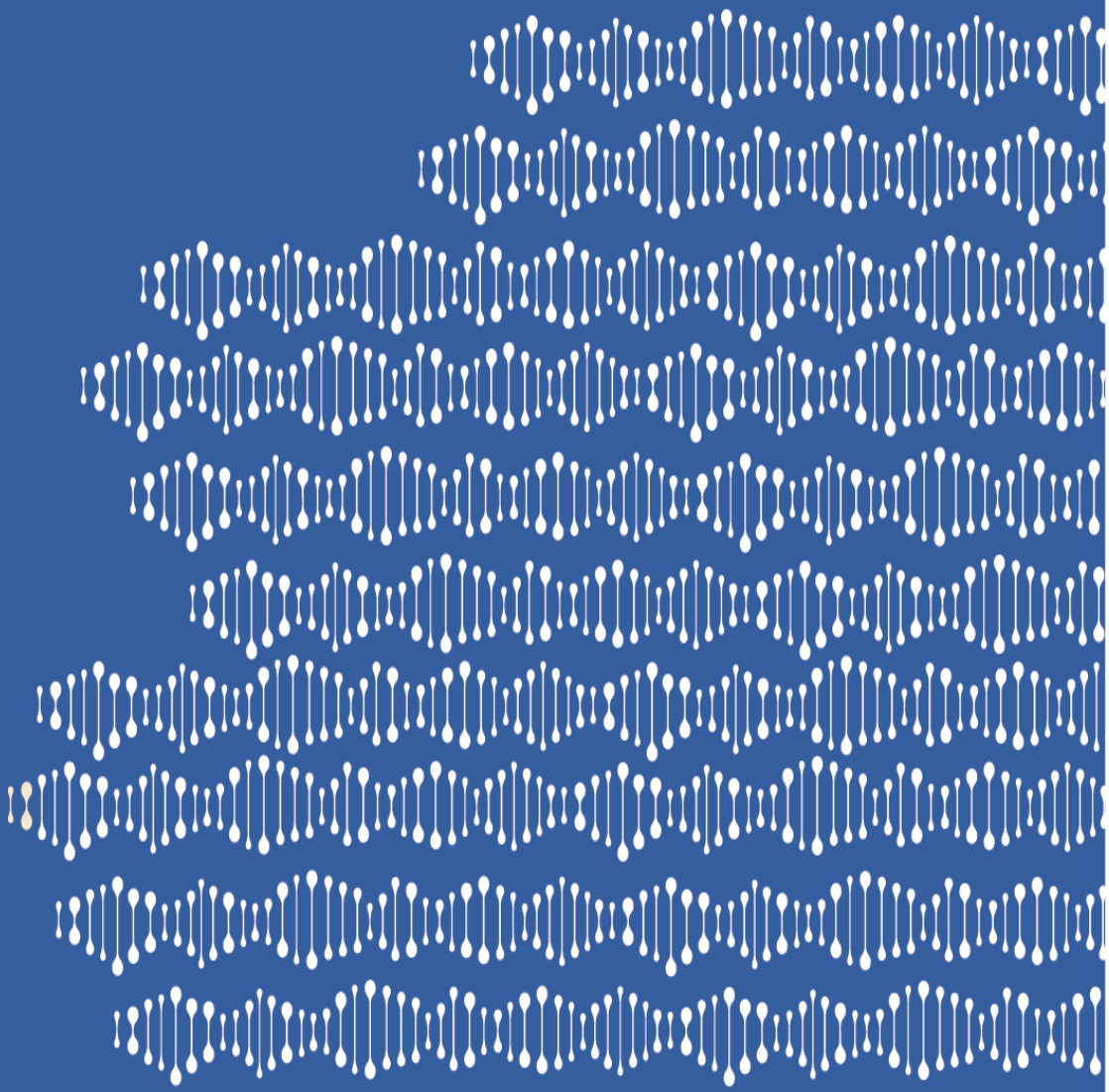
CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Meeting

February 21, 2024



CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Summary Overview of the February 21, 2024, Oversight Committee Meeting

This summary provides an overview of major agenda items and background on key issues for Committee consideration at the February 21, 2024, Oversight Committee meeting.

CEO Report
Wayne Roberts will present the CEO's report and address issues including FY 2024 grant funds available, the TAMEST award, CPRIT's 2023 Annual Report, personnel, and other topics. Mr. Roberts will also present his annual report required by Tex. Health & Safety Code § 102.260(c).

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

Chief Scientific Officer Report and Grant Award Recommendations
Dr. Michelle Le Beau will provide an update on the Academic Research Program and present the Program Integration Committee's (PIC) academic research and recruitment award recommendations. She will also present FY 2025 requests for applications (RFAs) for approval.

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
Ramona Magid will update the Oversight Committee on the on the Prevention Program and present the PIC's prevention award recommendations.

CPRIT does 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
Dr. Ken Smith will provide an update on the Product Development Research Program and will present the four proposed product development RFAs for FY 2025.

Appointments - Scientific Research and Prevention Programs Committee
Mr. Roberts has provisionally appointed five new members to CPRIT's Scientific Research and Prevention Programs Committees. CPRIT's statute requires the Oversight Committee to finalize the appointments with votes of approval. CPRIT has provided the appointees' biographical sketches for the Oversight Committee's consideration.

Advisory Committee Annual Presentations
Two of the Oversight Committee's six advisory committees – the Advisory Committee on Childhood Cancer and the Geographic Diversity Advisory Committee - will present annual reports and answer questions from the Oversight Committee.

Health & Safety Code § 102.1062 Waiver
Mr. Roberts will present a FY 2024 conflict of interest waiver pursuant to Texas Health and Safety Code 102.1062 for Prevention Program Manager Carlton Allen.

Proposed Amendments to 25 TAC Chapters 701 and 703
Ms. Eckel will present the proposed amendments to the agency's Chapters 701 and 703 administrative rules for the Oversight Committee's consideration and approval to publish in the *Texas Register*.

Texas Open Meetings Act (TOMA) and Public Information Act (PIA) Legislative Update
CPRIT's administrative rules require that the Oversight Committee receive training on changes to the TOMA and the PIA after each regular legislative session. CPRIT's legal staff will present amendments to the TOMA and PIA enacted by the 88th Legislature that are relevant to CPRIT's activities.

Chief Operating Officer Report and Contract Approval
Heidi McConnell will discuss the operating budget, performance measures, and debt issuance history for the first quarter of FY 2024 as well as provide an update on the CPRIT conference. She will also present a recommendation to increase the FY 2024 outside counsel contracts.

Communications Update
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 and the FY 2023 annual report.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Meeting Agenda

February 21, 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 for the November 15, 2023, meeting — Tab 1
4. Public Comment
5. Chief Executive Officer Report — Tab 2
   - CEO Report Pursuant to Health & Safety Code § 102.260(c)
6. Chief Compliance Officer Report and Compliance Certification of Grant Award Process — Tab 3
7. Chief Scientific Officer Report — Tab 4
   - Grant Award Recommendations
   - FY 2025 Requests for Applications
8. Chief Prevention Officer Report — Tab 5
   - Grant Award Recommendations
9. Chief Product Development Officer Report — Tab 6
   - FY 2025 Requests for Applications
10. Scientific Research and Prevention Program Committee Appointments — Tab 7
11. Advisory Committees — Tab 8
    - Childhood Cancer Advisory Committee Presentation
    - Geographic Diversity Advisory Committee Presentation
12. Health & Safety Code Section 102.1062 Waiver — Tab 9
13. Amendments to 25 T.A.C. Chapters 701 and 703 — Tab 10
    - Proposed Amendments to Chapters 701 and 703

14. Texas Public Information Act and Texas Open Meetings Act Legislative Update Tab 11
15. Chief Operating Officer Report Tab 12
16. Contract Approvals Tab 13
    - Outside Counsel Contract
17. Communications Program Update Tab 14
18. Personnel – Chief Executive Officer
19. Subcommittee Business
20. Compliance Investigation Pursuant to Health & Safety Code § 102.2631
21. Consultation with General Counsel
22. Future Meeting Dates and Agenda Items
23. Adjourn

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Meeting Minutes
November 15, 2023

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 8:29 a.m.

Roll Call/Excused Absences – Agenda Item 2

Committee Members Present
David Cummings, M.D.
Mahendra Patel, M.D., P.A.
Donald (Dee) Margo
Will Montgomery
Cindy Barberio Payne
Bill Rice, M.D.
Craig Rosenfeld, M.D.

Committee Members Absent
Ambrosio Hernandez, M.D.

Adoption of Minutes from the August 16, 2023, Meeting – Agenda Item 3, Tab 1

> **MOTION:**
> On a motion by Dr. Rosenfeld and seconded by Dr. Rice, the Oversight Committee voted unanimously to approve the minutes of the August 16, 2023, Oversight Committee meeting as presented.

Public Comment – Agenda Item 4

Presiding Officer Dr. Cummings noted for the record that no member of the public asked to address the Oversight Committee.

Chief Executive Officer Report – Agenda Item 5, Tab 2

Presiding Officer Dr. Cummings recognized Chief Executive Officer Wayne Roberts to present his report. He congratulated Mr. Roberts for receiving the Texas Healthcare & Bioscience Institute's (THBI) Luminary Award at the THBI Fall Policy Summit in October, noting that Mr.

Roberts received the award for his diligence, dedication, and commitment to championing cancer research, prevention, and breakthroughs over the last 10 years as CEO of CPRIT. The Oversight Committee members congratulated Mr. Roberts for the honor.

Mr. Roberts reported on the amount of funds available for FY 2024.

He updated the Oversight Committee on ARPA-H's announcement that it selected Texas for its highly anticipated Customer Experience Hub. Landing one of ARPA-H's three national headquarters in Texas is a major coup for the state. He reminded members that a CPRIT-led coalition worked on this effort for two years. Winning this ARPA-H competition validates Texas' position as a leading bioscience center in America. He noted that on the same day as the Texas announcement, ARPA-H awarded a $45 million cooperative agreement to the Rice University-led team with CPRIT Scholar Dr. Omid Veiseh as the principal investigator.

Mr. Roberts provided a brief report on the successful CPRIT Innovations Conference held October 2-3 in Galveston and congratulated the Academic Research program for recruiting its 300th scholar to the state.

Concluding his report, he informed the Oversight Committee that CPRIT will receive the 2024 Kay Bailey Hutchison Distinguished Service Award from the Texas Academy of Medicine, Engineering, Science and Technology (TAMEST). Mr. Roberts introduced TAMEST Executive Director, Dr. Terrence Henry, who provided a brief overview of the goals of TAMEST and the Kay Bailey Hutchison Distinguished Service Award. This is the first time that a state initiative has received the award. Mr. Roberts and Dr. Le Beau will receive the award on behalf of CPRIT at a ceremony held February 5, 2024, in Austin.

Following Mr. Roberts report, Presiding Officer Dr. Cummings informed the Oversight Committee that a scheduled fire drill for the Barbara Jordan Building would likely interrupt the meeting for an unknown period. To ensure that the Oversight Committee would be able to address all action items and to minimize disruption, he would call agenda items out of order.

Grantee Presentations – Agenda Item 6, Tab 3

Presiding Officer Dr. Cummings called on Chief Scientific Officer Dr. Michelle Le Beau to introduce CPRIT Scholar Dr. Omid Veiseh.

Following his presentation, an Oversight Committee member asked Dr. Veiseh about whether his team had considered using rat models for glioblastoma. Dr. Veiseh explained that they had not considered that option but that the team was open to collaboration and would be pleased to work with any good animal models that were predictive.

Another Oversight Committee member asked about whether Dr. Veiseh's platform was tracking biomarkers. Dr. Veiseh responded that the platform is producing immunotherapies, so the initial prototype was mostly tracking the produced immunotherapy and the pharmacodynamic responses, including potential toxicities.

In response to a member's question about the potential for crossing the blood-brain barrier with brain metastases or neurodegenerative diseases, Dr. Veiseh explained that he was particularly interested in this opportunity. His team was looking at nucleic acid delivery, leveraging insights from work with monoclonal antibodies.

At the conclusion of the questions, Presiding Officer Dr. Cummings congratulated Dr. Veiseh on his work and thanked him for his presentation. He noted for the record that he would leave this agenda item pending until after the fire alarm to avoid disrupting the next grantee presentation.

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

Presiding Officer Dr. Cummings recognized Mr. Roberts to present his appointments to CPRIT's Scientific Research and Prevention Programs Committees. Mr. Roberts presented nine appointments to the peer review panels:

Academic Research
Xuefeng Wang, Ph.D.

Prevention
Matthew (Mateo) P. Banegas, Ph.D., MPH, MS
Patricia I. Moreno, Ph.D.

Product Development Research
Paul de Figueiredo, Ph.D.
Diana Bytnar Fordyce, Ph.D.
M.N.V. Ravi Kumar, Ph.D.
David P. Rotella, Ph.D.
Feng Tian, Ph.D.
Semen O. Yesylevskyy, Ph.D.

MOTION:
On a motion by Mr. Montgomery and seconded by Mr. Margo, the Oversight Committee voted unanimously to approve the CEO's nine appointees to the Scientific Research and Prevention Program Committees.

Advisory Committees – Item 13, Tab 10

Presiding Officer Dr. Cummings recognized Mr. Roberts to present the Presiding Officer's new appointment to the advisory committees. Mr. Roberts presented Dr. Martha P. Mims' appointment to the Clinical Trials Advisory Committee.

MOTION:
On a motion made by Mr. Margo and seconded by Mr. Montgomery, the Oversight Committee voted unanimously to approve Dr. Mims' appointment to the Clinical Trials Advisory Committee.

Program Priorities for FY 2025 - Agenda Item 11, Tab 8

Presiding Officer Dr. Cummings recognized Mr. Roberts to address the FY 2025 program priorities. Mr. Roberts presented the FY 2025 program priorities to the Oversight Committee. He reported that there were no changes from the FY 2024 program priorities.

MOTION:
On a motion made by Mr. Montgomery and seconded by Mr. Margo, the Oversight Committee voted unanimously to approve the FY 2025 program priorities.

Amendments to 25 T.A.C. Chapters 701 – Agenda Item 15, Tab 12

Presiding Officer Dr. Cummings recognized assistant general counsel Cameron Eckel to present Amendments to 25 T.A.C. Chapters 701. Ms. Eckel presented the rule amendments to Chapter 701 for final adoption.

MOTION:
On a motion by Mr. Margo and seconded by Dr. Patel, the Oversight Committee voted unanimously to approve the final order adopting the rule changes to the Texas Administrative Code Chapters 701.

Health & Safety Code Section 102.1062 Waiver – Agenda Item 14, Tab 11

Presiding Officer Dr. Cummings recognized Chief Executive Officer Wayne Roberts to present the Health & Safety Code Section 102.1062 Waiver. Mr. Roberts explained his requested conflict of interest waiver for Program Manager for Product Development Dr. Michelle Leeuwon.

MOTION:
On a motion made by Mr. Margo and seconded by Dr. Patel, the Oversight Committee voted unanimously to approve the Health and Safety Code Section 102.1062 waiver for Dr. Leeuwon.

Communication Report – Agenda Item 18, Tab 15

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

In response to a question by an Oversight Committee member inquiring about updates to the *Texas Resource Guide*, Mr. Loeffler explained that staff expects to add helpful links and expand the resource categories to include legal resources.

Chief Prevention Officer Report – Agenda Item 9, Tab 6

Presiding Officer Dr. Cummings recognized Ramona Magid to present the prevention program update.

Ms. Magid presented her program update, including an overview of FY 2024 Review Cycle 1. She also described three requests for applications for the FY 2025 review cycle (Dissemination of CPRIT-funded Cancer Prevention and Control Interventions, Primary Prevention of Cancer, and Screening and Early Detection) proposed for approval.

In response to a question by an Oversight Committee member inquiring about the low rates of lung cancer screening in Texas, Ms. Magid explained that lung cancer screening is particularly difficult in rural areas. CPRIT grantees focus on provider education to encourage referrals to screening. She also mentioned that CPRIT convenes a quarterly meeting with lung cancer screening grantees working to address implementation issues.

In response to a question by an Oversight Committee member about CPRIT's impact on lung cancer screening in Texas, Ms. Magid stated that CPRIT has funded these projects for only a short time, so it is difficult to assess impact at this time.

> **MOTION:**
> On a motion made by Mr. Margo and seconded by Mr. Montgomery, the Oversight Committee voted unanimously to approve the proposed prevention program FY 2025 RFAs as presented by Ms. Magid.

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

Presiding Officer Dr. Cummings recognized Compliance Program Manager Stephen Nance to present the Compliance Report and Compliance Certification of Grant Award Process.

Mr. Nance presented the Compliance Report for the past quarter's activities.

In response to a question by an Oversight Committee member asking whether CPRIT sends a reminder to the principal investigator that a report is due, Mr. Nance responded that the entity's authorized signing official (ASO) receives a reminder email via CPRIT's grant management system 30 days before the report is due. CPRIT grant accountants also remind grantees to submit reports in a timely manner. Mr. Nance added that grantee staff turnover and an increase in new ASO appointments for Product Development and Academic Research grantees could be factors affecting timely reporting.

Following Mr. Nance's report, Presiding Officer Dr. Cummings noted for the record that Chief Compliance Officer Vince Burgess was unable to attend the meeting. Mr. Burgess provided his written Compliance Certification for the proposed academic research and product development grant awards in the Proposed Awards packet, confirming that the proposed awards and review process complied with all applicable state and agency requirements, prior to the meeting. No Oversight Committee members had questions for Mr. Nance regarding the certification.

