
Number of Prevention Grants Announced (Annual)			0			12			0			0	12	
Total Number of Education, Navigation and Training Services			147,203			156,011			172,412			163,363	638,989	
Total Number of Clinical Services			48,404			47,192			56,425			66,891	218,912	
Published Articles on CPRIT-Funded Projects (#)													968	
Clinical Studies (#)														273
Number of Patent Applications													41	
Number of Patents Resulting from													11	
Research														
Total Website Hits (Sessions)	14 201	11 400	13.405	0 570	10.000	17 343	11 710	14 675	14.504	0.000	0.000	15 200		
Total Unique Visitors to Wabsite (Users)	14,201	11,483	12,185	8,5/3	10,662	17,242	11,/18	14,675	14,504	9,888	9,099	15,290		
I otal Unique visitors to website (Users)	10,307	7,533	7,892	5,470	6,913	11,373	7,562	9,061	8,796	6,218	6,041	10,535		



#### CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

# MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	KRISTEN DOYLE, CHIEF EXECUTIVE OFFICER
SUBJECT:	CPRIT ACTIVITIES UPDATE FOR AUGUST/SEPTEMBER 2024
DATE:	OCTOBER 2, 2024

Topics in this memo address CPRIT activities in August and September, including recent milestones in our fight against cancer, a staffing update, outreach and legislative efforts, upcoming CPRIT-related events that may be of interest to Oversight Committee members, and updates from Compliance, Programs, and Operations.

#### **Recent Milestones in the Fight Against Cancer**

#### CPRIT Grantees in the News

• At a ceremony held July 9, CPRIT grantee Min Kang, PharmD., and Thomas Abbruscato, Ph.D., became the first recipients of the endowed Douglas Stocco Research Chair. The Texas Tech University System Board of Regents officially renamed the endowed chair, formerly known as the Texas Tech University Health Sciences Center's Research Endowment, in late November 2023 and made two appointments available.

Dr. Kang, a professor of pediatrics at Texas Tech University Health Sciences Center School of Medicine and associate vice president for research, is a renowned pharmacologist and cancer biologist accomplished in developing cancer treatments from laboratory science to clinical trials, especially in childhood cancers. She has worked with multiple preclinical studies and clinical trials consortia over the past two decades, informing the conduct of several clinical trials in both adult and pediatric cancers. Dr. Kang and the TTU Health Sciences Center have received three CPRIT Individual Investigator Research grants (RP101042, RP130547, RP170470), a Texas Regional Excellence in Cancer (TREC): Major Instrumentation Award grant (RP230447), and a Core Facility Support Awards grant (RP220631), which provides essential studies for clinical trials in pediatric cancers and drug development by small Texas biotech companies.

• The Advanced Research Projects Agency for Health (ARPA-H) announced an \$18 million award to Rice University, in collaboration with The University of Texas MD Anderson Cancer Center, to develop and validate a new system for improving the accuracy of tumor removal for breast and head and neck cancers. AccessPath is a novel, affordable, slide-free cancer pathology system designed to enable rapid, automatic classification of tumor margins in real-time. AccessPath is one of several projects funded through the ARPA-H Precision Surgical Interventions program announced August 16 as part of the broader \$150 million Biden-Harris administration Cancer Moonshot Initiative, which seeks to halve the cancer death rate by 2047.

The team, led by principal investigator and CPRIT grantee Rebecca Richards-Kortum, Ph.D., professor and director of the Rice360 Institute for Global Health Technologies at Rice University, are streamlining analysis for negative tumor margin classification while lowering cancer care costs and improving patient outcomes. The team plans to expand the range of hospitals able to provide accurate intra-operative tumor margin assessment, especially in low-resource settings.

Rice and Dr. Richards-Kortum have received two CPRIT Academic Research grants (RP100932, RP160460) in 2010 and 2016 totaling \$2.7 million.

• On August 23, NIH's National Center for Advancing Translational Research announced a \$44.2 million Clinical and Translational Science Award (CTSA) Program grant to Baylor College of Medicine and the University of Houston to create a regional hub called the Consortium for Translational and Precision Health (CTPH). CPRIT Scholar Christopher Amos, Ph.D., professor and director of Baylor College of Medicine's Institute for Clinical and Translational Research, leads the CTPH.

The CTPH is a partnership between the University of Houston and Baylor College of Medicine, along with the clinical and research groups within the Texas Medical Center, which supports infrastructure, services, community engagement, and workforce development to advance research and innovation in clinical and translational science. It will connect investigators with community healthcare organizations and government agencies that contribute to healthcare, clinical research, and policy in the region.

Baylor College of Medicine recruited Dr. Amos to Texas from the Dartmouth Geisel School of Medicine in 2017 with a \$6 million Established Investigator recruitment grant (RR170048). Co-Leaders of the CTPH include CPRIT grantee Fasiha Kanwal, M.D., professor of medicine and chief of the section of gastroenterology and hepatology at Baylor College of Medicine (RP200633, \$2.4 million), and Bettina M. Beech, Dr.PH., clinical professor of population health and the chief population health officer at the University of Houston.

• Each year, the Massachusetts Institute of Technology recognizes 35 people under the age of 35 who are leaders in research and entrepreneurship. Announced September 10, this year's class of "35 Innovators Under 35" includes CPRIT Scholar Christina Tringides, Ph.D., a newly appointed assistant professor in the Department of Materials Science and NanoEngineering at Rice University. Dr. Tringides built a new type of electrocorticogram, a thin device that sits directly on the brain during an invasive procedure - like the removal of a tumor or tissue responsible for epilepsy - recording electrical activity. These devices help surgeons to target the brain tissue to remove while avoiding tissue that is critical for movement or speech.

To improve on current technology, Dr. Tringides uses hydrogels, a class of polymers that, like the brain, exhibit properties of both liquids and solids. By modifying a hydrogel derived from alginate, a naturally occurring substance in seaweed, she created a film that closely matches the brain's mechanical properties and adheres to the brain's geometry in ways that current devices cannot. She embedded the gadget in spaghetti-like electrodes made from carbon nanotubes and flakes of graphene, a conductive form of carbon that can easily bend and flex. Researchers have used her prototype to record and map signals emitted by the brains of rats, including the hard-to-reach auditory cortex responsible for hearing that requires the device to bend more than 180 degrees.

Rice University recruited Dr. Tringides to Texas from Eidgenossische Technische Zurich in 2023 with a \$2 million CPRIT First-Time, Tenure-Track Faculty Member recruitment award (RR240005). She will develop technologies for mapping the brain for improved surgical removal of glioblastoma multiforme tissue, an aggressive brain tumor.

CPRIT grantee and biochemist Zhijian 'James' Chen, Ph.D. professor of Molecular Biology, director of the Center for Inflammation Research and the George L. MacGregor Distinguished Chair in Biomedical Science at The University of Texas Southwestern Medical Center, received two significant awards in recognition of his discovery of the cGAS enzyme – a critical component of the STING pathway. The cGAS enzyme senses invading pathogens and triggers the body's innate immune system. The STING pathway is like an alarm system that sounds when DNA enters a cell during an event of cellular stress, such as infection, cancer, or nutrient deprivation. Once this happens, the policing mechanism of the innate immune system is immediately called into action. Researchers are testing agonists (activators) of this signaling pathway in vaccine development and in combination with checkpoint inhibitors.

The Scientific Council of the Paul Ehrlich Foundation announced September 17 that it will award Dr. Chen, physician Andrea Ablasser from the École polytechnique fédérale de Lausanne, and virologist Glen Barber, Ph.D., from The Ohio State University, the Paul Ehrlich and Ludwig Darmstaedter Prize 2025. The Foundation will present the award, Germany's highest honor in the field of medicine, in Frankfurt on March 14, 2025.

On September 19, the Lasker Foundation awarded the 2024 Albert Lasker Basic Medical Research Award to Dr. Chen. The Lasker Awards, often called "America's Nobels" recognize significant advances in the understanding, diagnosis, treatment, cure, and prevention of human disease.

Dr. Chen and UT Southwestern have received seven CPRIT Academic Research grants (RP110430, RP120429, RP120718-P3, RP120718-C2, RP150498, RP160827, RP180725) totaling \$11.4 million since 2011. A Dallas-based biotech company, ImmuneSensor Therapeutics, is developing a new class of drugs that activate a patient's immune system to fight cancer based on Dr. Chen's seminal laboratory research at UT Southwestern. In an elegant example of completing the translational cycle, ImmuneSensor received a \$16.1

million CPRIT Product Development Research Award (DP220030) in 2022 for phase 2 clinical trials to evaluate the therapeutic efficacy of the combination of this novel STING agonist (IMSA101) with immune checkpoint inhibitors in solid tumors.

# Notable CPRIT-Supported Research and Prevention Accomplishments

• **Proteins for Skin Strength Also Control Cell Signaling.** Skin gets its strength from proteins called keratin intermediate filaments (KIFs), which are like tiny ropes inside skin cells that connect them together. There are 54 distinct types of these proteins, and skin cells make different combinations depending on the situation. However, scientists are still unsure why so many types of KIFs exist or how changes in their levels affect things like wound healing.

One common way to study proteins is to alter or remove the genes that make them. However, CPRIT Scholar Gaudenz Danuser, Ph.D., chair and professor in the Department of Bioinformatics and professor in the Department of Cell Biology at The University of Texas Southwestern Medical Center, realized that doing this to KIFs would weaken the skin, making it impossible to understand the other roles these proteins play.

Dr. Danuser and his team took a different approach. They created two groups of skin cells: one that made extra K6A keratin, which scientists have linked to wound healing, and another that produced more K5 keratin, which is typical in healthy skin. The research team grew these cells into artificial skin and observed cells activity. The team found that cells with higher K6A levels moved more easily and closed wounds faster than those with more K5. This movement depends on proteins called myosin motors, which generate the forces cells need to move. However, KIFs do not directly control these motors.

Further research showed that higher levels of K6A increased the activity of a molecular switch that triggers myosin motors, helping cells move. When K6A levels were lower, this switch did not activate at the same level, slowing cell movement.

The study, published in *Developmental Cell* on July 12, revealed that keratin filaments not only provide structural support but also function as platforms for signals that guide how skin cells behave, especially during wound healing. These findings will help researchers developing new treatments for skin diseases like ulcers and skin cancer.

UT Southwestern recruited Dr. Danuser from Harvard Medical School in 2012 with the support of a \$5 million CPRIT Recruitment of Established Investigators grant (R1225). Dr. Danuser holds the Patrick E. Haggerty Distinguished Chair in Basic Biomedical Science.

• Promising Results for the EXTEND Phase II Trial for Oligometastatic Pancreatic Ductal Adenocarcinoma. Metastatic pancreatic cancer is an aggressive type of cancer that spreads quickly to vital organs. Clinicians typically diagnose pancreatic cancer at a late stage, making treatment less effective and lowering survival rates. Currently, chemotherapy is the

main treatment option, but it only gives patients an average of seven months before the cancer worsens.

Chad Tang, M.D., associate professor, Department of Radiation Oncology, The University of Texas MD Anderson Cancer Center, and his team hypothesized that adding a targeted treatment called metastasis-directed therapy (MDT) to chemotherapy could help patients with limited metastatic pancreatic cancer live longer without their cancer progressing. MDT uses high-dose radiation to directly target cancer that has spread to other areas, and it has been successful in treating other types of cancer.

In the EXTEND trial (ClinicalTrials.gov identifier: NCT03599765), which began in 2019, the researchers studied 40 patients with pancreatic cancer that had spread to five or fewer locations. They found that patients who received both MDT and chemotherapy had better outcomes than those who received only chemotherapy. On average, the cancer stayed under control for 10.3 months with MDT, compared to just 2.5 months with chemotherapy alone.

These findings, published in the *Journal of Clinical Oncology* on August 5, suggest that MDT is a safe and effective way to help patients with pancreatic cancer live longer without their cancer getting worse. One likely reason for this benefit is that the radiation used in MDT may trigger a positive immune response in the body. Based on these promising results, MD Anderson will start a new Phase III trial called EXPAND in late 2024 to see if MDT can further improve both progression-free survival and overall survival for patients with metastatic pancreatic cancer.

MD Anderson and Dr. Tang received a \$2.4 million CPRIT Individual Investigator Research Award for Clinical Translation grant (RP180140) in 2018 in support of a randomized phase II basket trial to assess local control of limited metastatic cancer.

• Addressing a Critical Need – Treating Brain Tumors from Metastatic Breast Cancer. Brain tumors arising from metastatic breast cancer are common, and treatments like surgery, radiation, and other therapies often are not effective long term. Glioblastoma multiforme is another type of brain tumor, the most common and aggressive in adults, with a survival rate of less than two years despite hard-hitting treatments. A major challenge in treating brain tumors is the "blood-brain barrier," a natural defense that stops harmful substances from passing between the bloodstream and the brain, but it also blocks many cancer treatments.

Antibody-drug conjugates (ADCs) have shown promise in treating brain tumors. These drugs target proteins found on cancer cells while avoiding healthy cells. One such drug, Sacituzumab Govitecan (SG), is effective against a protein called TROP-2, which is present in many tumors but not found in normal brain tissue.

William Kelly, M.D., a CPRIT Early Clinical Investigator and assistant professor of hematology and oncology at The University of Texas Health Sciences Center at San Antonio, and his mentor and colleague Andrew J. Brenner, M.D., Ph.D., professor and chair of neurooncology research at the Mays Cancer Center at UT Health San Antonio, tested SG in the lab using mice with breast cancer that had spread to the brain. They found that the drug slowed tumor growth and helped the mice live longer. Based on these results, they launched a prospective window-of-opportunity clinical trial (NCT03995706) to evaluate SG in humans with either breast cancer that had spread to the brain or glioblastoma.

In the trial, 25 patients received SG before and after surgery to remove their brain tumors. For breast cancer patients, the treatment controlled the disease for an average of eight months, and for two months in glioblastoma patients. The drug also extended overall survival to about 35 months for breast cancer patients and 9.5 months for glioblastoma patients. The most common side effect was a reduction in white blood cells.

Researchers measured the amount of the active drug delivered to the brain and found that it reached effective levels in both types of tumors. The study also showed that SG successfully targets the TROP-2 protein, which was present in 100% of the breast cancer tumors and 78% of the glioblastoma tumors. The team concluded that SG penetrates brain tumors and has promising early results in treating these cancers. These findings support an ongoing phase 2 trial (NCT04559230) to further test SG in glioblastoma patients.

UT Health San Antonio and Dr. Kelly received a \$1.5 million CPRIT Early Clinical Investigator grant (RP210164) in 2021. UT Health San Antonio and Dr. Brenner received a \$756,000 Individual Investigator research grant (RP130548) in support of this research.

• Increased Energy Production by Mitochondria Associated with Kidney Cancer Metastasis. Mitochondria, often called the "powerhouses of the cell," are tiny structures inside cells that produce energy in the form of ATP, which powers various cell functions. In kidney cancer and many other cancers changes in mitochondria are common, but scientists do not fully understand how these changes impact the way that cancer cells use nutrients.

In a recent study, corresponding author Ralph DeBerardinis, M.D., Ph.D., professor, Department of Pediatrics, Howard Hughes Medical Institute Investigator, and Joel B. Steinberg, M.D., Distinguished Chair in Pediatrics in the Children's Research Institute at The University of Texas Southwestern Medical Center, collaborated with surgeons in the Department of Urology to investigate how kidney cancers process nutrients like sugar. They examined over 80 kidney cancer patients given labeled nutrients during surgery. The researchers found that tumors growing in the kidney had low mitochondrial activity, but when the cancer spread to other organs like the liver, lungs, or brain, mitochondrial activity increased.

In experiments with mice, the team discovered that stopping mitochondrial activity reduced the spread of cancer to the lungs, even though it did not affect the tumor growing in the kidney. On the other hand, increasing mitochondrial activity spread the cancer more easily, again without changing the tumor in the kidney.

The study, published in *Nature* on August 14, reports that while primary kidney tumors may downregulate mitochondrial function, metastatic tumors enhance it - highlighting a shift in

energy production strategies as the cancer spreads. These findings challenge long-standing assumptions and underscore the critical role of mitochondrial function in the spread of cancer to other parts of the body, offering new avenues for understanding and potentially treating metastatic kidney cancer.

UT Southwestern received a \$6 million CPRIT Multi-Investigator Research Awards grant (RP180778) in 2018 (P.I. Sean Morrison, Ph.D.; Project Leader Dr. DeBerardinis) to identify new therapeutic strategies that inhibit cancer progression.

• The Ultimate in Self-Promotion - Leukemia Cells Sequester Harmful mRNAs to Prevent the Production of Growth-Suppressing Proteins. According to the American Cancer Society, clinicians will diagnose nearly 21,000 new cases of acute myeloid leukemia (AML) in the U.S. in 2024, with a poor outlook for many types of AML, especially in older patients. A global team of scientists, including CPRIT Scholar Bruno Di Stefano, Ph.D., and other researchers from Baylor College of Medicine, has discovered how AML cells help themselves grow. These new findings, published online on August 21 in *Nature Cell Biology*, shed light on how AML cells survive and offer potential for new cancer treatments.

Previous research showed that leukemia cells influence the process of translating mRNAs into proteins to aid their growth, but the details were unclear. The investigators employed the powerful CRISPR technology to systematically turn off genes in both healthy and leukemia cells to uncover key differences. These studies revealed that a class of genes that regulate the function of "P-bodies" are crucial for AML cells, and that that leukemia cells had more P-bodies than normal cells.

First recognized two decades ago, P-bodies are a type of biomolecular condensate inside cells that serve as reservoirs sequestering specific mRNAs from the cellular machinery that translates them into proteins until the cells need them. By adjusting the stability of P-bodies, the scientists demonstrated that P-body formation is essential for AML to develop and survive. When they removed a protein called DDX6, which is crucial for creating P-bodies, the leukemia cells died in models of human AML, while normal blood cells were unaffected. This highlights the potential for targeting P-body formation as a treatment for AML.

AML is a complex disease and discovering a molecular pathway that might serve as its Achilles' heel has several important implications. These findings provide novel insights into the little studied mechanism of controlled mRNA translation in the context of cancer development. Since the DDX6 protein is a drug target, this opens the door to developing new cancer therapies focused on this mechanism.

Baylor College of Medicine recruited Dr. Di Stefano (RR200079) and co-author Eric Van Nostrand, Ph.D. (RR200040) to Texas in 2020 with CPRIT Recruitment of First-Time, Tenure-Track Faculty Members grants. The CPRIT Core Facility Support Award (RP180672, PI: Christine Beeton) supported the CPRIT Cytometry and Cell Sorting Core at Baylor College of Medicine serving this project. • Nature-Derived Nanobubbles Could Enable Biomedical Applications. Gas vesicles (GVs) are gas-filled organelles within bacteria composed of highly specialized protein shells that maintain stable gas-filled, bubble-like structures under extreme pressures. The water-dwelling photosynthetic bacteria that use GVs to float closer to sunlight have specific genes encoding the proteins that make up this special shell. GVs are some of the smallest bubbles known, and they can last for months by drawing gas from the surrounding liquid. Although scientists know these bacteria have specific genes that create the proteins forming the GV shells, they do not fully understand how these proteins come together to build the GV shells. Scientists are studying GVs for potential medical applications, such as imaging gene activity using ultrasound, MRI, or optical methods.

CPRIT Scholar Jiaozhi (George) Lu, Ph.D., assistant professor in the Department of Bioengineering, and his team in the Laboratory for Synthetic Macromolecular Assemblies at Rice University sheds light on the biology of GV formation, which could help scientists create them in the lab. While past research investigated how certain proteins work during GV formation, it often focused on individual interactions. Dr. Lu's team took a broader approach, studying all the possible protein interactions involved in building GVs. This allowed the researchers to better understand how the proteins depend on each other to create the GV shell.

The team developed a special test to study interaction between the 11 proteins known to be part of the assembly process. They deleted the genes responsible for specific proteins and monitored the results, which allowed them to map out the entire process of GV formation. Their research, published on September 3 in *The EMBO Journal*, provide a deeper understanding of the GV assembly mechanism, and pave the way for engineering GVs for use in biotechnology and medicine.

A key takeaway from Dr. Lu's research is that the process of GV assembly is extraordinarily complex, involving many interdependent elements. Some of the GV proteins form subnetworks, some need to interact with many parts of the system, and some change how they interact over time. This provides important insights and will serve as a starting point for further investigation into engineering GVs for practical applications

Rice University recruited Dr. Lu to Texas in 2019 with the support of a \$2 million CPRIT Recruitment of First-Time, Tenure-Track Faculty Members grant (RR190081).

• New Cancer Biomarkers Identified in Triple-Negative Breast Cancer May Aid the Selection of Therapy. A team of researchers led by Xiang H.-F. Zhang, Ph.D., director of the Lester and Sue Smith Breast Center and professor of molecular and cellular biology at Baylor College of Medicine, and collaborating institutions has made important discoveries about how triple-negative breast cancer (TNBC) affects a type of immune cell called B lymphocytes, found in the blood and bone marrow.

Their findings, published on September 12 in *Nature Cell Biology*, reveal two distinct patterns of changes in B cells that could serve as blood biomarkers. A cancer biomarker is a

signal in the body that can indicate the presence of cancer and help with diagnosis, treatment choices, and predicting the chances of the cancer returning. The biomarkers identified by the work may help doctors predict a patient's response to chemotherapy and immunotherapy.

Immunotherapies have improved outcomes for many cancer patients, but only 15 to 20% of people with TNBC benefit from these treatments. Dr. Zhang's lab investigated why some cancers do not respond to immunotherapy by studying how cancer interacts with other cells. Previous research showed that even before breast cancer spreads, it changes the way immune cells develop in bone marrow. To build on this, the team studied B cells from blood samples of patients and identified three groups based on how cancer affected the B cells.

The first group, TiBA-0, had normal B cells. The second group, TiBA-1, had fewer B cells, likely because of competition with other cells in the bone marrow. The third group, TiBA-2, had too many immature B cells, which were unable to fully develop because of interference from other immune cells called neutrophils. In this group, the immature B cells caused an increase in exhausted T cells, which weakens the immune response.

The researchers found that patients in the TiBA-1 and TiBA-2 groups had a weaker immune response and did not respond as well to treatment. In a study of 35 patients, most (79%) TiBA-0 patients responded well to chemotherapy and immunotherapy, while only one-third of the patients in the TiBA-1 and TiBA-2 groups had the same response. Importantly, the study also showed that researchers can detect these changes in immune cells throughout the body, not just in the tumor, meaning that clinicians could identify the changed immune cells with a simple blood test. The next step is to study these biomarkers in a larger group of patients over time to see how immune cells change during treatment. This could help doctors identify patients who may not respond well to standard treatments and need additional or alternative options.

Baylor College of Medicine received two CPRIT Core Facility Support Awards to support the laboratory studies critical for this research. The team performed the scRNA-seq at the Single Cell Genomics Core (RP200504), and the flow cytometry analysis at the Cytometry and Cell Sorting Core (RP180672).

# Personnel

CPRIT has filled 48 full-time equivalent positions, including a grant accountant hired August 30. CPRIT's new general counsel and new chief financial officer will join the agency on October 14 and October 21, respectively.

# **CPRIT Outreach**

Staff outreach activities during August and September include:
- Program Manager for Academic Research Dr. Myriam Casillas attended the National Cancer Institute webinar, "Cancer Prevention and Control in Mexico: Epidemiologic Research and Program Implementation" on August 8.
- Program Manager for Prevention Carlton Allen presented a CPRIT update at the Cancer Alliance of Texas quarterly meeting held August 8.
- Mr. Allen participated in the first American Cancer Society National Breast Cancer Roundtable (NBCRT) Risk Assessment Advisory Group. This is a group of professionals who address risk assessment, screening, risk reduction, and early diagnosis priorities within the NBCRT. This group oversees development of a resource that provides available risk assessment tools for breast cancer.
- On August 13, Senior Product Development Program Manager Dr. Abria Magee and Product Development Program Manager Dr. Michelle Leeuwon met with Dr. Ashkan Novin, founder and CEO at Genesist, LLC, a biotech startup specializing in CRISPR-based therapeutics for preventing cancer metastasis and recurrence. They discussed the company's interest in CPRIT funding.
- I attended the Austin Technology Council monthly meeting held August 14. Former Oversight Committee member Angelos Angelou presented his economic forecast for Austin and Texas and discussed the status of technology development. During his presentation, Mr. Angelou recognized the role that CPRIT has played in the growth of the life science economy over the past decade.
- On August 28, Dr. Magee met with Bob Trehy, Partner at MedInvest. MedInvest is a leading media, news, and conferencing company in the healthcare, biotech and medtech space. They are interested in CPRIT staff/leadership presentations at 2025 conferences. MedInvest typically holds its conferences in partnership with the National Institutes of Health, Cooley, Wilson Sonsini, Goodwin, McDermott Will & Emery, Fenwick, Perkins Coie, Venable, Freemind Consultants, and Torreya Partners.
- Dr. Magee met with Dr. Srinivas Bette on August 28. Dr. Bette is the founding partner of 4See Advisory in Dallas. 4See Advisory is a strategic advisory firm and investor. Dr. Magee and Dr. Bette discussed how CPRIT could educate their team of investors on the CPRIT product development application process and how they can help companies secure matching funds for CPRIT grants.
- On August 29, Dr. Magee attended the Texas-Israel Fireside Chat with Diagnostics Robotics CEO Dr. Kira Radinsky. She spoke to predictive patterns in cancer research as the next big step in healthcare AI with causal inference. Dr. Radinsky acknowledged CPRIT as an important agency in the state and a friend of the Texas-Israel Alliance.
- Deputy Executive and Chief Operating Officer Heidi McConnell and I met with a business delegation from Tampere, Finland, during their visit to Austin on September 9. The Finnish

delegation was particularly interested in opportunities to establish U.S. headquarters for Finnish companies in Texas. I made a presentation to the group regarding CPRIT's product development program.

- On September 10, Dr. Magee served on an investor panel at the Greater Houston Partnership Life Sciences Committee Meeting. The panel discussed the changing climate for life sciences investing in the Houston ecosystem. Other panel members included Dr. Michael Dilling, Executive Director of Commercialization, Technology Management at Baylor College of Medicine Ventures, Dr. Sahir Ali, CEO and Founder of Modi Ventures, and Mr. Marcus Nelson, Vice President of Business Analytics at the Texas Medical Center Venture Fund.
- Mr. Allen presented a *Texas Cancer Plan 2024* update at the Texas HPV Coalition meeting on September 10. The Texas HPV Coalition, with members from across the state, convenes to discuss the current state of HPV vaccinations and highlight HPV activities and projects. Mr. Allen was part of a panel discussion with the Cancer Alliance of Texas and The Immunization Partnership.
- Dr. Casillas attended the September 11 webinar, "NIH/NCI DCP Immunoprevention."
- I participated in the CPRIT round table event with Eric Danielson, managing director and NexPoint's head of real estate development, at the Texas Research Quarter (TRQ) on September 11. NexPoint is developing the TRQ, a life science focused innovation district planned in Plano as a major hub for life science that brings together multiple public and private sector stakeholders to advance innovation, improve educational opportunities, develop a skilled future workforce, and drive long-term economic impact in the Plano and surrounding area. The first phase of the project is redeveloping the former EDS 91-acre site. CPRIT Oversight Committee members Craig Rosenfeld and Tommy Taylor and former CPRIT CEO Wayne Roberts also attended the event.
- Dr. Magee presented an invited talk at the *AI in Health* conference hosted by the Ken Kennedy Institute at Rice University on September 11. Hundreds of AI experts from across the country attended the conference, which addressed the current state of AI in healthcare and public health. Dr. Magee's presentation focused on the agency's mission and AI companies funded by CPRIT's product development program.
- On September 13, Dr. Le Beau and I met with Martin Hyun, Chief Strategy Officer at DWD Healthcare. Mr. Hyun is advising Chungnam National University (CNU), South Korea, regarding their strategic plans to expand CNU's presence in Texas and foster closer ties with key players in the region's life sciences and bioprocessing ecosystem. CNU's two primary areas of interest are bioprocessing education/industry collaborations and facilitating market entry for Daejeon-based companies. Mr. Hyun and representatives from CNU will be in Houston visiting TMC and The University of Texas MD Anderson Cancer Center in late October and plan a visit in January for a technology showcase. While in Texas, they will meet with Dr. Magee and me to continue our discussion on potential collaboration.

- NCI Director Dr. W. Kim Rathmell invited Dr. Le Beau to co-chair the annual retreat held September 17 for the Directors of the NCI-designated Cancer Centers. The retreat, held at the NCI campus in Shady Grove, Maryland, addressed current challenges facing national cancer centers, including engaging communities in cancer research and clinical trials and enabling nation-wide efforts to achieve unifying cancer goals.
- I attended the Congressional Caucus on Childhood Cancer Summit in Washington, D.C., on September 19 on behalf of CPRIT. Rep. Michael McCaul has co-chaired the caucus for many years and is a strong advocate for pediatric and adolescent cancer research. I also attended the "Golden Toast" event hosted by the Carson Leslie Foundation immediately following the Summit.
- Dr. Magee attended the first week of the prestigious Governor's Executive Development Program (GEDP) September 23 – 27. Earlier this summer, the Office of the Governor approved CPRIT's nomination of Dr. Magee to join the GEDP Class XLII. The GEDP leads top executives in Texas state agencies and universities in organizational strategy, infrastructure management, resource management, and personal effectiveness through a three-week intensive educational program over three months. Several CPRIT staff members are GEDP alumni, including Ms. McConnell, Chief Operating Officer Vince Burgess, Director of Research Dr. Patty Moore, Compliance Director Stephen Nance, and myself. Dr, Magee will also attend GEDP training in October and December.
- On September 25 and 26 I attended and spoke at the Investor Dinner, sponsored by J.P. Morgan, and the TMCi Accelerator for Cancer Therapies (ACT) Summit Day in Houston. CPRIT funds the TMCi ACT, launched in collaboration with the Gulf Coast Consortia and The University of Texas Medical Branch, to support Texas-based biotech entrepreneurs and researchers contemplating translations alongside institutional technology transfer teams.
- Oversight Committee member Tommy Taylor and I attended the Texas Healthcare and Bioscience Institute (THBI) Luminary Dinner in August on September 26. THBI presented Luminary Awards to Sen. Joan Huffman, Rep. Donna Howard, and Tom Luce and the Lyda Hill Foundation.
- Chief Prevention Officer Ramona Magid and Mr. Allen attended the first annual meeting of CONNECT, the Colorectal Cancer Coordinating Center award project at Dell Medical Center on September 27. CPRIT colorectal cancer screening grantees and other stakeholders also attended.
- Dr. Magee met with multiple companies during August and September to discuss the application process for the product development program, including Zaffer Syed, the CEO of Aspira Medical (Houston-based medical device company focused on enhancing patient care and outcomes in ICUs worldwide through the early detection and management of aspiration pneumonia), Tushar Sharma, CEO of Vivify Medical (device to prevent benign prostatic

hyperplasia), and Dr. Sanket Chauhan, CEO and Founder of Surgical Automations (Dallasbased company, developing robots for colonoscopy).

# Legislative Outreach and Preparations for the 89th Legislative Session

- In August and September, I met with Senator West (August 8), Senator Blanco (August 8), and Senator Hughes (September 4) to provide an update on CPRIT's activities. I also met with legislative and leadership office staff including Savannah Mann (Senator Parker), Adria Franco (Lt. Governor Patrick), Andrew Blifford (Speaker of the House Rep. Phelan), and Maureen Metteauer (Sen. Committee on Health & Human Services).
- Deputy Executive and Chief Operating Officer Heidi McConnell and I attended the Bond Review Board Planning Meeting (August 13) and Board Meeting (August 22). The Bond Review Board approved CPRIT's FY 2025 bond issuance.
- On August 14, Ms. McConnell and I met with the Governor Abbott's newly appointed Budget Director, Brady Franks, and Policy Director, Michael Hull, along with CPRIT's assigned budget and policy analyst Mikel Moore. We provided an update on CPRIT and reviewed CPRIT's legislative appropriations request (LAR) for the 2026-2027 biennium.
- Ms. McConnell and I presented CPRIT's LAR at the Office of the Governor/Legislative Budget Board Joint Budget Hearing on August 29.

# **Upcoming Events**

There are several upcoming events related to CPRIT, CPRIT grantees, or cancer that may be of interest to Oversight Committee members. I have noted when CPRIT staff will be making presentations. Please contact me or the appropriate program staff if you would like more information about an event or meeting.

BioNTx IC3 2024 Life Science Summit (Dallas)
Belgian Life Science Company Delegation meeting (Houston)
Senior Product Development Program Manager Dr. Abria Magee will
serve as a panel member and participate in business meetings.
Product Development Advisory Committee Meeting (virtual)
Healthier Texas Summit (Austin)
Prevention Program Manager Carlton Allen will give a presentation and
serve as a panel moderator at the summit.
Texas A&M University System Chief Research Officers Retreat (Austin)
<i>I will give a presentation about CPRIT funding and priorities.</i>
Academic Research Peer Review Panel Meetings (virtual)
The University of Texas Southwestern Medical Center's Innovation Days (Dallas)

October 30	CPRIT's Advisory Committee on Clinical Trials in person meeting hosted
	by Baylor College of Medicine (Houston)
November 6 - 10	Society for Immunotherapy of Cancer (SITC) Annual Meeting (Houston)
	The Product Development Research Program will be part of the Tumor-
	Infiltrating Lymphocyte Panel on November 6.
November 10-11	Researchers' Roundup (Dallas)
November 11	Tour of the Rice University Biotechnology Launch Pad, meeting with
	CPRIT Scholar Dr. Omid Veiseh and other TMC partners, launch of
	Rice's strategic initiative (Houston)
November 13	American Cancer Society Cancer Action Network (ACS CAN) Policy
	Meeting – Diversity in Clinical Trials (Pegasus Park, Dallas)
November 20 – 22	National Colorectal Cancer Roundtable meeting (Fort Worth)
January 31	ACS-CAN Policy Meeting (Houston)

### Texas Cancer Plan 2024 Update

The *Texas Cancer Plan* (TCP) is a statewide strategic plan to reduce the cancer burden across Texas and improve the lives of Texans. CPRIT is statutorily responsible for developing the TCP. We issued the first TCP under CPRIT's leadership in 2012, with the second - and most recent - version issued in 2018. Consistent with CPRIT administrative rule § 701.11, which directs CPRIT to periodically update the TCP every seven years, we will officially release the new edition in December as a fully integrated online resource (similar to the recent versions of the CPRIT Annual Report). In preparation for official release, CPRIT will preview the *Texas Cancer Plan 2024* for the Oversight Committee at the November 20 meeting.

CPRIT Program Manager for Prevention Carlton Allen is leading the revision of the TCP, including meeting with multiple stakeholders. As the statewide call to action for cancer prevention, control, and research, the TCP identifies the challenges and issues that affect Texas and presents a set of goals, objectives, and strategies to help inform and direct communities in the fight against cancer. The TCP provides a coordinated, prioritized, and actionable framework that guides statewide and community efforts to mitigate the cancer burden.

CPRIT has engaged an array of stakeholders to enhance the TCP's effectiveness. Mr. Allen also worked with the Texas Cancer Registry and Behavioral Risk Factor Surveillance System to gather updated data relevant to the TCP. He collaborated closely with the Department of State Health Services (DSHS) on data integration and hosted town halls and forums to elicit input on goals, objectives, and strategic actions to inform and guide communities and stakeholders in the fight against cancer.

Multiple entities involved with the TCP's revision, execution, and evaluation, include:

• The Texas Comprehensive Cancer Control Program (TCCCP) and Chronic Disease Epidemiology Branch (CDE) at DSHS evaluate the plan and inform CPRIT, the Cancer Alliance of Texas (CAT), public health professionals, and other cancer prevention and control stakeholders in Texas of the current measures and progress Texas is making towards the TCP's goals and objectives. TCCCP also updates these groups on trends in cancer burden and assists in coordinating the implementation and periodic revision of the TCP.

- The Centers for Disease Control and Prevention's National Comprehensive Cancer Control Program (NCCCP) provides funding, guidance, and technical assistance to TCCCP to coordinate cancer prevention and control interventions, and to support the CAT.
- CAT is the state's comprehensive cancer control coalition, which TCCCP administers. DSHS has received funding from the NCCCP since 1998 to implement the state's cancer control plan and convene a statewide cancer control coalition. CAT's mission is to engage organizations, agencies, institutions, and individuals to work collaboratively to reduce the impact of cancer in Texas and promote the TCP.

CPRIT's strategic direction and funding opportunities align with the TCP but are, by necessity, a subset of the goals and objectives. The overall outcome and success of efforts to reduce the state's cancer burden will continue to depend on the cooperation, collaboration, and resources of stakeholders across Texas.

### **Compliance Program Update**

#### Submission Status of Required Grant Recipient Reports

As of September 18, 12 entities had not filed 14 academic research reports, seven prevention reports, and one product development report. 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 292 second-level reviews of grantee Financial Status Reports (FSRs) in August and September. Fifty-five FSRs (19%) 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 12 enhanced desk-based financial monitoring reviews in August and September. Desk reviews confirm financial, administrative, and programmatic compliance using data from CGMS/CARS with additional focus on an organization's internal controls, current and previous fiscal audits, and grantee report submission timeliness. 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. Compliance specialists are collaborating with three grantees to address enhanced desk review findings.

### Single Audit Tracking

Compliance specialists track the submission of grantees' independent audit reports, and the resolution of issues named in these reports. Grantees spending \$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.

#### 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, as well as 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 two annual match expenditure reviews in August. The total amount of match expenses reviewed by compliance staff for FY 2024 is \$29,752,281.89. The unallowable match expenses this fiscal year are related to unallowable travel costs, expenses previously requested for reimbursement on a financial status report, and unallowable late fees and interest charges.

#### Training and Support

CPRIT staff conducted two new grantee training webinars in August for Aakha Biologics and Bectas Therapeutics. The training covers 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 grantees to complete the initial compliance training program prior to receiving disbursement of grant award funds.

All new Product Development grantees will now participate in a revised New Grantee Training and will also receive FSR technical assistance training prior to the submission of their first FSR with expenses. This training is an interactive training, with grantee staff, the assigned CPRIT grant accountant, and compliance staff participating. CPRIT designed the training to help the grantee prepare the required FSR support documentation, including using the correct expense ledger template.

The new training highlights the resources available through the Grantee Resources tab on the CPRIT website, including match expenditures templates, match eligibility matrix, and a program specific checklist to aid in submitting the required documentation by expense category. The training incorporates a comprehensive review of the grantee's expense ledger, by category, along with all expense support documentation. This interactive process is a critical part of the technical assistance training, with the goal of reimbursing the grantee quickly and accurately, thereby allowing the grantee to access additional advanced funds in a timely manner to complete the goals and objectives of the grant. CPRIT staff conducted trainings in August for new CPRIT grantees Single Cell Biotechnology Inc., Crossbridge Bio, FixNip LTD., and March Biosciences.

# Academic Research Program Update

#### Recruitment FY 2024 Review Cycle 12

CPRIT's Application Receipt System (CARS) opened June 20 – August 20 for the first cycle of FY 2025 recruitment applications. The Scientific Review Council (SRC) reviewed 20 recruitment applications (total request \$52.6 million) on September 12. Dr. Le Beau will present the SRC's recommendations to the Program Integration Committee (PIC) and Oversight Committee in November.

FY 25.1 Mechanism	Received	Requested	Recommended	Recommended
Recruitment of Established Investigators	1	\$6,000,000	0	N/A
Recruitment of First-Time, Tenure Track Faculty Members	14	\$28,000,000	4	\$8,000,000
Recruitment of Rising Stars	5	\$18,594,367	1	\$4,000,000
TOTAL		\$52,594,367	5	\$12,000,000

Academic Research FY 2025 Cycle 1 (25.1)

CPRIT released seven RFAs on February 22 for the first review cycle of FY 2025 and accepted applications March 19 - June 11. Peer Review panels will meet in October. Dr. Le Beau will present the SRC's recommendations for FY 25.1 awards to the PIC and the Oversight Committee in February 2025.

FY 25 Cycle 1 Mechanism	Received	<b>Funds Requested</b>
Individual Investigator Research Award (IIRA)	220	\$196,400,895
IIRA for Computational Systems Biology of Cancer	29	\$29,833,203
IIRA for Cancer in Children and Adolescents	36	\$42,160,677
IIRA for Prevention and Early Detection	21	\$24,022,601
IIRA for Clinical Translation	26	\$41,025,711
IIRA for Early Onset Cancers	13	\$11,379,861
Collaborative Action Program (competitive renewal)	1	\$3,000,000
TOTAL	346	\$347,822,948

# Academic Research FY 2025 Review Cycle 2 (25.2)

CPRIT released six RFAs (listed below) for the second review cycle of FY 2025 on August 28 and will accept applications September 18 – December 10. Peer review panels will meet in March 2025. Dr. Le Beau will present the SRC's recommendations to the PIC and the Oversight Committee in May 2025.

• Core Facility Support Awards

Supports applications that facilitate the development or improvement of core facilities that will provide valuable services to support and enhance scientifically meritorious cancer research projects. Applicants may request funds to develop a new facility or to enhance the capabilities of an existing facility that will directly support and impact cancer research programs at the institution and in the region. CPRIT will look with special favor on applications that propose a facility that will serve cancer researchers at multiple Texas research institutions, in particular TREC-eligible institutions.

Award: The maximum duration for this award mechanism is 5 years. Applicants may request up to a maximum of \$3,000,000 in total costs.

• High-Impact/High-Risk Research Awards

Supports applications that explore the feasibility of high-risk projects that, if successful, would contribute major new insights into the etiology, diagnosis, treatment, or prevention of cancers. Using this mechanism, CPRIT intends to support innovative, developmental projects that focus on exceptionally promising topics that are not yet sufficiently mature to compete successfully for more conventional funding. CPRIT expects the HIHR Research Awards to provide the foundation for individual or multiple investigator peer-reviewed awards upon completion. The goal of this award mechanism is to fund uncommonly great ideas that merit the opportunity to acquire preliminary data.

Award: Applicants may request a total of \$250,000 for a period of up to 24 months.

#### • Early Clinical Investigator Awards

Solicits applications from institutions to provide cancer physicians early in their academic career the opportunity to develop clinical research skills and to gain experience in advanced methods and experimental approaches needed to become clinical investigators; to provide an opportunity to establish a partnership with a laboratory-based collaborator in order to design and conduct correlative studies needed to interpret the outcome of an interventional trial; to provide the protected time from clinical responsibilities required to develop and conduct investigator initiated clinical trials; and to increase the pool of clinical investigators at Texas academic institutions who are conducting patient-oriented studies, capitalizing on basic discoveries and translating them through conduct of innovative clinical trials involving cancer patients or individuals at risk for cancer.

Award: Up to \$1,000,000 (total costs) Maximum duration: 5 years

### • TREC: Core Facility Support Awards

Supports applications that facilitate the development or improvement of core facilities that will provide valuable services to support and enhance scientifically meritorious cancer research projects at TREC eligible institutions. Applicants may request funds to develop a new facility or to enhance the capabilities of an existing facility that will directly support and impact cancer research programs at the institution and in the region. CPRIT will look with special favor on applications that propose a facility that will serve cancer researchers at multiple Texas research institutions, in particular TREC-eligible institutions. Award: The maximum duration for this award mechanism is 5 years. Applicants may request up to a maximum of \$2,000,000 in total costs.

• *TREC: Advancing Innovative Individual Research Awards at TREC-Eligible Institutions* Supports research projects addressing critically important questions that will significantly advance knowledge of the causes, prevention, and/or treatment of cancer. This award allows experienced or early-career-stage cancer researchers the opportunity to explore new methods and approaches for investigating a question of importance that current research has not adequately addressed or for which there may be an absence of an established paradigm or technical framework.

Award: Applicants may request up to a maximum of \$750,000 in total costs. Duration: 3 years.

• TREC Pilot Study Award

Provides short-term funding to explore the feasibility of cancer research projects at TRECeligible institutions that, if successful, would contribute new insights into the etiology, diagnosis, treatment, or prevention of cancers forming the basis for applications for peerreviewed funding from CPRIT or other organizations. Award: Total of \$200,000 over a period of 2 years.

### Product Development Research Program Update

#### Product Development Research FY 2025 Review Cycle 1 (25.1)

CPRIT released four FY 2025 Product Development Research RFAs on April 15 and opened the portal for preliminary applications April 22 – May 1. CPRIT received 90 preliminary applications by the May 1 deadline. This is a record number of preliminary applications.

CPRIT assigned the preliminary applications to several review panels in May for individual evaluation and scoring. The review panels met to rank and score their assigned preliminary applications in late June. In early July, CPRIT issued 24 invitations to submit full applications to companies receiving the best preliminary application scores. Of the 24 invitations, 22 companies submitted their full applications to CPRIT by the July 25 deadline. These presented their proposals to the individual review panels in September. Based upon the application scores and presentations to the panels, nine companies will move forward to due diligence in October. The Product Development Review Council (PDRC) will meet in November to vote on its final recommendations. Dr. Smith will present the PDRC's recommendations to the PIC and the Oversight Committee in November.

	Prelim	Total	Full	Total	Due	Total
FY 2025 Cycle 1 Mechanism	Apps	Request	Apps	Request	Diligence	Request
Texas Therapeutic Company	20	\$236.6 M	9	\$114.4 M	5	\$48.0 M
Texas Device/Diagnostic Co.	13	\$109.6 M	5	\$43.0 M	1	\$12.6 M
Texas New Tech Company	13	\$98.4 M	2	\$7.5 M	0	N/A
Seed Company	44	\$149.2 M	6	\$17.4 M	3	\$8.2 M
TOTAL	90	\$593.8 M	22	\$181.3 M	9	\$68.9 M

#### **Prevention Program Update**

#### Prevention FY2025 Review Cycle 1 (25.1)

The prevention program released three RFAs on February 9 for the first review cycle of FY 2025. CPRIT received 24 applications by the June 6 deadline. Peer review panels met September 10 and 11. The Prevention Review Council (PRC) will meet October 18 to make recommendations to the PIC. Chief Prevention Officer Ramona Magid will present the PRC's recommendations to the PIC and the Oversight Committee in November.

Cycle 25.1 Mechanism	Apps	Funds Requested
Primary Prevention of Cancer	7	\$6.8 M
Cancer Screening and Early Detection	16	\$29.8 M
Dissemination of CPRIT-Funded Cancer Control Interventions	1	\$450,000
TOTAL	24	\$37.05 M

### Prevention FY2025 Review Cycle 2 (25.2)

The prevention program released three RFAs on August 26 for the second review cycle of FY 2025. CPRIT will accept applications for Cancer Screening and Early Detection awards, Dissemination of CPRIT-Funded Cancer Control Interventions awards, and Primary Prevention of Cancer awards through December 5, 2024. Peer review panels will meet in March 2025. Ms. Magid will present the Prevention Review Council's recommendations to the PIC and the Oversight Committee in May 2025.

# **Advisory Committees**

- The Clinical Trials Advisory Committee met August 2.
- The Advisory Committee on Childhood Cancers met August 26 and September 23.
- The Prevention Advisory Committee met September 20.

### **Operations and Finance Update**

CPRIT staff, including Dan Limas, Donna Cooper, and Heidi McConnell, prepared the agency's Legislative Appropriations Request (LAR) for the 2026-27 Biennium in ABEST, the state budget system. CPRIT submitted the LAR, which the Oversight Committee approved August 21, by the August 23 due date. CPRIT distributed paper copies of the LAR to the Governor's Office, Legislative Budget Board, and other legislative offices.

CPRIT resumed payment processing on September 9 following the annual shutdown of the State Treasury for the state's fiscal year end on August 31.

Michelle Huddleston, Donna Cooper, Lisa Nelson, and Heidi McConnell are working on the audit of CPRIT's FY 2024 financial statements with CPRIT's new financial auditor, Crowe, LLP.

CPRIT received proposals in response to the agency's conference meeting planner Request for Proposal (RFP). An evaluation team will be reviewing the proposals.

We received 10 proposals to the Chief Scientific Officer search firm RFP by the September 27 deadline. CPRIT will evaluate the proposals as quickly as possible to contract with a firm who will assist us in our search for a new CSO.

#### **Upcoming Subcommittee Meetings**

I have listed below the subcommittee meetings that CPRIT will hold in advance of the November 20 Oversight Committee meeting. CPRIT staff will make the subcommittee agenda and meeting materials available in Govenda one week prior to each meeting.

Board Governance Audit Prevention Academic Research Product Development November 7 at 10:00 a.m. November 8 at 12:00 p.m. November 12 at 12:00 p.m. November 13 at 12:00 p.m. November 14 at 10:00 a.m.

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CPRIT has awarded **2,017** grants totaling **\$3.65 billion**:

- 303 prevention awards totaling \$380.7 million
- 1,714 academic research and product development research awards totaling \$3.27 billion

Of the \$3.27 billion in academic research and product development research awards,

- 32.5% of the funding (\$1.06 billion) supports clinical research projects.
- 23.2% of the funding (\$757.2 million) supports translational research projects.
- 29.4% of funding (\$961.4 million) supports recruitment awards.
- 12.1% of the funding (\$397.2 million) supports discovery stage research projects.
- 2.8% of funding (\$90.4 million) supports training programs.

CPRIT has 12 open Requests for Applications (RFAs)

- 6 Academic Research
- 3 Academic Research Recruitment
- 3 Prevention



#### CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

### MEMORANDUM

TO:OVERSIGHT COMMITTEE MEMBERSFROM:KRISTEN DOYLE, CHIEF EXECUTIVE OFFICERSUBJECT:CPRIT ACTIVITIES UPDATE FOR OCTOBER 2024DATE:NOVEMBER 4, 2024

Topics in this memo address CPRIT activities in October, including preparations for the upcoming November 20 Oversight Committee meeting, recent milestones in our fight against cancer, a staffing update, outreach and legislative efforts, upcoming CPRIT-related events that may be of interest to Oversight Committee members, FY 2026 program priorities, and updates from Compliance, Programs, and Operations.

#### Planning for the November 15 Oversight Committee Meeting

The Oversight Committee will meet on Wednesday, November 20, in the Barbara Jordan Building at 8:30 a.m. We will have a full agenda with two advisory committee presentations, academic research, prevention, and product development grant award recommendations, the FY 2026 Oversight Committee Program Priorities, and the 2024 Texas Cancer Plan presentation. Please notify me as soon as possible if you are unable to attend the November 20 meeting or have schedule constraints that require you to arrive at the meeting after 8:30 a.m. or leave prior to 12:30 p.m.

You will receive an email from CPRIT by November 8 to access the Program Integration Committee's award recommendations via Govenda. The award portal available through the Govenda app has a summary of the award slates, as well as supporting documentation for each proposed award, including the application, CEO affidavit, summary statement, and grant pedigree. Please allow time to complete the individual conflict of interest checks and review the supporting material. If you have any issues accessing the Govenda app or navigating through the grant award recommendations, please contact Darren Castle (<u>dcastle@cprit.texas.gov</u>) or me.

I have attached a draft meeting agenda. CPRIT will post the final agenda for the Oversight Committee meeting by November 12. Oversight Committee members can access an electronic copy of the meeting packet through the Govenda app by November 13. Hard copies of the agenda and proposed award packet will be available at the meeting.

#### **Recent Milestones in the Fight Against Cancer**

#### CPRIT Grantees in the News

• On October 1, the American Society for Radiation Oncology (ASTRO) awarded CPRIT Scholar David Gius, M.D., Ph.D., its prestigious Career Recognition Mentorship Award. Dr. Gius, professor in the Department of Radiation Oncology and assistant dean of research at The University of Texas Health Science Center at San Antonio, also serves as the associate director for translational research at the Mays Cancer Center at UT Health San Antonio.

Dr. Gius is among three awardees receiving this recognition from ASTRO. The award honors individuals who have made significant contributions to mentorship and education in radiation oncology. Dr. Gius began mentoring in 1997, and has trained 65 undergraduate and graduate students, post-doctoral and clinical fellows, radiation oncologists, and junior faculty. Twenty-five of his trainees are currently faculty members at medical schools across the country. Dr. Gius specializes in breast and thoracic radiation oncology and investigates the cellular processes related to aging, metabolism, and cancer.

UT Health San Antonio recruited Dr. Gius to Texas in 2020 with the support of a \$6 million CPRIT Recruitment of Established Investigators grant (RR200112). Dr. Gius has the distinction of being the sole radiation oncologist to receive an Established Investigator research grant.

• At a press conference held October 3, The University of Texas Rio Grande Valley announced an \$18.4 million grant from the National Institutes of Health's National Institute on Minority Health and Health Disparities under the Research Centers in Minority Institutions (RCMI) program.

The RCMI award will establish the Rio Grande Valley Cancer Health Disparity Research Center. The center, co-led by principal investigator Dr. Subhash C. Chauhan, director of the South Texas Center of Excellence in Cancer Research and co-principal investigator Dr. Everardo Cobos, chair of medicine and oncology, will reduce cancer health disparities in underserved Hispanic communities. There are 24 RCMI centers in the nation, and four in Texas. The UTRGV center will conduct three major research projects focused on cancer health disparities in cervical cancer research (Dr. Cobbs), liver cancer (Dr. Chauhan), and social behavioral interventions (Dr. Deepu George).

The Rio Grande Valley, home to more than 1.3 million residents, has some of the highest rates of liver, gall bladder, stomach, and cervical cancers in the nation. The predominantly Hispanic population also bears a disproportionate burden of chronic liver diseases, including nonalcoholic fatty liver disease and hepatocellular carcinoma.

The South Texas Center of Excellence in Cancer Research at UTRGV and Dr. Chauhan received a \$6 million CPRIT Texas Regional Excellence in Cancer Award (RP230419) in

2023. UTRGV and Dr. Chauhan also received a \$2.5 million CPRIT Core Facility Support Awards grant (RP210180) in 2021.

 On October 4, The University of Texas Southwestern Medical Center appointed Ralph DeBerardinis, M.D., Ph.D., Director of the Eugene McDermott Center for Human Growth and Development. Dr. DeBerardinis is a professor of pediatrics and a member of the Harold C. Simmons Comprehensive Cancer Center. He currently directs the Genetic and Metabolic Disease Program at the Children's Research Institute at UT Southwestern. Dr. DeBerardinis, an international leader in research on cancer metabolism, received a Howard Hughes Medical Institute Investigator award in 2018. In 2020, the National Academy of Medicine elected Dr. DeBerardinis as a member, and in 2021 he received the Paul Marks Prize for Cancer Research from Memorial Sloan Kettering Cancer Center.

In 2016, the DeBerardinis Laboratory discovered that lung tumors can use lactate as a fuel source, challenging the nearly century-old observation known as the Warburg effect that considered lactate to be a waste product of tumor metabolism. The research opened new avenues for the study of potential therapeutics as well as new imaging techniques in lung cancer. His scientific contributions include pioneering new ways to study altered metabolism directly in cancer patients. As a clinician, Dr. DeBerardinis focuses on pediatric genetics and newborn screening for metabolic disorders. His laboratory studies the role of altered metabolic states in human diseases, particularly pediatric inborn errors of metabolism and cancer.

CPRIT has supported Dr. DeBerardinis' research on cancer metabolism through a Multi-Investigator Research Awards grant (RP180778), three Individual Investigator Research Awards (RP130272, RP160089, RP220337), one High-Impact, High-Risk Research Award (RP100437), and one Core Facility Support Awards (RP240494) totaling \$5.8 million.

• The National Institutes of Health (NIH) announced the 2024 Director's New Innovator Award recipients on October 10. The new awardees include four CPRIT Scholars. The Director's New Innovator Award, established in 2007, supports highly innovative research from promising Early-Stage Investigators. The awardees will receive \$2.4 million each from the NIH for their work.

Blair Benham-Pyle, Ph.D., assistant professor in the Department of Molecular and Cellular Biology, and Dan L Duncan Comprehensive Cancer Center at Baylor College of Medicine, focuses on developmental and regenerative biology. Her laboratory leverages the remarkable biology of the planarian flatworm to study stem cells, regeneration, aging, and cancer prevention. Baylor College of Medicine recruited Dr. Benham-Pyle in 2021 with the support of a \$2 million CPRIT Recruitment of First-Time, Tenure-Track Faculty Members grant (RR210037).

Steven Boeynaems, Ph.D., assistant professor in the Department of Molecular and Human Genetics and Dan L Duncan Comprehensive Cancer Center at Baylor College of Medicine, studies how cells detect and deal with stress. Dr. Boeynaems' research demonstrates that protein aggregation into biomolecular condensates allows cells to sense and respond to stress. His work focuses on unraveling the mechanisms behind this stress response, particularly in the context of brain cancer and neurodegenerative diseases. Baylor College of Medicine recruited Dr. Boeynaems in 2022 with the support of a \$2 million CPRIT Recruitment of First-Time, Tenure-Track Faculty Members grant (RR220094).