At approximately 9:32 the building's fire alarm sounded, and all meeting participants and attendees were directed to leave the premises immediately. The alarm was discontinued at

approximately 9:52 and the Oversight Committee meeting resumed at 9:55 with all members present except Dr. Hernandez.

Grantee Presentations – Agenda Item 6, Tab 3

Returning to agenda item 6, Presiding Officer Dr. Cummings asked Senior Program Manager for Product Development Dr. Abria Magee to introduce Mr. Kirk Dorius, CEO of Atom Mines, to present an update about the company's CPRIT-funded project.

Mr. Dorius presented Atom Mines' CPRIT supported project, "Enrichment of Stable Ytterbium-176 for Production of No-carrier-added Lutetium-177 for Radiotherapies."

An Oversight Committee member asked about how the screening and sorting works. Mr. Dorius explained how the mechanism works by sensing the difference in isotopes.

Another Oversight Committee member asked about the technology's intellectual property (IP) status. Mr. Dorius responded that Atom Mines has licensed the underlying IP from The University of Texas at Austin for application in medical isotopes.

In response to an Oversight Committee member's question about the process for recovering the isotope, Mr. Dorius explained that it was through oxidation and detailed some of the instruments used for the isotope separate process. An Oversight Committee member asked about the production of the instruments. Mr. Dorius responded that the instruments used were produced overseas for cost considerations.

Mr. Dorius described Atom Mines' separation system, which can be used for over 130 isotopes of over 30 elements and showed the production process of Lu-177 for cancer beta-therapies. An Oversight Committee member asked whether there are other isotopes produced in addition to beta. Mr. Dorius responded that the system produces gamma and other isotopes, but beta was still the major type produced.

An Oversight Committee member asked about the amount of energy consumed per unit of production and the beta-decay releases of high energy. Mr. Dorius explained that Atom Mines' process was highly energy-efficient, and the high energy released during beta-decay is used to kill cancer cells in radiotherapy.

In response to an Oversight Committee member's question about the molecular weight and value of Yb-176, Mr. Dorius responded that it was valuable, the process adds about 20x value to the molecule going into the system with 99.6% purity and targeting 99.8%. Another Oversight Committee member asked about the conversion efficiency. Mr. Dorius responded that Atom Mines recycles the material multiple times and resells the material after complete isotope extraction.

Presiding Officer Dr. Cummings congratulated Mr. Dorius for his progress and thanked him for his presentation.

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

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

Dr. Moore provided an update on the Academic Research program activities and presented the two recommended awards for Recruitment Cycles 24.1 and 24.2 totaling $7,990,000 and provided an overview of the recommended awards.

An Oversight Committee member commented on the potential for collaborative effort with Dr Veiseh, particularly in research using glioblastoma models.

Rank	Grant ID	Award	Score	Application Title	Candidate	Organization	Budget
1	RR240012	REI	**1.0**	Bone Marrow Microenvironment as Target and Source for Immunotherapy	Leo Luznik, MD	Baylor College of Medicine	$6,000,000
2	RR240005	RFTFM	**1.1**	Personalized therapies for glioblastoma using multifunctional hydrogel platforms	Christina M. Tringides, PhD	Rice University	$1,990,000

RFTFM- Recruitment of First-Time Tenure Track Faculty
REI- Recruitment of Established Investigators

Approval Process – Academic Research Awards

Compliance Certification

Presiding Officer Dr. Cummings reminded members that Mr. Burgess previously certified that the academic research program award process complied with all applicable requirements.

Conflict of Interest Notification

Presiding Officer Dr. Cummings noted for the record that no Oversight Committee member reported a conflict of interest with any academic research award recommendations presented.

MOTION:
On a motion made by Mr. Margo and seconded by Dr. Patel, the Oversight Committee members voted unanimously to approve the two recruitment award recommendations.

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

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

Presiding Officer Dr. Cummings invited Chief Product Development Officer Dr. Ken Smith to provide the product development program update and to introduce the Program Integration Committee's grant award recommendations.

Dr. Smith updated members on the product development program activities, presented the six recommended awards totaling $55.2 million, and provided an overview of the recommended awards.

Rank	Grant ID	Award	Company	Project Title	Score	Approved Budget
1	DP240073	TTC	March Biosciences Inc.	Advancing Clinical Development of MB-105 CD5 CAR-T cell Therapy for T-cell Lymphoma	2.0	$13,358,637
2	DP240088	TDDC	FixNip Ltd.	FixNip NRI (Nipple Reconstruction Implant)	2.3	$4,844,088
3	DP240091	TTC	Gradalis, Inc.	Vigil maintenance in PS ovarian patients	2.6	$9,965,266
4	DP240117	SEED	Single Cell Biotechnology Inc.	A Novel High Throughput Platform for Drug Screening Against Dormant and Migrating High-Grade Glioma Cells	2.8	$2,536,132
5	DP240095	TTC	Stingray Therapeutics, Inc.	A Phase 1-2 clinical study to evaluate SR-8541A plus balstilimab and botensilimab in MSS CRC patients	3.0	$13,881,458
6	DP240075	TNTC	Mongoose Bio LLC	Mongoose Bio Memory TCR-T Cell Discovery and Therapeutics for Empirically Validated Tumor Targets	3.8	$10,621,053

TTC: Texas Therapeutic Company
TDDC: Texas Device and Diagnostics Company
TNTC: Texas New Technologies Company
SEED: Seed Company

Dr. Smith informed members that if all proposed award recommendations are approved, the product development program will have approximately $20 million remaining in available grant funding for FY 2024. Accordingly, the product development program plans to release RFAs in early December for a second review cycle. Given the amount of the remaining funding, Dr. Smith explained that CPRIT will cap requested company award budgets at $5 million.

An Oversight Committee member asked about the time span between the beginning of preliminary application review and the end of budget negotiation. Dr. Smith responded that CPRIT started accepting preliminary applications on a rolling basis on May 1 and completed budget negotiation in early November.

Mr. Roberts informed the Oversight Committee that one of the proposed awardees, FixNip, a company that will relocate to Texas from Israel, was a company he met with during his 2022 trip to the country.

An Oversight Committee member asked about CPRIT's funding allocation among the CPRIT programs. Mr. Roberts responded that the overall research funding targeted split between the academic research and product development research programs is 70/30. He explained that it has only been in the past few years that the product development program has awarded the full targeted amount.

A member asked whether there is legislative guidance on funding allocations among programs. Mr. Roberts responded that CPRIT is statutorily authorized to award up to 10% of its funding for prevention programs but there are no restrictions regarding the research programs. When asked whether the Oversight Committee may change the funding allocation for FY 2024, Mr. Roberts explained that re-allocation decisions rest with the Oversight Committee and reminded members that the program plans have been based on approved RFAs for FY 2024 and FY 2025, so changes may be disruptive for the programs. Oversight Committee members discussed other funding options available to academic research and product development research program grant applicants.

An Oversight Committee indicated interest in knowing how many applicants reapply and if they do not reapply, where they go for funding.

The Oversight Committee members briefly discussed projects that address the side effects of cancer and cancer treatments. An Oversight Committee member asked whether the consideration of funding is made based only on a direct link to cancer or does it also include broader consequences of treatments. Mr. Roberts indicated that while the large majority of CPRIT projects directly address cancer diagnostics, cures, and treatments, CPRIT has also funded meritorious academic and product development research projects that tackle serious cancer treatment side effects, such as immune system suppression, graft vs. host disease, and incontinence.

An Oversight Committee asked whether there is need to expand the RFAs to address cancer side effects. Dr. Smith explained that this was not necessary for product development research projects because the current RFAs are broad. He also reported that CPRIT has a funding mechanism, the Texas New Technologies Company award, which is designed to include novel technologies outside of traditional therapeutics, devices and diagnostics.

Approval Process – Product Development Research Awards

Compliance Certification

Presiding Officer Dr. Cummings reminded members that Mr. Burgess previously certified that the product development research program award process complied with all applicable requirements.

Conflict of Interest Notification

Presiding Officer Dr. Cummings noted for the record that no Oversight Committee member reported a conflict of interest with any product development research award recommendations presented.

MOTION:
On a motion made by Mr. Margo and seconded by Dr. Patel, the Oversight Committee members voted unanimously to approve the six product development research award recommendations.

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

Presiding Officer Dr. Cummings reminded members that Mr. Roberts notified the Oversight Committee on November 10, 2023, that he seeks authority to disburse grant funds in advance to the six companies the board approved for awards.

MOTION:
On a motion made by Mr. Montgomery and seconded by Mr. Margo, the Oversight Committee members voted unanimously to approve the authorization of CPRIT to disburse grant funds via advance payments pursuant to the General Appropriations Act, Article IX, Section 4.02(a) to the six companies approved for awards upon execution of the award contract and the successful completion of tranches.

An Oversight Committee member congratulated the product development research program staff on the effort and progress made during the past two years to enhance the program. Mr. Roberts agreed, noting that all three CPRIT programs have strong leadership and staff support.

Chief Operating Officer Report – Agenda Item 16, Tab 13
Contract Approvals – Agenda Item 17, Tab 14

Presiding Officer Dr. Cummings recognized Chief Operating Officer Heidi McConnell to present her report and explain the recommended contract approval.

Ms. McConnell presented her report and updated the members on the successful 2023 CPRIT Innovations Conference, which CPRIT held in early October. She noted that CPRIT sent a post-conference survey to attendees that generated positive feedback, including 96% responding that the conference was good or excellent. She highlighted the presentation of the inaugural "Texans Conquer Cancer" awards to Secretary of State and former state senator Jane Nelson, former state representative Jim Keffer, former state representative Dr. John Zerwas, and former state senator and current Austin Mayor Kirk Watson.

The "Spark" video was played during her presentation.

In response to a question by an Oversight Committee member asking about the conference venue, Ms. McConnell agreed that staff was satisfied with the venue. Mr. Roberts added that attendees prefer the conference to take place in Austin, but CPRIT did not receive bids from Austin venues for the time periods that the agency identified for the conference.

In response to a question by an Oversight Committee member about holding the conference annually, Mr. Roberts explained that while the conference was important, it is a tremendous drain on staff resources. Ms. McConnell added that holding an annual conference would require CPRIT to hire staff whose jobs were dedicated solely to the conference.

Following her presentation, Ms. McConnell presented the internal audit services contract with Weaver and Tidwell for Oversight Committee approval.

> **MOTION:**
> On a motion by Dr. Patel and seconded by Mr. Margo, the Oversight Committee voted unanimously to approve the contract with Weaver and Tidwell to provide internal audit services.

Internal Auditor Report – Agenda Item 19, Tab 16

Presiding Officer Dr. Cummings recognized Daniel Graves to present the internal auditor report. Mr. Graves provided an update on CPRIT's internal audit report, the fiscal year 2024 Internal Audit Plan, the fiscal year 2023 Annual Internal Audit Report, and the following internal audit reports:

- Internal Audit Report over Purchasing Compliance
- Internal Audit Advisory Report over Post-Award Grant Compliance
- Internal Audit Follow-Up Procedures Report over Vendor Contract Compliance
- Internal Audit Follow-up Procedures Report over Communications
- Internal Audit Follow-up Procedures Report over Disaster Recovery and Business Continuity Planning Advisory Audit

There were no questions for Mr. Graves.

> **MOTION:**
> On a motion by Mr. Montgomery and seconded by Dr. Patel, the Oversight Committee voted unanimously to approve the five internal audit reports, the FY 2024 Internal Audit Plan and the FY 2023 Annual Internal Audit Report.

Presiding Officer Dr. Cummings announced the committee would go into closed session at 11:51 a.m. pursuant to Texas Government Code 551.076 to receive an update on the Internal Audit Report over Information Technology General Controls. He asked for Mr. Roberts, Ms. Doyle,

Ms. McConnell, Mr. Burgess, Mr. Nance, Ms. Eckel, Ms. Shannon Cusick, Mr. Soma Emenike, Mr. Graves, and Mr. Brett Nabors to join the members in closed session.

The Board reconvened in open session at 12:08 p.m.

MOTION:
On a motion by Dr. Rosenfeld and seconded by Mr. Montgomery, the Oversight Committee voted unanimously to approve the Internal Audit Report on Information Technology General Controls.

Subcommittee Business – Agenda Item 20
Compliance Investigation Pursuant to Health & Safety Code § 102.2631 – Agenda Item 21
Consultation with General Counsel – Agenda Item 22

Presiding Officer Dr. Cummings stated that the Oversight Committee would not take up standing items 20, 21, or 22.

Future Meeting Dates and Agenda Items – Agenda Item 23, Tab 18

The next regular Oversight Committee meeting will occur February 21, 2024.

Adjournment – Agenda Item 24

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

The meeting was adjourned at 12:08 p.m.

_____ _____
Signature Date

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	AGENDA ITEM 5: CHIEF EXECUTIVE OFFICER REPORT
DATE:	FEBRUARY 12, 2024

The Chief Executive Officer Report presented at the February 21 Oversight Committee meeting will include the following items. Other items will be added as warranted. In addition, attached behind this memo are copies of the November/December 2023 and January 2024 CPRIT Activity Updates for your reference.

FY 2024 Grant Awards Funds Available and CPRIT Dashboard (Attachments 1 and 2)

As shown in Attachment 1, if the Oversight Committee approves the Academic Research and Prevention awards at the Program Integration Committee's recommended level of $98.6 million, we will have $111.2 million to award in the remainder of FY 2024.

Attachment 2 is CPRIT's dashboard of metrics that we track on a regular basis.

TAMEST Award

On February 5, the Texas Academy of Medicine, Engineering, Science and Technology (TAMEST) awarded CPRIT the 2024 Kay Bailey Hutchison Distinguished Service Award. This is the highest honor that TAMEST bestows on individuals or organizations. CPRIT is the first state agency to receive this recognition.

Four members of the Oversight Committee were able to attend the ceremony, as well as several members of our senior staff.

This is an honor that everyone associated with CPRIT—Oversight Committee members, staff, peer reviewers, advisory committee members and some 1,900 grant recipients—can take great pride. We intend to have the two medals framed and displayed prominently in the CPRIT office.

Recognition of Donation from Travis County Emergency Services District No. 12

I am pleased to report that CPRIT is once again the beneficiary of Travis County Emergency Services District No. 12's "Fire Up for a Cure" fundraising effort for Breast Cancer month in October. ESD No. 12's Public Information Officer Kassidy Buth notified us in December that

their second annual t-shirt fundraiser netted $215 in proceeds that they donated to CPRIT. According to Ms. Buth, “It's been a real joy for our department to do this again this year.”

CPRIT’s FY 2023 Annual Report

CPRIT released its annual report for fiscal year 2023 on January 31. The report, which CPRIT makes available exclusively online at https://2023annualreport.cprit.texas.gov/, highlights the progress CPRIT and our grantees have made towards the agency’s three-part mission to invest in the cancer research prowess of Texas’ academic institutions, to create and grow the state’s life science infrastructure, and to identify and fund innovation in the prevention, identification, treatment and cures for cancer.

While the report is a team effort across the entire agency, CPRIT’s Communications Director Mark Loeffler, Digital Communications Specialist Justin Rand, technical writer Bridget Barstow, Information Resource Manager Shannon Cusick, and IT designer Royce Hart deserve special credit for the enormous amount of work necessary to put together the 2023 report. I also appreciate Deputy Executive Officer and General Counsel Kristen Doyle’s work with the annual report team and for her role in helping to conceptualize the highlights and features.

CEO Report on Progress and Continued Merit for FY 2023 Research Program
(Attachment 3)

Texas Health and Safety Code Sec. 102.260(c) requires the Chief Executive Officer to report at least annually to the Oversight Committee on the progress and continued merit of each research program. I am pleased to report FY 2023 marked another year of progress for CPRIT and its Academic Research, Prevention, and Product Development Research Programs. I have attached my FY 2023 report to this memo.

Personnel

CPRIT has filled 44 full-time equivalent positions and has several positions in progress, including an accountant position and grant compliance specialist position.

*****

CPRIT has awarded **1,909** grants totaling **$3.44 billion**

- 291 prevention awards totaling $354.8 million
- 1,618 academic research and product development research awards totaling $3.09 billion

Of the $3.44 billion in academic research and product development research awards,

- 32.6% of the funding ($1.01 billion) supports clinical research projects
- 23.4% of the funding ($722.4 million) supports translational research projects
- 29.1% of funding ($897.4 million) supports recruitment awards
- 12.0% of the funding ($370.1 million) supports discovery stage research projects
- 2.9% of funding ($90.4 million) supports training programs.