Hongjie Li, Ph.D., assistant professor in the Department of Molecular and Human Genetics and Dan L Duncan Comprehensive Cancer Center at Baylor College of Medicine, studies aging of the brain to increase the healthy lifespan of the brain. His lab identifies cellular mechanisms that contribute to brain aging, including glia-neuron interactions, systemic inflammatory signals, and the effect of age-related changes in the gut microbiota to brain aging. Baylor College of Medicine recruited Dr. Li in 2020 with the support of a \$2 million CPRIT Recruitment of First-Time, Tenure-Track Faculty Members grant (RR200063).

Javier Garcia-Bermudez, Ph.D., is an assistant professor in the Department of Pediatrics at The University of Texas Southwestern Medical Center. His laboratory researches the role of metabolic adaptive mechanisms in cancer progression. They use functional genetic screens to identify uncharacterized metabolic pathways that counteract metabolic stress to dissect the molecular underpinnings of these pathways and target them as potential cancer therapies. UT Southwestern recruited Dr. Garcia-Bermudez in 2021 with the support of a \$2 million CPRIT Recruitment of First-Time, Tenure-Track Faculty Members grant (RR210059).

• The National Academy of Medicine selected CPRIT Scholar Daniel J. Siegwart, Ph.D., as a Scholar in the Emerging Leaders in Health and Medicine Program. Dr. Siegwart, professor in the Departments of Biomedical Engineering and Biochemistry and the Harold C. Simmons Comprehensive Cancer Center at The University of Texas Southwestern Medical Center, is one of only 10 scientists and physicians from across the United States named to the Class of 2024. Each of the scholars appointed to three-year terms will address topics currently shaping the future of health and medicine.

At UT Southwestern, Dr. Siegwart's team studies and implements materials chemistry to enhance nanoparticle-based delivery of genomic medicines. Their groundbreaking research includes developing nanoparticles that penetrate deeply into tumors to deliver drugs, triggering an immune response to stop the growth and spread of liver and ovarian tumors in mice. Another study led by Dr. Siegwart demonstrated that genetic material tagged with a "cellular ZIP code," could prompt cells to secrete protein drugs into the bloodstreams of mice, effectively treating psoriasis and certain cancers. This innovative approach, which could someday allow the body to function as its own bio-factory and pharmacy, has the potential to enable patients to receive treatment at home rather than in hospitals.

UT Southwestern recruited Dr. Siegwart to Texas from the Massachusetts Institute of Technology in 2012 with the support of a \$2 million CPRIT Recruitment of First-Time, Tenure-Track Faculty Members grant (R1212). UT Southwestern and Dr. Siegwart received a \$900,000 CPRIT Individual Investigator grant (RP190251) in 2019 to support his research. • In recognition of Breast Cancer Awareness Month ABC 13 Eyewitness News (KTRK -Houston) reported a story on October 22, about the breast cancer crisis in Black women. Black women have an increased risk of breast cancer and an increased risk of dying from breast cancer - with a current mortality rate of 38% - compared to the population as a whole. However, if doctors find the cancer at an early stage, the cure rate is almost the same as for other women.

The news outlet reported on a Black woman who found a lump in her breast, but her doctor told her it was not cancer. One year later, while 23-weeks pregnant with her second child, she felt a lump again in the same breast. This time, the patient insisted on an appointment at The Rose Breast Center. An ultrasound confirmed it was cancer.

Early detection mammography screenings are the best means to fight breast cancer, which is 98% curable when detected early. Since its launch in 1986, The Rose has served nearly 800,000 patients and is the leading nonprofit breast health care organization in southeast Texas. The Rose provides access to screening, diagnostics, and treatment services to any woman regardless of her ability to pay. The Rose also offers the Mobile Mammography Program, which provides mammograms to women throughout 43 counties across Southeast Texas.

The Rose has received eight CPRIT Prevention grants (PP220015, PP190043, PP170091, PP150080, PP140171, PP120040, PP110154, PP100096) since March 2010 totaling \$11.2 million to support breast cancer screening services and education.

Notable CPRIT-Supported Research and Prevention Accomplishments

# • Following Breast Cancer's Migratory Path in Pursuit of New Therapies.

Triple-negative breast cancer (TNBC) is a particularly difficult form of breast cancer to treat because it does not have receptors for estrogen, progesterone, or HER2, which are common targets in other breast cancer therapies. Unfortunately, TNBC is aggressive and has a high 5-year mortality rate of 40%, affecting more than 20,000 people each year in the United States. Its tendency to metastasize and the lack of effective targeted treatments make it even more deadly.

To find new ways to treat TNBC, a research team led by Charles Foulds, Ph.D., and CPRIT Scholar Matthew J. Ellis, Ph.D., from the Lester and Sue Smith Breast Center at Baylor College of Medicine, studied specific enzymes that might drive the cancer's spread. Since targeting enzymes called kinases has been effective in other types of cancer treatment, and the U.S. Food and Drug Administration has already approved many kinase inhibitors for use, the team aimed to identify kinases that could serve as new therapeutic targets for TNBC.

Using a method the researchers had previously developed called the kinase inhibitor pulldown assay (KIPA) to quickly identify relevant kinases, the researchers analyzed tumor samples from 16 patients, grown in mice. As reported September 12 in *PNAS Nexus*, the researchers discovered that TNBC cells had elevated levels of a kinase called DeathAssociated Protein Kinase 3 (DAPK3). When researchers removed both copies of the DAPK3 gene from these cancer cells, the cells became less able to spread and invade other tissues.

Further analysis revealed two important parts of the DAPK3 protein: one that drives its enzyme activity, and another section called the leucine zipper, which binds to DNA and plays a role in spreading cancer. The research results showed that DAPK3 lowered levels of a protein called desmoplakin, which helps cells stick together, making cancer cells more likely to move and spread. Additionally, the team found that DAPK3 interacts with another protein, leucine zipper protein 1 (LUZP1), which helps stabilize DAPK3. This partnership between DAPK3 and LUZP1 could be a new target for therapies designed to prevent the spread of TNBC

Multiple CPRIT grants to Baylor College of Medicine supported this collaborative work. Dr. Bing Zhang received a \$1.2 million Individual Investigator Research Award for Computational Biology grant (RP220050) in 2022. Dr. Jeffrey Rosen received a Research Training grant (RP210027). Dr. Michael Lewis received two CPRIT Core Facility Support Awards grants (RP170691, RP220646) totaling \$8.76 million for patient-derived xenograft and advanced *in vivo* models and other critical technologies. Baylor College of Medicine recruited Dr. Bing Zhang from Vanderbilt University School of Medicine in 2016 with the support of a \$4 million Recruitment of Rising Stars grant (RR160027) and recruited Dr. Ellis from Washington University in 2014 with the support of a \$6 million Recruitment of Established Investigators grant (RR140033) in 2014.

• New Lung Cancer Screening Model Removes Barriers for Central Texas' Most Vulnerable. Project Director Brandon Altillo, M.D., and the team from Dell Medical School at The University of Texas at Austin and CommUnityCare Health Centers developed and assessed a lung cancer screening program to reduce disparities for low-income, uninsured, and minority populations in Central Texas.

The program, described in the September 27 edition of the *American Journal of Preventive Medicine*, uses a patient-centered approach that includes bilingual support, mailed outreach, telecare shared decision-making, smoking cessation plans, and no-cost low dose computer tomography (LDCT) screening. The findings revealed that 83% of patients completed LDCT, 49% of current smokers engaged in cessation counseling, and 31% reported quitting. The researcher found that those participants who formerly smoked were more likely to complete the LDCT than patients who currently smoked. There were no statistically significant differences in completion by age, gender, race/ethnicity, or insurance status. The researchers determined that the program achieved equitable implementation of lung cancer screening in a diverse Federally Qualified Health Center system.

"Our focus was not just on increasing lung cancer screenings but on ensuring that those most at risk — particularly those with financial or language barriers — could access care," said Dr. Altillo. "This program demonstrates that with targeted interventions, we can close gaps in health care and save lives." The University of Texas at Austin and Dr. Altillo received a \$2 million CPRIT Cancer Screening and Early Detection grant (PP240040) in 2024 and a \$1 million CPRIT Tobacco Control and Lung Cancer Screening grant (PP190063) in 2019 to support this project.

• DNA Vaccines for Cancer Prevention and Therapy? Multiple myeloma is a type of blood cancer that develops when abnormal plasma cells, which are responsible for producing antibodies, build up in the bone marrow. It is the second most common blood cancer. A condition called monoclonal gammopathy of undetermined significance (MGUS) precedes almost all cases of multiple myeloma. MGUS affects about 3.5 million people in the United States, or around 3.2% of people over 50.

Although treatments like antibody-based therapies and CAR T-cell therapies targeting a protein called B-cell maturation antigen (BCMA) have greatly improved outcomes for many multiple myeloma patients, not everyone responds to these treatments, and their effectiveness can be short-lived. To find new treatment options, researchers at Baylor College of Medicine are exploring different targets for immunotherapy, which could be especially helpful for patients whose cancer returns after BCMA-targeted therapy.

On October 1 in *NPJ Vaccines*, CPRIT Scholar Yong Li, Ph.D., a professor in the Department of Medicine and the Dan L Duncan Comprehensive Cancer Center, and his team shared their work on a new DNA vaccine targeting a protein called GPRC5D. Most people with multiple myeloma or MGUS have this protein in their hair follicles and bone marrow. Because the GPRC5D mRNA is more active in cancerous plasma cells than in normal ones, it could be a promising target for treating multiple myeloma.

Clinicians do not use DNA vaccines widely in medicine because of technical challenges. However, in their study using mouse models of multiple myeloma, Dr. Li's team found that a DNA vaccine targeting GPRC5D was effective at preventing tumor growth. When combined with another type of cancer treatment called PD-1 blockade, the vaccine was able to stop the growth of already established tumors. Tests using a version of the vaccine designed for humans showed comparable results, with the vaccine generating specific immune responses against GPRC5D. These findings suggest that GPRC5D-targeted DNA vaccines could be a useful, novel approach for both treating and preventing multiple myeloma.

Baylor College of Medicine recruited Dr. Li from the Cleveland Clinic Lerner College of Medicine in 2019 with the support of a \$6 million CPRIT Recruitment of Established Investigators grant (RR190043).

• How to make a "Long-lasting Impression." Allogeneic hematopoietic stem cell transplantation (Allo-HSCT) is a treatment where doctors use donor stem cells that are not a perfect genetic match to transplant into an individual fighting a blood disease or blood cancer. However, a common and serious complication of this treatment is graft vs. host disease (GVHD). In GVHD, the donor's immune cells attack the patient's body, especially

the gut, targeting crucial intestinal stem cells (ISCs). This damage can lead to severe illness and even death.

CPRIT Scholar Pavan Reddy, M.D., professor and director of the Dan L. Duncan Comprehensive Cancer Center at Baylor College of Medicine is a leading expert in transplantation. He is working to understand GVHD better and find ways to manage it. In a study published on October 3 in *Cell Stem Cell*, Dr. Reddy's team uncovered new details about how ISCs try to recover from damage caused by GVHD.

The research focused on how inflammation affects the metabolism of ISCs. Metabolism, the process cells use to generate energy, plays a key role in helping ISCs repair and regenerate. The team discovered that inflammation disrupts the normal energy-making process (oxidative phosphorylation) in ISCs, which leads to lasting changes in how these cells control their genes. These changes make the ISCs less effective at regenerating and healing the gut. Even after the inflammation subsides, the ISCs retain these negative effects, struggling to respond to future damage.

This research shows that inflammation leaves a lasting imprint on the DNA of ISCs, affecting their ability to recover and function properly, which could help explain the long-term complications seen in patients with GVHD.

Baylor College of Medicine recruited Dr. Reddy to Texas in 2022 with the support of a \$6 million CPRIT Recruitment of Established Investigators grant (RR220033).

• Exploiting Tumor Heterogeneity to Inform Therapy and Predict Outcomes. Lung cancer is the leading cause of cancer deaths worldwide, with non-small cell lung cancer (NSCLC) making up 80-85% of cases. Even though computer tomography (CT) scans have helped detect lung cancer earlier, giving some patients a better chance of a cure, about one-third of those diagnosed at Stage I experience a recurrence after surgery and eventually die from the disease. To address this, researchers are searching for biomarkers that could identify the patients that will need extra treatment after surgery to lower their risk of recurrence. However, the challenge is that lung tumors often vary significantly within a single tumor (known as intratumor heterogeneity), which makes predicting recurrence more difficult.

A major study, led by CPRIT Scholar Chao Cheng, Ph.D., an associate professor in the Department of Medicine at Baylor College of Medicine, and Jianjun Zhang, M.D., Ph.D., an associate professor in the Department of Thoracic/Head and Neck Medical Oncology, Division of Cancer Medicine at The University of Texas MD Anderson Cancer Center, investigated whether analyzing different regions of a single tumor could improve the prediction of recurrence. The team used 880 tumor samples from 350 patients, including data from public (TRACERx) and internal sources (MD Anderson Cancer Center Multiregional Profiling in Lung Cancer - MDAMPLC) to pinpoint molecular features linked to a higher risk of recurrence after surgery.

They discovered that differences in gene activity across distinct parts of the same tumor -RNA intratumor heterogeneity (RNA-ITH) - provided more accurate predictions of a patient's survival compared to looking at the average gene activity. By accounting for RNA-ITH, they improved the accuracy of 11 existing gene-based models used to predict outcomes. They also developed a new, more precise gene signature called Prognosis-Associated Clonally Expressed Genes (PACEG) that considers the behavior of both tumor and immune cells.

This study, published on October 5 in *NPJ Precision Medicine*, shows that analyzing multiple regions of a tumor in NSCLC provides a clearer picture of a patient's risk, emphasizing the need to consider tumor diversity when assessing lung cancer prognosis.

Baylor College of Medicine recruited Dr. Cheng from the Geisel School of Medicine in 2018 with the support of a \$4 million CPRIT Recruitment of Rising Stars grant (RR180061). Baylor College of Medicine and Dr. Cheng also received a \$1 million Individual Investigator grant (RP240380) in 2024 to study clonal hematopoiesis for improving lung cancer risk assessment. The University of Texas MD Anderson Cancer Center and Dr. Zhang received a \$4.6 million CPRIT Multi-Investigator Research Awards grant (RP160668) in 2016. They recently received a \$1.1 million Individual Investigator Research Award in 2024 (RP240441) to study precision lung cancer interception by targeting high-risk lung nodules.

#### • University of Texas at Dallas Faculty and CPRIT Scholar "Looks into Mirror

**Molecules" to Develop New Drugs.** One fascinating example of nature's ingenuity is "chemical enantiomers" — two substances that have the exact same chemical structure but are mirror images of each other, like your left and right hands. CPRIT Scholar Filippo Romiti, Ph.D., assistant professor of chemistry and biochemistry at The University of Texas at Dallas, and his team have developed a new chemical reaction that can selectively create either the left-handed or right-handed version of these mirror-image molecules. This advancement is important for creating new treatments for cancer, infections, depression, inflammation, and other health conditions.

Being able to make only the left- or right-handed version of a molecule, in a cost-effective way, is crucial for developing new medicines. Many natural compounds with medical potential exist in minute amounts in nature, making them difficult to study or use.

In their study, the researchers developed a fast, energy-efficient reaction that mimics the construction of these molecules in nature. Specifically, they managed to add a chemical group called a prenyl group—a step that has been hard for scientists to reproduce in the lab. The researchers developed this method to synthesize a family of over 400 natural products called polycyclic polyprenylated acylphloroglucinols (PPAPs), which have a wide range of health benefits, including fighting cancer, HIV, Alzheimer's, depression, epilepsy, and obesity.

To prove their method works, Dr. Romiti's team successfully created both enantiomers of eight different PPAPs, including nemorosonol, a natural compound from a Brazilian tree

known for its antibiotic properties. Early studies evaluating their synthesized version of nemorosonol against lung and breast cancer cell lines provided by John Minna M.D., director of the Hamon Center for Therapeutic Oncology Research at The University of Texas Southwestern Medical Center, suggested that the compound had promising anti-cancer activity

Published on October 10 in *Science*, this research marks a major step forward in how chemists can efficiently produce substantial amounts of biologically active molecules. It also opens up new opportunities to design improved versions of natural compounds that work better or more selectively in the body, paving the way for innovative, targeted medicines

The University of Texas at Dallas recruited Dr. Romiti from the University of Strasbourg in 2022 with support of a \$2 million CPRIT Recruitment of First-Time, Tenure-Track Faculty Members grant (RR220016).

### Personnel

CPRIT has filled 52 full-time equivalent positions, including eight long-term contract employees. CPRIT welcomed two new members of our senior staff, John Ellis and Grant Weaver, in October.

- Mr. Ellis joined CPRIT as our new general counsel on October 14. He most recently served as the Chief Compliance and Risk Officer for the Texas Department of Information Resources, where he oversaw programs to manage risk and operationalize compliance with legal and ethical standards. Mr. Ellis also worked for the Office of the Attorney General, successively as Chief of the General Counsel Division, Special Counsel to the First Assistant Attorney General, and Associate Deputy Attorney General for Policy and Communications. Before joining state government, he served as legal counsel in the United States Senate.
- Mr. Weaver is CPRIT's first Chief Financial Officer, joining CPRIT on October 21. He has two decades of fiscal management experience, including a background in bond finance, in various capacities at state agencies and institutions of higher education, including the Texas Department of Transportation, The University of Texas System, the Office of Attorney General, and the Commission on the Arts, where he served as Chief Financial Officer.

# **CPRIT Outreach**

Staff outreach activities during October include:

• Senior Program Manager for Product Development Research Dr. Abria Magee met with members of the Governor's Economic Development Office and the DeSoto Development

Corporation on October 1 to discuss Project Star and other projects in the pipeline in DeSoto. Dr. Magee discussed funding mechanisms in the product development program and eligibility for companies involved in Project Star.

- Oversight Committee member Tommy Taylor attended the 10th Annual BioNTx iC<sup>3</sup> Life Science & Healthcare Innovation Summit in Arlington on October 3 4. The summit showcased the vibrant growth of North Texas as a hub for life sciences.
- Program Manager for Prevention Carlton Allen attended the Colorectal Cancer Summit hosted by Exact Sciences and Fight Colorectal Cancer in Madison, Wisconsin on October 7-9. The summit focused on engaging colorectal cancer screening leaders from across the country to share experiences, collectively address screening challenges, and ignite action.
- On October 7, Dr. Magee presented to the Belgium Life Sciences Delegation hosted by the Greater Houston Partnership and the Belgian Trade Office in Houston. Following the presentation, Dr. Magee met with several Belgian-based companies including, PDC\*line Pharma, which specializes in developing cancer vaccines, Theratrame S.A. which is focused on small molecule inhibitors for cancer treatments, CERHUM, a medtech start-up that has developed a new generation of highly osteoconductive, patient-specific, 3D-printed bioceramic bone grafts and implants, and Insilicare, which specializes in AI-based clinical decision support software for glucose control (insulin & nutrition therapy) in critically ill patients.
- Chief Prevention Officer Ramona Magid and Mr. Allen attended the Healthier Texas Summit held in Austin on October 10 11. Public health and wellness leaders addressed Texas communities' evolving challenges and opportunities for change. Mr. Allen presented on "Developing Texas' Cancer Strategy: Collaboration & Charting Direction" and participated in a panel discussion, "Reducing Cancer Mortality and Morbidity Through Strategic Planning and Impactful Strategies."
- I gave a presentation about CPRIT's funding and priorities at the Texas A&M University System Chief Research Officer's Retreat held in Austin on October 16.
- On October 16, General Counsel John Ellis and I met with Philip Rocha, Office of the Governor's Economic Development and Tourism, to discuss CPRIT's programs.
- Product Development Program Manager Dr. Michelle Leeuwon attended the ARPA-H Emerging Health Innovators (EHI) Initiative Information Session II held October 17. The session highlighted the EHI Initiative's goal to increase research funding access for early career investigators and community innovators, focusing on technology-driven and community-centered innovations. Insights from a current survey will guide a forthcoming funding opportunity.
- Dr. Le Beau participated in a day-long Association of American Cancer Institutes (AACI) New Directors meeting held in conjunction with the annual AACI meeting held in Chicago

on October 20 - 22. The New Directors meeting featured multiple panels and discussions designed to provide new directors with information relevant to all aspects of leading a clinical and research Cancer Center, as well as applying for and maintaining National Cancer Institute's formal designation as a nationally recognized Cancer Center. Dr. Le Beau participated in the panel discussing approaches to selecting and mentoring senior leadership. Participants included leaders from The University of Texas MD Anderson Cancer Center, The University of Texas Health Science Center at San Antonio, and The University of Texas at Austin.

- Chief Operating Officer Heidi McConnell, Chief Financial Officer Grant Weaver, Mr. Ellis, and I hosted a delegation from Chungnam National University in CPRIT's office on October 21. The South Korean delegation is interested in developing partnerships and collaborations in Texas to further training, life science research, and product development.
- I attended the launch event for the American Cancer Society's BrightEdge Cancer Accelerator held on October 22 at Pegasus Park in Dallas.
- On October 24, Dr. Leeuwon met with CERHUM, which prints bone and technical ceramics for medical applications, in a follow-up meeting. They discussed appropriate funding mechanisms and possible collaborations in Texas to expand their device application to cancer patients and enhance treatment outcomes.
- I attended the Consero Healthcare General Counsel Forum in Las Colinas on October 27 29.
- On October 29, Oversight Committee member Craig Rosenfeld and I attended The University of Texas Southwestern's Medical Center's Innovation Days held at Pegasus Park in Dallas.

#### Legislative Outreach and Preparations for the 89<sup>th</sup> Legislative Session

- Ms. McConnell, Ms. Magid, and I met with Andria Franco (Lt. Governor Patrick) on October 7 to discuss the upcoming release of the *2024 Texas Cancer Plan*, the legislative session, and Senate interim charge.
- Ms. McConnell and I met with Sen. Juan "Chuy" Hinojosa to provide an update on CPRIT's activities and the upcoming legislative session.
- On October 14, Ms. McConnell and I met with Maureen Metteauer (Senate Committee on Health & Human Services) to discuss the upcoming release of the *2024 Texas Cancer Plan*, the legislative session, and the Senate interim charge.

- Ms. McConnell and I met with Lt. Governor's staff on October 15 to discuss issues in the upcoming legislative session and CPRIT's FTE count.
- Ms. McConnell and I met with Dean Sen. Judith Zaffirini on October 18 to provide an update on CPRIT's activities and the upcoming legislative session.
- On October 21, Ms. McConnell and I met with Speaker of the House Rep. Dade Phelan's staff to discuss CPRIT's FTE count and LAR.
- Oversight Committee Presiding Officer Dr. David Cummings, Ms. McConnell and I met with Rep. Drew Darby on October 23 to provide an update on CPRIT's activities and the upcoming legislative session.
- Oversight Committee Presiding Officer Dr. David Cummings, Ms. McConnell and I met with Sen. Charles Perry on October 23 to provide an update on CPRIT's activities and the upcoming legislative session.
- On October 24, Ms. McConnell and I met with Office of the Governor staff to discuss CPRIT's FTE count and LAR.
- I have meetings scheduled with Sen. Kelly Hancock (November 12), Sen. Pete Flores (November 20), and Sen. Sarah Eckhardt (December 4). I will continue to meet with state senators and their staff in the run up to the start of the 89<sup>th</sup> Legislative Session to update members on CPRIT's activities. After the November 5 election, I will expand my focus to include meetings with state representatives.

# **Upcoming Events**

There are several upcoming events related to CPRIT, CPRIT grantees, or cancer that may be of interest to Oversight Committee members. I have noted when CPRIT staff will be making presentations. Please contact me or the appropriate program staff if you would like more information about an event or meeting.

November 5	Executive Association of Houston (Houston Country Club)
	At CPRIT grantee David Arthur's invitation, I will make a presentation to
	this group about the CPRIT program.
November 6 - 10	Society for Immunotherapy of Cancer Annual Meeting (Houston)
	The Product Development Research Program will be part of the Tumor-
	Infiltrating Lymphocyte Panel on November 6.
November 10-11	Researchers' Roundup (Pegasus Park, Dallas)
	CPRIT co-hosts the conference for childhood and adolescent cancer
	researchers. Dr. Le Beau, Dr. Moore, Mark Loeffler, Justin Rand, and I
	will attend.

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### Texas Cancer Plan 2024 Update

CPRIT is statutorily responsible for developing the *Texas Cancer Plan* (TCP). The TCP is a statewide strategic plan to reduce the cancer burden across Texas and improve the lives of Texans. We issued the first TCP under CPRIT's leadership in 2012, with the second - and most recent - version issued in 2018.

Consistent with CPRIT administrative rule § 701.11, which directs CPRIT to periodically update the TCP every seven years, we will officially release the new edition in December as a fully integrated online resource (similar to the recent versions of the CPRIT Annual Report). In preparation for official release, Ms. Magid and Mr. Carlton will preview the *2024 Texas Cancer Plan* for the Oversight Committee at the November 20 meeting.

#### **Program Priorities for FY 2026**

The three program subcommittees will discuss program priorities for FY 2026 in their upcoming subcommittee meetings in preparation for the Oversight Committee's vote to adopt the priorities at the November 20 meeting.

#### **Compliance Program Update**

#### Submission Status of Required Grant Recipient Reports

As of October 23, 11 entities had not filed 18 academic research reports, and one product development report. 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 185 second-level reviews of grantee Financial Status Reports (FSRs) in October. Thirty-three FSRs (18%) 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 October. Desk reviews confirm financial, administrative, and programmatic compliance using data from CGMS/CARS with additional focus on an organization's internal controls, current and previous fiscal audits, and grantee report submission timeliness. 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. Compliance specialists are collaborating with two grantees to address enhanced desk review findings.

### Onsite Reviews

CPRIT completed one onsite review in October. Onsite reviews are the most extensive monitoring activity conducted by CPRIT and include virtual or field visits led by compliance grant monitoring staff. CPRIT monitors 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 during onsite reviews. Onsite monitoring enables CPRIT compliance staff to assess a grantee's capability, performance, and compliance with applicable laws, rules, and policies. Compliance specialists have cleared all onsite review findings.

#### Single Audit Tracking

Compliance specialists track the submission of grantees' independent audit reports and the resolution of issues named in these reports. Grantees spending \$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 requests more time by the due date of the required audit and CPRIT's CEO approves the request.

#### 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, as well as 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 in October. The total amount of match expenses reviewed by compliance staff for FY 2025 is \$8,882,626.71. Compliance staff identified no unallowable match expenses for FY 2025.

### Training and Support

CPRIT staff conducted a series of Annual Compliance Training webinars on October 2-3 and October 30 for 85 grantee staff. Training is specific to each program area (Academic Research, Product Development Research, and Prevention) and allows for an interactive experience and an opportunity to focus on topics relevant to each program. The training covers grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. This was the second 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.

# Academic Research Program Update

# Recruitment FY 2025 Review Cycle 1

CPRIT's Application Receipt System (CARS) opened June 20 – August 20 for the first cycle of FY 2025 recruitment applications. The Scientific Review Council (SRC) reviewed 20 recruitment applications (total request \$52.6 million) on September 12. Dr. Le Beau will present the SRC's recommendations to the Program Integration Committee (PIC) and Oversight Committee in November.

FY 25 Cycle 1 Mechanism	Received	Requested	Recommended	Recommended
<b>Recruitment of Established</b> <b>Investigators</b>	1	\$6,000,000	0	N/A
Recruitment of First-Time, Tenure Track Faculty Members	14	\$28,000,000	4	\$8,000,000
<b>Recruitment of Rising Stars</b>	5	\$18,594,367	1	\$4,000,000
TOTAL	20	\$52,594,367	5	\$12,000,000

Recruitment FY 2025 Review Cycle 2

CPRIT's CARS opened August 21 – October 21 for the second cycle of FY2025 applications. The SRC will review these applications on November 14. Dr. Le Beau will present the recommended applications to the Oversight Committee in February 2025.

FY 25 Cycle 2 Mechanism	Apps	Funds Requested
<b>Recruitment of Established Investigators</b>	1	\$6,000,000
<b>Recruitment of First-Time, Tenure Track Faculty</b> <b>Members</b>	2	\$4,000,000
Recruitment of Rising Stars	4	\$16,000,000
TOTAL	7	\$26,000,000

#### Academic Research FY 2025 Cycle 1 (25.1)

CPRIT released seven RFAs on February 22 for the first review cycle of FY 2025 and accepted applications March 19 - June 11. Peer Review panels met October 16 - 25. Dr. Le Beau will present the SRC's recommendations for FY 25.1 awards to the PIC and the Oversight Committee in February 2025.

FY 25 Cycle 1 Mechanism	Apps	<b>Funds Requested</b>
Individual Investigator Research Award (IIRA)	220	\$196,400,895
IIRA for Computational Systems Biology of Cancer	29	\$29,833,203
IIRA for Cancer in Children and Adolescents	36	\$42,160,677
IIRA for Prevention and Early Detection	21	\$24,022,601
IIRA for Clinical Translation	26	\$41,025,711
IIRA for Early Onset Cancers	13	\$11,379,861
Collaborative Action Program (competitive renewal)	1	\$3,000,000
TOTAL	346	\$347,822,948

Academic Research FY 2025 Review Cycle 2 (25.2)

CPRIT released six RFAs for the second review cycle of FY 2025 on August 28 and will accept applications September 18 – December 10. Peer review panels will meet in March 2025. Dr. Le

Beau will present the SRC's recommendations to the PIC and the Oversight Committee in May 2025.

# Product Development Research Program Update

### Product Development Research FY 2025 Review Cycle 1 (25.1)

In early July, CPRIT issued 24 invitations to submit FY 2025 Product Development Research full applications to companies receiving the best preliminary application scores. Of the 24 invitations, 22 companies submitted their full applications to CPRIT by the July 25 deadline. These presented their proposals to the individual review panels in September. Based upon the application scores and presentations to the panels, nine companies moved forward to due diligence in October. The Product Development Review Council (PDRC) met on October 28 to vote on its final recommendations. Dr. Smith will present the PDRC's recommendations to the PIC and the Oversight Committee in November.

	Prelim	Total	Full	Total	Due	Total
FY 2025 Cycle 1 Mechanism	Apps	Request	Apps	Request	Diligence	Request
Texas Therapeutic Company	20	\$236.6 M	9	\$114.4 M	5	\$48.0 M
Texas Device/Diagnostic Co.	13	\$109.6 M	5	\$43.0 M	1	\$12.6 M
Texas New Tech Company	13	\$98.4 M	2	\$7.5 M	0	N/A
Seed Company	44	\$149.2 M	6	\$17.4 M	3	\$8.2 M
TOTAL	90	\$593.8 M	22	\$181.3 M	9	\$68.9 M

# **Prevention Program Update**

# Prevention FY2025 Review Cycle 1 (25.1)

The prevention program released three RFAs on February 9 for the first review cycle of FY 2025. CPRIT received 24 applications by the June 6 deadline. Peer review panels met on September 10 and 11. The Prevention Review Council (PRC) met on October 18 to develop the list of award recommendations. Chief Prevention Officer Ramona Magid will present the PRC's recommendations to the PIC and the Oversight Committee in November.

Cycle 25.1 Mechanism	Apps	Funds Requested
Primary Prevention of Cancer	7	\$6.8 M
Cancer Screening and Early Detection	16	\$29.8 M
Dissemination of CPRIT-Funded Cancer Control Interventions	1	\$450,000
TOTAL	24	\$37.05 M

### Prevention FY2025 Review Cycle 2 (25.2)

The prevention program released three RFAs on August 26 for the second review cycle of FY 2025. CPRIT will accept applications for Cancer Screening and Early Detection awards, Dissemination of CPRIT-Funded Cancer Control Interventions awards, and Primary Prevention of Cancer awards through December 5. Peer review panels will meet in March 2025. Ms. Magid will present the Prevention Review Council's recommendations to the PIC and the Oversight Committee in May 2025.

### Other Activities

CPRIT held a training webinar for Prevention program grantees on the use of the redesigned Quarterly Progress Report on October 1. More than 50 grantee staff attended the first training.

### **Advisory Committees**

- The Clinical Trials Advisory Committee (Work Group Subcommittee) met October 4.
- The Product Development Advisory Committee met October 10 to discuss CPRIT's product development program, including the FY 2025 review cycle and funding.
- The Advisory Committee on Childhood and Adolescent Cancers met October 28.
- The Clinical Trials Advisory Committee held an in-person meeting in Houston on October 30.

# **Operations and Finance Update**

#### CPRIT FY 2024 Financial Audit

CPRIT's new financial auditor, Crowe, LLP, is working with Chief Operating Officer Heidi McConnell, Operations Manager Lisa Nelson, and CPRIT accountants Michelle Huddleston and Donna Cooper on the audit of CPRIT's FY 2024 financial statements. Some of Crowe's audit procedures differ from the audit procedures used by CPRIT's previous financial auditor, McConnell and Jones LLP. In particular, Crowe does not require an organization's board members and executive management to complete written fraud risk and related party questionnaires. Instead, they conduct interviews with selected executive management who have knowledge of financial processes, accounting systems, and potential for fraudulent activity. Members of the Crowe team will also interview the Oversight Committee Presiding Officer on these matters.

#### Procurement

• CPRIT received 10 proposals for the Chief Scientific Officer search firm services RFP. Ms. McConnell, Ms. Nelson, and I evaluated the proposals and interviewed three candidates. Following a review of the three firms' best and final offers, we made a final selection on

October 31. The identified firm's final offer does not exceed the amount authorized by the Oversight Committee on September 25.

Oversight Committee members will receive a request from Govenda to complete the financial interest disclosure survey for the firm selected. Your prompt responses to the request will assist us with finalizing the contract as quickly as possible.

• CPRIT received two responses for the agency's conference meeting planner request for proposals (RFP). The evaluation team, including Ms. McConnell, Mr. Loeffler, Mr. Rand, and Shannon Cusick, evaluated the proposals. Ms. McConnell will present their recommendation for a conference meeting planning firm at the upcoming Oversight Committee meeting.

#### **Upcoming Subcommittee Meetings**

I have listed the subcommittee meetings that CPRIT will hold in advance of the November 20 Oversight Committee meeting below. CPRIT staff will make the subcommittee agenda and meeting materials available in Govenda one week prior to each meeting.

Board Governance	November 7 at 10:00 a.m.
Audit	November 8 at 12:00 p.m.
Prevention	November 12 at 12:00 p.m.
Academic Research	November 13 at 12:00 p.m.
Product Development	November 14 at 10:00 a.m.

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#### CPRIT has awarded **2,017** grants totaling **\$3.65 billion:**

- 303 prevention awards totaling \$380.7 million
- 1,714 academic research and product development research awards totaling \$3.27 billion

Of the \$3.27 billion in academic research and product development research awards,

- 32.5% of the funding (\$1.06 billion) supports clinical research projects.
- 23.2% of the funding (\$757.2 million) supports translational research projects.
- 29.4% of funding (\$961.4 million) supports recruitment awards.
- 12.1% of the funding (\$397.2 million) supports discovery stage research projects.
- 2.8% of funding (\$90.4 million) supports training programs.

CPRIT has 12 open Requests for Applications (RFAs)

- 6 Academic Research
- 3 Academic Research Recruitment
- 3 Prevention

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#### CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

### MEMORANDUM

TO:OVERSIGHT COMMITTEE MEMBERSFROM:VINCE BURGESS, CHIEF COMPLIANCE OFFICERSUBJECT:COMPLIANCE PROGRAM UPDATEDATE:NOVEMBER 12, 2024

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

As of October 28, nine entities had not filed nine academic research 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 571 second-level reviews of grantee Financial Status Reports (FSRs) in August, September, and October. One hundred seventeen FSRs (20%) 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 requests more time by the due date of the required audit and CPRIT's CEO approves the request.

#### Desk Reviews

CPRIT staff performed 15 enhanced desk-based financial monitoring reviews in August, September, and October. Desk reviews are intended to confirm financial, administrative, and programmatic compliance using data from CGMS/CARS with additional focus on an organization's internal controls, current and previous fiscal audits, and grantee report submission timeliness. 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. Compliance specialists are collaborating with one grantee to address enhanced desk review findings.

#### **Onsite Reviews**

CPRIT completed one onsite review in August, September, and October. Onsite reviews are the most extensive monitoring activity conducted by CPRIT and include virtual or field visits led by compliance grant monitoring staff. CPRIT monitors 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 during onsite reviews. Onsite monitoring enables CPRIT compliance staff to assess a grantee's capability, performance, and compliance with applicable laws, rules, and policies. Compliance specialists have cleared all 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, as well as 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 seven annual match expenditure reviews in August, September, and October.
The total amount of match expenses reviewed by compliance staff for FY 2025 is \$8,882,626.71. No unallowable match expenses have been identified for FY 2025.

# Training and Support

CPRIT staff conducted two new grantee training webinars in August for Aakha Biologics and Bectas Therapeutics. The training covers 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 grantees to complete the initial compliance training program prior to receiving disbursement of grant award funds.

All new Product Development grantees will now participate in a revised New Grantee Training and will also receive FSR technical assistance training prior to the submission of their first FSR with expenses. This training is an interactive training with grantee staff, the assigned CPRIT grant accountant, and compliance staff participating. CPRIT designed the training to help the grantee prepare the required FSR support documentation, including using the correct expense ledger template.

The new training highlights the resources available through the Grantee Resources tab on the CPRIT website, including match expenditures templates, match eligibility matrix, and a program specific checklist to aid in submitting the required documentation by expense category. The training incorporates a comprehensive review of the grantee's expense ledger, by category, along with all expense support documentation. This interactive process is a critical part of the technical assistance training, with the goal of reimbursing the grantee quickly and accurately, thereby allowing the grantee to access additional advanced funds in a timely manner to complete the goals and objectives of the grant. CPRIT staff conducted trainings in August for new CPRIT grantees Single Cell Biotechnology Inc., Crossbridge Bio, FixNip LTD., and March Biosciences

CPRIT staff conducted a series of Annual Compliance Training webinars on October 2-3 and October 30 for 85 grantee staff. Training is specific to each program area (Academic Research, Product Development Research, and Prevention) and allows for an interactive experience and opportunity to focus on topics relevant to each program. The trainings cover grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. This was the second training series offered this year for the annual compliance training requirement which requires the Authorized Signing Official (ASO) and at least one other employee from each grantee organization to attend an annual compliance training by December 31 of each year.

## FY 2024 Compliance Program Activities Summary

CPRIT's Compliance Program functions are designed to actively support the integrity and transparency of CPRIT's agency processes. FY 2024 Compliance Program highlights include:

• Grant Recipient Report Monitoring –The number of delinquent reports in FY 2024 averaged 26 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 four fiscal years are represented in the chart below:

Second-level Reviews of Financial Status Reports (FSRs) – The Compliance team
performed a second-level review of 2,195 FSRs in FY 2024. FSRs 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 Program Update - November 2024

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- Training and Education In FY 2024, CPRIT staff provided 40 grantee trainings including annual compliance trainings, new grantee trainings, trainings for new Authorized Signing Officials (ASOs), and FSR technical assistance trainings. Over 465 grantee staff attended these training opportunities provided to our active grantees.
- Annual Compliance Attestation 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. Grantees have until December 31 to submit the completed attestation. As part of the annual attestation process, product development grantees must submit documentation demonstrating compliance with the Texas Location Criteria, pursuant to Texas Administrative Code §701.19. The Compliance team reviewed and processed 59 attestations submitted by grantees.
- Single Audit Reviews 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 Compliance team reviewed 34 audits and Agreed Upon Procedures (AUP) reports and worked with 1 grantee to remediate audit findings.
- Compliance Monitoring Reviews (Enhanced Desk and Onsite) The Compliance team performed 86 compliance reviews (51 enhanced desk reviews, 35 onsite reviews) during FY 2024.



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Nine of the 51 enhanced desk reviews completed contained findings. Seven of the nine reviews that contained findings (78%) were related to timeliness of report submission by the grantee.



Fifteen of the 35 onsite reviews completed contained findings. Eight of the 15 reviews that contained findings (53%) were related to timeliness of report submission by the grantee.



• 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 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 twenty-one annual match expenditure reviews for FY 2024. The total amount of match expenses reviewed by compliance staff for FY 202 is \$29,752,281.89. The amount of unallowable expenses was \$302,229.06. The primary reasons for unallowable match expenses for FY 2024 were related to unallowable travel costs, expenses previously requested for reimbursement on a financial status report, and unallowable late fees and interest charges.



For Product Development grantees, the total amount of match expenses reviewed in FY 2024 increased by \$5,288,429.78 (21 reviews completed in FY2024 versus 20 reviews in FY 2023). In FY 2024, there was an increase in unallowable match expenses of \$163,571.06. Approximately \$221,000 of the unallowable match expenses were from one grantee.





#### CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

## MEMORANDUM

TO:OVERSIGHT COMMITTEE MEMBERSFROM:RAMONA MAGID, CHIEF PREVENTION OFFICERSUBJECT:PREVENTION PROGRAM UPDATEDATE:NOVEMBER 12, 2024

### FY 2025 Review Cycle 1 (25.1)

The Prevention Program released three RFAs, *Primary Prevention of Cancer, Cancer Screening and Early Detection*, and *Dissemination of CPRIT-Funded Cancer Control Interventions* on February 9, 2024, for the first cycle of FY 2025. Peer review took place on September 10-11 and the Prevention Review Council (PRC) met on October 18 to make recommendations to the Program Integration Committee (PIC). Ms. Magid will present the Prevention Review Council's recommendations to the PIC and the Oversight Committee in November 2024.

Mechanism	Apps Received	Funds Requested
Cancer Screening and Early Detection	16	\$29,771,943
Primary Prevention of Cancer	7	\$6,827,098
Dissemination of CPRIT-Funded Cancer Control Interventions	1	\$449,929
TOTAL	24	\$37,048,970

### FY 2025 Review Cycle 2 (25.2)

The Prevention Program released three RFAs, *Primary Prevention of Cancer, Cancer Screening and Early Detection*, and *Dissemination of CPRIT-Funded Cancer Control* Interventions, on September 26 for the second cycle of FY 2025. Peer review will take place in February 2025, and the Prevention Review Council (PRC) will meet in March 2025, to make recommendations to the Program Integration Committee (PIC). Ms. Magid will present the Prevention Review Council's recommendations to the PIC and the Oversight Committee in May 2025.

### **Proposed FY 2026 Requests for Applications**

CPRIT is recommending the release of three Requests for Applications for FY 2026.

## **Dissemination of CPRIT- funded Cancer Prevention and Control Interventions**

The 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 across the state through adaptation or replication.

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

## **Primary Prevention of Cancer**

The 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.

## **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	Maximum Duration
Појест Турс	Funding	
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
<b>Maintenance Expansion</b> –		
vaccination/tobacco cessation	\$2.5 million	5 years

## **Screening and Early Detection**

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.
- **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

## **Other Activities**

Carlton Allen, Program Manager for Prevention, participated in a Colorectal Cancer Summit hosted by Exact Sciences and Fight Colorectal Cancer in Madison Wisconsin. The summit was a three-day event focused on engaging colorectal cancer (CRC) screening leaders from across the country to share experiences, collectively address screening challenges, and ignite action.

Ramona Magid, Chief Prevention Officer, and Carlton Allen attended the Healthier Texas Summit held in Austin on October 10-11. Thought leaders and health champions in public health and wellness gathered to address Texas communities' evolving challenges and opportunities for change. Mr. Allen presented on "Developing Texas' Cancer Strategy: Collaboration & Charting Direction" and participated in a panel discussion, "Reducing Cancer Mortality and Morbidity Through Strategic Planning and Impactful Strategies".



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

### MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	CARLTON ALLEN, PROGRAM MANAGER FOR PREVENTION
SUBJECT:	2024 TEXAS CANCER PLAN
DATE:	NOVEMBER 20, 2024

#### 2024 Texas Cancer Plan Update

The *Texas Cancer Plan* (TCP) is a statewide strategic plan to reduce the cancer burden across Texas and improve the lives of Texans. CPRIT is statutorily responsible for developing the TCP. We issued the first TCP under CPRIT's leadership in 2012, with the second - and most recent - version issued in 2018. Consistent with CPRIT administrative rule § 701.11, which directs CPRIT to periodically update the TCP every seven years, we will officially release the new edition in December as a fully integrated online resource (similar to the recent versions of the CPRIT Annual Report). In preparation for official release, CPRIT will preview the *2024 Texas Cancer Plan* for the Oversight Committee at the November 20 meeting.

CPRIT Program Manager for Prevention Carlton Allen is leading the revision of the TCP, including meeting with multiple stakeholders. As the statewide call to action for cancer prevention, control, and research, the TCP identifies the challenges and issues that affect Texas and presents a set of goals, objectives, and strategies to help inform and direct communities in the fight against cancer. The TCP provides a coordinated, prioritized, and actionable framework that guides statewide and community efforts to mitigate the cancer burden.

CPRIT will release the TCP in December. The 2024 TCP is now fully digital and interactive. This enhanced format allows a comprehensive, adaptable approach for improving cancer prevention, care, and survivorship across Texas. Reviewing the Executive Summary will allow users to get a quick, high-level overview of the overall feel of the Plan. The "Cancer Burden" section provides a deep dive into the various challenges Texans face in their fight against cancer. The heart of the TCP, "The Plan," outlines specific goals and objectives to address Texas' unique cancer landscape. Lastly, the "Interactive Page" is one of our most exciting features. It is highly customizable, allowing users to filter data by region, cancer type, demographic, or risk factor.

CPRIT has engaged an array of stakeholders to enhance the TCP's effectiveness. Mr. Allen also worked with the Texas Cancer Registry and Behavioral Risk Factor Surveillance System to gather updated data relevant to the TCP. He collaborated closely with the Department of State Health Services (DSHS) on data integration and hosted town halls and forums to elicit input on goals, objectives, and strategic actions to inform and guide communities and stakeholders in the fight against cancer.

Multiple entities involved with the TCP's revision, execution, and evaluation, include:

- The Texas Comprehensive Cancer Control Program (TCCCP) and Chronic Disease Epidemiology Branch (CDE) at DSHS evaluated the plan and informed CPRIT, the Cancer Alliance of Texas (CAT), public health professionals, and other cancer prevention and control stakeholders in Texas of the current measures and progress Texas is making towards the TCP's goals and objectives. TCCCP also updates these groups on trends in cancer burden and assists in coordinating the implementation and periodic revision of the TCP.
- The Centers for Disease Control and Prevention's National Comprehensive Cancer Control Program (NCCCP) provides funding, guidance, and technical assistance to TCCCP to coordinate cancer prevention and control interventions, and to support the CAT.
- CAT is the state's comprehensive cancer control coalition, which TCCCP administers. DSHS has received funding from the NCCCP since 1998 to implement the state's cancer control plan and convene a statewide cancer control coalition. CAT's mission is to engage organizations, agencies, institutions, and individuals to work collaboratively to reduce the impact of cancer in Texas and promote the TCP.

CPRIT's strategic direction and funding opportunities align with the TCP but are, by necessity, a subset of the goals and objectives. The overall outcome and success of efforts to reduce the state's cancer burden will continue to depend on the cooperation, collaboration, and resources of stakeholders across Texas.

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#### 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 20, 2024

#### **Update Summary**

The Academic Research Program is requesting approval to release six RFAs for Fiscal Year 2026, Cycle 1. No new RFAs are included in this cycle. The Academic Research Program is proposing one new program priority. With approval by the Oversight Committee of the Academic Research Programs new priority "Cancer survivorship research to enhance the health and well-being of all cancer survivors and caregivers" this language and concept will be added to the FY26.1 RFAs and all RFA going forward. The FY26.1 RFAs will be released on January 14, 2025, with the CPRIT Application Receipt System opening on February 18, 2025, and closing on May 6, 2025. Virtual peer review will be conducted in September 2025. CPRIT's Chief Scientific Officer will present the Scientific Reviews Council's recommendation to the PIC and Oversight Committee in November 2025.

On October 30, the Clinical Trials Advisory Committee convened an in-person meeting hosted by Baylor College of Medicine in Houston. On November 5, Dr. Moore spoke at the National Council of University Research Administrators (NCURA). CPRIT and the Carson Leslie Foundation rounded up preeminent childhood and adolescent cancer researchers working towards a cure, to discuss, encourage and identify collaboration at the Researchers RoundUP 2024 held on November 10-11 at Pegasus Park in Dallas. It was a very productive conference, full of insightful presentations, breakout groups, and engaging conversations. The outcome of Researchers RoundUP will help frame CPRIT's Childhood and Adolescent Cancer-focused Requests for Applications.

#### ACTION ITEM #1: Proposed 26.1 RFAs

#### Individual Investigator Research Awards (IIRA)

Supports applications for innovative research projects addressing critically important questions that will significantly advance knowledge of the causes, prevention, and/or treatment of cancer. Areas of interest include laboratory research, translational studies, and/or clinical investigations. Award: Up to \$300,000 per year. Exceptions permitted if extremely well justified; maximum duration: 3 years.

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# Individual Investigator Research Awards for Computational Systems Biology of Cancer (IIRACSBC)

Supports applications for innovative mathematical and/or computational research projects addressing questions that will advance current knowledge in the (a) mechanisms that tie altered gene expression and downstream molecular mechanisms to functional cancer phenotypes and/or (b) mechanisms that tie tumor morphology to functional cancer phenotypes and/or mechanisms that tie treatment sequence and combination to evolving functional cancer phenotypes (that emerge as a result of treatment selection). Award: Up to \$350,000 in total costs per year for up to 3 years. Exceptions permitted if extremely well justified.

# Individual Investigator Research Awards for Cancer in Children and Adolescents (IIRACCA)

Supports applications for innovative research projects addressing questions that will advance knowledge of the causes, prevention, progression, detection, or treatment of cancer in children and adolescents. Laboratory, clinical, or population-based studies are all acceptable. CPRIT expects the outcome of the research to reduce the incidence, morbidity, or mortality from cancer in children and/or adolescents in the near- or long-term.

Award: Up to \$300,000 per year. Exceptions permitted if extremely well justified; maximum duration: 4 years.

# Individual Investigator Research Awards for Prevention and Early Detection (IIRAP)

Supports applications which propose clinical and population-based projects designed to develop effective prevention and early detection interventions to reduce cancer risk, mortality, and morbidity among Texans. Projects that propose such research collaborations with existing CPRIT Prevention Program awardees including the CPRIT funded *Texas Collaborative Center for Hepatocellular Cancer* (https://www.bcm.edu/research/labs-and-centers/research-centers/texas-collaborative-center-for-hepatocellular-cancer) and cancer survivorship research to enhance the health and well-being of all cancer survivors and caregivers, are strongly encouraged.

Award: Up to \$300,000 per year. Exceptions permitted if extremely well justified; maximum duration: 4 years.

## Individual Investigator Research Awards for Clinical Trials (IIRACT)

Supports applications that propose innovative cancer clinical studies in adults or children and adolescents that are hypothesis driven and involve patients enrolled prospectively on a clinical trial. Areas of interest include clinical studies of new or repurposed drugs, hormonal therapies, immune therapies, surgery, radiation therapy, stem cell transplantation, combinations of interventions, or therapeutic devices. Clinical trial must be planned to begin when the contract is awarded.

Award: Up to \$400,000 per year. Maximum duration: 4 years. Exceptions permitted if extremely well justified.

### Individual Investigator Research Awards for Early-Onset Cancers (IIRAEOC)

Supports innovative research projects that will significantly advance the knowledge of etiology, prevention, cancer biology, and treatment of early-onset cancers. Award: Up to \$300,000 per year for a 3-year period

### Fiscal Year 2025 Cycle 2 (FY25.2) RFAs

The following FY25.2 RFAs were posted on August 28, 2024. CPRIT's Application Receipt System (CARS) opened for applications on September 18, 2024, and will close on December 10, 2024. Virtual Peer Review will be conducted in March 2025. Dr. Le Beau will present the Scientific Review Council's recommendations to the PIC and the Oversight Committee in May 2025.

#### Core Facility Support Awards (R-25.2 CFSA)

Supports applications that facilitate the development or improvement of core facilities that will provide valuable services to support and enhance scientifically meritorious cancer research projects. Funds may be requested to develop a new facility or to enhance the capabilities of an existing facility that will directly support and impact cancer research programs at the institution and in the region. CPRIT will look with special favor on applications that propose a facility that will serve cancer researchers at multiple Texas research institutions, in particular TREC-eligible institutions.

Award: The maximum duration for this award mechanism is 5 years. Applicants may request up to a maximum of \$3,000,000 in total costs.

#### High-Impact/High-Risk Research Awards (R-25.2 HIHR)

Supports applications that explore the feasibility of high-risk projects that, if successful, would contribute major new insights into the etiology, diagnosis, treatment, or prevention of cancers. Using this mechanism, CPRIT intends to support innovative, developmental projects that focus on exceptionally promising topics that are not yet sufficiently mature to compete successfully for more conventional funding. The HIHR Research Awards are expected to provide the foundation for individual or multiple investigator peer-reviewed awards upon completion. The goal of this award mechanism is to fund uncommonly great ideas that merit the opportunity to acquire preliminary data.

Award: Applicants may request a total of \$250,000 for a period of up to 24 months.

### Early Clinical Investigator Awards (R-25.2 ECI)

Solicits applications from institutions to provide cancer physicians early in their academic career the opportunity to develop clinical research skills and to gain experience in advanced methods and experimental approaches needed to become clinical investigators; to provide an opportunity to establish a partnership with a laboratory-based collaborator in order to design and conduct correlative studies needed to interpret the outcome of an interventional trial; to provide the protected time from clinical responsibilities required to develop and conduct investigator initiated clinical trials; and to increase the pool of clinical investigators at Texas academic institutions who are conducting patient-oriented studies, capitalizing on basic discoveries and translating them through conduct of innovative clinical trials involving cancer patients or individuals at risk for cancer.

## Award: Up to \$1,000,000 (total costs) Maximum duration: 5 years

## TREC: Core Facility Support Awards (R-25.2 TREC: CFSA)

Supports applications that facilitate the development or improvement of core facilities that will provide valuable services to support and enhance scientifically meritorious cancer research projects at TREC-eligible institutions. Funds may be requested to develop a new facility or to enhance the capabilities of an existing facility that will directly support and impact cancer research programs at the institution and in the region. CPRIT will look with special favor on applications that propose a facility that will serve cancer researchers at multiple Texas research institutions, in particular TREC-eligible institutions.

Award: The maximum duration for this award mechanism is 5 years. Applicants may request up to a maximum of \$2,000,000 in total costs.

# **TREC:** Advancing Innovative Individual Research Awards at TREC-Eligible Institutions (R-25.2 TREC: AIIRA)

Supports research projects addressing critically important questions, that will significantly advance knowledge of the causes, prevention, and/or treatment of cancer. This award allows experienced or early-career-stage cancer researchers the opportunity to explore new methods and approaches for investigating a question of importance that has been inadequately addressed or for which there may be an absence of an established paradigm or technical framework. **Award:** Applicants may request up to a maximum of \$750,000 in total costs. Duration: 3 years.

### TREC Pilot Study Award (RFA R-25.2 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.

### Fiscal Year 2025 Cycle 1 (FY25.1) RFAs

The following FY25.1 RFAs were posted on February 22, 2024. CPRIT's Application Receipt System (CARS) opened for applications on March 19, 2024, and closed on June 11, 2024. Virtual Peer Review was conducted in October 2024. Dr. Le Beau will present the Scientific Review Council's recommendations to the PIC and the Oversight Committee in February 2025.

### Individual Investigator Research Awards (IIRA)

Supports applications for innovative research projects addressing critically important questions that will significantly advance knowledge of the causes, prevention, and/or treatment of cancer. Areas of interest include laboratory research, translational studies, and/or clinical investigations. Award: Up to \$300,000 per year. Exceptions permitted if extremely well justified; maximum duration: 3 years.

# Individual Investigator Research Awards for Computational Systems Biology of Cancer (IIRACSBC)

Supports applications for innovative mathematical and/or computational research projects

addressing questions that will advance current knowledge in the (a) mechanisms that tie altered gene expression and downstream molecular mechanisms to functional cancer phenotypes and/or (b) mechanisms that tie tumor morphology to functional cancer phenotypes and/or mechanisms that tie treatment sequence and combination to evolving functional cancer phenotypes (that emerge as a result of treatment selection). Award: Up to \$350,000 in total costs per year for up to 3 years. Exceptions permitted if extremely well justified.

# Individual Investigator Research Awards for Cancer in Children and Adolescents (IIRACCA)

Supports applications for innovative research projects addressing questions that will advance knowledge of the causes, prevention, progression, detection, or treatment of cancer in children and adolescents. Laboratory, clinical, or population-based studies are all acceptable. CPRIT expects the outcome of the research to reduce the incidence, morbidity, or mortality from cancer in children and/or adolescents in the near- or long-term.