CPRIT has 7 open Requests for Applications (RFAs)

- 3 Academic Research Recruitment
- 7 Academic Research
- 3 Prevention

FY 2024 GRANT AWARD FUNDS AVAILABLE

General Obligation Bond Proceeds

	Prevention	Academic / Product Development Research	1% Grant Funding Buffer	Operating Budget	Total Appropriations
Available Appropriated Funds	$ 27,478,429	$ 251,369,432		$ 21,152,139	$ 300,000,000
Appropriations Transfer to DSHS		$ (3,118,032)		$ 3,118,032	
Adjusted Appropriations	$ 27,478,429	$ 248,251,400		$ 24,270,171	$ 300,000,000
Total Available for All Grants			$ 275,729,829		
1% of Total Available Grant Funding			$ 2,757,298		
Adjusted Grant Award Funding	27,478,429	$ 245,494,102			$ 272,972,531

	Prevention Grants	Academic Research Grants	PD Research Grants		
Total Available for Grant Awards (Total GO Bond Proceeds Less Operating Budget)	$ 27,478,429	$ 173,775,980	$ 74,475,420		$ 275,729,829
Total Available for Grant Awards Incorporating 1% Grant Funding Buffer	$ 27,478,429	$ 171,845,871	$ 73,648,231		$ 272,972,531
Announced Grant Awards					
11/15/23 ACR Recruitment Awards (2)	$ -	$ 7,990,000	$ -		
11/15/23 PDR Company Grant Awards (6)	$ -	$ -	$ 55,206,634		
Announced Grant Award Subtotal	$ -	$ 7,990,000	$ 55,206,634	$ -	$ 63,196,634
Available Funds as of November 16, 2023	$ 27,478,429	$ 163,855,871	$ 18,441,597		$ 209,775,897
Pending Grant Awardss-PIC Recommendations					
ACR Recruitment Awards (7)	$ -	$ 26,000,000	$ -		
ACR IIR Awards (Multi-Category, 39)	$ -	$ 46,689,675	$ -		
Prevention Grant Awards (12)	$ 25,902,480	$ -	$ -		
Pending Award Subtotal	$ 25,902,480	$ 72,689,675	$ -		$ 98,592,155
Total Recommended Grant Funding Committed	$ 25,902,480	$ 80,679,675	$ 55,206,634		$ 161,788,789
Potential Available Funds as of February 22, 2024	$ 1,575,949	$ 91,166,196	$ 18,441,597		$ 111,183,742
1% Grant Funding Buffer	$ -	$ 1,930,109	$ 827,189		$ 2,757,298
Total Remaining Funds	$ 1,575,949	$ 93,096,305	$ 19,268,786		$ 113,941,040

Operating Budget Detail	
Indirect Administration	$ 4,910,893
Grant Review & Award Operations	$ 16,058,895
Salary Adjustment	$ 182,351
Subtotal, CPRIT Operating Costs	$ 21,152,139
Cancer Registry Operating Cost Transfer	$ 3,118,032
Total, Operating Costs	24,270,171

CPRIT MANAGEMENT DASHBOARD
FISCAL YEAR 2024

	SEPT	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	CUMULATIVE (ANNUAL)	CUMULATIVE (TO DATE)
ACCOUNTABILITY														
Announced Grant Awards	0		8										8	
New Grant Contracts Signed	7	11	3	3	3								27	
New Grant Contracts In Negotiation			12										12	
Grant Reimbursements Processed (#)	158	169	150	180	151								808	
Grant Reimbursements Processed ($)	$ 21,014,507	$ 20,145,254	$ 12,238,992	$ 21,326,886	$ 24,511,438								$ 99,237,078	
Revenue Sharing Payments Received	$ 250	$ 33,193	$ 104,746	$ 4,991	$ 209								$ 143,389	$ 9,791,985
Grants Awarded (#)/ Applications Rec'd (#)	19%	19%	19%	19%	19%									
Grantee Compliance Trainings	2	3	1	5	0								11	
Grantee Compliance Monitoring Visits	0	0	3	3	4								10	
Awards with Delinquent Reimbursement Submission (FSR)			0											
Awards with Delinquent Matching Funds Verification			1											
Awards with Delinquent Progress Report Submission			4											
MISSION														
Open RFAs	3	7	7	11	11									
Prevention Applications Received	0	0	0	0	0								0	1,017
Product Development Preliminary Applications Received	0	0	0	63	0								63	199
Product Development Full Applications Received	0	0	0	0	0								0	675
Academic Research Applications	4	5	4	5	3								21	9,077
Help Desk Calls/Emails	122	67	105	201	124								619	
Number of Research Grants Announced (Annual)	0		2										2	
Recruited Scientists Contracted														299
Number of Product Development Grants Announced (Annual)	0		6										6	
Life Science Companies Recruited (in TX)														17
Number of Product Development Jobs Created & Maintained														1,482
Number of Prevention Grants Announced (Annual)			0										0	
Total Number of Education, Navigation and Training Services			147,203										147,203	
Total Number of Clinical Services			48,417										48,417	
Published Articles on CPRIT-Funded Projects (#)														
Clinical Studies (#)														273
Number of Patent Applications														
Number of Patents Resulting from Research														
TRANSPARENCY														
Total Website Hits (Sessions)	14,201	11,483	12,185	8,573	10,662									

CPRIT MANAGEMENT DASHBOARD
FISCAL YEAR 2024

	SEPT	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	CUMULATIVE (ANNUAL)	CUMULATIVE (TO DATE)
Total Unique Visitors to Website (Users)	10,307	7,533	7,892	5,470	6,913									

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	TEXAS HEALTH & SAFETY CODE SECTION 102.260(C) REPORT ON THE MERIT AND CONTINUED PROGRESS OF CPRIT'S PROGRAMS IN FY 2023
DATE:	FEBRUARY 21, 2024

Summary

Texas Health and Safety Code § 102.260(c) requires the Chief Executive Officer to report at least annually to the Oversight Committee on the progress and continued merit of each research program. I am pleased to report FY 2023 marked another year of progress for CPRIT and its Academic Research, Prevention, and Product Development Research programs. In FY 2023 CPRIT approved 109 grants totaling $269.04 million to 29 organizations throughout the state. Key metrics continue to indicate that CPRIT is affecting Texas' national standing in both cancer research and the biomedical industry. CPRIT's investment is attracting, creating, and expanding the research capabilities of our institutions of higher education and the state's life science industry, expediting innovation, and increasing the likelihood of breakthroughs in cancer prevention and cures.

This report provides an overview illustrating the progress made in advancing CPRIT's mission to create and expedite innovation in cancer research and cancer prevention. Aligning program activities with the program priorities adopted by the Oversight Committee is a good gauge of progress and merit; this report highlights each program's implementation of the FY 2023 program priorities. CPRIT's 2023 Annual Report, which is available to read at https://2023annualreport.cprit.texas.gov/ , provides more information on CPRIT program priorities and awards, including a summary of research findings reported by grantees in FY 2023 and notable grantee highlights.

Regarding progress made by individual grant projects within each of CPRIT's three programs, Texas Administrative Code § 703.21 requires all CPRIT grantees to submit progress reports at least annually. Outside experts evaluate these progress reports to ensure that the grantee has made appropriate progress and should continue work under the grant. To the extent that an expert reviewer determines that a grant project is not making progress towards the project goals and objectives, CPRIT has several options, including contract termination.

ARPA-H Comes to Texas

A notable milestone, which demonstrates the continued merit of all three of CPRIT's programs, occurred when the Advanced Research Projects Agency for Health (ARPA-H) competitively selected Texas to serve as one of its three region hubs for ARPANET-H, which is a nationwide health innovation network. The ARPA-H Customer Experience hub, headquartered in Pegasus Park in Dallas, "will take a human-centered approach to design products and services" and will incorporate "end-user considerations at all stages of research and development." ARPA-H's selection of Texas demonstrates Texas' strong leadership reputation in healthcare research, development, and technological innovation that is due in no small part to grantees across CPRIT's three programs.

Notably, one of ARPA-H's first awards was to a CPRIT Scholar Dr. Omid Veiseh who is a bioengineer at Rice University. Dr. Veiseh leads a team of engineers, physicians, and multidisciplinary specialists under the $45 million cooperative agreement grant from ARPA-H. The project, which includes CPRIT grantee institutions The University of Texas MD Anderson Cancer Center and the University of Houston, will develop sense-and-respond implant technology (Hybrid Advanced Molecular Manufacturing Regulator) that could slash U.S. cancer-related deaths by more than 50%.

Academic Research Program

CPRIT's Academic Research Program supports innovative and meritorious projects that are discovering new information about cancer that can lead to prevention, early detection, and cures; translating new and existing discoveries into practical advances in cancer diagnosis and treatment; and increasing the prominence and stature of Texas in the fight against cancer. In FY 2023, CPRIT's Oversight Committee approved 85 Academic Research and Recruitment Awards totaling $166.88 million. Notably in FY 2023, the Academic Research program awarded its 300th CPRIT scholar recruitment grant.

Academic Research Program Priorities

The Oversight Committee adopted the following FY 2023 program priorities for the Academic Research Program:

- Recruit of outstanding cancer researchers to Texas;
- Support a broad range of innovative initiated research projects;
- Invest in core facilities;
- Implementation research to accelerate adoption and deployment of evidence-based prevention and screening interventions;
- Computational biology and analytic methods;
- Childhood and adolescent cancers;
- Hepatocellular cancer; and
- Expanding access to innovative clinical trials

CPRIT Scholars continue to serve as a shining example of CPRIT's positive impact on cancer research in Texas. As mentioned above, CPRIT awarded its 300th CPRIT Scholar award in FY2023. As of August 31, 2023, CPRIT has invested $865.6 million to recruit 302 CPRIT Scholars to 20 universities and research institutions across the state, adding the equivalent of 8,000+ years of productive research to Texas.

In addition to the success of the recruitment program, the Academic Research Program fulfilled other program priorities during FY2023. The Texas National Cancer Institute Connect Study (RP230426) addresses the priority to implement research to accelerate adoption and deployment of evidence-based prevention and screening interventions. The goal of this grant is to better understand causes of cancer and better prevention by collecting information for study participants who range from 40 to 65 years old with no cancer history. RP230426 will fund the Texas Connect for Cancer Prevention Study and develop a statewide cohort within the National Cancer Institute (NCI) Connect for Cancer Prevention Study. Due to the size and varied population within the state of Texas, information gathered though this grant will be critical to building a distinctive database to better understand the causes of cancer.

Prevention Program

CPRIT's Prevention Program continues to support effective, evidence-based prevention programs available to underserved populations in the state. Prevention Program grants help Texans reduce the risk of cancer, identify cancers earlier, and assist people in finding cancer treatment. As of August 31, 2023, prevention grants have provided 9 million prevention services, including 3.6 million clinical services. Through CPRIT-funded screenings, 39,154 cancers and cancer precursors have been discovered. In FY2023, the Oversight Committee approved 17 prevention grants totaling $26.9 million. Notably, the prevention program reached an impressive milestone in FY2023 by providing the 400,000th Texan with their first cancer screening.

Prevention Program Priorities

The Oversight Committee adopted the following FY 2023 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;
- Underserved populations; and
- Program assessment to identify best practices, use a quality improvement tool, and guide future program direction.

The Active Living After Cancer Program (ALAC), which received its first CPRIT grant in 2013, is an example of how the Prevention Program reaches populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence. The program provides training and education to cancer survivors about how they can maintain a physically active lifestyle. ALAC is

a partnership between M.D. Anderson and community organizations in Houston, El Paso, Tyler, and Beaumont, that develop relationships with local healthcare organizations. These relationships allow the program to reach survivors who are medically underserved, Spanish-speaking, or live in rural areas. More than 1,750 cancer survivors enrolled in ALAC program over the past nine years, and approximately 75% complete the program. CPRIT recently approved grant awards PP230074 and PP230069 to enable ALAC to continue providing the program through community partners. The dissemination grant, PP230069, will allow the program to reach even more cancer survivors in the state by developing an online toolkit to help other community cancer centers provide ALAC to their patients.

Product Development Research Program

CPRIT's Product Development Research Program funds innovative and scientifically meritorious product development projects with the potential of translating research discoveries into commercial products to benefit cancer patients. During FY 2023, the Oversight Committee approved seven Product Development Research awards totaling $75.2 million. Through August 31, 2023, CPRIT has cumulatively approved 68 product development research awards to 56 companies totaling a commitment of $639.3 million.

The Product Development Research program continues to be a vital component in building the life sciences infrastructure and community in Texas. Through August 31, 2023, CPRIT companies raised $6.6 billion in additional investments after their CPRIT awards (a 10:1 funding ratio). These additional investments and activities testify to the quality of the CPRIT-funded projects and CPRIT's review process. CPRIT-funded companies continue to help not only the life sciences ecosystem, but also the Texas economy with a $630.8 million increase in business activity in CPRIT programs and employment of 1,482 Texans at CPRIT-funded companies.

Product Development Research Program Priorities

The Oversight Committee adopted the following 2023 Product Development Research Program Priorities:

- Funding novel projects that offer therapeutic or diagnostic benefits not currently available, 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 institutions;
- Supporting new company formation in Texas or attracting promising companies to Texas that will recruit staff with life sciences expertise, especially experienced C-level staff to lead to seed clusters of life science expertise at various Texas locations; and
- Providing appropriate return on Texas taxpayer investment.

CPRIT grantee, Invectys USA, Inc. serves as an example of a company developing novel projects that address large or challenging unmet medical needs. After receiving a Product Development Research Company Relocation grant (DP200034) in 2020, Invectys established a U.S. headquarters in Houston to continue its work on developing novel immune-therapeutic solutions for advanced cancers. Specifically, the goals of DP200034 are to advance the company's chimeric antigen receptor (CAR) T platform and to enable Invectys to conduct clinical trials in Texas. In July 2023, Invectys received Fast Track designation from the U.S. Food and Drug Administration based on compelling data from the company's Investigational New Drug submission and the potential for addressing the unmet need for patients with HLA-G positive advanced or metastatic renal cell carcinoma (RCC) who have failed other RCC therapies. Invectys initiated a Phase I/2a clinical trial (NCT05672459) at The University of Texas MD Anderson Cancer Center in June 2023 for HLA-G-positive solid tumor patients, particularly those with kidney and ovarian cancers.

Conclusion

CPRIT's three programs show merit and progress and should continue operations. The work conducted under the purview of CPRIT's programs is part of an iterative cycle with observations emerging from the laboratory making their way to the public and back again to the laboratory. Essential players in this cycle are basic scientists, physician scientists, clinical researchers, product development entrepreneurs, public health professionals, health care providers, patients, community organizations, early-stage companies, and research institutions across Texas.

Through CPRIT's programs the state is investing in intellectual and research support infrastructure that is attracting, creating and expanding research capabilities of Texas institutions of higher education and the Texas life science industry, expediting innovation, and increasing the likelihood of breakthroughs in cancer prevention and cures.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	CPRIT ACTIVITIES UPDATE FOR NOVEMBER - DECEMBER 2023
DATE:	DECEMBER 22, 2023

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

Recent Milestones in the Fight Against Cancer

CPRIT Grantees in the News

- Artificial intelligence (AI) holds promise for revolutionizing many aspects of medical care; nonetheless, concerns remain regarding the introduction and application and AI-based technologies. When President Biden issued an Executive Order October 30 establishing regulations and standards on the use of AI, he highlighted a program at The University of North Texas Health Science Center at Fort Worth – the Intelligence/Machine Learning Consortium to Advance Health Equity and Researcher Diversity, or AIM-AHEAD program - as an important part of his plan to "advance responsible AI innovation by a wide range of health care technology developers that promotes the welfare of patients and workers in the healthcare sector."

  The AIM-AHEAD program, led by CPRIT grantee Jamboor Vishwanatha, Ph.D., is a National Institutes of Health-funded national consortium created in partnership with the Health Science Center that seeks to ensure the inclusion and fair representation of underrepresented communities and minority groups as AI and machine learning technology continues to grow rapidly. The UNT Health Science Center at Fort Worth received $102 million in 2021 to lead the AIM-AHEAD coordinating center, consisting of several cores at various institutions across the nation, with the leadership core housed at UNT under the direction Dr. Vishwanatha, vice president of the Health Science Center's Institute for Health Disparities.

  CPRIT awarded the UNT Health Science Center at Fort Worth and Dr Vishwanatha $4.7 million in 2017 and 2021 to establish and continue a training program for the next generation of biomedical and osteopathic medical students to pursue careers in cancer and health disparities (RP170301, RP210046).

- On November 3, PLUS Therapeutics, a clinical-stage pharmaceutical company developing targeted radiotherapeutics with advanced platform technologies for central nervous system cancers, announced that the U.S. Food and Drug Administration granted Orphan Drug Designation to rhenium (186Re) obisbemeda to treat breast cancer with leptomeningeal metastases. Leptomeningeal metastases are a rare and typically fatal complication of advanced cancer affecting the fluid-lined structures surrounding the brain and spinal cord. The FDA grants orphan drug status to an investigational drug or biological product intended to prevent, diagnose or treat a rare diseases or condition affecting fewer than 200,000 people in the United States. Companies with an orphan drug designation are eligible for certain benefits, including assistance in the drug development process, tax credits for clinical costs, exemptions from certain FDA fees and seven years of post-approval marketing exclusivity.

  The company also hosted a virtual Key Opinion Leader event on November 20 to discuss new Phase 2 ReSPECT-GBM data in recurrent glioblastoma previously presented at the Society for NeuroOncology Conference.

  CPRIT awarded Austin-based PLUS Therapeutics a $17.6 million Texas Company Product Development Award (DP220039) in 2022 to develop Rhenium-186 to treat leptomeningeal metastases.

- OncoNano Medicine presented positive preclinical data regarding the effective delivery of interleukin-12 (IL-12) with the company's ON-BOARD™ platform technology on November 3 at the 38th Annual Meeting of the Society for Immunotherapy of Cancer. The study findings show that researchers achieved encapsulation of a therapeutic IL-12 fusion protein (IL-12Fc) for tumor specific delivery and pH-dependent activation using the ON-BOARD™ polymeric micelle technology. OncoNano is developing a new class of cancer products using principles of molecular cooperativity in their design to exploit pH as a biomarker to diagnose and treat solid tumors with high specificity.