Award: Up to \$300,000 per year. Exceptions permitted if extremely well justified; maximum duration: 4 years.

# Individual Investigator Research Awards for Prevention and Early Detection (IIRAP)

Supports applications which propose clinical and population-based projects designed to develop effective prevention and early detection interventions to reduce cancer risk, mortality, and morbidity among Texans. Projects that propose such research collaborations with existing CPRIT Prevention Program awardees including the CPRIT funded *Texas Collaborative Center for Hepatocellular Cancer* (https://www.bcm.edu/research/labs-and-centers/research-centers/texas-collaborative-center-for-hepatocellular-cancer) are strongly encouraged.

Award: Up to \$300,000 per year. Exceptions permitted if extremely well justified; maximum duration: 4 years.

## Individual Investigator Research Awards for Clinical Trials (IIRACT)

Supports applications that propose innovative cancer clinical studies in adults or children and adolescents that are hypothesis driven and involve patients enrolled prospectively on a clinical trial. Areas of interest include clinical studies of new or repurposed drugs, hormonal therapies, immune therapies, surgery, radiation therapy, stem cell transplantation, combinations of interventions, or therapeutic devices. Clinical trial must be planned to begin when the contract is awarded.

Award: Up to \$400,000 per year. Maximum duration: 4 years. Exceptions permitted if extremely well justified.

### Individual Investigator Research Awards for Early-Onset Cancers (IIRAEOC)

Supports innovative research projects that will significantly advance the knowledge of etiology, prevention, cancer biology, and treatment of early-onset cancers. Award: Up to \$300,000 per year for a 3-year period

## **Collaborative Action Program (CAP) to Reduce Liver Cancer Mortality in Texas: Collaborative Action Center (Competitive Renewal)**

Supports a competitive renewal of one single Collaborative Action Center whose function will be to innovatively expand the administrative services, resources, and support to CPRIT funded hepatocellular cancer research projects.

Award: Up to \$3,000,000 in total costs for a period of 5 years

Table 2: Application	Submission	data for	FY2025 (	Cycle 1
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Mechanism	Submitted	Total Funding Requested	
Individual Investigator Research Award (IIRA)	220	\$196,400,895.00	
Individual Investigator Research Awards for Computational Systems Biology of Cancer (IIRACSBC)	29	\$29,833,203.00	
Individual Investigator Research Awards for Cancer in Children and Adolescents (IIRACCA)	36	\$42,160,677.00	
Individual Investigator Research Awards for Prevention and Early Detection (IIRAP)	21	\$24,022,601.00	
Individual Investigator Research Awards for Clinical Translation (IIRACT)	26	\$41,025,711.00	
Individual Investigator Research Awards for Early Onset Cancers (IIRA-EOC)	13	\$11,379,861.00	
CAP: CAC	1	\$3,000,000.00	
Total	346	\$347,822,948.00	

## FY2025 Recruitment Update

CPRIT's Application Receipt System (CARS) opened for the first cycle of FY2025 applications on June 21, 2024, and closed on August 20, 2024. The Scientific Review Council reviewed these applications on September 12, 2024, and recommended applications will be presented to the Oversight Committee in November 2024.

## Table 2: Recruitment Application Submission data for Cycle 25.1

Mechanism	Applications	Funds	Applications	Funds	
	Received	Requested	Recommended	Requested	
Recruitment of Established	1	\$6,000,000	0	\$0	
Investigators					
Recruitment of Rising Stars	5	\$18,594,367	1	\$4,000,000	
Recruitment of First-Time,	14	\$28,000,000	4	\$8,000,000	
Tenure Track Faculty Members					
TOTAL	20	\$52,594,367	5	\$12,000,000	

CPRIT's Application Receipt System (CARS) opened for the second cycle of FY2025 applications on August 21, 2024, and closed on October 21, 2024. The Scientific Review Council reviewed these applications on November 14, 2024, and recommended applications will be presented to the Oversight Committee in February 2025.

<b>Table 3: Recruitment Application</b>	1 Submission	data for	Cycle 25.2
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Mechanism	Applications	Funds
	Received	Requested
Recruitment of Established	1	\$6,000,000
Investigators		
Recruitment of Rising Stars	4	\$16,000,000
Recruitment of First-Time,	2	\$4,000,000
Tenure Track Faculty Members		
TOTAL	7	\$26,000,000

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#### CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

### MEMORANDUM

To:OVERSIGHT COMMITTEE MEMBERSFrom:KEN SMITH, PHD, CHIEF PRODUCT DEVELOPMENT OFFICERSubject:PRODUCT DEVELOPMENT RESEARCH PROGRAM UPDATEDate:NOVEMBER 20, 2024

## Product Development FY 2025 Review Cycle 1

CPRIT released four FY 2025 Product Development Research RFAs on April 15th and opened the portal to receive preliminary applications on April 22<sup>nd</sup>. By the May 1<sup>st</sup> deadline, CPRIT had received 90 preliminary applications, including submissions from 32 companies located outside Texas in states such as Massachusetts, California, Georgia, Pennsylvania, New Jersey, Florida, Michigan, Oregon, Delaware, Iowa, New Mexico, and Arizona, as well as from South Korea, Israel, and Germany. Based on preliminary review panel decisions, 24 companies were invited to submit full applications, and we received 22 full applications by the July 25<sup>th</sup> deadline, requesting a total funding of \$181,109,160. Nine projects advanced to due diligence after full application review, with a combined request of \$68,863,933. Texas Therapeutic Company (TTC) led with 9 applications reviewed, 5 progressing to due diligence, and a due diligence request of \$48,024,636. Texas Diagnostic Development Company (TDDC) had 5 applications reviewed, with 1 advancing, requesting \$12,600,000. Seed funding saw 6 applications reviewed, with 3 advancing to due diligence, requesting \$8,239,297. The total requested budget after due diligence for all mechanisms is \$68,863,933. Following further review, the PDRC convened October 28<sup>th</sup> and finalized ranking and funding recommendations for nine projects. I have been working with all 9 companies recommended for funding to negotiate budget reductions, and the recommended awards include projects with a total negotiated budget of \$63,566,375.

25.1 Grant Mechanisms	Prel im App s	Prelim Apps \$ Request	25.1 Invited Apps	Invited App \$ Request	Full App	Full App \$ Request
Texas Therapeutic Company	20	\$236,584,572	9	\$114,424,364	9	\$113,372,324
Texas Device & Diagnostic Co.	13	\$109,574,852	5	\$43,035,019	5	\$42,715,083
Texas New Technologies Company	13	\$98,408,190	2	\$7,464,681	2	\$7,593,656
Seed Company	44	\$149,191,696	8	\$23,283,750	6	\$17,428,097
TOTAL	90	\$593,759,310	24	\$188, 207,814	22	\$181,109,160

#### FY 2025 Cycle 1 Award Recommendations

# FY 2025 Requests for Applications

I recommend that the Oversight Committee approve the proposed FY 2025 Product Development requests for applications (RFAs):

# Competitive Cost Adjustment

These awards will be eligible to prior CPRIT funded companies which have demonstrated their ability to complete their goals and objectives in a timely fashion and which demonstrate the need to obtain additional CPRIT funds to complete the goals and objectives or expand these goals and objectives. Companies who previously negotiated their budgets with CPRIT prior to awards may apply to have these negotiated funds added to their budgets. The process will be competitive, peer-reviewed and will include a range of awards some of which may be less than \$1M.

We plan to release these RFAs in early January and open the portal for the applications, with award announcements planned for the May 2025 Oversight Committee meeting.

# **CPRIT Intellectual Property Database**

Following the progress made in August 2024, CPRIT's IP database has continued to operate smoothly, effectively managing IP and commercialization activities for grantee institutions. In response to feedback and in line with our commitment to data integrity, CPRIT is now focused on a data cleaning project to enhance the accuracy of all active Invention records.

This project involves a thorough review of record details, ensuring that files are accurately associated, and that inventor and grantee information aligns with original disclosure documents. Public patent data will also be incorporated to update missing or incorrect information, covering approximately 613 active records. The project is set to be completed within five months, subject to data complexity, further strengthening CPRIT's support for funded projects through reliable, well-maintained records.

# Product Development Advisory Committee (PDAC)

The PDAC met October 10 to discuss CPRIT's product development program to discuss the FY 2025 review cycle.

# PDR Outreach

In October 2024, the Product Development Research Program engaged in strategic outreach activities to expand CPRIT's collaborations and strengthen its research initiatives. Dr. Magee met with the Governor's Economic Development Office and the

DeSoto Development Corporation to discuss Project Star, presented CPRIT's funding mechanisms to the Belgium Life Sciences Delegation, and engaged with companies like PDC\*line Pharma and Insilicare for potential partnerships. Dr. Leeuwon participated in the ARPA-H Emerging Health Innovators Information Session, gaining insights into expanding funding opportunities, and held follow-up meetings with CERHUM to explore funding options and collaboration in Texas for bone and ceramic implants aimed at cancer treatment.

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#### CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

## MEMORANDUM

TO:OVERSIGHT COMMITTEE MEMBERSFROM:KRISTEN DOYLE, CHIEF EXECUTIVE OFFICERSUBJECT:PROGRAM PRIORITIES FOR FY 2026DATE:NOVEMBER 5, 2024

#### **Summary and Recommendation**

I recommend that the Oversight Committee approve the program priorities for fiscal year 2026 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 will discuss the priorities proposed for fiscal year 2026 with their respective subcommittee. With two exceptions, the fiscal year 2026 program priorities are the same as the priorities adopted by the Oversight Committee last November for fiscal year 2025.

This memo also provides a report on the cumulative metrics for the adopted program priorities as well as several examples of cross-program priorities.

#### Background

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 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 the November quarterly meetings to provide CPRIT staff with more lead time for preparing and releasing RFAs for the next fiscal year. Adopting the 2026 program priorities at the November 20, 2024, Oversight Committee meeting allows the priorities to guide the fiscal year 2026 RFA process.

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.

### **Priorities for FY 2026**

The Chief Officers for the Prevention, Product Development Research, and Academic Research programs recommend proposed fiscal year 2026 priorities for their respective programs. With the two exceptions noted below for the Academic Research and Prevention programs, the fiscal year 2026 program priorities are unchanged from the adopted priorities for fiscal year 2025.

• The Academic Research program proposes adopting a new program priority related to cancer survivorship research that will enhance the health and well-being of cancer survivors and caregivers.

<u>Reason for the Change</u>: Advances in cancer treatments have led to a 33% reduction in the cancer death rate in the past three decades. In 2024, there are over 18 million individuals – or about 5% of the population – living with a history of cancer in the United States. Although the improved survival for cancer patients is welcome, it brings with it an associated need to improve long-term health and welfare as well as follow-up medical care for cancer patients.

Cancer survivors experience increased physical, psychosocial, and economic adversities caused by the cancer diagnosis and long-term effects of cancer treatments. Cancer survivors are also at risk for late effects or secondary health problems due to their cancer treatments and, therefore, require long-term follow-up care, which includes secondary cancer prevention counseling and assessment for short-term and late effects, including the increased risk of comorbidities, recurrence, and development of secondary cancers.

Cancer survivorship research holds promise for reducing the morbidity and mortality associated with cancer and its' treatment. Examples include clinical trials examining deescalation of cancer therapy to reduce toxicity, the identification of risk factors and biomarkers for long-term toxicity and second malignant neoplasms, and prevention and implementation research to improve cancer screening and early detection of subsequent cancers.

• The Prevention program proposes eliminating the program priority related to a program assessment that identifies best practices, serves as a program tool, and guides future program direction.

<u>Reason for the Change</u>: The program priority is no longer necessary because the grantee has completed the assessment for FY 2010 - 2020 prevention awards. The Oversight Committee can reinstate this priority when it is meaningful to conduct another assessment.

## Assessing the Impact of Program Priorities and Reporting on Outcomes

The Oversight Committee approved its inaugural set of priorities at the November 19 quarterly meeting. CPRIT began quantifying the impact of its program priorities using measures introduced with the awards approved by the Oversight Committee at its August 17, 2016, quarterly meeting. CPRIT reports on the outcomes of program priorities through various avenues, including in CPRIT's annual report, through special sections on our website, and in metrics reported to legislators and CPRIT stakeholders.

CPRIT calculates the impact of the Oversight Committee's program priorities primarily through two metrics: the total number of approved awards that are associated with each program priority and the total amount of approved funding associated with each program priority. CPRIT program officers report these two metrics for each program priority to the Oversight Committee in the presentation and written materials that accompany each proposed slate of awards.

I have attached tables for the Academic Research, Product Development Research, and Prevention programs that reflect the metrics for each program priority. The tables include information for both active priorities and for priorities that the programs no longer report. Many of the approved awards fulfill more than one program priority. CPRIT attributes the full amount of the award to each program priority that the project meets.

In addition to the metrics, CPRIT publicly reports through several avenues the outcomes resulting from the decade-long implementation of these program priorities. CPRIT dedicates one section of our annual report to CPRIT's program priorities, which includes examples of a "priority in practice" for each of the three programs. Long-term projects, such as the recently released "CPRIT-Funded Core Facilities Interactive Map" (<u>https://cprit.texas.gov/our-programs/academic-research/core-facilities</u>), the CPRIT Scholar landing page (<u>https://cprit.texas.gov/grants-funded/cprit-scholars</u>), the prevention projects maps (<u>https://cprit.texas.gov/our-programs/prevention/portfolio-maps</u>), the Texas Resource Guide (<u>https://cprit.texas.gov/media/3521/cc\_one-pager\_august\_2024.pdf</u>) are available through CPRIT's website. CPRIT also invites grantees to present their projects at Oversight Committee meetings and features grantee projects fulfilling CPRIT program priorities in the monthly activities report.

## **Priorities Across CPRIT's Three Programs**

In addition to the priorities specific to each grant program, the proposed fiscal year 2026 program priorities also reflect priorities across CPRIT's three programs. These overarching priorities, which remain the same as those adopted for fiscal year 2025, inform the Program Integration Committee on balancing the portfolio across the Academic Research, Product Development Research, and Prevention programs.

Program staff does not report the total number of approved awards and funding amounts associated with these cross-program priorities. Provided below are examples of how each program addresses these overarching priorities.

## **Prevention and Early Detection Initiatives**

<u>Academic Research Program Implementation</u> - Create the evidence base for novel approaches to risk assessment, prevention, early detection, and interventions that could translate into implementation prevention research.

• RP190022 and RP220011 - A Randomized, Controlled Trial Comparing the Immunogenicity of 2 Doses vs. 3 Doses of the 9-valent HPV Vaccine in Males and Females 15–26 Years of Age

Based on her experience gained from two CPRIT-funded prevention projects (PP150004, PP190004) to expand a successful HPV vaccination program, Abbey Berenson, M.D., Ph.D., The University of Texas Medical Branch at Galveston, determined that only 34% of adolescents 13-17 years-old have completed the series of three doses of the 9-valent HPV vaccine. Researchers have concluded that the current requirement of completing a three-dose series is a deterrent to full vaccination.

With CPRIT funding to UTMB and Dr. Berenson, she designed and conducted a randomized, clinical trial of a two-dose schedule of the HPV vaccine in patients 15-26 years of age. Results, published in January 2024 in the *New England Journal of Medicine Evidence*, show that two doses of the HPV vaccine offer similar protection as three doses for males aged 15-26. The researchers observed comparable results for females. Although the Advisory Committee on Immunization Practices currently recommends that individuals continue to receive three doses, Dr. Berenson's findings are adding to the growing body of evidence regarding appropriate doses of HPV vaccination, which is the safest and most effective way to prevent a number of HPV-related cancers.

• RP240143 - Leveraging "Passport for Care" in a Telehealth Framework to Improve Equitable Access to Survivorship Services

Survivorship care plans (SCPs) facilitate the transition from cancer treatment to cancer survivorship, by summarizing the cancer treatment received, the risk for late effects, and related recommendations for late effects surveillance. SCPs serve as a roadmap for long-term follow-up care. Leveraging a partnership with the Children's Oncology Group (COG) Long-Term Follow-Up Guidelines, Maria Gramatges, M.D., Ph.D., Baylor College of Medicine, continued to develop the CPRIT-funded "Passport for Care" as a clinical decision support system for healthcare professionals. It generates a personally tailored SCP from clinician user-entered diagnosis and treatment information. Numerous COG members, both in the United States and international partners, use the Passport for Care as a web-based tool.

Dr. Gramatges' work is an extension of the original Passport for Care projects undertaken by Dr. David Poplack, Dr. Gramatges, and colleagues at Baylor College of Medicine through CPRIT Prevention Program funding mechanisms (PP130070, PP170036, PP220017). She and her team are converting the Passport for Care into a telehealthcompatible format to reach health care providers and children and adolescent survivors of childhood cancer in medically underserved areas of Texas and the nation.

<u>Prevention Program Implementation</u> - Implement programs that place innovative, evidencebased approaches into practice and continue to fund effective approaches.

• PP100039, PP120229, PP150061, PP200009, and PP240019 - *The C-SPAN Coalition: Colorectal Screening and Patient Navigation* 

The C-SPAN project, directed by Keith Argenbright, M.D., The University of Texas Southwestern Medical Center, delivers mailed invitations to complete a home fecal immunochemical test (FIT) screening to all eligible patients, with centralized processes to promote screening completion and evidence based follow up. The reach of the program began with one county, grew to 22 and then 57 counties, and now serves 67 counties in Northeast Texas.

The program coordinates community education and outreach efforts to offer screenings to individuals, established community partnerships to provide clinical services across a broad geography, and navigation tools to ensure successful linkage to care and access to treatment. This same framework serves as the model for six other CPRIT-funded breast, cervical, and lung cancer screening projects.

• PP180086 and PP220022 - *Liver Cancer Prevention among those with Experiences of Homelessness* 

This project, directed by Vanessa Schick Tsai, Ph.D., The University of Texas Health Science Center at Houston's School of Public Health, San Antonio, reduces the risk of hepatocellular carcinoma in homeless and at-risk populations by providing education for viral hepatitis, screening for the Hepatitis B virus (HBV) and Hepatitis C virus (HCV), immunizing those who are HBV naïve, and treating those who are HCV positive.

The in-house program increases engagement and adherence by "meeting people where they are" and eliminating often insurmountable barriers to care for HBV and HCV. Vaccination against HBV and achieving sustained HCV viral suppression improves the health of homeless adults and improves population health by reducing transmission of viral hepatitis to others. <u>Product Development Research Program Implementation</u> - Fund new technologies and methods for early cancer detection and prevention.

• DP220054 - Clinical Validation of the MiTR-core (Minimally Invasive Targeted Resection) Technology for Early Lung Cancer Intervention

Prana Thoracic (previously Nucore Inc.) is a Houston-based medical device company developing novel technologies for early interception, diagnosis, and treatment of lung cancer. Prana's Minimally invasive Targeted Resection (MiTR-core) is the first medical device designed to safely remove lung nodules in a simple, quick, and minimally invasive procedure. The MiTR-core procedure enables clinicians to remove suspicious nodules upon initial detection, and provide a definitive diagnosis of the nodule, while sparing healthy lung tissue. In the event of cancer, MiTR provides direct access to the nodule site for further targeted therapy.

• DP220063 - RadOnc-AI: An Artificial Intelligence Guided Dose-Prediction Platform for Radiation Oncology

Radiation therapy is a critical part of combinatorial cancer care. The dose must be sufficient to kill the targeted tumor, while also not causing collateral damage to nearby healthy tissues and organs. Each person's unique medical history and needs factor into developing precise and individualized treatment plans. Oncology teams create radiation plans, called directives, but estimating the dose is tedious, iterative, time-consuming, and imprecise. A doctor can spend 10+ hours creating a single patient's directive, and the clinical team may take 24-48 hours to finalize the plan.

InformAI, Inc. is building RadOnc-AI, software that uses a form of artificial intelligence (AI) called deep learning to fully automate this directive planning. The AI evaluates the person's medical data and tumor images to predict the optimal radiation dose.

Cancer patients treated at larger hospitals with specialized doctors tend to have better outcomes than those treated at small clinics, who have a reduced survival rate of 20%. InformAI will ensure that patients across Texas receive equitable access to quality treatment plans.

## **Early Translational Research**

<u>Academic Research Program Implementation</u> - Fund the continuum of cancer research - population, basic, translational, and clinical research - that could develop new discoveries into practical advances.

 RP220150 – Enhancing Antitumor Immunity In Metastatic Cancers RP180343 – Developing Therapeutics for HPV-associated Cancers RP120094 and RP140140 – Creating Imaging Technologies for Precise Surgical Removal of Head and Neck Cancers

### RP120897 – Innovating Nanotherapeutics for Targeted Cancer Treatment

Researchers from The University of Texas Southwestern Medical Center founded OncoNano Medicine, a Dallas-based company, in 2014. OncoNano's approach to cancer therapy uses technologies developed by UT Southwestern's Jinming Gao, Ph.D., with the support of five pivotal CPRIT academic research awards. OncoNano, which has received multiple CPRIT Product Development awards, embodies CPRIT's cross-program objectives by advancing the continuum from academic research to clinical healthcare innovations in oncology.

Through 11 inventions that resulted in five issued U.S. patents, CPRIT's academic research and product development research awards have facilitated OncoNano's journey from lab-based research to its status as a clinical-stage biopharmaceutical company. Key milestones, such as the progression of Pegsitacianine, which received FDA Breakthrough Therapy Designation for peritoneal carcinomatosis, have marked OncoNano's transition to clinical and commercial development. The company has initiated a Phase 3 clinical trial and received authorization from the U.S. Food and Drug Administration for the investigational new drug application of ONM-501, a STING agonist, which helps activate the innate immune system and the body's response against cancer cells.

 RP170427- Ambient Mass Spectrometry for Preoperative Molecular Diagnosis of Thyroid Fine Needle Aspirate Biopsies DP240245 - Development of the Ultimate Surgical Sensing System for Intraoperative Tissue Sensing and Surgical Guidance

MS Pen Technologies, supported by CPRIT funding, is advancing groundbreaking solutions for intraoperative cancer detection and precision surgery. Building on foundational research funded through an academic research grant (RP170427) for the MasSpec Pen's use in preoperative molecular diagnosis, MS Pen Technologies has since received a CPRIT Product Development Research Award (DP240245) to develop the Ultimate Surgical Sensing System (Ultiss MD). This innovative platform combines the MasSpec Pen with mass spectrometry and artificial intelligence/machine learning analytics to enable real-time, label-free tissue identification, addressing the critical issue of incomplete cancer resection. By focusing initially on lung cancer—where effective intraoperative decision-making is vital—MS Pen Technologies' work exemplifies CPRIT's commitment to fostering research across the cancer care continuum, from foundational studies to clinical application, transforming scientific discoveries into tangible advances in patient care.

<u>Prevention Program Implementation</u> - Harness emerging technologies that expedite the development of early cancer detection, risk assessment, and interception to implement novel prevention services.

• Collaborative Action Center (CAC) Hepatocellular cancer

• PP240017 - Expanding Access to Cervical Cancer Screening through Primary HR-HPV Testing and Self-Sampling.

Along with vaccination against the human papillomavirus (HPV), cervical cancer screening, early detection, and treatment of cervical precancers are effective interventions for preventing cervical cancer. Screening is the most effective strategy for preventing cervical cancer in the current generation.

A second-generation screening method, screening with primary testing for high-risk HPV (HR-HPV), improves screening outcomes and reaches people for whom cytology-based screening is inaccessible. Compared to first-generation screening that requires provider performed cytology testing, minimally trained lay persons can conduct the primary HR-HPV testing through self-sampling. Numerous countries have implemented primary HR-HPV testing. Compared to provider-performed screening, primary HR-HPV testing is associated with more than a two-fold increase in screening participation among under screened women.

This CPRIT-funded project conducted by Jane Montealegre, Ph.D. and Kathleen Schmeler, M.D., at The University of Texas MD Anderson Cancer Center, increases access to cervical cancer screening, early detection, and linkage to treatment in underserved populations that receive care in safety net health systems. Program pillars include: 1) health system changes guided by the American Cancer Society National Roundtable for Cervical Cancer Screening Implementation Roadmap; 2) provider training and practice facilitation; 3) patient education; 4) patient navigation; and 5) capacity building using Project ECHO® (Extension for Community Healthcare Outcomes) and the existing ECHO Network.

The project leads are developing an effective and sustainable model for the integration of primary HR-HPV testing with self-sampling in clinical practice to serve as blueprint for implementation throughout health systems in Texas and the U.S.

<u>Product Development Research Program Implementation</u> - Fund early-stage companies that are bridging the gap between basic research and product development.

• DP240117 - A Novel High Throughput Platform for Drug Screening Against Dormant and Migrating High-Grade Glioma Cells

Doctors diagnose nearly 12,000 adults with glioblastoma (GBM) in the U.S. each year. Despite more than three decades of efforts, the median survival rate is unchanged at 14-18 months, with the five-year survival rate at 6%. Emerging evidence identifies two cell populations, migrating and dormant cells, which promote tumor recurrence and mortality in GBM. However, researchers lack methods for identifying, retrieving, and analyzing dormant and migrating cancer cells. Current methods of drug discovery focus on rapid cell growth and most drugs developed for GBM do not target dormant and migrating cells. Without a platform to help researchers retrieve and analyze dormant and migrating cells, there is no way to target these critical cell populations in drug development.

CPRIT-funded SingleCell Biotechnology has developed tests for identifying, isolating, and testing dormant and migrating cells and has completed preliminary work on the core components of the tumor drug discovery platform. The company received a \$2.5 million Seed Company Product Development Research Award in 2023 to optimize and validate a single integrated platform that identifies dormant and migrating cells, which researchers can then use, for the first time, to screen drug libraries and identify druggable targets for effectively killing dormant and migrating high grade glioma cells. The company plans for validated tests to assist successful drug development against GBM tumors.

## Enhance Texas' Research Capacity and Life Science Structure

<u>Academic Research Program Implementation</u> - Increase the cancer research infrastructure across Texas by investing in researcher recruitment, training grants and core facilities.

• Several CPRIT-funded core facilities support drug discovery or cryogenic Electron Microscopy (cryo-EM). Together with the recruitment of numerous CPRIT Scholar structural biologists, chemical biologists, and cryo-EM experts involved in structurebased drug design, Texas has established a drug discovery and development powerhouse.

CPRIT Scholar Cassian Yee, (R1301) participated in the CPRIT-funded TMCi Accelerator for Cancer Therapeutics (ACT) 2023 cohort. Through the ACT program Dr. Yee created an endogenous T-cell therapy platform that overcomes critical challenges in creating and utilizing cell-based therapies. This led to a Product Development Research grant (DP240075) awarded in 2024 to Dr. Yee's company, Mongoose Bio.

The University of Texas Southwestern Medical Center (RP240521), MD Anderson Cancer Center (RP180819), Baylor College of Medicine (RP220646) and UTHealth San Antonio (RP220599) have pediatric CPRIT-funded core facilities developing pediatric patient-derived xenograft models, technology for screening for drug sensitivity using these models and primary cancer cells, and integrated clinical and research data commons – unique national resources that have facilitated the analysis of pediatric cancers and the development of novel therapeutic approaches.

 RP210042 - Collaborative Training of a New Cadre of Innovative Cancer Prevention Researchers (The University of Texas Health Science Center at Houston) RP210043 - Cancer Therapeutics Training Program (Texas A&M University System Health Science Center) RP210037 - Systems Epidemiology for Cancer Training Program (Baylor College of Medicine) CPRIT has awarded 31 Training Grant awards to support training the next generation of cancer researchers, including a number of awards focused on training in cancer prevention and, more recently, an innovative advanced program in systems epidemiology.

• RP210153 - The University of Texas El Paso/The University of Texas MD Anderson Cancer Center Partnership for Hispanic Cancer Disparities Research RP2300499 – The University of Texas Rio Grande Valley South Texas Center of Excellence in Cancer Research (ST-CECR)

CPRIT established the Texas Regional Excellence in Cancer (TREC) program awards to strengthen cancer research at institutions located in regions of Texas that have historically received low levels of peer-reviewed cancer research funding. The TREC multicomponent award supports the development of a cancer research center with a cohesive theme relevant to the cancer burden of the region, including the recruitment of new cancer research faculty, support for investigator-initiated research projects of existing faculty, and for the development of Core services providing state-of-the art technologies.

UTEP received a \$5.9 million TREC award in 2021 to establish a unique multidisciplinary Center for the Study of Hispanic Cancer Disparities as a sustainable framework that cultivates cutting-edge research focused on the role of mediators of cancer screening, detection, development, and progression among Hispanic individuals. UTEP subsequently received a TREC: Institutional Postdoctoral Training award in 2023 to recruit outstanding postdoctoral fellows, especially those from underrepresented racial and ethnic groups, individuals with disabilities, and individuals from disadvantaged backgrounds, and train them as the next generation leaders in cancer research to address cancer disparities.

UTRGV received a \$6 million TREC award in 2023 to establish the ST-CECR, the first research center of its kind in the Rio Grande Valley. The ST-CECR takes a comprehensive approach to reduce cancer health disparities in this region by defining novel etiological, lifestyle, and environmental factors influencing cancer development and outcomes, and developing a cancer health disparity research workforce in the Rio Grande Valley.

<u>Prevention Program Implementation</u> - Implementing systems change, developing partnerships and collaborations, training community and healthcare providers, and creating new jobs.

• PP230060 - Coordinating Center for Colorectal Cancer across Texas (CONNECT)

Colorectal cancer is the second leading cause of cancer-related deaths in Texas and ranks 48th among states for colorectal cancer screening completion. Available data suggests that population-based programs can be particularly effective and that critical components for increasing screening rates include high level champions, stakeholder involvement, a convening entity, data driven approaches, defined goals, understanding assets and

resources, creating synergies across systems, and collaborations across public health, community organizations and health care organizations.

The University of Texas at Austin and Dr. Navkiran Shokar received a \$3 million Prevention grant to create the Colorectal Cancer Screening Coordinating Center. The Center serves as a convening entity and central hub of resources, tools, and content expertise accessible by stakeholders across the state. It consists of an advisory steering committee; a statewide stakeholder network and five cores – Administrative; Community-based, Implementation, Engagement, Education and Health Communication; Clinical Implementation, Modeling, Mapping, Cost effectiveness and Data; and Advocacy. The work of the center will culminate in creating the infrastructure, capacity, and resources to propel Texas' CRC screening efforts forward.

• PP110241 - EPICO: Education to Promote Improved Cancer Outcomes PP160048 - Training CHWs for More Effective Cancer Education and Navigation PP200055 - Advancing the Access to Cancer Training, Information, Outreach, and Navigation (ACTION) Project for CHW Dissemination of Resources to At-Risk Texas Regions

CPRIT has awarded Texas A&M University System Health Science Center and Dr. Jane Bolin more than \$1.1 million to develop a project the develops a replicable, sustainable tailored training program for community health workers (CHW) on prevention, detection, treatment, survivorship, and navigation for breast, cervical, colorectal, liver and lung cancers.

The program integrates cancer expertise and community knowledge to develop culturally appropriate education materials, trains promotores in tailoring techniques to adapt their education to characteristics of residents they serve, and it builds infrastructure to make the trainings publicly available to ensure replication and sustainability. The project's online component aids in disseminating the training and materials for utilization by organizations and CHWs in Texas and beyond.

The program is one of the choices for required continuing education units for both CHWs and CHW Instructors as part of the Texas Community Health Worker Training and Certification program.

<u>Product Development Research Program Implementation</u> - Grow the life sciences industry and infrastructure in Texas while creating new employment opportunities.

• CP120038 - Formation of The Texas Cancer Therapeutics Process Development Lab

Kalon Biotherapeutics received a \$7.9 million Product Development Research grant in 2012 to create a cancer therapeutics process development lab at the Texas A&M University System's National Center for Therapeutics Manufacturing. FujiFilm Diosynth Biotechnologies acquired Kalon in late 2014 and is now a contract development and

management organization (CDMO) that provides cell culture, microbial fermentation, cell therapy, gene therapy and vaccine services for companies across Texas and the United States. The company boasts over 3,000 employees in eight sites, including College Station.

• DP230079 - Building Differentiated Cell Therapy Manufacturing Technologies to Attract Value- Added Biotech Partnerships

Cell therapies offer the potential for single-dose cures of cancer. CTMC brings together the leading complex biologics manufacturing technology organization and the leading clinical cancer center to enable innovation from academia and biotech to accelerate Cell Therapy's impact on cancer patients.

Though there has been progress on allogenic or "off-the-shelf" cellular therapies, most early phase therapies are autologous processes, with a dedicated manufacturing run for each patient. These personalized immunotherapies start with the collection of the patient's own cells or tumor samples, which scientists modify or re-engineer depending on the therapeutic modality and indication, then stimulate for growth to expand the cell number, and infuse back into the patient.

Cell therapy is particularly challenging to develop and manufacture since every donor is unique, necessitating a robust process that can support modification and expansion for each patient and cells requiring additional support for growth and expansion ex-vivo. Additionally, viral vectors utilized in the modification/engineering of the cells are critical raw materials that require their own manufacturing process. Resilience Texas dba CTMC received a \$9.1 million Product Development Research grant (DP230079) in 2023 to build platforms and bolster expertise at the CTMC site in Houston that reduces manufacturing time, variability, and cost to reach patients, who often have no other options, faster and more efficiently.

### **Recommendation and Next Steps**

CPRIT staff recommend approval of the FY 2026 program priorities as proposed. We will use the newly adopted program priorities to develop RFAs for the fiscal year 2026 CPRIT grant review cycles.
Academic Research On-Going Priorities	Total	Total	<b>Fiscal Year</b>
	Awards	Funding	Introduced
Recruitment of Outstanding Cancer Researchers to Texas	253	\$764,077,301	FY 2016
A Broad Range of Innovative, Investigator-Initiated Research Projects	515	\$569,043,852	FY 2016
Childhood Cancers	120	\$233,126,101	FY 2017
Computational Biology and Analytic Methods	73	\$173,913,137	FY 2016
Investment in Core Facilities	59	\$214,503,792	FY 2017
Population Disparities	49	\$117,031,705	FY 2016
Expand Access to Innovative Clinical Trials	45	\$94,495,392	FY 2020
Hepatocellular Cancer	39	\$88,920,245	FY 2019
Implementation Research to Accelerate Adoption and Deployment of Evidence-Based Prevention, Early Detection, Risk Assessment, and Interventions	45	\$86,677,202	FY 2016
Drug Discovery	28	\$74,907,595	FY 2023
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Academic Research Priorities No Longer Reported	Total	Total	<b>Fiscal Year</b>
	Awards	Funding	Introduced
Enhance Research Capacity and Life Science Infrastructure	29	\$99,560,385	FY 2016
Rare and Intractable Cancers, Including Childhood Cancers (not reported after August 2016)	6	\$21,702,622	FY 2016
Rare and Intractable Cancers	4	\$3,544,461	FY 2016
(not reported after November 2016)			
(not reported after August 2017)	15	\$27,944,376	FY 2017
Disparities	5	\$8 138 500	EV 2017
(not reported after August 2017)	5	\$6,156,500	11 2017
Novel Projects with Therapeutic or Diagnostic Benefits Not Available (not reported after August 2019)	5	\$7,599,384	FY 2019
Stimulating Commercialization of Technology Developed at Texas Institutions (not reported after August 2021)	9	\$24,116,849	FY 2019
Decrease Cancer Burden Through Prevention, New Diagnostics, Treatments, and Effective Translation into Products (not reported after May 2021)	8	\$30,320,920	FY 2021
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Product Development Research - On-Going Priorities	Total Awards	Total Funding	Fiscal Year Introduced
Providing Appropriate Return on TX Taxpayer Investment	52	\$435,174,405	FY 2017
Funding Projects Addressing Large or Challenging Unmet Medical Needs	52	\$435,174,405	FY 2017
Funding Novel Projects That Offer Therapeutic or Diagnostic Benefits, i.e. Disruptive Tech	46	\$397,928,233	FY 2017
Investing in Early Stage Projects When Private Capital is Least Available	47	\$395,399,482	FY 2017
Supporting New Company Formation in Texas or Attracting Promising Companies to Texas That Will Recruit Staff With Life Sciences Expertise, Especially C-level Executives	36	\$298,307,738	FY 2017
Stimulating Commercialization of Technologies Developed at Texas Research Institutions	32	\$25,344,028	FY 2017
Product Development Research Priorities - No Longer Reported	Total Awards	Total Funding	Fiscal Year Introduced
Funding Companies Bringing Important Products to Market (not reported after November 2017)	2	\$32,146,716	FY 2017
Early Translational Research (not reported after November 2017)	2	\$32,146,716	FY 2017
Enhance Texas' Research Capacity and Life Science Infrastructure (not reported after November 2017)	2	\$32,146,716	FY 2017
Rare and Intractable Cancers, Including Childhood Cancers (not reported after November 2017)	2	\$32,146,716	FY 2017

Prevention - On-Going Priorities	Total Awards	Total Funding	Fiscal Year Introduced
Populations With Obstacles to Cancer Prevention, Detection, Diagnostic Testing, Treatment, and Survivorship Services	144	\$224,452,847	FY 2016
Geographic Areas of the State Disproportionately Affected by Cancer Incidence, Mortality, or Cancer Risk Prevalence	106	\$179,873,371	FY 2017
Populations Disproportionately Affected by Cancer Incidence, Mortality, or Cancer Risk Prevalence	109	\$178,639,752	FY 2017
Prevention Priorities - No Longer Reported	Total Awards	Total Funding	Fiscal Year Introduced
(not reported after August 2016)	9	\$8,677,278	FY 2016
Populations and Geographic Areas of Greatest Need and Potential for Impact (not reported after August 2016)      Target Areas of TX Where Significant Disparities in Incidence or Mortality Exist (not reported after August 2016)	9 8	\$8,677,278 \$8,285,098	FY 2016 FY 2016
Populations and Geographic Areas of Greatest Need and Potential for Impact (not reported after August 2016) Target Areas of TX Where Significant Disparities in Incidence or Mortality Exist (not reported after August 2016) Prevention Program Assessment (not reported after February 2022)	9 8 1	\$8,677,278 \$8,285,098 \$748,936	FY 2016 FY 2016 FY 2022



CANCER PREVENTION & RESEARCH Institute of Texas

# Proposed Program Priorities For FY 2026



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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 2025 at the November 15, 2023, 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 longterm 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;
- 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.



Cancer Prevention & Research Institute of Texas

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 move 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 <u>do not</u> 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 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 ensure 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 in cancer incidence and mortality

#### 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
- Cancer survivorship research to enhance the health and well-being of all cancer survivors and caregivers.

#### **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 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:



- Cancer Prevention & Research Institute of Texas
- 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 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 continuum of primary, secondary, and tertiary cancer prevention

#### **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

#### **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 successfully 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) have a higher investment risk and 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. Scientists need funds for research and development activities taking place between the stages of discovery science - traditionally funded by grants from federal sources and foundations - and late term development and commercialization of drugs, devices, diagnostic tests, and biologicals – often 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 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.

7-28



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

#### MEMORANDUM

TO:OVERSIGHT COMMITTEE MEMBERSFROM:KRISTEN DOYLE, CHIEF EXECUTIVE OFFICERSUBJECT:APPOINTMENTS TO THE SCIENTIFIC RESEARCH AND<br/>PREVENTION PROGRAMS COMMITTEEDATE:NOVEMBER 12, 2024

#### **Summary and Recommendation**

I have appointed two experts to CPRIT's Scientific Research and Prevention Programs Committee. CPRIT's statute requires Oversight Committee approval for the appointments. At their November 7 meeting, the two members of the Board Governance subcommittee attending the subcommittee meeting reviewed the appointees to the Product Development Research peer review panels.

#### 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 two appointees at its November 7 meeting. Although the two members attending the meeting had no questions or concerns regarding the appointments, they did not take a vote to recommend their approval because the subcommittee did not have a quorum of members.

#### Appointments to the Product Development Peer Review Panels

Name	Organization	Title	Expertise
Bruce S. Thomson, PHD	Resilience, INC	Vice President, Technical Lead;	Cell and gene therapy development executive
Stergios Zacharoulis, MD	Columbia University Medical Center	Associate Professor of Pediatric Oncology, Director of Pediatric Neuro-Oncology	Pediatric oncology, drug development, and novel devices/technologies.



BRUCE S. THOMPSON, PHD CELL AND GENE THERAPY DEVELOPMENT EXECUTIVE

#### PROFILE

Cell and gene therapy-focused executive capable of building and sustaining high performing technical teams. Highcaliber scientific thinker possessing strong multi-tasking skills and a keen ability inspire teams, and manage complex deliverables and timelines.. Tech savvy and efficiency focused with experience in large pharma, biotech and academics.

#### CONTACT

bsthom01@gmail.com linkedin.com/in/bruce-s-thompson/ (314) 608-1213

#### **EXPERIENCE**

#### VICE PRESIDENT, TECHNICAL LEAD; CELL THERAPY AND NUCLIEC ACID FRANCHISES, RESILIENCE, INC

#### JUNE 2021-PRESENT

Responsible for technical oversight of process and analytical development teams in the areas of cell therapy and nucleic acids. Responsible for direct management of ~45 staff members across 3 US sites, including the establishment of strategy, goals and OKRs, P&L accountability for modalities and sites and client interface as technical leader of the organizations.

#### VICE PRESIDENT, PROCESS SCIENCES, LYELL IMMUNOPHARMA SEPTEMBER 2018-MAY 2021

SEPTEMBER 2018-MAY 2021

Build and led team of 16 process, analytical and lentiviral vector development scientists to deliver multiple Phase 1 cellular therapy programs at a fast-paced startup biotech company.

#### SR. SCIENTIFIC DIRECTOR, FRED HUTCHINSON CANCER RESEARCH CENTER

#### MAY 2017-SEPTEMBER 2018

Responsible for oversight ~60 staff members ranging from process development scientists to manufacturing operators and quality assurance staff. Worked to establish key metrics for translation of early research programs from ~ 15 Investigator labs to Phase 1 studies.

#### **EDUCATION**

#### PHD, MICROBIOLOGY AND IMMUNOLOGY

UNIVERSITY OF LOUISVILLE, LOUISVILLE, KY May 2005

#### **MS, BIOCHEMISTRY**

THE OHIO STATE UNIVERSITY, COLUMBUS, OH May 1999

#### **BACHELOR OF ARTS IN BIOLOGY**

UNIVERSITY OF LOUISVILLE, LOUISVILLE, KY June 1997, Graduated Cum Laude

#### **KEY SKILLS AND CHARACTERISTICS**

Strong leadership, scientific, interpersonal & communication skills • Keen understanding of CMC requirements for Cell & Gene Therapy products • Ability to work collaboratively, build and inspire teams • Problem Solving • Grace under pressure • Change agile • Patient-focused

#### **LEADERSHIP EXPERIENCE**

- Vice President of Process Sciences, Lyell Immunopharma. Recruited to build the CMC and manufacturing strategy for an early stage biotech (as employee #7). Established early external CDMO strategy for raw materials, such as plasmid DNA and lentiviral vector. Heavily involved in budgeting and planning to build internal manufacturing capabilities and facilities, internal technology development strategy for process unit operations and analytical testing strategy and CMC regulatory strategy to support early preIND and IND filings. Responsible for technology evaluation, facility fitting and internalization and optimization of several technologies entering Lyell through collaborations, such as engineered TCR programs (with GlaxoSmithKline), personalized neoantigen gene-edited autologous TCR programs (with PACT Pharma) and several academic CART programs with Fred Hutchinson Cancer Research Center and Stanford University (scientific founding institutions), as well as tech transferring those programs to our clinical GMP production facility. Member of the Technical Operations Leadership Team (TOLT), responsible for departmental budgeting, establishing business practices, early steering and governance committees (e.g., CMC programs, specification and data review committees, etc), and developing high performing talent, teams and ways of working.
- Sr. Scientific Director, Therapeutic Products Program (TPP), Fred Hutchinson Cancer Research Center. Responsible for leading the clinical manufacturing teams (~60 scientists and operators) in the production of cGMP biologics and cell and gene therapy products for clinical Phase 1 and 2 trials. Additional responsibilities include oversight of the Process Development team and technology transfer into the cGMP facilities, as well as regulatory CMC strategy and support (preIND and IND) for ongoing studies. Responsible for new technology assessment and introduction into the cGMP manufacturing facilities, determining scientific strategy related to internal facility expansion(s), external project and technology collaborations and future innovations. Accountable for multimillion dollar budget to support group functions and manufacturing operating costs.
- Pharmaceutical Sciences Team Leader (PSTL), Pfizer, Inc. Responsible for developing CMC strategy for the allogeneic CART programs, including project oversight of the process and analytical control strategies, regulatory agency interactions and IND/IMPD filings, manufacturing and alliance relationships (member of the Joint Steering Committees for each program) and stewardship of the project budgets and timelines. PSTL for 7 projects; leading teams responsible for process, analytical and formulation development, manufacturing/delivery of non-clinical Regulatory Toxicology and GMP clinical supplies and associated CMC regulatory packages for programs in Phase 1-3 development of teams comprised of 8-10 scientists from Analytical, Bioprocess, Formulation development, Quality Assurance, Regulatory, Supply Chain Management, Outsourcing, Project Management and various other subject matter experts. Responsible for dotted line professional mentorship and development of team members.
- Expertise in creation and communication of milestones, timelines, budgets and other critical information (manufacturing activities, etc) in a concise manner to key stakeholders across the company

•

- Regulatory writing Expertise in preparing regulatory documents, such as briefing packages for preIND and preCTA (Health Canada) filings, IND/IMPD and CTA filings and amendments, QA documents for laboratory and manufacturing investigations, and other technical packages for regulatory queries, etc
- Ability to work across sites, organizations, skills sets, and areas of expertise. Able to work in a virtual environment with the skills to lead others through influence (as opposed to direct line management) to achieve project deliverables under tight timelines
- Presentation skills Expertise in preparation and delivery of technical information, timelines, and program strategy materials to a wide variety of audiences from technical scientists to executive leadership
- Time management skills Expertise in understanding/developing priorities, managing multiple project deliverables, responsibilities and timelines
- Technical writing Expertise in preparing research papers, GxP methods and documentation, technical reports and white papers, presentations and abstracts as well as scientific letters of intent for funding and regulatory applications

#### PRIOR EMPLOYMENT HISTORY

Associate Research Fellow, Pharmaceutical Sciences Team Leader Pfizer, Inc, St. Louis, MO Jan 2008 – May 2017

- Held positions of increasing responsibility within the Bioassay, Analytical and Project and Portfolio Management groups in the BioTherapeutics Pharmaceutical Sciences division (Promoted from Sr. Scientist through organization to Associate Research Fellow over 9 years)
- Pharmaceutical Sciences Team Leader for 5-7 projects; responsible for deliverables related to project transitions from Discovery Research and subsequent development of early Phase programs for First in Human through Phase 3 readiness activities and transition to commercial organization

Led the Pfizer build out of the allogeneic CART assets for the CMC division, including establishing CMC project teams, representing CMC on several joint steering committees with partners and leading CDMO negotiations to establish external manufacturing strategy

- Project lead for a prophylactic vaccine in the Analytical R&D division 

   Led the development of the analytical control strategy for manufacturing and release/stability testing for the *C. difficile* prophylactic vaccine now in late stage development, including method development (throughout the product lifecycle), preparation of regulatory materials (preIND, IND, CTA documents), and project management during progression from First in Human through Phase 3 manufacturing preparations
  - Communication of analytical deliverables to Vaccines Sr. management and key program stakeholders (Clinical, Commercial and Business Unit)
- Bioassay development scientist and project lead for several vaccine and monoclonal antibody/conjugate compounds 

   Responsible for development and qualification of potency assays (cell-based and ELISA) for biologics and vaccines
  - Responsible for regulatory strategy related to release specifications and characterization strategy, reference standard qualification and bridging
  - Responsible for reagent production/qualification, characterization assays (BiaCore, MSD, reporter gene and cell-based proliferation assays, collaborative efforts with Discovery Research and other Organizational lines, such as Drug Safety and Pharmacokinetics/Pharmacodynamics)

#### Postdoctoral Research Scholar

Washington University in St. Louis 2005-2008

• Collaborative research project working with Drs. Daved Fremont in Immunology and Biochemistry and Mike Diamond in Infectious Disease at Washington University on mechanisms of antibody neutralization of West Nile Virus

Developed expertise in cloning, protein production and purification, characterization of protein and antibody interactions using biophysical techniques (X-ray crystallography, circular dichroism, surface plasmon resonance (SPR), and fast protein liquid chromatography (FPLC), SDS PAGE Electrophoresis, Western blotting, protein cross-linking, and mass spectrometry (MS) analysis

• Developed expertise in virology, BSL2 and BSL3 tissue culture techniques, FACS, ELISAs, confocal and fluorescence microscopy, live virus infection assays, density gradient virus purification, as well as several other mammalian tissue culture techniques

#### TEACHING EXPERIENCE

2005	Infectious Disease Scholars Program, Washington University in St. Louis, St. Louis, Missouri
2002	Graduate Teaching Assistant, Medical Microbiology Laboratory, Department of Microbiology & Immunology, University of Louisville, Louisville, Kentucky.
1999	Graduate Teaching Assistant, Department of Molecular Genetics, The Ohio State University, Columbus, OH
MENTORSHIP	

2023 Visiting Scholar, Wyss Institute at Harvard University

#### PUBLICATIONS

Stewart MD, Keane A, Butterfield LH, Levine BL, Thompson BS, Xu Y, Ramsborg C, Lee A, Kalos M, Koerner C, Moore T, Markovic I, Lasiter L, Ibrahim R, Bluestone J, Sigal E and Allen J. Accelerating the development of innovative cellular therapy products for the treatment of cancer. Cytotherapy. 2020 May;22(5):239-246. doi: 10.1016/j.jcyt.2020.01.014. Epub 2020 Mar 18

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Thompson BS, Moesker B, Smit JM, Wilschut J, Diamond MS, Fremont DH. A therapeutic antibody against west nile virus neutralizes infection by blocking fusion within endosomes. PLoS Pathog. 2009 May;5(5):e1000453. doi: 10.1371/journal.ppat.1000453. Epub 2009 May 29.

Huang S, Gilfillan S, Kim S, Thompson B, Wang X, Sant AJ, Fremont DH, Lantz O, Hansen TH. MR1 uses an endocytic pathway to activate mucosal-associated invariant T cells. J Exp Med. 2008 May 12;205(5):1201-11.

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Chung KM, Nybakken GE, Thompson BS, Engle MJ, Marri A, Fremont DH, Diamond MS. Antibodies against West Nile Virus nonstructural protein NS1 prevent lethal infection through Fc gamma receptordependent and -independent mechanisms. J Virol. 2006 Feb;80(3):1340-51.

Thompson BS, Chilton PM, Ward JR, Evans JT, Mitchell TC. The low-toxicity versions of LPS, MPL adjuvant and RC529, are efficient adjuvants for CD4+ T cells. J Leukoc Biol. 2005 Dec;78(6):1273-80.

Thompson BS, Mata-Haro V, Casella CR, Mitchell TC. Peptide-stimulated DO11.10 T cells divide well but accumulate poorly in the absence of TLR agonist treatment. Eur J Immunol. 2005 Nov;35(11):3196-208.

Thompson BS, Mitchell TC. Measurement of daughter cell accumulation during lymphocyte proliferation in vivo. J Immunol Methods. 2004 Dec;295(1-2):79-87. Epub 2004 Oct 27.

Mitchell TC, Thompson BS, Trent JO, Casella CR. A short domain within Bcl-3 is responsible for its lymphocyte survival activity. Ann N Y Acad Sci. 2002 Dec;975:132-47.

Lock RB, Thompson BS, Sullivan DM, Stribinskiene L. Potentiation of etoposide-induced apoptosis by staurosporine in human tumor cells is associated with events downstream of DNA-protein complex formation. Cancer Chemother Pharmacol. 1997;39(5):399-409..

Lock R, Thompson B, Stribinskiene L. Differential ability of 2,4-dinitrophenol to modulate etoposide cytotoxicity in mammalian tumor cell lines associated with inhibition of macromolecular synthesis. Int J Oncol. 1996 Feb;8(2):305-11.

References are available upon request

#### **BIOGRAPHICAL SKETCH**

Provide the following information for the Senior/key personnel and other significant contributors in the order listed on Form Page 2. Follow this format for each person. **DO NOT EXCEED FOUR PAGES.** 

NAME	POSITION TITLE
	4
era commons user name (credential, e.g., agency login)	

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)

INSTITUTION AND LOCATION	DEGREE (if applicable)	MM/YY	FIELD OF STUDY

Please refer to the application instructions in order to complete sections A, B, C, and D of the Biographical Sketch.

Program Director/Principal Investigator (Last, First, Middle):

Program Director/Principal Investigator (Last, First, Middle):

Program Director/Principal Investigator (Last, First, Middle):



Navkiran K. Shokar, MA, MD, MPH is professor and chair of the Department of Population Health, Associate Dean for Community Affairs and co-lead for cancer prevention and control within the Livestrong Cancer Institutes at Dell Medical School at the University of Texas at Austin. She was born and raised in England where she received her Master of Arts degree from the University of Cambridge and her medical degree from the University of Oxford Medical School. She was previously at UTMB Galveston and Texas Tech University Health Sciences Center El Paso. Dr. Shokar's research focuses on multilevel clinic and communitybased interventions that bridge the divide between public health, the community and the health care system in order to address cancer health disparities among racial/ethnic minorities and vulnerable populations. Her work incorporates theory-based health promotion methods and culturally tailoring to maximize intervention effectiveness.



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

# **Prevention Advisory Committee Report**

November 20, 2024

Presented By: Navkiran K. Shokar, MD MPH MA

# PAC Member Roster

Keith Argenbright, MD (Vice Chair)	UT Southwestern, Moncrief Cancer Institute
Abbey Berenson, MD PhD	UTMB, Galveston
Roxana Cruz, MD	Texas Association of Community Health Centers, Inc.
Ashley Dedmon, MPH, CHES	Living Beyond Breast Cancer
Dorothy Gibbons	The Rose
Amanda Hall, MD	Texas Department of State Health Services
Ernest Hawk, MD, MPH	UT MD Anderson Cancer Center
David Lakey, MD	UT System
Rakhshanda Rahman, MD	Texas Tech University Health Sciences Center
Kenneth Ramos, MD, PhD	Texas A & M University
Navkiran Shokar, MD MPH (Chair)	Dell Medical School, UT Austin
Suncerria Tillis, MBA	Exact Sciences
Laura Wood, CHES	American Cancer Society



## Active Projects by Cancer Type





## Active Projects by Focus Area





# Active Projects by Type of Prevention

**Active Projects by Prevention Type** 



- Primary Prevention
- Secondary Prevention
- Tertiary Prevention



## Prevention Services Trends and 2024 Activity





### **CPRIT Prevention Projects Across Texas**

### • Delivered Over 9.9 Million Education and Clinical Services

3.8 M Education & Training Services2.3 M Navigation Services

### 3.8 M Clinical Services

- Vaccinations
- Tobacco Cessation
- Screening: breast, cervical, colorectal, liver, and lung
- Genetic testing and counseling
- Survivor care

These programs reach underserved populations in every region of the state through evidence-based direct interventions with quantifiable public health impact exceeding current performance in the service area.



Counties Of Residence Of People Served By CPRIT Prevention Projects


# Screening Outcomes as of August 2024

### • Providing Life Extending Results

**1,887,103** Screenings **206,456** Diagnostics



**422,501** People never before screened

40,907 Precursors detected

5,573 Cancers detected



# Major Accomplishments

- Expanded Prevention Advisory Committee membership to include industry representatives
- CPRIT Innovations Conference
- Colorectal Cancer Treatment Initiative
- First focused statewide cancer prevention effort Colorectal Cancer Screening Coordinating Center
  - Create a plan to scale efforts across the state leveraging existing infrastructure, convene stakeholders, share resources and expertise, education, navigation, highlight barriers and creatively build solutions.