  Southlake-based OncoNano announced November 28 that clinicians dosed the first patient in its Phase 1 clinical trial evaluating ONM-501, a dual-activating polyvalent STING (STimulator of INterferon Genes) agonist for immuno-oncology applications formulated with OMNI™, the company's core immune activating polymer technology. The ONM-501 trial (NCT06022029) is a multicenter Phase 1, dose escalation and dose expansion study in patients with advanced solid tumors and lymphomas.

  OncoNano is a spinout company from The University of Texas Southwestern Medical Center. Since 2014, the company has received three CPRIT Product Development Awards totaling $31.4 million (DP140072, DP190086, DP200081) to develop technology to image and stage metastatic cancer as well as to develop a nanovaccine for human papilloma virus (HPV) associated cancers.

- The University of Texas Health Science Center at San Antonio highlighted the CPRIT grant award to expand an HPV vaccination program among survivors of childhood cancer in the university's online newsletter issued November 8. The project, co-directed by Allison

Grimes, M.D., M.S.C.I., clinical associate professor of pediatric oncology with Mays Cancer Center at UT Health San Antonio, and L. Aubree Shay, Ph.D., M.S.S.W., The University of Texas Health Science Center at Houston School of Public Health, aims to increase HPV vaccination rates among childhood cancer survivors who are patients of 10 pediatric oncology centers that serve 225 Texas counties. CPRIT awarded UTHealth San Antonio a prevention grant totaling $1 million (PP180080) to establish the program in 2018 and a second $1 million (PP230061) in 2023 to expand the program.

- The University of Texas MD Anderson Cancer Center launched the Institute for Data Science in Oncology (IDSO) on November 9, uniting MD Anderson's clinical and research communities in transformative data efforts and offering new opportunities for collaborations across the institution and externally. Located in the Texas Medical Center's Helix Park and housed in the TMC^3 Collaborative Building, IDSO brings top data scientists together with cancer researchers and clinicians and integrates the most advanced approaches to improve patients' lives. CPRIT Scholar Bissan Al-Lazikani, Ph.D., director of Therapeutics Data Science and professor in the Department of Genomic Medicine, co-leads IDSO. MD Anderson recruited Dr. Al-Lazikani to Texas from the London Institute of Cancer Research with the support of a $6 million CPRIT Recruitment of Established Investigators grant (RR210007) in 2020.

- Panhandle Breast Health co-hosted an early detection services event on November 9 at Amarillo College's Washington Street campus. The event is part of the "Transcending Limits Cancer Screening Initiative" and offered education and resources about screenings for breast/chest cancer, cervical cancer, and colorectal cancer, including "Get F.I.T. to Stay FIT," a CPRIT-funded colorectal cancer screening program serving 32 counties in the Texas Panhandle. Get F.I.T. to Stay FIT provides outreach, education, navigation, screening and prevention for uninsured men and women in medically underserved areas. The program uses a free, at-home testing method, Fecal Immunochemical Test (F.I.T.), for colorectal cancer screening. CPRIT has awarded three prevention grants to Texas Tech University Health Sciences Center and one to the University Health System for this program since 2015, with a total of $7.4 million in funding (PP150031, PP180031, PP210017, PP220051).

- The James P. Allison Institute at The University of Texas MD Anderson Cancer Center hosted its inaugural scientific symposium on November 10, at the TMC^3 Collaborative Building in the Texas Medical Center's Helix Park. The event drew more than 400 leading scientists, including three Nobel laureates, from multiple disciplines to share groundbreaking immunotherapy and immunobiology research. MD Anderson created the Allison Institute to advance exceptional discovery, translational and clinical research that will integrate immunobiology across all disciplines. By gaining a comprehensive understanding of the immune system, the institute aims to lead groundbreaking research that will bring the benefits of immunotherapy to all patients. Nobel laureate and CPRIT Scholar James P. Allison, Ph.D., is the director of the Allison Institute and regental professor and chair of Immunology at MD Anderson. MD Anderson recruited Dr. Allison from the Memorial Sloan-Kettering Cancer Center to Texas in November 2011 with the support of a $10 million CPRIT Recruitment of Established Investigators grant (R1203).

- Perimeter Medical Imaging, a commercial-stage medical technology company, reported third quarter financial results and provided a corporate update on November 14. Company highlights included advancing to the next stage of an ARPA-H grant funding program, positive discussions with the FDA and alignment on key elements of Perimeter's ongoing clinical trial, initiation of additional clinical trial sites at Mayo Clinic in Florida and the University of Washington Fred Hutchinson Cancer Center in Seattle, and the recent appointment of Adam Hodges, an experienced MedTech executive, to Vice President for Sales and Marketing. The Houston and Toronto based company received a $7.5 million CPRIT product development grant (DP190087) in 2019 to develop ultra-high-resolution, real-time, advanced imaging tools for cancer surgery.

- KBTX3 (serving Bryan and College Station) aired an interview November 17 with Marivel Sanchez, MPH, program coordinator for the Texas Cancer Screening, Training, Education and Prevention (C-STEP) Program at Texas A&M University System Health Science Center. Texas C-STEP provides critical safety-net services, such as free cancer screenings and certain advanced diagnostics, to uninsured, underserved, and low-income Texans through the Texas A&M family medicine residency training program. More than fifty agencies or service providers have partnered with Texas C-STEP to provide patient referrals for low dose computed tomography lung cancer screenings. Texas A&M University System Health Science Center received a $1 million CPRIT Prevention grant (PP210027) in August 2021 to promote lung cancer prevention education, support smoking cessation programming, and provide residents of 13 counties with lung cancer screenings and patient navigation to reduce barriers and improve early detection of lung cancer.

- On November 22, The University of Texas Southwestern Medical Center announced that the 2023 list of "Highly Cited Researchers" recognized more than a dozen UT Southwestern scientists, including eight CPRIT grantees (Zhijian Chen, Ph.D.; Ralph DeBerardinis, M.D., Ph.D.; Joseph Hill, M.D., Ph.D.; John Minna, M.D., Eric Olson, Ph.D.; Philipp Scherer, Ph.D.; Lijun Sun, Ph.D.; and CPRIT Scholar Sean Morrison, Ph.D.). The Institute for Scientific Information at Clarivate, a British analytics company, produces the annual list, which recognizes the top 1% of researchers from around the world who have published multiple highly cited papers over the last decade and rank in the top 1% of citations for a field or fields. This year's list includes 6,849 researchers from institutions in 67 countries demonstrating significant and broad influence in their chosen field or fields of research.

- Labiotech's November 28 article, "Five Companies Shaping Texas' Growing Biotech Hubs" featured CPRIT-grantee Gradalis. Carrollton-based Gradalis received a $9.9 million product development award (DP240091) in 2023 to support the company's phase 2 clinical study of Vigil in platinum-sensitive patients who have recurrent ovarian cancer with a homologous recombination proficient (HRP) molecular profile. Vigil is a fully personalized, patient-specific cancer immunotherapy with potential applications across multiple solid tumor types. The company has also initiated phase 2 studies in Ewing's sarcoma, as well as phase 1 studies in breast cancer, melanoma, non-small cell lung cancer, colon cancer, and hepatocellular cancer.

- On December 7, the National Institutes of Health announced a four-year, $4 million cooperative research agreement grant to Texas A&M University Health Science Center to create the Gulf Coast Consortium Research Evaluation and Commercialization Hub (GCC-Reach). Led by CPRIT grantee Peter Davies, M.D, Ph.D., professor and director of the Center for Translational Cancer Research at the Texas A&M Health Institute of Bioscience and Technology, this multi-institutional commercialization hub will support the development and commercialization of transformative health care treatments based on research discoveries. In addition to Texas A&M Health, other GCC-Reach partners are the Gulf Coast Consortia members as well as colleagues from Texas Southern University, The University of Texas Medical Branch, and TMC Innovation. Participating primary and co-investigators include CPRIT grantee Suzanne Tomlinson, Ph.D., director of research programs for the Gulf Coast Consortia, and CPRIT grantee Veronica Ajewole, Pharma.D., associate professor in the Department of Pharmacy Practice and Administration at Texas Southern University.

  Over the next four years, the GCC-Reach will train academic entrepreneurs and scientists within GCC member institutions, Texas Southern University, and regional research institutions to navigate the process of successfully commercializing their novel discoveries. The consortium aims to launch 60 early-stage biomedical companies to attract venture investments and additional grant funding.

  CPRIT has long recognized the need to support the translation and commercialization of transformative health care treatments based on research discoveries in the laboratories of Texas investigators, and supports this process through multiple mechanisms, including the $5.4 million award to TMC Innovation and Dr. Thomas Luby for the "Accelerator for Cancer Therapeutics" at TMC (RP190674). Dr. Davies is the principal investigator of two CPRIT Core Facility Support Awards (RP150578, RP200668), totaling nearly $10 million, that provide specialized resources to support cancer-related drug discovery research, as well as a $3.1 million research training award focused on equipping scientists with the essential skills and knowledge to translate cancer discoveries into commercially viable cancer therapeutics (RP210043).

- The University of Texas Southwestern Medical Center announced December 12 that the National Academy of Inventors (NAI) selected CPRIT grantee Jinming Gao, Ph.D., professor of Biomedical Engineering, Cell Biology, Otolaryngology – Head and Neck Surgery, and Pharmacology, as a NAI fellow in recognition of his efforts to develop innovative nanotechnology platforms to improve cancer diagnosis and treatment. Dr. Gao holds 16 U.S. patents and 72 foreign patents in the fields of polymer biomaterials, nanoparticle drug delivery, tumor surgical imaging, and cancer immunotherapy; biotech companies have licensed 13 of these patents.

  With the support of five CPRIT academic research grants totaling $5.7 million (RP120094, RP120897, RP140140, RP180343, RP220150) awarded to UT Southwestern and Dr. Gao since 2012, the Gao Lab is developing synthetic polymer nanoparticles that release their payload after entering an acidic environment. Dr. Gao and Baran Sumer, M.D., Professor of

Otolaryngology – Head and Neck Surgery at UT Southwestern, co-founded OncoNano Medicine Inc., a startup created to commercialize this technology. OncoNano, which has subsequently received multiple CPRIT product development awards, is currently in clinical trials for its interoperative fluorescence imaging agent that detects cancerous tissue in patients undergoing solid tumor removal.

Notable CPRIT-Supported Research and Prevention Accomplishments

- **Identifying a Potential "Fountain of Youth" for Blood Forming Stem Cells.** DNA methylation, an epigenetic modification, involves adding methyl groups to DNA. DNA methylation does not change the DNA itself, but it can affect the activity level of certain genes - often turning them off. This process is crucial for normal development and is involved in key biological processes, such as aging and cancer development. Extended regions in the genome known as partially methylated domains (PMDs) have fewer methyl groups and are typically not active in making proteins. Although scientists recognize the link between PMDs and aging and cancer, they do not fully understand their molecular mechanisms and biological impacts.

  Research led by CPRIT-funded investigators, including CPRIT Scholar Yun Huang, Ph.D., and CPRIT grantee Yubin Zhou, M.D., Ph.D., both with the Institute of Biosciences and Technology at Texas A&M University, provides new insights into the formation of PMDs in blood-forming cells and their connection to aging. Published online October 26 in the journal *Nature Aging*, the researchers report a mechanistic link between disrupted DNA methylation at PMDs and the relocation of tightly packed heterochromatin in aged blood-forming cells called hematopoietic stem and progenitor cells (HSPCs). The researchers discovered that the enzyme TET2, which affects genes involved in the body's immune and inflammatory responses, controls the heterochromatin relocation. This process contributes to the functional decline of aged HSPCs.

  Early mutations in the TET2 gene make HSPCs more likely to change their DNA arrangement as they age. This increases the risk of these cells developing into certain types of blood cancers. However, scientists may be able to reverse this process with specific inhibitors - such as reverse transcriptase inhibitors - that target and suppress these gene changes, thus restoring the normal function of aged cells.

  The study's findings improve scientists' understanding of how DNA methylation and changes in DNA packaging work together, which is crucial for maintaining heterochromatin function and protecting the stability of genetic material in stem cells. This pivotal research also suggests potential new therapeutic methods for reversing age-related defects in the blood forming HSPCs. This offers hope for treating conditions like unexplained anemia in older adults and reducing the incidence of aggressive myeloid leukemias in the elderly. Other CPRIT-funded collaborating investigators include Dr. Xiaodong Cheng of The University of Texas MD Anderson Cancer Center, and Dr. Margaret Goodell from the Baylor College of Medicine and the Dan L. Duncan Comprehensive Cancer Center.

Texas A&M University Health Science Center recruited Dr. Huang to Texas from the La Jolla Institute for Immunology with a $1.8 million First-Time, Tenure-Track Faculty Member award (RR140053) in 2014. A $250,000 CPRIT High Impact-High Risk award (RP210070) to Texas A&M University Health Science Center and Dr. Zhou supported this research.

- **Developing the "Chemistry" for Long-Term, Stable Bonds.** Most cancer drugs work by attaching to a specific protein that drives cancer growth and blocking that protein from functioning. These drugs often fail because of a weak attachment to the protein. CPRIT Scholar Dr. Ku-Lang (Ken) Hsu is pursuing an alternative approach using covalent chemistry to design more effective drugs that form a tighter, more stable covalent bond with the targeted protein. Dr. Hsu's innovative technique, called SuTEx (short for sulfur-triazole exchange chemistry), involves creating drugs that seek out certain underexplored nucleophile sites on proteins - particularly tyrosine and lysine - to form a strong covalent bond while avoiding the traditional nucleophilic cysteine amino acids. Dr. Hsu's team is currently testing this chemistry in animal models. A new biotech startup, Hyku Biosciences, has licensed the SuTEx technology and raised $56 million for further development.

  Combining multiple disciplines of chemistry in a novel approach to drug design, Dr. Hsu's research at The University of Texas at Austin uses SuTEx to target ribonucleoprotein (RNP) complexes. These complexes are crucial in cancer cells because they help regulate protein production in response to various stresses, including cancer treatments. RNPs play an important role in how cancer cells adapt and evolve, but scientists do not fully understand their composition and function in cancer. Dr. Hsu is leveraging SuTEx chemistry to study cancer relevant RNPs for insight into how tumors cope with stress. This research may lead to novel ways to target cancer cells by interfering with stress responses.

  As reported October 7 in the journal *Nature Communications*, a significant research advancement by Dr. Hsu's team is developing a new method called PACCE (photoactivatable competition and chemo-proteomic enrichment). This groundbreaking method uses chemical probes to attach to and study protein-RNA interactions in living cells. PACCE is a powerful tool in the laboratory with the potential to provide essential insights for drug discovery and develop new cancer therapies that work by controlling crucial protein-RNA interactions.

  UT Austin recruited Dr. Hsu to Texas from the University of Virginia with the support of a $4 million CPRIT Rising Star recruitment award (RR220063) in 2022.

- **CPRIT Fostered Collaborative Science Leads to Breakthroughs in Personalizing Treatment for Brain Tumors.** One of the most unusual collaborations fostered by CPRIT grants brings together CPRIT Scholar Thomas Yankeelov, Ph.D., an oncology expert and biomedical engineer, and Karen Willcox, Ph.D., an aerospace engineer and director of the Oden Institute for Computational Engineering and Sciences, both at The University of Texas at Austin. Bound by a commitment to use computer science to advance their fields, this collaborative team applies artificial intelligence to develop the "digital twin" - a

mathematical model that virtually represents a physical object and the way that object changes - to develop a real-time, personalized treatment plan. In this case, the object is a high-grade glioma. The research published October 11 in *Frontiers in Artificial Intelligence* could lead to personalized treatment planning that incorporates tumor biology with real-time monitoring of the tumor's response throughout the patient's treatment and recovery.

The investigators created data-driven predictive digital twins that they have personalized to the individual patient, incorporating known risks to inform optimal clinical decision-making. Using a clinical dataset for the mechanistic model's parameters, researchers initially form (or shape) the digital twin, which the researchers then personalize to an individual patient using Bayesian model calibration for assimilating patient-specific, real-time MRI data. Using these data, the digital twin predicts how the patient would respond to different dosages and lengths of radiotherapy. Ultimately, the digital twin provides a suite of patient-specific optimal radiotherapy treatment regimens incorporating two competing clinical objectives: maximizing tumor control while minimizing the toxicity from radiotherapy. The investigators note that by using a Bayesian framework, the digital twin accounts for the uncertainty in a patient's data, and in their predicted response to therapy.

The investigators tested the method by simulating 100 virtual high-grade glioma patients with tumor growth and responses to treatment typically observed in actual patients. Their results showed a significant improvement over traditional radiotherapy, delaying tumor progression by approximately 6 days. For the same level of tumor control as the standard-of-care, the digital twin provided optimal treatment options that lead to a median reduction in radiation dose by 16.7% (10 Gy) compared to the standard total dose of 60 Gy.

Although these are early results with simplified models, they highlight the potential for significant improvements in patient outcomes. The digital twin allows for tumor control that is equivalent to the current standard-of-care, but with the use of lower total doses of radiation. Clinicians can personalize the digital twin related to the location and size of the tumor, and fine-tune treatment by incorporating data related to how the tumor will respond to the radiotherapy. The method provides a range of optimal treatment; thus, the physician has multiple options, including the use of increased radiation doses for patients with aggressive cancer, where standard treatments do not lead to sufficient tumor control.

UT Austin recruited Dr. Yankeelov to Texas from Vanderbilt University with a $6 million CPRIT Scholar Award (RR160005) in 2015. A $1.1 million CPRIT Individual Investigator Research Award for Computational Systems Biology of Cancer (RP220225) granted to UT Austin and co-author David Hormuth, Ph.D., also supported this research.