## Cancer Trends

- 1. Rising earlier age onset cancers
- 2. Rising obesity-related cancers
- 3. Disparities in cancer outcomes remain
- 4. Blood based cancer detection
  - 1. PAC is committed to safe and effective cancer detection and screening
  - 2. Supportive of thoroughly and rigorously testing new methods before they are deployed in practice
  - Need for wider understanding about the state of science around blood borne early detection tests for cancer



# PAC Recommendations

- Integrate and coordinate with the Texas Cancer Plan recommendations
- Identify the next cancer focus area for a statewide screening RFA
- Scale ongoing efforts, promote collaboration, sharing of resources, experiences and best practices.
- Facilitate the development of a comprehensive statewide cancer prevention, early detection, and access to care strategy
- Accelerate Research and Capacity in Prevention and Control Research
- Encourage strategies to support CPRIT funded program development in a diverse array of organizations
- Broader engagement with different stakeholder types



# Questions ?

### Navkiran K Shokar, MA, MD, MPH Chair, CPRIT Prevention Advisory Committee

Professor and Chair Department of Population Health Associate Dean for Community Affairs Lead, Cancer Prevention and Control Dell Medical School, University of Texas at Austin navkiran.shokar@austin.utexas.edu





Min Hee Kang, PharmD Distinguished University Professor, Professor of Pediatrics, Texas Tech University Health Sciences Center

Min Hee Kang, PharmD is Associate Vice President for Research, Distinguished University Professor and Professor of Pediatrics at the Texas Tech University Health Sciences Center School of Medicine. She earned her Bachelor in Pharmacy in South Korea in 1990, and her PharmD from the University of Colorado Health Sciences Center, Denver in 1998. After completing her PharmD, she joined the National Cancer Institute, National Institutes of Health as a post-doctoral fellow. In 2005, Min accepted an assistant professor position at the University of Southern California-Children's Hospital Los Angeles. Min co-directed the National

Cancer Institute Pediatric Preclinical Development Program in vitro testing laboratory for 10 years, and the data she generated resulted in numerous publications and several early-phase pediatric clinical trials. Min was recruited to TTUHSC as an assistant professor in 2008. She was promoted to an associate professor with tenure in 2011 and to professor in 2015. Dr. Kang's research has been continuously funded by both the Cancer Prevention and Research Institute of Texas (CPRIT) and the National Institutes of Health (NIH). Dr. Kang has received recognition for her research and teaching, including President's Young Investigator award in 2010, President's Excellence in Research Award in 2013, University Distinguished Faculty in 2015, and the Outstanding Faculty Award by TTUHSC Student Governance Association 2014 and 2015. She has authored over 120 peer-reviewed publications, and her Hindex is 46. She serves as a reviewer on NIH Study Sections.



CANCER PREVENTION & RESEARCH Institute of Texas

### Geographic Diversity Advisory Committee November 2024 Report

Min Kang, Pharm.D., Co-Chair Geographic Diversity Advisory Committee



TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER

# Geographic Diversity Advisory Committee

### Mission:

The Geographic Diversity Advisory Committee advises the Oversight Committee and staff on universities' special needs and challenges in *developing cancer research capacity* in locations far away from the cancer research centers in the major metropolitan areas.



# Geographic Diversity Advisory Committee

- GDAC was formed in the summer of 2021.
- We held monthly meetings for first year.
- We shifted to quarterly meetings in mid-2022.
- We have had two meetings since we last presented to Oversight Committee last February; one in April and one in November. We also held a Symposium in June.



# **Geographic Diversity Advisory Committee**

Member	University
Joseph Heppert, Ph.D.	Texas Tech University
Min Kang, Pharm.D.	Texas Tech University Health Science Center
Robert Kirken, Ph.D.	The University of Texas El Paso
Raj Lakshmanaswamy, Ph.D.	Texas Tech University Health Science Center, El Paso
Ken Ramos, M.D., Ph.D.	Texas A&M University
Daniel Romo, Ph.D.	Baylor University
Sarah Williams-Blangero, Ph.D.	The University of Texas Rio Grande Valley



# GDAC member institutions

**TREC:** The members represent universities that are located 100 miles or more from a National Cancer Institute Designated Cancer Center in Houston, Dallas, or San Antonio.





Cancer Prevention & Research Institute of Texas

## **Texas Regional Excellence in Cancer Award**

- TREC Awards continue to be highly successful at building capacity in cancer research across the state of Texas.
- GDAC has worked with CPRIT to expand funding opportunities targeted towards TREC-eligible institutions.
- The new funding opportunities are fostering rapid expansion of cancer research at TREC-eligible institutions.



## TREC Academic Research Award as of Aug 2024

Funding Mechanism	No. of Awards	CPRIT investment	No. of Patents filed	No. of Publications
TREC awards	14	\$34.62M	5	48
*Follow-on-funds: \$13.73M				

- 1<sup>st</sup> TREC funding opportunity announced (Aug 2020) and funded 2 projects
  - Texas Regional Excellence in Cancer award: \$6M over 5 years Recipients: UTEP and TTUHSC (Lubbock)
- 2<sup>nd</sup> TREC funding opportunities announced (Sep 2021) and funded 3 projects
  - Texas Regional Excellence in Cancer award: \$6M over 5 years Recipients: UTRGV, TTUHSC (El Paso), Texas A&M
- 3<sup>rd</sup> TREC funding opportunities announced (Jan 2023) and funded 8 projects
  - TREC: Institutional Postdoctoral Training Award: \$850,000 over 3 yrs Recipients: UTEP
  - TREC: Major Instrument Award: \$1M over 2 years
    Recipients: TTUHSC (Lubbock), Texas A&M, Baylor University
  - TREC: Pilot Study Award: \$200,000 over 2 years
    Recipients: UTRGV, TTUHSC (Lubbock), Texas A&M, TTUHSC (El Paso)



## **Texas Regional Excellence in Cancer Awards**

- University of Texas at El Paso. Center for the Study of Hispanic Cancer Disparities.
- Texas Tech Health Sciences Center. Texas Regional Excellence in Cancer Developmental Therapeutics Center.
- Texas A&M University System Health Science Center. Gene-Environment-Lifestyle Interactions in Cancer.
- Texas Tech University Health Sciences Center at El Paso. Impacting Cancer Outcomes in Hispanics.
- University of Texas Rio Grande Valley. South Texas Center of Excellence in Cancer Research.



# **TREC** virtual symposium

- 1<sup>st</sup> TREC Virtual Symposium: June 21, 2024.
- Purpose: to present research and promote collaboration among TREC institutions.
- Two to three presentations from each of the TRECeligible institutions highlighted the breadth of cancer research being conducted at these institutions.
- Also, the meeting demonstrated what a huge impact CPRIT is having on science at these institutions.
   Thank you!



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# The University of Texas at El Paso

CPRIT GDAC Meeting November 2024



CANCER PREVENTION & RESEARCH Institute of Texas

### **UTEP's Hispanic Cancer Health Disparities Strategy**





### Funds Awarded to UTEP's CRPIT ESIs

UTEP/UTMDACC Partnership for Hispanic Cancer Disparities Research CPRIT-Texas Regional Excellence in Cancer Award (TREC), 2021-2026 PI: Marc Cox \$5.8M

Goal: Collaborate with UT MD Anderson Cancer Center to provide mentoring to 5 ESI cancer researchers and recruit 2 more faculty to UTEP as part of establishing the Center for Hispanic Cancer Disparities.

#### Postdoctoral Training Program (PDTP) CPRIT 2023-2026 Pls: Drs. Weiqin Lu & Anita Quintana \$0.85M

Goal: Develop a postdoctoral training program by recruiting individuals from underrepresented groups and train them to be the next generation of leaders in cancer research.





CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

	NIH (PI)	NIH (co- I)	*Other (PI)	*Other (co- I)	Total
2021- 2022	11	7	12	8	38
2022- 2023	8	3	20	10	41

\*External funding excluding NIH \*\*PI at Naval Research Laboratory, DC

Funds Awarded to CRPIT ESIs			
	NIH	*Other	Total
2021-2022	\$3,463,097	\$238,827	\$3,701,924
2022-2023	\$403,018	\$680,672	\$1,083,590

Recruited Faculty			
Weiqin Lu	Pharmaceutical Sciences	Pancreatic Cancer	
Anna Eiring	<b>Biological Sciences</b>	Myeloid Leukemia	

### **CPRIT PDTP Recruited 3 Postdocs as of Nov-2024:**

	Name	Area	Previous Institution
1	Md Zahirul Islam	Cancer bioinformatics	UTEP
2	Zahid Rafiq	Pancreatic Cancer	UT MDACC
3	Fabian Romero	Cancer therapeutics	U. Colorado Anschutz 9-26

# **TTUHSC SOM Cancer Center**

- 30 members across multiple clinical and basic science departments
- \$36 million in active peer-reviewed external grant funding
- \$3 million in new external grant funding in 2023
- \$80 million in external grant funding over the 16-yr life of the Center
- Multiple resource laboratories that support regional and national clinical trials
- From 2014 to 2024, the Cancer Center has banked specimens consented for research from > 6000 adults and children with cancer





# **TTUHSC TREC**

- Funded September 2021 •
- Cores supported: •
  - Administrative Core
  - Flow Cytometry Core 0
  - South Plains Oncology Consortium 0
  - **Cancer Biobanking Core** 0
  - Pharmacokinetics Core
  - **Regulatory Science Core** Ο
  - **Biostatistics/Bioinformatics Core**
- External Advisory Council:
  - Julia Glade-Bender, MD
  - Michael Hogarty, MD 0
  - Gail Eckhardt, MD 0
  - Jerry Shay, PhD 0

- Vice Chair of Pediatrics, Memorial Sloan Kettering Cancer Center
- Children's Hospital of Philadelphia
  - Associate Dean of Experimental Therapeutics, Baylor College of Med.
    - Associate Director, Simmons Comprehensive Cancer Center, UTSW



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### **TTUHSC TREC Junior Faculty Accomplishments**

- First TREC "graduate": Yangzom Bhutia, DVM PhD, investigates a novel drug target for pancreatic cancer. Received a 5-year, \$1.5 million NCI RO1 grant, June 2023.
- First TREC faculty recruit: Nighat Noureen, PhD, Recruited Spring 2023, cancer bioinformatics, co-investigator on a NCI \$1.5 million, 5year clinical trial support grant awarded fall 2024.
- Second TREC faculty recruit: Balakrishna Koneru, PhD, summer 2023, novel drug targets for osteosarcoma.
- Erin Barr, MD, pediatric oncologist named chair of national COG firstin-child clinical trial of ATM kinase inhibitor.





# **CPRIT- Funded Core Labs at TTUHSC**

- Cancer Animal Models Core (Director: Scott Trasti, DVM)
  - Provides a robust facility for growing human cancers in immunocompromised mice. This core supports the COG Childhood Cancer Repository and the TTUHSC TREC biobanking work with adult cancers.

### West Texas Pharmacology Core (Director: Min Kang, PharmD)

- Provides pharmacokinetics and pharmacodynamic support for both preclinical and clinical studies, including GLP pharmacokinetics.
- Telomere Maintenance Mechanism Lab (Director: Pat Reynolds, MD PhD)
  - Carries out molecular assays that are biomarkers needed for assessing prognosis and understanding results of multiple COG national phase III clinical trials.
- Flow Cytometry Core (Director: Min Kang, PharmD)
  - BD flow cytometry analyzer and a BD cell sorter that supports a COG national phase III clinical trial by analyzing binding of a therapeutic antibody as a biomarker of therapy resistance.





### **CPRIT TREC Junior Faculty Research Leads in the "Impacting Cancer Outcomes in Hispanics" Grant**

- Dr. Anna Eiring (PI): R15 and ACS grant
- Dr. Shrikanth Gadad (PI): R16 and ACS grant
- Dr. Ramadevi Subramani Reddy (Site PI) NCI/NSF SPARK Grant and (PI) Coldwell Foundation grant





### **CPRIT TREC "Impacting Cancer Outcomes in Hispanics" Grant**

- Established a tumor biorepository
- Establishing core service facilities in histology, imaging and cytometry





# **Diversifying Support for TREC-Eligible Institutions (New RFA's)**

- Release of RFA: Aug 2024 (due: Dec 10, 2024)
  - TREC: Pilot Study Award (\$200,000 over 2 yrs)
  - TREC: Advancing Innovative Individual Research Award (\$250,000/yr x 3 yrs)
  - TREC: Core Facility Support Award (\$400,000/yr x 5 yrs)



## **Exploring New TREC Funding Mechanisms And Conference Activity**

- TREC-eligible institutions have fewer resources and support for cancer research than major research institutions located near NCI-designated National Cancer Centers.
- Contributing presentations at conferences fosters opportunities for collaboration (that will expand research) and highlight the broad impact of TREC research programs. An example is the American Association for Cancer Research Annual Conference on Health Disparities.



CPRIT funding awarded to TREC-eligible institutions is transformational for those universities, facilitating:

- Expanded research on cancer;
- Growth of the Texas workforce focused on cancer research;
- Inclusion of underserved populations in basic and clinical research; and
- Positive impact on the health of the local population.



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#### CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

### MEMORANDUM

TO:OVERSIGHT COMMITTEE MEMBERSFROM:KRISTEN P. DOYLE, CHIEF EXECUTIVE OFFICERSUBJECT:SECTION 102.1062 WAIVER – JOHN ELLIS FY 2025DATE:NOVEMBER 13, 2024

### Waiver Request and Recommendation

I request that the Oversight Committee approve a FY 2025 conflict of interest waiver for John Ellis, CPRIT's General Counsel, pursuant to Health & Safety Code Section 102.1062 "Exceptional Circumstances Requiring Participation." Mr. Ellis' sister-in-law and brother-in-law, Hope Synder and Dylan Synder, both work as healthcare professionals at Baylor Scott & White Health in Temple. While Mr. Ellis' in-laws will not be part of any team applying for a CPRIT grant or receiving salary support from a CPRIT grant, this waiver ensures transparency regarding their employment at a grantee entity. I recommend approval because together with the waiver's proposed limitations, adequate protections are in place to mitigate factors other than merit and the established grant criteria affecting the award and management of grant funds.

### Background

Baylor Scott & White employs Mr. Ellis' sister-in-law, Hope Synder, as a licensed clinical social worker in Temple. Baylor Scott & White employs Mr. Ellis' brother-in-law, Dylan Snyder, as a hospital charge nurse at the hospital in Temple. Baylor Scott & White employs more than 49,000 individuals and 7,300 active physicians at 51 hospitals and 800 patient care sites.

Entities associated with Baylor Scott & White have applied for and received CPRIT grants. Baylor Scott & White Research Institute, which is the dedicated research and development arm of the Baylor Scott & White healthcare system, is a grant recipient with one active academic research award (RP230426). In total, Baylor Scott & White Research Institute has received five CPRIT academic research grant awards since 2010.

Mr. Ellis' relatives are not involved in current or past CPRIT grant projects or grant applications and do not receive salary support from CPRIT grant funds. However, Texas Health & Safety Code § 102.106(c)(3) finds a professional conflict of interest exists when a relative within the second degree of affinity or consanguinity of the individual involved in the CPRIT review process is an employee of a grant recipient or grant applicant. Mr. Ellis' sister-in-law and brother-in-law fall within the second degree of affinity and consanguinity to Mr. Ellis. CPRIT considers the institution as the grant applicant or recipient, in this case Baylor Scott & White and Baylor Scott & White Research Institute, rather than the individuals who submit a grant application or receive a grant award. Furthermore, CPRIT's administrative rule §702.13(c) classifies this type of professional conflict of interest as one that raises the presumption that the existence of the conflict may affect the impartial review of all other grant applications submitted pursuant to the same grant mechanism in the grant review cycle. A person involved in the review process that holds one of the conflicts included in the § 702.13(c) "super conflict" category must recuse himself or herself from participating in the "review, discussion, scoring, deliberation and vote on all grant applications competing for the same grant mechanism in the entire grant review cycle, unless a waiver has been granted..."

Texas Health & Safety Code § 102.1061 requires a CPRIT employee with this professional conflict of interest to recuse himself from an application that comes before the employee for review or other action and not access information regarding the matter.

### **Exceptional Circumstances Requiring Participation**

To approve a conflict of interest waiver, the Oversight Committee must find that there are exceptional circumstances justifying the conflicted individual's participation in the review process. Mr. Ellis' role as CPRIT's General Counsel requires him to negotiate award contracts with Baylor Scott & White and Baylor Scott & White Research Institute and to provide legal advice to CPRIT staff and the Oversight Committee regarding issues that may affect these two entities. Given the nonexistent involvement of Mr. Ellis' relatives in any activities related to CPRIT research projects undertaken by Baylor Scott & White or Baylor Scott & White Research Institute, the need for Mr. Ellis' legal expertise and advice outweighs the extremely unlikely opportunity for him to act in a manner influenced by bias toward his relatives.

### **Proposed Waiver and Limitations**

In granting the waiver of the conflict of interest set forth in Health & Safety Code Section 102.106(c)(3), I recommend that the Oversight Committee permit Mr. Ellis to perform all duties assigned as General Counsel subject to the limitations stated below:

- 1. Mr. Ellis may negotiate award contracts, contract amendments, and provide legal advice to CPRIT staff and CPRIT Oversight Committee members regarding issues affecting Baylor Scott & White, Baylor Scott & White Research Institute, and other entities related to Baylor Scott & White;
- 2. Mr. Ellis may attend peer review meetings and PIC meetings as an observer, including meetings that include applications from Baylor Scott & White, Baylor Scott & White Research Institute, and other entities related to Baylor Scott & White;
- 3. Mr. Ellis may have access to grant application information, including information related to Baylor Scott & White, Baylor Scott & White Research Institute, and other entities related to Baylor Scott & White except as noted in item number 5;
- 4. Mr. Ellis will inform the Chief Executive Officer of any CPRIT grant application or grant award that includes his sister-in-law or brother-in-law as part of the grantee team and/or includes his sister-in-law or brother-in-law as staff paid by CPRIT grant funds;
- 5. CPRIT will prevent Mr. Ellis from accessing application review data for any applications under review that includes his sister-in-law or brother-in-law as part of the grantee team and/or includes his sister-in-law or brother-in-law as staff paid by CPRIT grant funds;

6. In the event that an issue arises that this waiver does not address, the Chief Executive Officer and Chief Compliance Officer may review the circumstances and determine whether Mr. Ellis should recuse himself from involvement in these or other regular job duties as appropriate. The Chief Executive Officer will report such circumstances and recusal determination to the Oversight Committee.

Regarding item number 2, Mr. Ellis will continue to follow CPRIT's established policy that prohibits CPRIT employees from actively participating in peer review committee meetings. As part of his CPRIT duties, Mr. Ellis may attend peer review committee meetings as an observer but does not participate in substantive discussion of any grant application, does not score any application, and does not vote on any application. CPRIT contracts with an independent thirdparty observer to document that all participants follow CPRIT's observer policy. The independent third-party observer report is available to the Oversight Committee prior to any action taken related to the grant award recommendations. Following Oversight Committee action, the independent third-party observer report is publicly available.

### **Important Information Regarding this Waiver and the Waiver Process**

- The Oversight Committee may amend, revoke, or revise this waiver, including the list of approved activities and duties and the limitations on duties and activities. Approval of any change to the waiver granted shall be by a vote of the Oversight Committee in an open meeting.
- CPRIT limits this waiver to the conflict of interest specified in this request. To the extent that Mr. Ellis has a conflict of interest with an application that is not the conflict identified in Section 102.106(c)(3), then Mr. Ellis will follow the required notification and recusal process.

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#### CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

### MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	JOHN ELLIS, GENERAL COUNSEL CAMERON ECKEL, ASSISTANT GENERAL COUNSEL
SUBJECT:	CHAPTER 703 PROPOSED RULE CHANGES
DATE:	NOVEMBER 13, 2024

### **Summary and Recommendation**

The Board Governance Subcommittee convened on November 7 to discuss the suggested rule changes to Texas Administrative Code §§ 703.13 and 703.26. Publication of the anticipated rule changes in the *Texas Register* is the first step in the agency rulemaking process. If the Oversight Committee approves posting, CPRIT staff will bring back the proposed rule amendments and any public comments in February for final approval.

### Discussion

CPRIT's administrative rules set policy guiding CPRIT's grant review and grant contracting processes as well as managing other requirements of Texas Health and Safety Code Chapter 102. State law requires agencies to use a rulemaking process, which includes an opportunity for the public to comment on the rule changes before the agency adopts the final policy.

The Board Governance Subcommittee met on November 7 to discuss three proposed rule changes to Chapter 703.

First, the amendment to § 703.13(b) increases the grant recipient audit threshold from \$750,000 to \$1 million. Grantees who receive state funds in an amount at or above the threshold must obtain an audit and provide it to CPRIT. CPRIT follows the threshold set in the Texas Grant Management Standards (TxGMS), published by the Comptroller's Office. The Comptroller released a new version of TxGMS on October 1st, increasing the audit threshold to \$1 million.

Next, the proposed change to § 703.26(b) replaces an outdated reference to the Uniform Grant Management Standards (UGMS) with TxGMS. After TxGMS went into effect, CPRIT amended its rules to replace references to UGMS with TxGMS. This non-substantive change corrects a reference that was previously overlooked.

Finally, the amendment to § 703.26(e) adds to the list of unallowable grantee expenses, "Reimbursements to employees for their out-of-pocket health insurance premium or other health care expenses which are not made through an employer-sponsored plan established under Section 105 of the Internal Revenue Code." This clarifies that CPRIT practices follow current laws and regulations governing these expenses.

### Next Steps

If approved by the Oversight Committee, CPRIT will submit the proposed rule changes to the Secretary of State for publication in the *Texas Register*. The publication date begins the 30-day period for soliciting comment from interested members of the public. CPRIT will also post the proposed rule changes on our website and announce the opportunity for public comment via CPRIT's electronic list serve. CPRIT legal staff will summarize any comments received from the public for the Oversight Committee's consideration when approving the final rule changes in February.

The Cancer Prevention and Research Institute of Texas ("CPRIT" or "the Institute") proposes amending 25 Tex. Admin. Code §§ 703.13(b) and 703.26 relating the grant recipient audit threshold, unallowable grant recipient expenses, and a reference to Texas Grant Management Standards.

#### Background and Justification

The proposed amendment to § 703.13(b) increases the grant recipient audit threshold from \$750,000 to \$1 million. The amendment harmonizes CPRIT's administrative rules with recent changes to the Texas Grant Management Standards (TxGMS) published by the Comptroller of Public Accounts. Currently, CPRIT grantees who expend \$750,000 or more in state funds must obtain either an annual single independent audit, a program specific independent audit, or an agreed upon procedures engagement. CPRIT follows the guidance in TxGMS to determine the audit threshold. On October 1, 2024, the Comptroller's of Public Accounts released a new version of TxGMS that increased the threshold to \$1 million.

CPRIT proposes amending § 703.26(e) to add the following as an unallowable expense for grant recipients, "Reimbursements to employees for their out-of-pocket health insurance premium or other health care expenses which are not made through an employer-sponsored plan established under Section 105 of the Internal Revenue Code." For these expenses to be considered fringe benefits that are reimbursable from CPRIT grant funds, the employer must have an established health reimbursement arrangement program under Section 105 of the Internal Revenue Code. Thus, this amendment clarifies that CPRIT program standards for reimbursements conform to other relevant laws.

Lastly, the Institute proposes a non-substantive, technical amendment to § 703.26(b). This amendment proposes replacing an outdated reference to the Uniform Grant Management Standards (UGMS) with a reference to TxGMS. CPRIT relied on UGMS, the predecessor to TxGMS, as guidance for grant recipients and referred to it in the Institute's administrative rules. When TxGMS went into effect, CPRIT updated its administrative rules to replace references to UGMS with references to TxGMS. The proposed amendment to § 703.26(b) corrects a reference that was inadvertently excluded from the previous update.

#### Fiscal Note

John Ellis, General Counsel for the Cancer Prevention and Research Institute of Texas, has determined that for the first five-year period the rule change is in effect, there will be no foreseeable implications relating to costs or revenues for state or local government due to enforcing or administering the rules.

#### Public Benefit and Costs

Mr. Ellis has determined that for each year of the first five years the rule change is in effect the public benefit anticipated due to enforcing the rule will be clarifying grantee reporting obligations and consequences.

Small Business, Micro-Business, and Rural Communities Impact Analysis

Mr. Ellis has determined that the rule change will not affect small businesses, micro businesses, or rural communities.

Government Growth Impact Statement

The Institute, in accordance with 34 Texas Administrative Code §11.1, has determined that during the first five years that the proposed rule change will be in effect:

(1) the proposed rule change will not create or eliminate a government program;

(2) implementation of the proposed rule change will not affect the number of employee positions;

(3) implementation of the proposed rule change will not require an increase or decrease in future legislative appropriations;

(4) the proposed rule change will not affect fees paid to the agency;

(5) the proposed rule change will not create new rule;

(6) the proposed rule change will not expand existing rule;

(7) the proposed rule change will not change the number of individuals subject to the rule; and

(8) The rule change is unlikely to have an impact on the state's economy. Although the change is likely to have a neutral impact on the state's economy, the Institute lacks enough data to predict the impact with certainty.

Submit written comments on the proposed rule changes to Mr. John Ellis, General Counsel, Cancer Prevention and Research Institute of Texas, P. O. Box 12097, Austin, Texas 78711, no later than January 7, 2025. The Institute asks parties filing comments to indicate whether they support the rule revision proposed by the Institute and, if the party requests a change, to provide specific text for the proposed change. Parties may submit comments electronically to jellis@cprit.texas.gov or by facsimile transmission to 512/475-2563.

#### Statutory Authority

The Institute proposes the rule changes 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. Mr. Ellis has reviewed the proposed amendments and certifies the proposal to be within the Institute's authority to adopt.

There is no other statute, article, or code affected by these rules.

<rule>

§703.13. Audits and Investigations.

(a) Upon request and with reasonable notice, an entity receiving Grant Award funds directly under the Grant Contract or indirectly through a subcontract under the Grant Contract shall allow, or shall cause the entity that is maintaining such items to allow the Institute, or auditors or investigators working on behalf of the Institute, including the State Auditor and/or the Comptroller of Public Accounts for the State of Texas, to review, inspect, audit, copy or abstract its records pertaining to the specific Grant Contract during the term of the Grant Contract and for the three year period following the date the last disbursement of funds is made by the Institute or all reports required pursuant to the Grant Contract are submitted and approved, whichever date is later.

(1) A Grant Recipient shall maintain its records pertaining to the specific Grant Contract for a period of three years following the date the last disbursement of funds is made by the Institute or all reports required pursuant to the Grant Contract are submitted and approved, whichever date is later.

(2) The Grant Recipient may maintain its records in either electronic or paper format.
(b) Notwithstanding the foregoing, the Grant Recipient shall submit a single audit determination form no later than 60 days following the close of the Grant Recipient's fiscal year. The Grant Recipient shall report whether the Grant Recipient has expended <u>\$1 million</u> [\$750,000] or more in state awards during the Grant Recipient's fiscal year. If the Grant Recipient has expended <u>\$1 million</u> [\$750,000] or more in state awards in its fiscal year, the Grant Recipient shall obtain either an annual single independent audit, a program specific independent audit, or an agreed upon procedures engagement as defined by the American Institute of Certified Public Accountants and pursuant to guidance provided in subsection (e) of this section.

(1) The audited time period is the Grant Recipient's fiscal year.

(2) The audit must be submitted to the Institute within thirty (30) days of receipt by the Grant Recipient but no later than nine (9) months following the close of the Grant Recipient's fiscal year and shall include a corrective action plan that addresses any weaknesses, deficiencies, wrongdoings, or other concerns raised by the audit report and a summary of the action taken by the Grant Recipient to address the concerns, if any, raised by the audit report.

(A) The Grant Recipient may seek additional time to submit the required audit and corrective action plan by providing a written explanation for its failure to timely comply and providing an expected time for the submission.

(B) The Grant Recipient's request for additional time must be submitted on or before the due date of the required audit and corrective action plan. For purposes of this rule, the "due date of the required audit" is no later than nine (9) months following the close of the Grant Recipient's fiscal year.

(C) Approval of the Grant Recipient's request for additional time is at the discretion of the Institute. Such approval must be granted by the Chief Executive Officer.

(c) No reimbursements or advances of Grant Award funds shall be made to the Grant Recipient if the Grant Recipient is delinquent in filing the required audit and corrective action plan. A Grant Recipient that has received approval from the Institute for additional time to file the required audit and corrective action plan may receive reimbursements or advances of Grant Award funds during the pendency of the delinquency unless the Institute's approval declines to permit reimbursements or advances of Grant Award funds until the delinquency is addressed.

(d) A Grant Recipient that is delinquent in submitting to the Institute the audit and corrective action plan required by this section is not eligible to be awarded a new Grant Award or a continuation Grant Award until the required audit and corrective action plan are submitted. A Grant Recipient that has received approval from the Institute for additional time to file the required audit and corrective action plan may remain eligible to be awarded a new Grant Award or a continuation Grant Award unless the Institute's approval declines to continue eligibility during the pendency of the delinquency.