- **Employing the Metabolic Profile for Treatment Stratification in Ovarian Cancer.** Despite the remarkable progress made in the treatment of many cancers, ovarian cancer remains one of the most challenging malignancies with a high mortality rate. For more than two decades, the primary treatment for high-grade serous ovarian cancer (HGSC) has been a combination of taxanes and platinum-based chemotherapy. However, patients often develop

resistance to chemotherapy due to various factors like genetic changes and metabolic adaptations.

New findings from CPRIT-supported research published online November 3 by *NPJ Precision Oncology* may help explain why some ovarian cancer patients respond differently to chemotherapy, a crucial step towards developing more effective treatments. A research team led by Livia S. Eberlin, Ph.D., associate professor of surgery, Vice Chair for Research, and the Translational Research and Innovations Endowed Chair at Baylor College of Medicine and the Dan L. Duncan Comprehensive Cancer Center; and Anil K. Sood, M.D., professor and Vice Chair for Translational Research in the Departments of Gynecologic Oncology and Cancer Biology at The University of Texas MD Anderson Cancer Center, conducted a study to understand the relationship between the metabolic diversity within the tumor environment and the response to therapy in HGSC. They analyzed different types of metabolic molecules (nucleotides, proteins, sugars, and lipids) in tissue samples from patients both before and after neoadjuvant chemotherapy. Their approach involved a detailed examination of HGSC samples from patients treated following a specific surgical procedure, providing valuable insights into the metabolic changes associated with chemotherapy response.

The research team used mass spectrometry (MS), a powerful technique for analyzing the molecular composition of tissues. Specifically, they employed desorption electrospray ionization (DESI)-MS, which can detect a wide range of metabolites and lipids directly from tissues under normal conditions. They combined this technique with traditional tissue staining to visualize tissue structure. Additionally, the team corroborated their metabolic findings with molecular data using global proteomics and phosphoproteomics techniques, which involve analyzing proteins and their modifications in the tissues.

Their findings revealed distinct metabolic differences in the tumor-rich areas compared to the surrounding microenvironment before and after therapy. Before chemotherapy, metabolites associated with poor treatment response existed in abundance in the tumors. These included DNA nucleotide metabolism indicators (suggesting high cell proliferation) and signs of hypoxia (low oxygen levels) in the surrounding microenvironment. After chemotherapy, the poor-response tumors showed changes in metabolites related to DNA nucleotide metabolism, amino acid metabolism, nucleotide biosynthesis, and the urea cycle. The researchers developed a predictive model based on these metabolic changes that classified patients' responses to chemotherapy with 75% accuracy. This groundbreaking work not only enhances the understanding of how ovarian cancer responds to chemotherapy at the metabolic level but also opens the door for new treatment strategies and the possibility of personalized treatment plans based on these metabolic signatures.

A $250,000 CPRIT Individual Investigator Award for Clinical Translation (RP180381) granted to Baylor College of Medicine and Dr. Eberlin in 2018 supported this work.

- Rice University's Biotech Launch Pad is developing an implantable electrocatalytic on-site oxygenator (ecO2) device to autonomously administer and regulate therapeutics for the

patient. A study, led by a team of researchers, including CPRIT Scholar Omid Veiseh, Ph.D., associate professor of bioengineering and faculty director of the Rice Biotech Launch Pad, and published November 9 in *Nature Communications*, details the development of the rechargeable ecO2 device, which produces oxygen to keep cells alive inside an implantable "living pharmacy."

Cell-based therapies have potential to treat many different types of diseases including endocrine disorders, autoimmune syndromes, cancers and neurological degeneration, but the survival of these cells for extended periods are necessary to produce effective treatments. The current treatment options to deliver oxygen to cells, however, require bulky equipment and have limited oxygen production and regulation. This ecO2 breakthrough technology has the potential to reshape the landscape of disease treatment and the future of research and development in the field of cell-based therapies.

Rice University recruited Dr. Veiseh from the Massachusetts Institute of Technology with the support of a $2 million CPRIT Recruitment of First-Time, Tenure-Track Faculty Members grant (RR160047) in 2016.

- A multi-Center study co-led by CPRIT Scholar Carlos L. Arteaga, M.D. Professor of Internal Medicine, Director of the Harold C. Simmons Comprehensive Cancer Center, and Associate Dean of Oncology Programs at The University of Texas Southwestern Medical Center, supports a new targeted therapy for a difficult-to-treat form of breast cancer that has become resistant to other treatments and has no curative options. As reported in the November 14 issue of the *Annals of Oncology*, this therapeutic strategy, which uses three different drugs, significantly delayed progression and extended survival for breast cancer patients with mutations in the HER2 gene.

  Nearly 10% of patients with metastatic breast cancer have cancer promoting HER2 mutations in the absence of HER2 gene amplification or overexpression. Although these tumors initially respond to HER2-inhibiting drugs, they eventually stop responding after new mutations develop. To slow or stop progression of tumors bearing HER2 mutations, Dr. Arteaga and his colleagues, including Nisha Unni, M.D., Associate Professor of Internal Medicine, and Ariella Hanker, Ph.D., Assistant Professor of Internal Medicine, tested various combinations of three different drugs among 71 breast cancer patients treated at 23 medical centers around the world. All the patients were positive for mutations in their HER2 gene, as well as positive for the presence of hormone receptors on the tumor cells, cell-surface proteins that can fuel cell growth and often occur in conjunction with HER2 overactivity.

  For 39% of patients receiving the triple drug combination of neratinib, a HER2 tyrosine kinase inhibitor; fulvestrant, which inhibits estrogen receptors; and trastuzumab, a HER2 blocking antibody, their tumor growth slowed, stopped, or reversed. The partial or complete response continued for an average of 14.4 months, with about 8.3 months free from cancer progression. Those taking only fulvestrant or fulvestrant and trastuzumab showed no response as assessed by CT scans or MRIs.

The researchers plan a first-in-class multi-institutional neoadjuvant trial of neratinib and the aromatase inhibitor, letrozole, in patients with newly diagnosed invasive lobular breast cancer with HER2 mutations. This research is practice-changing and provides a new treatment option. Notably, the National Comprehensive Cancer Network has added this three-drug combination to its internationally used treatment guidelines.

UT Southwestern recruited Dr. Arteaga to Texas from Vanderbilt University School of Medicine with a $6 million Established Investigator recruitment award (RR170061) in 2017.

- On November 17, Medicenna Therapeutics presented the longer term follow up results from its Phase 2b clinical trial of bizaxofusp at the Society for Neuro-Oncology 2023 Annual Meeting held in Vancouver, Canada. Steven Brem, M.D., gave a poster presentation and an oral summary, reporting that the multi-center, open-label, single-arm Phase 2b study, enrolled and treated 44 patients with rGBM following surgery or radiotherapy ± adjuvant therapy or other experimental therapies. A separate analysis to establish a matched External Control Arm (ECA) collected rGBM data from 81 patients who received treatment contemporaneously at major clinical centers using current standard of care. The data demonstrated that a single treatment with bizaxofusp increased median overall survival by 72% compared to the ECA (12.4 months vs. 7.2 months). Overall survival for bizaxofusp-treated patients increased 370% at Year 1 and increased more than 50% at Year 2. Importantly, bizaxofusp doubled median overall survival (14.5 months vs. 7.2 months) regardless of IL4R expression (high or low) compared to ECA. The study did not report any systemic or clinically significant laboratory abnormalities. Treatment-related adverse events were primarily neurological or aggravation of pre-existing neurological deficits due to rGBM.

  Houston and Toronto based Medicenna, a clinical stage immunotherapy company developing novel, highly selective versions of IL-2, IL-4 and IL-13 Superkines and first in class Empowered Superkines, received a $14.14 million New Company Product Development Award grant (DP150031) in 2015 to conduct two clinical trials to test the safety, effectiveness, and dosage of bizaxofusp (formerly MDNA55), the Company's first-in-class IL-4R targeted therapy to treat patients with rGBM.

- **Texas Researchers Develop a Game-Changing Resource for Research on Childhood Cancers.** Childhood cancers are the leading cause of disease-related death in children in the United States. Although the average five-year survival rate for children with solid cancers exceeds 80%, survival for patients with metastatic or intractable tumors is still poor, and current treatment regimens cause long-term health problems.

  Patient-derived xenografts (PDXs) are a critical tool in cancer research, particularly in preclinical studies for testing drug responses and understanding rare cancers like pediatric solid tumors. Scientists create PDXs by transplanting human tumor tissues into immunocompromised mice, either subcutaneously (under the skin) or orthotopically (in the same organ or tissue from which the tumor originated). These models are essential because

they allow for the study of tumor tissues in a living organism by closely mimicking human cancer environments.

However, a key question in using PDXs is how accurately they continue to represent the original patient tumors (PTs). In adult cancers, multiple research studies show that PDXs closely resemble PTs. Yet analyses of large cohorts provide evidence that PTs can evolve when PDXs continue to propagate in mice, leading to questions about their reliability as models. Unfortunately, researchers have lacked extensive PDX data for large sample sizes of pediatric solid tumors, making a similar analysis impossible.

With the publication of a groundbreaking study in *Nature Communications* on November 22 describing the largest collection of early-passage PDXs from pediatric solid tumors - comprising 68 PDXs established from 65 patients across 16 rare cancer types - researchers studying childhood cancers now have a powerful new tool. A large investigative team developed this impressive resource, led by Peter J. Houghton, Ph.D., Raushan T. Kurmasheva, Ph.D., and Siyuan Zheng, Ph.D., at the Greehey Children's Cancer Research Institute and the Mays Cancer Canter at The University of Texas Health Science Center at San Antonio and The University of Texas Southwestern Medical Center and the Simmons Comprehensive Cancer Center.

In the study, the researchers performed genomic profiling on both PDXs and the original PTs. They found that about 70% of the PDXs closely matched the genetic makeup of the PTs. However, in roughly 30% of cases, there was less similarity. The researchers observed this dissimilarity primarily in PTs with high genetic diversity. In such cases, a minor aggressive subclone in the PT often became dominant in the PDX. This finding suggests that interactions between the tumor's genetic diversity and the patient's immune response may be responsible for these differences.

This research has important clinical implications. Although it may make sense to use PDXs in parallel with patient treatment to find personalized therapies, this study indicates that such an approach might be misleading for highly heterogeneous tumors and underscores the need to study the original patient tumor as well. In addition, the investigators showed that the innate immune system in some patients may have suppressed the more aggressive cancer subclones. Thus, leveraging this antitumor immunity in combination with more conventional treatments like surgery may benefit these patients. The researchers have molecularly characterized these PDXs and made them available to the scientific community upon request.

Multiple CPRIT awards supported this work, including two Core Facility Support Awards totaling $9 million to UT Health San Antonio and Dr. Peter Houghton and Dr. Kurmasheva (RP160716, RP220599), and a $1.2 million Individual Investigator Research Award for Cancer in Children and Adolescents (RP180319) to UT Southwestern and Dr. Stephen Skapek. In addition, the Genome Sequencing Center Research, supported by two CPRIT Core Facility grants (RP160732, RP220662) totaling $7.5 million awarded to UT Health San Antonio and Dr. Yidong Chen provided research services. CPRIT Scholar Dr. Siyuan Zheng (RR170055) also contributed to this work.

- **Deep-Learning Analysis of Tissue Images Reveals Clinical Insights.** Cancer diagnosis and prognosis have traditionally relied on pathologists analyzing stained slides of tumor tissue, providing detailed insights into the tumor's morphology. While artificial intelligence (AI) and deep-learning methods have shown promise in identifying various cell types in both healthy and diseased tissues, they have so far been unable to evaluate the individual spatial interactions of cells within tissues. However, a groundbreaking development from a research team led by CPRIT grantee Guanghua Xiao, Ph.D., at The University of Texas Southwestern Medical Center is changing this. They have developed an innovative AI model, called Ceograph, that analyzes the arrangement of cells in tissue samples. Published December 11 in *Nature Communications*, the new model demonstrates remarkable accuracy in predicting cancer patient outcomes, marking a significant step forward in using AI for personalized cancer treatment strategies.

  Ceograph emulates the way pathologists examine tissue slides, first detecting cells and their positions in the images. It then identifies cell types, their morphology, and distribution, ultimately creating a detailed map of the cells' arrangement and interactions. This method represents a significant advancement in tissue analysis, moving beyond traditional approaches.

  Researchers tested Ceograph in three clinical scenarios using pathology slides. It outperformed existing methods in predicting patient outcomes in each scenario. In the first test, it accurately distinguished between two subtypes of lung cancer – adenocarcinoma and squamous cell carcinoma. In the second, Ceograph predicted the likelihood of precancerous oral lesions turning into cancer, focusing on changes in the structure and closeness of epithelial cells. In the last test, the model identified lung cancer patients most likely to respond to treatments targeting the epidermal growth factor receptor (EGFR) by using the shape of tumor nuclei and the proximity of stroma cells to predict the effectiveness of EGFR tyrosine kinase inhibitors.

  These findings demonstrate the increasing importance of AI in medical care, particularly in pathology. Ceograph not only improves the accuracy and efficiency of pathology analyses but also provides deeper insights into the biological processes at play in cancer. Its ability to predict various clinical outcomes holds great promise for the development of personalized treatment strategies. This advancement in AI and machine learning represents a significant leap in cancer care, potentially transforming how we diagnose and treat cancer in the future.

  A $1.3 million CPRIT Individual Investigator Research Award for Childhood and Adolescent Cancer (RP230330) granted to UT Southwestern and Dr. Xiao, and a $5.4 million Core Facility Support Award for the Pediatric Cancer Data Core (RP180805) granted to UT Southwestern and Dr. Yang Xie supported this work.

- **Leveraging Instability and Chaos in Tumor Cells to Therapeutic Advantage.** Preferentially Expressed Antigen in Melanoma (PRAME) is a protein antigen found in melanoma cells and recognized by the body’s immune T cells. PRAME, typically expressed primarily in the testis, can become abnormally active in various types of cancer, often

indicating a poor prognosis. This is especially true in uveal melanoma (UM), the most common primary cancer of the eye, which can lead to metastatic disease in up to half of the patients. In UM tumors, scientists have linked the presence of PRAME with aneuploidy (an abnormal number of chromosomes), metastasis, and poor outcomes for patients.

Recent research led by CPRIT Scholar J. William Harbour, M.D., professor and chair of the ophthalmology department at The University of Texas Southwestern Medical Center and the Simmons Comprehensive Cancer Center, sheds new light on the role of PRAME in cancer. The study found that PRAME is normally active in spermatogonia during meiotic crossing-over – a crucial phase in sexual reproduction where chromosomes exchange genetic material and undergo repair. However, when UM cells and otherwise normal eye melanocytes express PRAME, it leads to increased DNA breaks, chromosome exchange, and telomere instability. This process also results in the formation of micronuclei, a key indicator of chromosome segregation errors and aneuploidy, which are common features in cancer.

The findings suggest that PRAME plays a role in regulating normal genetic recombination during meiosis; and when it is misexpressed in tumor cells, it causes genomic instability. This instability seems to be partly due to PRAME's impact on cohesin protein complexes. These complexes are essential for proper chromosome alignment and segregation during cell division, as well as for DNA repair. PRAME acts as a CUL2 ubiquitin ligase, a type of enzyme that tags proteins for degradation. It specifically targets SMC1A, a core component of the cohesin complex. Surprisingly, instead of leading to the degradation of SMC1A, PRAME's action alters its function within the cohesin complex, causing defects in DNA repair.

PRAME's high expression in tumors, which causes increased DNA damage, presents a potential vulnerability. In studies exploiting this weakness, researchers found that tumor cells with high PRAME expression are sensitive to therapies that inhibit PARP1/2, enzymes involved in DNA repair. By blocking these enzymes, it reduces the cells' ability to repair DNA damage, making them more susceptible to cancer treatments. Targeting this specific weakness suggests potential new treatments for cancers where PRAME is highly expressed.

UT Southwestern recruited Dr. Harbour to Texas from the University of Miami School of Medicine with a $6 million CPRIT Established Investigator Award (RR220010) in 2022. Immatics N.V. is currently conducting several early phase clinical trials evaluating therapies targeting PRAME, namely in its TCR-engineered cell therapy (TCR-T) approach ACTengine IMA203, and next-generation Bispecific T cell engaging receptor (TCER) IMA402. Immatics, based in Houston and Tübingen, Germany, received a $19.7 million CPRIT Product Development Research award in 2015 (DP150029) to develop personalized cellular therapies targeting multiple cancer types.

Personnel

CPRIT has filled 44 full-time equivalent positions and has several positions in progress, including an accountant position, executive assistant, and grant compliance specialist positions.

88th Texas Legislature, 3rd and 4th Called Sessions

The 30-day third called session of the 88th Texas Legislature adjourned *Sine Die* on November 7; Governor Abbott called them back for the fourth called session that afternoon. The fourth called session adjourned *Sine Die* on December 5. The legislature did not consider any issues affecting CPRIT.

CPRIT Outreach

Staff outreach activities during November and December include:

- Academic Research Program Manager Dr. Myriam Casillas attended the virtual meeting, "Reducing Cancer Care Inequities: Leveraging Technology to Enhance Patient Navigation," which is part of the President's Cancer Panel ongoing meeting series, held November 2-3.