(e) For purposes of this rule, an agreed upon procedures engagement is one in which an independent certified public accountant is hired by the Grant Recipient to issue a report of findings based on specific procedures to be performed on a subject matter.

(1) The option to perform an agreed upon procedures engagement is intended for a non-profit or forprofit Grant Recipient that is not subject to Generally Accepted Government Audit Standards (also known as the Yellow Book) published by the U.S. Government Accountability Office. (2) The agreed upon procedures engagement will be conducted in accordance with attestation standards established by the American Institute of Certified Public Accountants.

(3) The certified public accountant is to perform procedures prescribed by the Institute and to report his or her findings attesting to whether the Grant Recipient records are in agreement with stated criteria.

(4) The agreed upon procedures apply to all current year expenditures for Grant Awards received by the Grant Recipient. Nothing herein prohibits the use of a statistical sample consistent with the American Institute of Certified Public Accountants' guidance regarding government auditing standards and 2 CFR Part 200, Subpart F, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards."

(5) At a minimum, the agreed upon procedures report should address:

- (A) Processes and controls;
- (B) The Grant Contract;
- (C) Indirect Costs;
- (D) Matching Funds, if appropriate;
- (E) Grant Award expenditures (payroll and non-payroll related transactions);
- (F) Equipment;
- (G) Revenue Sharing and Program Income;
- (H) Reporting; and
- (I) Grant Award closeout.

(6) The certified public accountant should consider the specific Grant Mechanism and update or modify the procedures accordingly to meet the requirements of each Grant Award and the Grant Contract reviewed.

(f) For purposes of this rule, a program specific audit should address:

(1) Sample of awards;

- (2) Reporting;
- (3) Indirect costs;
- (4) Matching funds, if appropriate;
- (5) Expenditures;
- (6) Expenditure Reporting;
- (7) Personnel Level of Effort Reporting;
- (8) Grant Closeout;
- (9) Performance Measures;
- (10) Publications and Acknowledgements;

(11) Title to equipment;

(12) Contract certifications;

(13) Changes in Principal Investigator or Program Director;

(14) Intellectual Property and revenue sharing;

(15) Early termination and event of default; and

(16) Any other issue identified by the Institute, the Grant Recipient, or the person performing the program specific audit.

(g) 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 Grant Management Standards (TxGMS) adopted by the Comptroller's Office. If guidance from <u>TxGMS [the Uniform Grant Management Standards]</u> 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 revenuefunded 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.

(18) Reimbursements to employees for their out-of-pocket health insurance premium or other health care expenses which are not made through an employer-sponsored plan established under Section 105 of the Internal Revenue Code.

(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.

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#### CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

## MEMORANDUM

TO:OVERSIGHT COMMITTEE MEMBERSFROM:HEIDI MCCONNELL, DEPUTY EXECUTIVE AND CHIEF OPERATING<br/>OFFICERSUBJECT:CHIEF OPERATING OFFICER REPORTDATE:NOVEMBER 8, 2024

## **CPRIT Financial Overview for FY 2024, Quarter 4**

#### FY 2024, Quarter 4 Operating Budget

CPRIT has an adjusted FY 2024 budget of \$6 million in Indirect Administration and \$16.4 million in Grant Review and Award Operations which incorporate \$614,401 carried forward from FY 2023 to FY 2024 for a several contract extensions and IT projects.

CPRIT expended or obligated 78% of the \$6 million Indirect Administration budget and fully obligated the \$16.4 million in Grant Review and Award Operations budget.

CPRIT received approximately \$266,485 in revenue sharing payments during the fourth quarter which includes a royalty payment for \$187,822 from Merck & Co., Inc. from the sales revenue of WELIREG<sup>™</sup> (belzutifan). Revenue sharing payment deposits from CPRIT's inception total more than \$10.4 million through the end of August 2024.

#### FY 2024, 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 2024. The results are:

- A total of 857,901 people served through CPRIT prevention and control grants, exceeding the 750,000-person served goal;
- One company relocation to Texas out of the projected three relocations;
- Being within range of the 141.0 annual age-adjusted mortality rate at 138.0;
- A total of 935 published articles on CPRIT-funded research, achieving 93.5% of the 1,000-article target; and
- A total of 3,590 jobs created or maintained, exceeding the 3,000-job target.

#### Debt Issuance History

As reported in February, May, and August 2024, TPFA issued CPRIT's total requested general obligation bond proceeds in the amount of \$298.4 million in FY 2024. There are no updates through the end of FY 2024.

#### Cancer Prevention and Research Institute of Texas Quarterly Financial Report As of August 31, 2024

	Indirect Administration (B.1.1.)													
		Aŗ	2024 opropriated	2024 Budgeted	% of Total Budget	Ac Gi	tual Expenditures & ant Encumbrances (FYTD)	I	Remaining Budget	Percent Expended	Estimated Expenditure (YTD)	s	Lapse/Ove	erspent
1001	Salaries and Wages	\$	1,847,425	\$ 1,930,411		\$	1,930,411		(0)	100%	\$ 1,930,4	11	\$	(0)
1002	Other Personnel Costs		38,785	107,840			107,840		0	100%	107,8	40		0
2001	Professional Fees and Services		1,808,662	1,980,859			1,029,220		951,639	52%	1,029,2	20	ç	<del>)</del> 51,639
2003	Consumable Supplies		24,000	24,000			6,600		17,400	28%	6,6	00		17,400
2004	Utilities		58,600	58,600			41,500		17,100	71%	41,5	00		17,100
2005	Travel		45,000	69,526			69,526		0	100%	69,5	26		0
2006	Rent-Building		11,000	33,112			33,112		0	0%	33,1	.12		0
2007	Rent-Machine and Other		32,172	32,172			7,022		25,150	22%	7,0	122		25,150
2009	Other Operating Expenses		1,045,249	1,783,611			1,460,313		323,297	82%	1,460,3	13	3	323,297
	Subtotal - Indirect Administration (B.1.1.)	\$	4,910,893	\$ 6,020,132	2.02%	\$	4,685,546	\$	1,334,586	78%	\$ 4,685,5	46	\$ 1,3	334,586

#### Grant Review and Award Operations (A.1.3.)

							Act	ual Expenditures &			E	stimated		
			2024			% of Total	Gra	ant Encumbrances	Remaining	Percent	Exp	oenditures		
		A	ppropriated	2024	4 Budgeted	Budget		(FYTD)	Budget	Expended		(YTD)	Lapse/O	verspent
1001	Salaries and Wages	\$	3,505,873		4,151,525		\$	4,424,275	\$ (272,751)	107%	\$	4,424,275	\$	(272,751)
1002	Other Personnel Costs		45,000		139,654			139,654	0	0%		139,654		0
2001	Professional Fees and Services		12,419,373		11,761,810			11,566,807	195,003	98%		11,566,807		195,003
2003	Consumable Supplies		-		-			-	-	0%		-		-
2004	Utilities		12,000		12,000			-	12,000	0%		-		12,000
2005	Travel		45,000		45,000			30,143	14,857	67%		30,143		14,857
2009	Other Operating Expenses		71,649		310,866			310,866	0	100%		310,866		0
	Subtotal - Grant Operations (A.1.3.)	\$	16,098,895	\$	16,420,855	5.51%	\$	16,471,745	\$ (50,890)	100%	\$	16,471,745	\$	(50,890)

	Grants														
		А	2024 ppropriated		2024 Budgeted	% of Total Budget	A G	ctual Expenditures & Grant Encumbrances (FYTD)		Remaining Budget	Percent Expended	E	Estimated Expenditures (YTD)	L	apse/Overspent
4000 4000	Grants - Prevention (A.1.2) Grants - Research (A.1.1.)	\$	27,671,780 248,251,400	\$ \$	25,968,624 249,522,349		\$	25,902,480 135,886,309	\$ \$	66,144 113,636,040	100% 54%	\$	25,902,480 135,886,309	\$	66,144 113,636,040
	Subtotal - Grants	\$	<mark>275,923,180</mark>	\$	275,490,973	92.47%	\$	161,788,789	\$	<b>113,702,184</b>	<mark>59%</mark>	\$	161,788,789	\$	113,702,184
	Grand Totals	\$	296,932,968	\$	297,931,960	100.00%	\$	182,946,079	\$	114,985,880	61%	\$	182,946,079	\$	114,985,880

## Cancer Prevention and Research Institute of Texas Cancer Prevention and Research Institute Fund Account - 5136 As of August 31, 2024

	8/0 <sup>-</sup> 8/3	1/2024- 1/2024	AY 2 as	Vear to Date 0f 8/31/2024	
Beginning Balance : 9/01/2023			\$	600,506	
Increases:					
(1) (2)	\$	-	\$	-	
Total Increases	\$	-	\$	600,506.00	
Reductions: Expenditures - Appropriated	\$ \$ \$	- - -	\$ \$ \$	- - -	
Total Reductions	\$	-	\$		
Ending Balance: 8/31/2024			\$	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, 2024

	8/0 8/	01/2024- 31/2024	AY 2 as	24 Year to Date of 8/31/2024
Beginning Balance : 9/01/2023			\$	101,766.48
Increases:				
(1) License Plate Revenue Received	\$	685.66	\$	6,436.75
Interest	\$	178.44	\$	2,056.00
Total Increases	\$	864.10	\$	110,259.23
Reductions:				
Expenditures - Appropriated	\$	-	\$	-
		-		-
Total Reductions	\$	-	\$	-
Ending Balance: 8/31/2024			\$	110,259.23

Note:

Balance forward from 2023 License Plate \$101,766.48

# Cancer Prevention and Research Institute of Texas Appropriated Receipts - 666 As of August 31, 2024

		 8/01/2024- 8/31/2024	AY 24 `	Year to Date as of 8/31/2024
Beginning	Balance : 9/01/2023		\$	243,044.65
Increases:				
(1)	Product Development Application Fees Received	\$ 500.00	\$	29,500.00
(2)	Conference Registration Fees	\$ -	\$	84,640.00
(3)	Conference Registration Fees-Credit Card	\$ -	\$	1,761.70
Total Increa	ases	\$ 500.00	\$	115,901.70
Reductions	:			
	Conference Expenditures - Appropriated	\$ -	\$	(242,131.00)
	Credit Card Fees Expended	\$ -	\$	(1,761.70)
	Refund-Application Fees	\$ -	\$	-
	Legal Services Expenses (Application Fees)	\$ (85,312.50)	\$	(85,312.50)
Total Redu	ctions	\$ (85,312.50)	\$	(329,205.20)
Ending Bal	ance: 8/31/2024		\$	29,741.15

Forward balance for FY 2022 is \$55,246.90 Application Fees Conference Fee for FY 2023 is \$187,797.75

# Cancer Prevention and Research Institute of Texas Interest & Sinking Fund Account - 5168 As of August 31, 2024

			8/01/2024- 8/31/2024	AY 24	Year to Date as of 8/31/2024	
Beginning	g Balance : 9/01/2023			\$	6,390,606.01	
Increases	S:					
(1)	Revenue Sharing / Royalties	\$ \$	263,234.81 -	\$ \$	842,448.12 -	
Total Incr	eases	\$	263,234.81	\$	7,233,054.13	
Reduction	<b>ns:</b> Expenditures - Appropriated	\$ \$ \$	- - -	\$ \$	-	
Total Red	luctions	\$	-	\$	<u> </u>	
Ending B	alance: 8/31/2024			\$	7,233,054.13	

Balance forward from FY 2023 is \$6,390,606.01

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	750,000	195,607	203,203	228,837	230,254	857,901	114.39%
Number of Entities Relocating to TX for Cancer Research Related Projects	3	0	0	1	0	1	33.33%
Annual Age-adjusted Cancer Mortality Rate	138.0	N/A	N/A	N/A	N/A	141.0	102.17%
Number of Published Articles on CPRIT- Funded Research Projects	1,000	N/A	N/A	N/A	N/A	935	93.50%
Number of New Jobs Created and Maintained	3,000	N/A	N/A	N/A	N/A	3,590	119.67%

#### Cancer Prevention and Research Institute of Texas FY 2024, Quarter 4 Performance Measure Report

#### 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 continue to provide cancer prevention clinical services such as mammograms and colonoscopies.

#### 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 relocate operations to Texas. A company must meet 4 of CPRIT's 7 criteria for a relocation to be considered complete. This year one company who received a CPRIT award has been able to complete this process.

#### 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.



Fiscal Year	A	Amount ppropriated	Dated Issued	Aı	mount Issued	Amo	unt 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	ć	225,000,000	Sontombor 7, 2010	¢	11 800 000			Commercial Daner Notes	Sorios A. Tayabla		
2011	Ş	223,000,000	September 7, 2010	ې د	F1 000 000				Taxable Series 2011	Par amount of now monoy	Eived Pate Pends All In True
2011			August 10, 2011	Ş	51,000,000			G.O. Bonds	Taxable Series 2011	Par amount of new money	Fixed Rate Bonds All-In-True
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	Sentember 7, 2011	¢	3 200 000			Commercial Paper Notes	Series A. Tavable	Refunded as G.O. Bonds	
2012	Ļ	300,000,000	December 8, 2011	<u>ې</u> د	3,200,000			Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2012			March 2, 2012	ې د	12 300 000			Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2012			lune 21, 2012	Ś	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	Ş	300,000,000	September 6, 2012	Ş	9,600,000			Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2013			May 16,2013	Ş	13,400,000			Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
						Ş	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	Taxable Series 2014	Par amount of refunding; Refunded	Fixed Rate Bonds All-In-True
								Bonds)		\$237.88M of GOCP CPRIT Series A	Interest Cost 3.327184%
						\$	162,500,000				
2015	ć	200,000,000	November 5, 2014	ć	57 600 000			Commercial Deper Notes	Sorios A. Tayabla	Pofundad as G.O. Ponda	
2015	Ş	300,000,000	April 20, 2014	ې د				Commercial Paper Notes	Series A, IdXdDle	Refunded as G.O. Bonds	
2015			April 29, 2014	ې د	75 000 000			Commercial Paper Notes	Series A, Taxable	Perfunded as G.O. Bonds	
2013			Julie 20, 2015	ڔ	73,000,000	ć	244 600 000	commercial raper Notes	Jenes A, Taxable		
						Ŷ	244,000,000				

Fiscal Year	Amount Appropriated	Dated Issued	Am	ount Issued	Amo I	ount 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		
2019		July 12, 2019	\$	54,000,000			Commercial Paper Notes	Series A, Taxable		
					Ş	207,700,000				

	Amount	Data d Januard	•		Amo	ount Issued for	<b>Commercial Paper or GO</b>	Carries	Commente	
Fiscal Year	Appropriated	Dated Issued	A	mount issued		Fiscal Year	Bond Issuance	Series	Comments	Interest Rate
2020		September 16, 2019	\$	64,300,000			Commercial Paper Notes	Series A, Taxable		
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	Sentember 11, 2020	Ś	75 000 000			Commercial Paner Notes	Series A Taxable		
2021	\$300,000,000	lanuary 14, 2021	ې د	59,000,000			Commercial Paper Notes	Series A. Taxable		
2021		April 29, 2021	Ś	68,900,000			Commercial Paper Notes	Series A, Taxable		
2021		August 12, 2021	\$	57.400.000			Commercial Paper Notes	Series A, Taxable		
			Ŧ	01)100,000	Ś	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				
2023	\$300,000,000	September 20, 2022	\$	79,500,000			Commercial Paper Notes	Series A, Taxable		
2023		March 2, 2023	\$	66,000,000			Commercial Paper Notes	Series A, Taxable		
2023		April 6, 2023	\$	79,000,000			Commercial Paper Notes	Series A, Taxable		
2023		June 15, 2023	\$	59,200,000			Commercial Paper Notes	Series A, Taxable		
2023		August 29, 2023	\$	350,000,000			G.O. Bonds (Refunding Bonds)	Taxable Series 2023	Par amount of refunding	Fixed Rate Bonds All-In-True Interest Cost 5.020317%
2023		August 29, 2023	\$	14,600,000			G.O. Bonds	Taxable Series 2023	Par amount of new money proceeds	Fixed Rate Bonds All-In-True Interest Cost 5.020317%
					\$	298,300,000				

# **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
2024	\$ 300,000,000	October 4, 2023	\$ 92,800,000		Commercial Paper Notes	Series A, Taxable		
		November 15, 2023	\$ 92,800,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2023A	Par amount of refunding	Fixed Rate Bonds All-In-True Interest Cost 6.129887%
		November 15, 2023	\$ 205,600,000		G.O. Bonds	Taxable Series 2023A	Par amount of new money proceeds	Fixed Rate Bonds All-In-True Interest Cost 6.129887%
				\$ 298,400,000				

# **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
2025	\$ 300,000,000	September 24, 2024	\$ 86,000,000		Commercial Paper Notes	Series A, Taxable		Interest rate of 4.87%
				\$ 86,000,000				
TOTAL ISSU	JED TO DATE			\$ 3,196,100,000				



### CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

## MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	HEIDI MCCONNELL, DEPUTY EXECUTIVE AND CHIEF OPERATING OFFICER
SUBJECT:	CONFERENCE PLANNING AND COORDINATING SERVICES CONTRACT
DATE:	NOVEMBER 8, 2024

#### Recommendation

CPRIT staff recommends awarding a contract to Innovation Event Management, LP (IEM) in Austin, Texas, for \$190,788 for conference planning and coordinating services to assist the agency with organizing the next Innovations Conference.

IEM has extensive experience organizing large scale conferences for other Texas state agencies with the largest meeting having approximately 5,000 attendees and 300 exhibitors. They coordinate similar events for federal agencies, nonprofit associations, and trade organizations. IEM has relationships with convention centers, convention and visitors bureaus, and hotels throughout the state which will assist with outreach to an assortment of possible venues for the next conference. In addition, they have technological capabilities including QR code scanning and attendee session tracking.

#### Background

CPRIT received two proposals in response to the agency's request for proposal (RFP) issued in July for a vendor to provide conference planning and coordinating services. There was no incumbent vendor.

Upon finalization of the contract, the new vendor's initial duties will be providing guidance to CPRIT on the statement of services for a conference venue RFP and assisting CPRIT with the venue selection.

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## Cancer Prevention & Research Institute of Texas

## MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	KRISTEN DOYLE, CHIEF EXECUTIVE OFFICER
	HEIDI MCCONNELL, DEPUTY EXECUTIVE AND CHIEF OPERATING OFFICER
SUBJECT:	STATE AGENCY EMPLOYMENT LEVEL
DATE:	NOVEMBER 12, 2024

On September 27, I sent letters to the Governor's Office and Legislative Budget Board notifying them that CPRIT exceeded the cap of 44.0 full-time equivalent (FTE) by 4.5 FTEs for a total of 48.5 FTEs in the fourth quarter of FY 2024. Until the last quarter of FY 2024, CPRIT had operated with an employment level below the FTE cap authorized in the agency's bill pattern in the General Appropriations Act.

CPRIT exceeded the cap because we have been successful in hiring staff to fill open positions and retaining staff to meet agency needs. The agency employs 10 contractors to augment agency capabilities in grant report review, general agency operations, and information technology and security support. Those 10 contractors include:

- four (4) grant accountants\* (review quarterly grant reimbursement requests and required annual financial reports including HUB, inventory, and matching fund reports);
- a grant compliance specialist\* (performs second level review of quarterly grant reimbursement requests);
- an executive assistant (provides administrative support for the entire agency including arranging staff travel; prepares meeting books for Oversight Committee meetings and subcommittee meetings; arranges Oversight Committee travel for quarterly meetings);
- a systems analyst (maintains and updates the prospective grant award portal for the Oversight Committee; batches the nightly approved grant reimbursement report data from grant management platform to CAPPS for payment);
- a front-end developer\* (ongoing website maintenance including accessibility requirements; annual development of interactive, statutorily required Annual Report);
- a developer (transitioning the compliance group's grant compliance system to a new platform);
- a cybersecurity analyst\*(monitor, analyze, and mitigate threats to the agency's information security controls under the Information Security Officer).

CPRIT has included the roles with an asterisk beside in the exceptional item request for 10 additional FTEs in our Legislative Appropriations Request for the 2026-27 Biennium.

14-2



#### CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

## MEMORANDUM

TO:OVERSIGHT COMMITTEE MEMBERSFROM:KRISTEN DOYLE, CHIEF EXECUTIVE OFFICERSUBJECT:CHIEF SCIENTIFIC OFFICER SALARY ADJUSTMENTDATE:NOVEMBER 18, 2024

#### **Summary and Recommendation**

I recommend that the Oversight Committee vote at its November 20 meeting to approve a five percent salary increase for Chief Scientific Officer Dr. Michelle Le Beau, increasing her exempt position salary from \$639,300 to \$671,300. Increasing Dr. Le Beau's salary is consistent with the Appropriations Act authority approved by the 88<sup>th</sup> Texas Legislature in 2023. Presiding Officer Dr. Cummings concurs with my recommendation.

Article IX, Section 3.04(d) of the General Appropriations Act for the 2024-25 Biennium requires Oversight Committee approval of any salary increase for an exempt position. The Texas Open Meetings Act permits the Oversight Committee to discuss this request in closed session before acting in an open meeting. If one or more members contact me requesting that the Oversight Committee discuss this in closed session, we will do so near the end of the upcoming meeting.

#### Background

In CPRIT's Legislative Appropriations Request (LAR) for the 2024 – 2025 biennium, we sought approval for a 10% increase to the Chief Scientific Officer's exempt position salary. We contended that the increase was necessary to maintain some degree of parity between the Chief Scientific Officer salary and other similar positions in the academic research field (i.e. Comprehensive Cancer Center director). This would be particularly important from a recruitment perspective, should that become necessary. The 88<sup>th</sup> Texas Legislature approved CPRIT's request, providing for a five-percent increase in FY 2024, followed by a second five-percent increase in FY 2025. The Oversight Committee approved the FY 2024 five-percent increase at its meeting in August 2023.

CPRIT has requested another 10% increase for the Chief Scientific Officer's position in our LAR for the 2026 – 2027 biennium. Deputy Executive and Chief Operating Officer Heidi McConnell and I testified at a meeting convened by the Legislative Budget Board and the Officer of the Governor in August that the increase is necessary to maintain parity and assist recruitment efforts if necessary. We have also spoken about this request with several senators in meetings ahead of the upcoming session.

## Discussion

In addition to recognizing her exemplary work on behalf of CPRIT, I want to increase Dr. Le Beau's salary because doing so is consistent with the legislative authority CPRIT sought and received in the 2023 legislative session. Given that we are seeking approval for the same exceptional item request in the upcoming legislative session, it is important that CPRIT act to carry out the previously granted authorization. This will also provide CPRIT with some additional salary flexibility should it become necessary as we recruit the next Chief Scientific Officer in 2025.

## **Next Steps**

I recommend that the Oversight Committee vote to approve the five percent salary increase for the Chief Scientific Officer's position. The General Appropriations Act requires board approval in a public meeting for any increase to an exempt position's salary. Because this is a personnel action, the Texas Open Meeting Act permits the governing board to discuss the issue in closed session before acting in the public meeting. **If you would like to discuss the recommended salary increase in a closed session, please let me know as soon as possible.** Presiding Officer Dr. Cummings will move the meeting into closed session on November 20 if one or more members request that we do so. Please contact me if you have any questions or need more information.



#### CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

## MEMORANDUM

TO:OVERSIGHT COMMITTEE MEMBERSFROM:MARK DALLAS LOEFFLERSUBJECT:COMMUNICATIONS UPDATEDATE:NOVEMBER 12, 2024

These are highlights of the CPRIT communications team efforts since the August Oversight Committee meeting.

#### **Publications / Websites**

- Created design and began implementing 2024 Texas Cancer Plan; due by December
- Continuing content creation for 2024 CPRIT Annual Report
- Assisted with posting new CPRIT Core Facilities Map to website

## Audio / Video

- Captured video interviews to support upcoming Annual Report
- Captured video interviews at Researchers Roundup in Dallas to produce recap

#### **Media Relations**

The communications team posted and distributed several media advisories and press releases related to CPRIT programs and news:

- Press Release (Aug. 21): CPRIT awards more than \$60 million to boost Texas' fight against cancer
- Press Release (website news Oct. 24): CPRIT Welcomes New Staff

#### **Direct Communication**

The communications team distributed the following listerv emails to our list since the August meeting:

- PRESS RELEASE: August 2024 OC Meeting (Aug. 21)
- Upcoming Events: Healthier Texas Summit (Aug. 22)
- CPRIT Prevention Program Releases New RFAs August 2024 (Aug. 26)
- CPRIT Academic Research Program Releases Cycle 25.2 RFAs (Aug. 30)
- CPRIT unveils new online core facility map of Texas (Sept. 3)
- Upcoming Events: Healthier Texas Summit (Last Call) (Oct. 3)
- ACS CAN North Texas Policy Forum 2024 (Nov. 6)
- November 2024 Oversight Committee Meeting Notice (Nov. 13)

## Newsclips

We shared **648** articles and social media posts through CPRIT ENews from August 12 to November 8, 2024.

## **Social Media Statistics**

Social	Media	from A	uaust 8	2024	to Nove	mhor 8	2024
sociai	meana	JI OM A	ugusi 0,	2024,	io novel	nder o,	2024

Facebook	X	LinkedIn
7.51% post engagement rate	<b>3.3%</b> engagement rate	7.95% engagement rate
<b>1,308</b> Fans (+18)	<b>3,633</b> followers (+12)	<b>4,152</b> followers (+278)
Top Post: <b>15.33%</b>	Top Tweet: <b>4,245</b>	Top Post: 6,508 impressions
engagement (9/19/24)	impressions (8/21/24)	(8/21/24)

Website Hits and Visitors August 8, 2024, to November 8, 2024

Users	New Users	Sessions (Visits)	Pageviews	Engage Rate
31,833	30,395	46,803	94,570	54.34%

## **Top Performing Posts**

### FACEBOOK: 9/19/24

#CPRIT CEO Kristen Doyle recently joined City of Plano, Texas Government Mayor John Muns at the Texas Research Quarter, a life science development at the former campus of EDS to discuss how CPRIT funding supports innovation enterprises like this across Texas. #TexansConquerCancer

CPRIT September 19 · 📀

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## X: 8/21/24

BREAKING NEWS: #CPRIT approved \$60.6 million in grants to advance the state's fight against cancer, including CPRIT Scholar recruitment awards, support for critical core facilities and innovative clinical trials.

READ HERE: https://ow.ly/WVeE50T3aqv



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## LINKEDIN: 8/21/24

BREAKING NEWS: hashtag#CPRIT approved \$60.6 million in grants to advance the state's fight against cancer, including CPRIT Scholar recruitment awards, support for critical core facilities and innovative clinical trials.

**READ HERE:** https://ow.ly/Mvws50T3aqs



Cancer Prevention and Research Institute of Texas ers

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## August 2024 Oversight Committee Internal Audit Status Report October 31, 2024

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.

#### 2025 Internal Audit Plan and Schedule

Based on the approval of the 2025 Internal Audit Plan by the Oversight Committee in the August meeting, we have coordinated and planned the timing of the internal audits and follow-up procedures for the 2025 Internal Audit Plan.

2025 NEW INTERNAL AUDITS					
Internal Audit	Description	Status			
Post-Award Grant Monitoring	Internal Audit will include an evaluation of risks and internal controls in place related to CPRIT's Post- Award Grant Monitoring processes. Activities to be evaluated include the processes for the review of financial statement reports and reimbursement of funds to grant recipients.	January 2025			
Procurement and P- Cards Advisory	Advisory Internal Audit will include an evaluation of risks and internal controls in place related to CPRIT's P-Card processes a. Activities to be evaluated include the processes for use of CPRIT's p-cards and the utilization of the state's p-card rebates.	February 2025			
Non-Grant Expenditures	Internal Audit will include an evaluation of risks and internal controls in place related to CPRIT's non- grant expenditure processes. Activities to be evaluated include the review of invoices, vendor payments, vendor monitoring. and the cancellation of warrants in the CAPPS system.	January/February 2025			

2025 INTERNAL AUDIT FOLLOW-UPS				
Communications Follow-Up	Internal Audit will perform follow-up procedures to validate remediation of the one high risk finding that is partially remediated.	May 2025		
IT General Controls Follow-Up	Internal Audit will perform follow-up procedures to validate the remediation of the one finding remaining open, which substantial progress was made towards remediation.	May 2025		

During the August Oversight Committee meeting the fiscal year 2025 Internal Audit Plan and Annual Report were approved. In compliance with the Texas Internal Audit Act, these documents were submitted to the SAO, Governor's Office and the LBB before November 1, 2024.

Daniel Graves

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