- Director of Research Dr. Patty Moore traveled to Baylor Scott & White Charles A. Sammons Cancer Center in Dallas November 13 -14 to attend the National Cancer Institute site visit for the CPRIT-funded Texas Connect for Cancer Prevention Study Award. The visit included a tour of the Baylor Scott & White Biorepository and the Baylor Scott & White Health and Wellness Center at the Juanita J. Craft Recreation Center, a Texas CONNECT study patient recruitment site.

- On November 6, Chief Product Development Officer Dr. Ken Smith and Senior Program Manager for Product Development Dr. Abria Magee met with several senior leaders from Yosemite to explore opportunities for collaboration. Yosemite, a newly launched spinoff from Emerson Collective, is an independent investment firm focused on opportunities across the oncology ecosystem.

- Deputy Executive Officer and General Counsel Kristen Doyle and Dr. Magee presented a CPRIT Product Development Program update at the BIO Houston Texas Life Science Forum held November 7 in Houston.

- On November 14 Chief Scientific Officer Dr. Michelle Le Beau, Ms. Doyle, and I met with representatives from Texas A&M University and Texas A&M University-Kingsville via videoconference regarding clinical trial initiatives.

- Dr. Magee met with the leadership team from ProximaCo, a clinical research organization that provides consulting, clinical, and technological solutions and advising to life sciences companies, with a specific focus on innovation on November 28. They discussed opportunities for collaboration.

- Dr. Michelle Le Beau participated in the virtual quarterly meeting of the combined National Cancer Institute's Board of Scientific Advisors and National Cancer Advisory Board held November 30. The meeting focused on legislative updates impacting the NCI's budget, as well as providing advice to the NCI on ongoing initiatives and reviewing proposed Request for Applications.

- Ms. Doyle and I met with the American Cancer Society Cancer Action Network on December 6 to discuss their plans for conferences in Houston on February 22 and in the Rio Grande Valley in late February or early March.

- In conjunction with the State Agency Council, The Governor's Commission for Women, and Partnership for Children, CPRIT staff once again generously contributed to the Holiday Wishes List project, for Texas Children in protective services foster care led by Dr. Moore. Volunteers collected the gifts for distribution on December 6.

- Prevention Program Manager Carlton Allen participated moderated a panel discussion on December 7 at this year's American Cancer Society Cancer Action Network (ACS CAN) North Texas Policy Forum at McKesson Corporate Headquarters in Irving. The panel addressed the opportunities and challenges in providing cancer screening to all Texans, including highlighting what health organizations can do to break down barriers to screening.

- Dr. Le Beau attended the 65th annual meeting and exposition of the American Society for Hematology held December 9-12 in San Diego. The conference featured the latest advancements in clinical care and research in malignant and benign hematological diseases. The meeting also provided the opportunity to meet with several CPRIT grantees and attend their platform and poster presentations.

- On December 11, Dr. Moore and CPRIT Technical Writer Bridget Barstow attended the State Agency Council and Governor's Commission for Women holiday event at the Governor's Mansion, which Mrs. Abbott hosted. At the event, members created gifts bags for the Department of Family and Protective Services caseworkers in Travis County who submitted wish lists for the Holiday Wishes project.

- Chief Operating Officer Heidi McConnell attended the Texas IT Leadership Forum on December 12 in Austin.

- Dr. Le Beau, Ms. Doyle, and I attended several ARPA-H webinars and virtual meetings in November and December. These meetings primarily focused on a new ARPA-H initiative to improve clinical trials and clinical trial access – the Accelerating Clinical Trial Readiness

(ACTR) program. Through ACTR, ARPA-H's goal is to enable 90% of all eligible Americans to take part in a clinical trial within a half hour of their home. ARPA-H issued a "Network Activation Call" on ACTR seeking input from organizations with relevant experience and expertise in areas such as enrollment and consent, decentralized trials in health care settings, distribution of common trial protocols, and data collection. Dr. Le Beau submitted comments on behalf of CPRIT on December 1. Based on the feedback received, ARPA-H will release the final initiative description and funding opportunity in 2024.

Compliance Program Update

Submission Status of Required Grant Recipient Reports

As of December 14, 10 entities had not filed nine academic research reports, two product development reports, and five prevention reports. CPRIT's grant accountants and compliance specialists review and process incoming reports and reach out to grantees to resolve filing issues. In most cases, CPRIT does not disburse grant funds until the grantee files the required reports. In some instances, grantee institutions may be ineligible to receive a future award if the grantee does not submit required reports.

Financial Status Report Reviews

CPRIT's compliance specialists performed 293 second-level reviews of grantee Financial Status Reports (FSRs) in November and December. Forty FSRs (14%) 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 four enhanced desk-based financial monitoring reviews in November and December. 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 one grantee to address desk review findings.

Onsite Reviews

CPRIT completed six onsite reviews in November and December. 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 grantees' capability, performance, and compliance with applicable laws, rules, and policies. Compliance specialists are collaborating with three grantees to address 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, one grantee has not 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. Compliance staff is working with the grantee to submit the required audit.

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. This opportunity to self-report, in the form of a checklist, provides a baseline of grantee compliance and allows compliance specialists to proactively work with grantees towards full compliance prior to a desk review or onsite review. As of December 14, 17 of the 59 grantees have submitted their annual compliance attestation. 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.

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 one annual match expenditure review in November and December. The total amount of match expenses reviewed by compliance staff for FY 2024 is $3,536,936.63. The unallowable match expenses for FY 2024 total $39,354.26.

Training and Support

CPRIT staff conducted four new Authorized Signing Official (ASO) training webinars in November and December for The University of Texas at Austin, Baylor Research Institute, The University of Texas Health Science Center at Tyler, and Pulmotect Inc. The ASO 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 ASOs to complete compliance training within 60 days of the change.

Academic Research Program Update

Recruitment FY 2024 Review Cycle 3 and 4

CPRIT accepted recruitment applications June 21 through October 20 for the third and fourth review cycles of FY 2024. CPRIT's Scientific Review Council (SRC) reviewed the applications on November 16. Dr. Le Beau will present the SRC's award recommendations for recruitment awards to the Program Integration Committee (PIC) and the Oversight Committee in February 2024.

FY 24 Mechanism	Received	Funds Requested	Recommended	Recommended Funds
Recruitment of Established Investigators	2	$12,000,000	1	$6,000,000
Recruitment of First-Time, Tenure Track Faculty Members	3	$ 6,000,000	2	$4,000,000
Recruitment of Rising Stars	4	$14,000,000	2	$8,000,000
TOTAL	**9**	**$32,000,000**	**5**	**$18,000,000**

Academic Research FY 2024 Review Cycle 1 (24.1)

CPRIT posted five Individual Investigator RFAs for the first review cycle of FY 2024 on February 17, accepting applications March 15 through June 14, 2023. Peer reviewers met in October to evaluate the 315 applications. Dr. Le Beau will present the SRC's recommendations for the cycle 24.1 grants to the PIC and the Oversight Committee in February 2024.

FY 24 Cycle 1 Mechanism	Received	Funds Requested
Individual Investigator Research Award (IIRA)	228	$233,894,288
IIRA for Computational Systems Biology of Cancer	18	$36,108,737
IIRA for Cancer in Children and Adolescents	35	$47,815,216
IIRA for Prevention and Early Detection	15	$27,050,403
IIRA for Clinical Translation	19	$19,850,946
TOTAL	**315**	**$364,719,590**

Academic Research FY 2024 Review Cycle 2 (24.2)

On September 14, CPRIT released several RFAs (Core Facilities Support Awards, High-Impact/High-Risk Research Awards, Multi-Investigator Awards, and Clinical Investigator Award) for the second cycle of FY 2024 and will accept applications October 17 – January 16, 2024. Peer review panels will meet virtually in late April 2024 to consider the applications. Dr. Le Beau will present the SRC's recommendations to the PIC and the Oversight Committee in August 2024.

Product Development Research Program Update

Product Development FY 2024 Cycle 2 Review (24.2)

At the last Oversight Committee meeting, Chief Product Development Officer Dr. Ken Smith notified the board that the product development program would initiate a second review cycle for FY 2024 to award up to $20 million. Because of the smaller overall award budget for this cycle, CPRIT capped the maximum amount a non-Seed company may request at $5 million. The regular $3 million budget cap for Seed awards remains the same in this cycle.

CPRIT released four FY 2024 Product Development Research RFAs on November 29 and opened the portal to receive preliminary applications December 1. CPRIT received 63 preliminary applications by the December 11 deadline. After completing conflict of interest checks and completing administrative review, CPRIT assigned the 60 preliminary applications to eight review panels on December 15. (CPRIT administratively withdrew three applications for non-compliance.)

24.2 Mechanism	Preliminary Apps	Requested
Texas Therapeutic Company	17	$84.1 M
Texas Device/Diagnostic Company	2	$10.0 M
Texas New Technologies Company	10	$47.8 M
Seed Company	31	$88.1 M
TOTAL	**60**	**$230.0 M**

Reviewers will individually evaluate and score the 60 preliminary applications through mid-January. Following individual review, each panel will meet to rank its assigned preliminary applications.

CPRIT will issue invitations to submit full applications for the 24.2 cycle by January 24. In addition to the companies submitting preliminary applications in this cycle, seven companies are eligible to submit full applications in the 24.2 cycle based on their performance in the 24.1 preliminary application review cycle. While we plan to review up to 15 full applications, the number of new invitations to submit full applications will depend on how many of the seven companies decide to participate in the 24.2 cycle (where they will be bound by the $5 million budget cap per application.) Those seven companies must notify CPRIT by mid-January if they plan to submit a full application in the 24.2 cycle.

All invited companies will have until February 13 to submit their full applications, with live presentations to the full review panel occurring March 18 – March 27. Following due diligence, the Product Development Review Council (PDRC) will submit its final recommendations to the PIC. Dr. Smith plans to present the PDRC's recommendations to the PIC and the Oversight Committee in May.

Prevention Program Update

Prevention FY 2024 Review Cycle 1 (24.1)

The Prevention Program released two prevention RFAs on May 5 for the first cycle of FY 2024. CPRIT received 29 proposals totaling $46.7 million by the August 30 deadline. Peer review took place December 5 – 6. The Prevention Review Council (PRC) will meet in January to make final recommendations. Chief Prevention Officer Ramona Magid will present the PRC's recommendations to the PIC and the Oversight Committee in February.

Cycle 24.1 Mechanism	Applications	Funds Requested
Primary Prevention of Cancer	13	$19,384,419
Cancer Screening and Early Detection	16	$27,272,619
TOTAL	**29**	**$46,657,038**

Advisory Committees

- The University Advisory Committee met November 3.
- The Clinical Trials Advisory Committee met December 15.

Operations and Finance Update

McConnell & Jones LLP completed the audit of CPRIT's FY 2023 financial statements issuing an "unmodified," or clean report with no identified material weaknesses or significant deficiencies. The McConnell & Jones audit team presented these results to the Audit Subcommittee on December 11. We have submitted the audit report to the Office of the Comptroller of Public Accounts, State Auditor's Office, Governor's Office, and Legislative

Budget Board. CPRIT staff who primarily provided the requested documents and other information required of the audit include CPRIT accountant Michelle Huddleston, CPRIT Operations Manager Lisa Nelson, and Chief Operating Officer Heidi McConnell.

During the same period that McConnell & Jones was conducting the audit, Ms. Huddleston and Ms. McConnell completed the agency's FY 2023 Annual Financial Report and submitted it to the Governor's Office, Legislative Budget Board, and Office of the Comptroller of Public Accounts by the November 20 deadline.

Operations Specialist Dan Limas and Ms. McConnell completed the agency's FY 2024 Operating Budget and submitted it two days ahead of the December 1 deadline to the Governor's Office and Legislative Budget Board. State agencies must complete an Operating Budget document in every even-numbered state fiscal year.

Contracts, Purchasing and HUB Coordinator Don Brandy and Ms. McConnell completed the agency's FY 2024 Agency Procurement Plan and submitted it to the Office of the Comptroller of Public Accounts on November 29, one day ahead of its due date.

Upcoming Subcommittee Meetings

Listed below are the subcommittee meetings in advance of the February 21 Oversight Committee meeting. We will send instructions for signing onto the Microsoft Teams platform along with the subcommittee agenda and meeting materials one week prior to each meeting.

Board Governance	February 8 at 10:00 a.m.
Audit	February 12 at 10:00 a.m.
Prevention	February 13 at 12:00 p.m.
Academic Research	February 14 at 12:00 p.m.
Product Development	February 15 at 10:00 a.m.

******

CPRIT has awarded **1,909** grants totaling **$3.44 billion:**

- 291 prevention awards totaling $354.8 million
- 1,618 academic research and product development research awards totaling $3.09 billion

Of the $3.09 billion in academic research and product development research awards,

- 32.6% of the funding ($1.01 billion) supports clinical research projects
- 23.4% of the funding ($722.4 million) supports translational research projects
- 29.1% of funding ($897.4 million) supports recruitment awards
- 12.0% of the funding ($370.1 million) supports discovery stage research projects
- 2.9% of funding ($90.4 million) supports training programs.

CPRIT has seven open Requests for Applications (RFAs)

- 3 Academic Research Recruitment
- 4 Academic Research Projects

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	CPRIT ACTIVITIES UPDATE FOR JANUARY 2024
DATE:	FEBRUARY 1, 2024

Topics in this memo address CPRIT activities in January, including preparations for the upcoming February 21 Oversight Committee meeting, recent milestones in our fight against cancer, the FY 2023 annual report, a staffing summary, outreach efforts, and updates from Compliance, Programs, and Operations.

Planning for the February 21 Oversight Committee Meeting

The Oversight Committee will meet in person on Wednesday, February 21, in the Barbara Jordan Building. The meeting will begin at 8:30 a.m. We will have a full agenda with grant award recommendations, annual reports from the Advisory Committee on Childhood Cancer and the Geographic Diversity Advisory Committee, and an executive session. Please notify me as soon as possible if you are unable to attend the February 21 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 February 9 with a link and password to access the Program Integration Committee's award recommendations via the grant award portal. The portal 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.

Attached is a draft meeting agenda. CPRIT will post the final agenda for the Oversight Committee meeting by February 13. Oversight Committee members will receive an electronic copy of the agenda packet by February 14. 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

- In December, the Texas Academy of Medicine, Engineering, Science, and Technology (TAMEST) announced that CPRIT Scholar Nidhi Sahni, Ph.D., associate professor, Department of Epigenetics and Molecular Carcinogenesis at The University of Texas MD

Anderson Cancer Center, will receive the 2024 Mary Beth Maddox Award and Lectureship in cancer research at the TAMEST 2024 Annual Conference February 5 - 7. The award recognizes women scientists in Texas bringing new ideas and innovations to the fight against cancer. TAMEST established the award in 2022 in honor of Mary Beth Maddox, former Executive Director of TAMEST, who passed away after a valiant battle with pancreatic cancer.

TAMEST is honoring Dr. Sahni for her role in identifying novel biomarkers and drug targets in cancer, which scientists expect to have a significant impact on cancer by translating into more effective prognosis and therapy for the disease. She has pioneered "functional variomics" as an approach to identify mechanisms by which DNA sequence variation impacts diseases, establishing a new field with a major influence on precision oncology, early detection and therapeutics in cancer. Her research program involves integrating experimental and computational systems biology focused on genotype and phenotype relationships in cancer. Her research findings establish that disease-causing mutations are likely to upset molecular interactions in signaling networks, shaping cellular properties. Dr. Sahni will promote her work and discoveries across the state at an established lecture and seminar series at TAMEST member institutions with National Cancer Institute-designated Cancer Centers (Baylor College of Medicine, MD Anderson, The University of Texas Health Science Center at San Antonio, and The University of Texas Southwestern Medical Center.)

MD Anderson recruited Dr. Sahni to Texas from the Dana-Farber Cancer Institute with a $2 million First-Time, Tenure-Track Faculty Member award in 2015 (RR160021).

- CPRIT Scholar Vincent Tagliabracci, Ph.D., and CPRIT grantee Benjamin Deneen, Ph.D., will each receive 2024 Edith and Peter O'Donnell Awards in their fields from TAMEST at its 2024 Annual Conference. TAMEST is recognizing Dr. Tagliabracci, associate professor, Michael L. Rosenberg Scholar in Medical Research at The University of Texas Southwestern Medical Center, for broadening the understanding of pseudokinases, a family of enzymes that play key roles in many physiological and pathological processes. TAMEST selected renowned neuroscientist Dr. Deneen, professor, director for the Center for Cancer Neuroscience at Baylor College of Medicine, for his groundbreaking research that opened an entirely new field of study benefiting brain tumor patients and providing insights into a wide range of developmental diseases.

  The Honorable Kay Bailey Hutchison and Nobel Laureates Michael S. Brown, M.D., and Richard E. Smalley, Ph.D., co-founded TAMEST in 2004. With more than 335 members, 8 Nobel Laureates and 22 member institutions, TAMEST is composed of Texas-based members of the three National Academies (National Academy of Medicine, National Academy of Engineering and National Academy of Sciences) and other honorific organizations, and brings together Texas' brightest minds in medicine, engineering, science and technology to foster collaboration, and to advance research, innovation and business in Texas.

UT Southwestern brought Dr. Tagliabracci to Texas from the University of California, San Diego with a $2 million First-Time, Tenure-Track Faculty Member award in 2015 (RR150033). CPRIT has awarded Baylor College of Medicine and Dr. Deneen research grants totaling $2.7 million for his study of gliomas.

- Salarius activated their Phase 1/2 clinical trial for hematologic cancer at The University of Texas MD Anderson Cancer Center on January 3. The trial, which is now recruiting participants, has shown positive preliminary outcomes. Researchers report a 60% objective response rate and a disease control rate in first-relapse Ewing sarcoma patients treated with seclidemstat and a chemotherapy concoction. Dallas-based Salarius received a $16.1 million CPRIT New Company Product Development grant (DP160014) in 2016 to develop their lead protein inhibitor, seclidemstat.

- Livia Eberlin, Ph.D., associate professor in the division of surgical oncology and vice chair for research in the Michael E. DeBakey Department of Surgery at Baylor College of Medicine, received a $3 million grant from The Marcus Foundation. that Dr. Eberlin's lab will use the funds to further develop and validate the MasSpec Pen technology in breast cancer surgeries. The MasSpec Pen is a first-in-field technology that enables ex vivo and in vivo tissue identification in seconds based on molecular analysis, to help guide resection in breast cancer and other cancer surgeries. Baylor College of Medicine announced January 3 that the Eberlin Lab successfully implemented the tool in a pilot clinical study in the operating room at Baylor with 22 breast cancer patients. The Marcus Foundation funding will help enroll 200 patients at Ben Taub Hospital and Baylor St. Luke's Medical Center. Surgeons will use the MasSpec Pen intraoperatively for breast tissue analysis, surgical margin evaluation and to ultimately determine how the technology performs in comparison to the current clinical approach. The goal is to achieve higher than 95% accuracy and for the MasSpec Pen technology to perform faster than current standards. CPRIT awarded Dr. Eberlin and her previous institution, The University of Texas at Austin, $1.4 million in three grants (RP160776, RP170427, RP180381) to develop the MasSpec Pen.

- Merck announced January 5 that the FDA approved Welireg (belzutifan) for a second cancer indication - relapsed or refractory advanced renal cell carcinoma (RCC), the most common form of kidney cancer. The FDA initially approved the oral HIF-2 alpha inhibitor Welireg as the first drug in its class for von Hippel-Lindau disease, an inherited condition that can cause tumors to develop in various organs of the body. The approval in RCC is for patients previously treated with PD-1/L1 and VEGF-targeted therapies, and is the first new therapeutic class available for eligible patients with advanced RCC in nearly a decade. CPRIT awarded Dallas-based Peloton Therapeutics $3.2 million CPRIT Product Development Research grant (R1009) in 2010 to develop the indication that became Welireg. Merck acquired Peloton in 2019.

- Rice University launched the Rice Synthetic Biology Institute (RSBI) on January 10. CPRIT Scholar Caroline Ajo-Franklin, Ph.D., professor of biosciences, bioengineering, and chemical and biomolecular engineering, will lead the RSBI with the support of an interdisciplinary faculty steering committee. The RSBI will catalyze collaborative research in synthetic

biology and its translation into technologies that benefit society. Synthetic biology is a multi-disciplinary field of science that focuses on living systems and organisms. It applies engineering principles to develop new biological parts, devices, and systems or to redesign existing systems found in nature to address societal needs. Rice brought Dr. Ajo-Franklin to Texas in 2019 from the Lawrence Berkeley National Laboratory with a $6 million CPRIT Recruitment of an Established Investigator Award (RR190063).

- KFOX14 interviewed Jennifer Molokwu, Ph.D., on January 11 as part of its coverage of National Cervical Health Awareness Month. Dr. Molokwu, associate professor, vice-chair of Research, Department of Family and Community Medicine at Texas Tech University Health Sciences Center at El Paso, encouraged women to have annual pap smears to prevent cervical cancer. The Texas Tech University Health Sciences Center at El Paso and Dr. Molokwu have received three CPRIT Prevention grants totaling $5.4 million to support the *De Casa en Casa 3* and *De Casa en Casa 4: Cervical Cancer Screening in Underserved Rural and Border Communities in West and South Texas programs* (PP200006, PP230059) and the *Tiempo de Vacunarte* (Time to Get Vaccinated) 2 program (PP190058). The *Tiempo de Vacunarte 2* program prevents and reduces the burden of HPV-associated cancers among the underserved, predominantly Hispanic and rural populations along the Texas-Mexico border.

- Salarius announced January 16 that the U.S. Patent and Trademark Office issued U.S. Patent No. 11,773,080, titled "Deuterium-enriched isoindolinonyl-azepanediones and related compounds and methods of treating medical disorders using same." This patent covers the composition of matter for novel molecular glue degraders and expires in mid-2039. Dallas-based Salarius received a $16.1 million CPRIT New Company Product Development grant (DP160014) in 2016 to develop their lead protein inhibitor, seclidemstat.

- Allterum Therapeutics announced January 24 that the National Cancer Institute's Experimental Therapeutics (NExT) Program approved support for the company's key product development activities related to its 4A10 monoclonal antibody targeting acute lymphoblastic leukemia. The NExT Program advances promising new drug discovery and development projects and brings cancer therapeutics into the clinic by providing milestone-driven resources for projects focused on developing therapies for unmet needs in oncology. The NExT Program will support Allterum's pivotal GLP toxicology study and the initial GMP manufacturing of 4A10, which will enable the company to submit an Investigational New Drug application and to launch its Phase I clinical trial in 2024. Hoston-based Allterum received a $2.9 million Texas Seed Company award in 2019 (DP190025) for preclinical work developing 4A10. Following the successful completion of their Seed Company award, Allterum received an $11.7 million Texas Therapeutic Company award from CPRIT (DP230071) in May 2023 to support clinical development of 4A10.

Notable CPRIT-Supported Research and Prevention Accomplishments

- **Systems Biology Strategy Suggests Targeting Protein Methylation May Improve PARP Inhibitor Therapy.** Inherited mutations in the BRCA1 or BRCA2 genes disrupt the body's ability to repair DNA damage. A type of cancer therapy using PARP inhibitors can target

this defect. These inhibitors block a specific DNA repair protein (PARP1), which can extend the time patients with BRCA1/2-mutant cancers live without their disease getting worse. However, many patients eventually become resistant to this treatment, leading to a poor overall survival rate and the critical need for new treatment strategies.

One promising area of research involves protein arginine methyltransferases (PRMTs), enzymes that modify the amino acid arginine by adding a methyl group. PRMTs play a role in regulating gene transcription and RNA splicing and are involved in several cancer-related processes. Dr. Nidhi Sahni, a CPRIT Scholar at The University of Texas MD Anderson Cancer Center, is investigating PRMTs as potential targets for cancer therapy. Her findings, published in the December 19 edition of *Cell Reports Medicine*, suggest a new way to combat breast cancer and other tumors.

Dr. Sahni and her team tested inhibitors of various PRMTs on a panel of five cancer cell lines. They found that these inhibitors suppressed a key DNA replication stress response protein known as ATR. ATR is crucial for stopping DNA replication in cells under stress. By suppressing ATR with PRMT inhibitors, the team created a defective DNA replication stress response pathway in the cancer cells.

The researchers then exploited the defect by combining PRMT inhibition with PARP inhibitors, a type of chemotherapy that induces DNA replication stress. They discovered that inhibiting PRMT1 or PRMT5 made cancer cells much more sensitive to DNA damage caused by PARP inhibitors.

While both PRMT1 and PRMT5 inhibitors were effective in stopping tumor cell growth, the PRMT1 inhibitors were more toxic to healthy mammary epithelial cells. Further studies with PRMT5 inhibitors showed strong synergy in both patient-derived organoids and patient-derived xenografts in live models. Importantly, the models tolerated the combination of PRMT5 inhibition with PARP inhibition without harmful side effects.

Since the FDA has already approved PARP inhibitors for clinical use in several tumors - including BRCA1/2-mutant breast cancers, and researchers are evaluating PRMT5 inhibitors in clinical trials, these findings could lead to the development of a potent and well-tolerated combination therapy using PRMT5 and PARP inhibitors for cancer treatment.

MD Anderson recruited Dr. Sahni to Texas from the Dana-Farber Cancer Institute with a $2 million First-Time, Tenure-Track Faculty Member award in 2015 (RR160021). Dr. Sahni and MD Anderson also received a $900,000 Individual Investigator award in 2022 (RP220292).

- **When is it Safe to Stop Immunotherapy?** Colorectal cancer is a major health issue in the U.S., ranking as the third most common cancer and the third leading cause of cancer-related deaths, excluding skin cancers. In 2023, 52,550 people died from this disease. A type of treatment known as immune checkpoint inhibitors (ICIs) has been effective against some solid tumors, including colorectal cancers that have certain genetic characteristics,

specifically high microsatellite instability (MSI-H) or deficient DNA mismatch repair (dMMR). To date, the U.S. Food and Drug Administration has approved four ICIs for treating advanced MSI-H/dMMR colorectal cancer.

However, until recently, it was unclear what happens when a patient stops ICI treatment after their disease is under control. This uncertainty made treatment decisions challenging. A study reported in the December issue of *Cancer Research Communications* provides some clarity. The study, led by Van Morris, M.D., associate professor, Department of Gastrointestinal Medical Oncology, The University of Texas MD Anderson Cancer Center, found that most patients with metastatic colorectal cancer whose cancer did not progress while on ICIs had no disease progression two years after stopping treatment.

Dr. Morris's team conducted a retrospective analysis of 64 patients with MSI-H/dMMR metastatic colorectal cancer treated between 2014 and 2022. These patients either received an ICI targeting PD-1 or PD-L1, alone or in combination with an ICI targeting CTLA-4. All the patients experienced a lasting benefit from the ICI treatment before stopping it for different reasons – either due to prolonged benefit or because of side effects – after a median treatment duration of 17.6 months.

The researchers found that nearly two years after stopping immunotherapy, 88% of these patients did not have their cancer come back. The survival rate without cancer progression was 98% after one year, 91% after two years, and 84% at three years post-treatment. Importantly, the survival rates were similar regardless of the reasons for stopping the treatment or other patient and disease characteristics. Even among the few patients whose cancer did progress, all responded well when they resumed ICI treatment.

This study's findings are significant for clinical practice. They suggest that patients with MSI-H/dMMR colorectal cancer who stop their ICI treatment have a high likelihood that their cancer will not return. This information will help doctors guide patients in making informed decisions about whether or when to stop immunotherapy.

CPRIT awarded a $1 million Individual Investigator award to MD Anderson and Dr. Morris in 2022 (RP220416) to fund this research.

- **Good Cellular Signal Matters to Cancers Too!** Spatial transcriptomics (ST) is a range of technologies that lets scientists determine what types of cells are in a tissue sample and where they are located by looking at the genes expressed in those cells. ST allows researchers to see how cells communicate with each other and how they develop over time and space within the tissue. Despite the number of ST platforms available, there are no cost-effective options able to analyze single cells in detail, cover the entire range of genes expressed (the transcriptome), and work with large tissue samples.

  Previous studies have found that the patterns of gene expression in cells are related to the features seen in images of the tissue under a microscope (histology). This suggests that researchers may be able to predict the gene expression by looking at histologic tissue

sections. However, existing methods do not fully take advantage of the detailed cellular information provided by these high-resolution images.

A research team, including CPRIT grantee Dr. Linghua Wang from The University of Texas MD Anderson Cancer Center, developed a new method to address this limitation. Their approach, described in the January 2 issue of *Nature Biotechnology*, mimics how a pathologist examines tissue slides: first looking at the overall structure of the tissue, and then focusing on the detailed structure of the cells. This method, called iStar (Inferring Super-resolution Tissue ARchitecture), uses a technique to extract features from images that capture both the big picture and the detailed characteristics of the tissue.

iStar uses a system called a hierarchical vision transformer (HViT), which researchers have already trained on publicly available images of tissue stained with hematoxylin and eosin. This system first looks at small 16x16 pixel areas to get detailed tissue features, and then at larger 256x256 pixel areas to understand the overall tissue structure. After this, a neural network uses these features to predict gene expression at a super high resolution.

The iStar method has broad applications for researchers and patients. In research, it can help study gene expression in tissue samples at nearly the level of individual cells. Clinically, iStar may assist diagnosis and classification of tumors by predicting gene expression from histology images, leading to better treatment choices for patients. This is particularly useful in situations where only images are available, like in some referral cases or in low-resource countries.

CPRIT awarded MD Anderson and Dr. Wang a $900,000 Individual Investigator award in 2020 (RP200385) to support this research.

- **Changes in the Gut Microbiome May Influence Distant Cancer Growth.** The microbial community in our intestines, also known as gut microbiota, plays a vital role in our health. It interacts with our body to support immunity and metabolism, and can even influence the development, progression, and treatment response of cancers. One key player in this interaction is Interleukin-17 (IL-17), a proinflammatory cytokine produced by T cells, which are part of the immune system. IL-17 signaling helps maintain a healthy balance of gut microbes, but researchers have linked it to several diseases, including cancer. Interestingly, blocking IL-17 can interfere with the body's ability to combat tumors.

  Scientists do not fully understand how IL-17 signaling in the gut influences tumors located in other parts of the body. This gap in knowledge prompted Florencia McAllister, M.D., associated professor, Department of Clinical Cancer Prevention at The University of Texas MD Anderson Cancer Center, to investigate the effects of removing the IL-17 receptor either throughout the body or specifically in the gut in laboratory models. Her study, published in the January 8 issue of *Cancer Cell*, explores how this approach could lead to new cancer treatments.

The researchers discovered that deleting the IL-17 receptor caused an imbalance in gut bacteria, known as dysbiosis. This dysbiosis triggered an immune response that led to the growth of pancreatic and brain tumors located far from the gut. The growth of these tumors was due to an increase in a subset of T cells known as Th17, which is the primary source of IL-17 in human and mouse pancreatic cancers, as well as immune B cells that travel to distant tumors. They found that the IL-17 signaling influenced by the gut microbiota led to increased activity of certain enzymes (DUOX2/NOX oxidase), resulting in more reactive oxygen species and DNA damage in tumor cells. Scientists have linked this process to a higher risk of tumor growth and a worse prognosis in pancreatic tumors.

Using antibiotics to target specific bacteria linked to tumor-promoting behavior, or deleting IL-17 receptors in all cancer cells, reversed these negative effects. These findings suggest that in clinical trials targeting IL-17 or similar molecules, investigators should also monitor changes in the gut microbiome. Using antibiotics or fecal microbial transplantation to maintain a healthy microbial balance may improve the effectiveness of cancer treatments.

CPRIT awarded MD Anderson and Dr. McAllister a $2 million Individual Investigator Research Award in 2020 (RP200173), which supported this study.

- **CPRIT Scholar Develops a Sensitive Diagnostic Approach to Detect Oncogenic Kinases in Minute Cancer Biopsies.** Protein and lipid kinases are enzymes that play a crucial role in signaling processes within our bodies, affecting various biological functions. In many cancers, changes in genes that code for these kinases lead to abnormal kinase activity, which can drive the development and progression of the disease. Targeting these malfunctioning kinases with specific treatments has been an effective strategy for several types of cancer. For instance, in breast cancer therapy, accurately identifying and measuring the ERBB2 protein kinase is essential for deciding on the best treatment.

  The standard method for diagnosing such conditions in a clinical setting is through Immunohistochemistry (IHC). The IHC method is semi-quantitative and has low throughput, meaning it can only assess a few proteins at a time. In contrast, mass spectrometry-based proteomics offers a more quantitative approach, allowing for the assessment of hundreds of kinases accurately and simultaneously.

  A breakthrough reported in the January 16 issue of *Clinical Proteomics* comes from researchers at Baylor College of Medicine and the Dan L. Duncan Comprehensive Cancer Center, led by CPRIT Scholar Dr. Matthew J. Ellis. They have developed a kinase inhibitor pulldown assay (KiP) that can enrich and quantify small amounts of kinases present in biopsy samples. KiP uses multiple kinase inhibitors as a capture matrix to pull down and profile the human protein kinome, which is the full set of kinases in a cell or tissue. When combined with sensitive mass-spectrometry techniques, it provides a more precise analysis.

  Initially, the researchers tested the KiP method on patient-derived xenograft models (PDX), identifying various differentially expressed and biologically relevant kinases. From these tests, the research team developed an optimized method called single-shot parallel reaction

monitoring (PRM) for better quantitative accuracy. They then applied this method to small protein samples typical of those obtained from core needle biopsies of human cancers. The initial prototype targeted 100 kinases and successfully replicated results from comprehensive proteomic and transcriptomic profiling done on patient derived PDX models.

When applied to patient biopsies of two subtypes of breast cancer (Luminal and HER2), the KiP-PRM method correctly categorized the cancers by subtype. The researchers also developed the necessary stable, labeled peptide standards and protocols for clinicians to use this method as a clinical diagnostic technology. This new protein mass spectrometry method has significant potential for improving scientists' understanding of each cancer's unique druggable landscape. This will lead to better research and, ultimately, clinical care. Additionally, this approach to identifying key kinases in cancer will be valuable in finding other therapeutically relevant targets in cancer treatment.

Baylor College of Medicine brought Dr. Ellis to Texas from Washington University in 2014 with a $6 million CPRIT Recruitment of an Established Investigator Award (RR140033). Three CPRIT Core Facility awards (RP120092, RP170005, RP210227) totaling $15 million to the Baylor College of Medicine Mass Spectrometry Proteomics Core made the mass spectrometry studies possible.

- **Novel CAR NK-Cell Therapy May Offer Benefit in Patients with B Cell Malignancies.** Cellular immunotherapy using a patient's own engineered chimeric antigen receptor (CAR) T cells, particularly those targeting the CD19 antigen, has shown impressive results in treating B cell malignancies. However, this approach has limitations, including high costs, long production times, and potential severe side effects like cytokine release syndrome and neurotoxicity. Clinicians must administer these treatments in specialized centers because of the potential side effects, further limiting access to this potentially life-saving therapy. As a result, there is a growing interest in developing more accessible, cost-effective, potent and safe "off-the-shelf" cell therapies.

  Dr. Katy Rezvani and her team at The University of Texas MD Anderson Cancer Center conducted a Phase I/II trial in 37 patients with relapsed or refractory B-cell malignancies using CAR natural killer (NK) T cells derived from umbilical cord blood, modified to target CD19. Published January 17 in *Nature Medicine*, their findings showed encouraging results: 48.6% of patients responded to the treatment within 100 days, and the one-year progression-free survival and overall survival rates were 32% and 68%, respectively. Notably, there were no severe cases of cytokine release syndrome, neurotoxicity, or graft-versus-host disease.

  An important discovery in this trial was the impact of donor selection criteria for the cord blood used in manufacturing CAR NK cells. Units of cord blood preserved within 24 hours of collection and those with low nucleated red blood cell content led to significantly better outcomes. Cells from these units resulted in a one-year progression free survival rate of 69% and an overall survival rate of 94%, a stark contrast to lower rates from units with higher nucleated red blood cell content or longer times to cryopreservation.

The trial also highlighted promising response rates in patients with different types of B-cell malignancies. For instance, 100% of patients with low-grade non-Hodgkin lymphoma responded to the treatment at 30 days post-treatment, compared to 67% of those with chronic lymphocytic leukemia and 41% of those with diffuse large B cell lymphoma. These patients were more likely to experience progression-free survival after one year.

A significant advantage of CAR NK cells is their potential for mass production and storage, making them readily available for immediate use. This means cells from a single donor could treat hundreds of patients, potentially increasing access to therapy, reducing treatment time, and lowering costs. MD Anderson is already applying the study's identified donor selection criteria in ongoing and future trials with engineered cord blood NK cells. These trials are expanding to target other antigens and malignancies, including solid tumors, using engineered cord blood NK cells.

MD Anderson received a $1.2 million CPRIT Individual Investigator Research Award for Clinical Translation (RP180466) in 2018 that supported this work.

- **Practice-changing study may significantly reduce the incidence of HPV-associated cancers.** The Human Papilloma Virus (HPV) is a significant health concern because it is closely linked to several types of cancer, including almost all cases of cervical cancer and most cases of anal, vaginal, oropharyngeal, and penile cancers. Although there are safe and effective vaccines that prevent infection by the most cancer-causing strains of HPV, U.S., vaccination rates are low - with only 34% of adolescents aged 13-17 fully vaccinated. At least 80% of the population must receive vaccinations to halt the spread of the most dangerous HPV strains.

  One of the challenges in increasing vaccination rates is the requirement for multiple doses. Scientists currently recommend that adolescents who start the vaccine series before turning 15 receive two doses, while those who start at 15 or older need three doses. This difference is due to the lack of clinical trial data on the effectiveness of the 2-dose schedule in the older age group.

  To address this gap, Abbey Berensen, M.D., Ph.D., professor of obstetrics and gynecology and director of the Center for Research in Women's Health at The University of Texas Medical Branch, designed and conducted a randomized clinical trial on the effectiveness of two doses of the vaccine in individuals aged 15-26. The study involved randomly assigning 860 participants to either a two-dose or a three-dose vaccine schedule. The main goal was to see if participants developed HPV antibodies after the final vaccine dose, a sign that the vaccine is working.

  Due to the importance of the results on clinical practice, the January 23 issue of *NEJM Evidence* reported an interim analysis of the results in female participants in the ongoing study. The results showed that one month after the final dose, both groups had almost the same success rate in developing these antibodies – 100% in the two-dose group and 99% in the three-dose group, with no serious side effects. If the study's final results (antibodies

present six months following the last vaccine dose) corroborate the early findings that two doses of the vaccine are as effective as three doses in older adolescents and young adults, then this practice-changing study may have great impact on the HPV vaccine uptake. Reducing the number of required doses makes it easier and more cost-effective for people to get vaccinated, which in turn may greatly reduce the number of HPV-related cancers.

CPRIT awarded UTMB and Dr. Berenson two CPRIT Individual Investigator Research Awards in Prevention (RP190022, RP220011) totaling $3.5 million that supported this work and extended these studies to evaluate the efficacy of 2-doses vs. 3-doses of the HPV vaccine in young adult females. Dr. Berenson is the Principal Investigator of multiple awards totaling more than $20.5 million through the CPRIT Prevention Program (PP120150, PP150004, PP160010, PP160058, PP180012, PP200005, PP200048, PP200057, and PP210020) that deliver cancer prevention services to rural and underserved populations.

CPRIT's 2023 Annual Report

CPRIT released its annual report for fiscal year 2023 on January 31. The report, which CPRIT makes available exclusively online at https://2023annualreport.cprit.texas.gov/, highlights the progress CPRIT and our grantees have made towards the agency's three-part mission to invest in the cancer research prowess of Texas' academic institutions, to create and grow the state's life science infrastructure, and to identify and fund innovation in the prevention, identification, treatment and cures for cancer.

State law mandates that CPRIT must submit an annual report to the governor and the Texas legislature by January 31 of each year. CPRIT's statute specifies several required components for the report, including the grants approved for the year, a summary of research findings, an assessment of CPRIT's grants and the overall strategy of the research program, an estimate of how much cancer has cost the state, the agency's compliance activities, and information related to reviewers' conflicts of interest requiring recusal. In addition to these components, CPRIT incorporates grantee highlights and program features that illustrate the connection between the grants that CPRIT funds and the advancements made in Texas' fight against cancer.

While the report is a team effort across the entire agency, CPRIT's Communications Director Mark Loeffler, Digital Communications Specialist Justin Rand, technical writer Bridget Barstow, Information Resource Manager Shannon Cusick, and IT designer Royce Hart deserve special credit for the enormous amount of work necessary to put together the 2023 report. I also appreciate Deputy Executive Officer and General Counsel Kristen Doyle's work with the annual report team and for her role in helping to conceptualize the highlights and features.

Personnel

CPRIT has filled 45 full-time equivalent positions and has several positions in progress, including an accountant position and grant compliance specialist positions.

CPRIT Outreach

Staff outreach activities during January include:

- On January 8 and January 18, Deputy Executive Officer and General Counsel Kristen Doyle and I met with representatives of the Texas Advanced Nuclear Reactor Working Group (TANWG). Governor Abbott directed the Public Utility Commission to establish TANWG to study and plan for the use of advanced nuclear reactors in Texas. One idea the working group is discussing is a grant program to distribute funds potentially available in future legislative sessions. At their request, we met with TANWG representatives to discuss grant making best practices and how to model CPRIT's grant making process. I expect the discussions to continue in the months ahead.

- Product Development Program Manager Dr. Michelle Leeuwon virtually attended the Redefining Early Stage Investments (RESI) JPM conference January 9-10, and met with several companies to discuss CPRIT funding opportunities and to identify collaboration prospects. Companies included Remmie Health (a NIH SEED and Techstars UnitedHealthcare portfolio company building AI-powered diagnosis for ear-nose-throat conditions); Frezent (a therapeutics company using bispecific antibodies to block the metabolism in dormant cancer cells); Kortuc (a Japan-based company using radiosensitizers for enhancement of radiotherapy and immunotherapy); Profound Ventures (a California-based fund starting companies out of The University of Texas at Arlington that focuses on molecular diagnostic testing and clinical monitoring and outcomes); iSono Health (a med-tech using AI-enabled, FDA-cleared 3D ultrasound technology for breast cancer); OncoRx Insights (a company providing AI-driven digital health solutions); and FlexPerc (a consulting firm addressing the needs for multi-disciplinary treatment approach for cancer patients).

- Senior Product Development Program Manager Dr. Abria Magee spoke at the welcome event held January 22 for the 2024 Texas Medical Center Innovation (TMCi) Accelerator for Cancer Therapeutics (ACT) cohort. She provided an overview of CPRIT and a detailed presentation of the Product Development Research program. Funded by a $5.4 million CPRIT core facility grant (RP190674) awarded in 2019, the ACT program is a collaboration between the TMCi and the Gulf Coast Consortia. The program provides training, resources and mentoring to Texas inventors and startups looking to bring novel cancer therapies from early drug discovery to commercialization.

- Academic Research Program Manager Dr. Myriam Casillas attended the January 23 webinar "Understanding and Optimizing Social Support Across the Cancer Care Continuum." The webinar is part of the NCI Office of Cancer Survivorship Director's Series.

- Chief Operating Officer Heidi McConnell, Ms. Doyle, and I met on January 24 with cancer research advocates to discuss the 89th Texas Legislature that convenes in January 2025.

- Director for Research Dr. Patty Moore virtually attended the "Breaking Boundaries: AI's Role in Advancing Science and Innovation" event held January 25 at the Texas Tech University Innovation Hub. BioNTX sponsored the event.

- Dr. Casillas virtually attended the Cancer Moonshot Seminar Series on January 25.

- In January Dr. Magee met with several companies to discuss CPRIT funding opportunities and to identify collaboration prospects. Companies included IA Global Ventures (a venture capital group and accelerator focused on supporting foreign-born founders to flourish in the United States); PDX Pharma (a biopharmaceutical company using nano- technology and cancer systems biology to develop immunotherapies for cancer); and MyAI (a tech startup developing a multi-category platform to help users obtain service from human agents.)

- CPRIT joined the American Cancer Society (ACS) National Breast Cancer Round Table in January. As a member of the roundtable, CPRIT will work with other members to share information, identify needs and opportunities, and address gaps in research, programs, activities, and services relating to breast cancer care and control. Chief Prevention Officer Ramona Magid and Prevention Program Manager Carlton Allen are CPRIT's representatives. ACS has also asked Mr. Allen to serve on the ACS Area Board for Louisiana and East Texas. As part of the board, Mr. Allen will work with other members to develop and implement strategies to help ACS deliver priority programs.

- The University of Texas at Tyler named Mr. Allen as one of its inaugural "40 Under 40" alumni award recipients. UT Tyler will recognize the achievements of the 40 outstanding young alumni leaders at its 2024 Homecoming on March 22.

- Dr. Leeuwon co-authored the chapter "Proprietary strategies in precision medicine" in the recently published reference book *Comprehensive Precision Medicine*. CPRIT grantee Kenneth S. Ramos, director, Texas A&M Regional Center of Excellence in Cancer, served as editor-in-chief.

Compliance Program Update

Submission Status of Required Grant Recipient Reports

As of January 23, 20 entities had not filed 93 academic research reports, four product development reports, and three prevention reports. CPRIT's grant accountants and compliance specialists review and process incoming reports and reach out to grantees to resolve filing issues. In most cases, CPRIT does not disburse grant funds until the grantee files the required reports. In some instances, grantee institutions may be ineligible to receive a future award if the grantee does not submit required reports.

Financial Status Report Reviews

CPRIT's compliance specialists performed 119 second-level reviews of grantee Financial Status Reports (FSRs) in January. Thirteen FSRs (11%) needed resubmission due to insufficient or inaccurate documentation sent by the grantee. CPRIT's grant accounting staff completes the first review of the FSRs and supporting documentation before routing them to the compliance specialists for final review and disposition.

Desk Reviews

Compliance specialists performed three enhanced desk-based financial monitoring reviews in January. 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 have cleared all desk review findings.

Onsite Reviews

CPRIT completed four onsite reviews in January. 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 grantees' capability, performance, and compliance with applicable laws, rules, and policies. Compliance specialists are collaborating with three grantees to address 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, one grantee has not 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. Compliance staff is working with the grantee.

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. This opportunity to self-report, in the form of a checklist, provides a baseline of grantee compliance and allows compliance specialists to proactively work with grantees towards full compliance prior to a desk review or onsite review. All grantees have submitted their annual compliance 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. Compliance specialists are collaborating with product development grantees to review documentation.

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 January. The total amount of match expenses reviewed by compliance staff for FY 2024 is $15,235,972.21. The unallowable match expenses for FY 2024 total $221,364.79.

Training and Support

CPRIT staff conducted two new Authorized Signing Official (ASO) training webinars in January for Asylia Therapeutics and Stellanova Therapeutics. The ASO 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 ASOs to complete compliance training within 60 days.

Academic Research Program Update

Recruitment FY 2024 Review Cycle 3 - 5

CPRIT accepted recruitment applications June 21 - November 20, 2023, for the third, fourth and fifth review cycles of FY 2024. CPRIT's Scientific Review Council (SRC) reviewed the applications on November 16, 2023, and December 14, 2023. Dr. Le Beau will present the SRC's recommendations to the Program Integration Committee (PIC) and the Oversight Committee in February.

FY 24 Mechanism	Received	Requested	Recommended	Recommended
Recruitment of Established Investigators	3	$18,000,000	2	$12,000,000
Recruitment of First-Time, Tenure Track Faculty Members	4	$ 8,000,000	3	$6,000,000
Recruitment of Rising Stars	6	$22,000,000	3	$12,000,000
TOTAL	**13**	**$48,000,000**	**8**	**$30,000,000**

Academic Research FY 2024 Review Cycle 1 (24.1)

CPRIT posted five Individual Investigator RFAs for the first review cycle of FY 2024 on February 17, 2023, accepting applications March 15 - June 14, 2023. Peer reviewers met in October to evaluate the 315 applications. Dr. Le Beau will present the SRC's recommendations for the cycle 24.1 grants to the PIC and the Oversight Committee in February.

FY 24 Cycle 1 Mechanism	Received	Funds Requested
Individual Investigator Research Award (IIRA)	228	$233,894,288
IIRA for Computational Systems Biology of Cancer	18	$36,108,737
IIRA for Cancer in Children and Adolescents	35	$47,815,216
IIRA for Prevention and Early Detection	15	$27,050,403
IIRA for Clinical Translation	19	$19,850,946
TOTAL	**315**	**$364,719,590**

Academic Research FY 2024 Review Cycle 2 (24.2)

On September 14, 2023, CPRIT released several RFAs for the second cycle of FY 2024 and accepted applications October 17, 2023 – January 16, 2024. Peer review panels will meet in late April 2024 to consider the applications. Dr. Le Beau will present the SRC's recommendations to the PIC and the Oversight Committee in August.

FY 24 Cycle 2 Mechanism	Received	Funds Requested
Clinical Investigator Award	6	$6,624,889
Core Facility Support Awards	22	$58,593,485
High-Impact/High-Risk Research Awards	101	$25,065,092
Multi-Investigator Research Awards	18	$77,774,808
TOTAL	**147**	**$168,058,274**

Product Development Research Program Update

Product Development FY 2024 Cycle 2 Review (24.2)

CPRIT released four FY 2024 Product Development Research RFAs for the 24.2 review cycle on November 29, 2023, and opened the portal to receive preliminary applications December 1, 2023. CPRIT received 63 preliminary applications by the December 11, 2023, deadline. After administratively withdrawing three applications for non-compliance, CPRIT assigned the 60 preliminary applications to eight review panels on December 15, 2023. Because of the smaller overall award budget ($20 million) remaining for the 24.2 cycle, CPRIT capped the maximum amount a non-Seed company may request at $5 million. The regular $3 million budget cap for Seed awards remains the same in this cycle.

The reviewers individually evaluated and scored the assigned preliminary applications and then met as a panel January 18 – 22 to rank the preliminary applications. The Product Development Review Council (PDRC) met January 23 to finalize a comprehensive ranked list of preliminary applications.

On January 24 CPRIT issued invitations to submit full applications to the eleven companies receiving the best preliminary application scores in the 24.2 cycle. In addition to the companies submitting preliminary applications in the 24.2 cycle, seven companies were eligible to submit full applications based on their performance in the 24.1 preliminary application review cycle. Five of those seven companies indicated their intention to submit full applications in the 24.2 cycle where they will be bound by the $5 million budget cap per application.

24.2 Mechanism	Prelim Apps	Total Requested	Invited for Full Apps*	Total Requested
Texas Therapeutic Company (TTC)	17	$84.1 M	5	$25.0 M
Texas Device/ Diagnostic Company	2	$10.0 M	0	--
Texas New Tech Company (TNTC)	10	$47.8 M	2	$ 9.9M
Seed Company	31	$88.1 M	9	$27.0 M
TOTAL	**60**	**$230.0 M**	**16**	**$61.9 M**

* This number includes the five applicants (two TTC, one TNTC, and two Seed Companies) who received invitations to submit full applications during the 24.1 review cycle.

All 16 invited companies must submit their full applications by February 13. Live presentations to the full review panel will occur March 18 – March 27. Following due diligence, the PDRC will submit its final recommendations to the PIC. Dr. Smith will present the PDRC's recommendations to the PIC and the Oversight Committee in May.

Prevention Program Update

Prevention FY 2024 Review Cycle 1 (24.1)

The Prevention Program released two prevention RFAs on May 5, 2023, for the 24.1 review cycle. CPRIT received 29 proposals totaling $46.7 million by the August 30, 2023, deadline. Peer review took place December 5 – 6. The Prevention Review Council (PRC) met January 12 to make final recommendations. Chief Prevention Officer Ramona Magid will present the PRC's recommendations to the PIC and the Oversight Committee in February.

Cycle 24.1 Mechanism	Applications	Funds Requested
Primary Prevention of Cancer	13	$19,384,419
Cancer Screening and Early Detection	16	$27,272,619
TOTAL	**29**	**$46,657,038**

Advisory Committees

- The Clinical Trials Advisory Committee working group met January 10.
- The Product Development Advisory Committee met January 11.
- The Geographic Diversity Advisory Committee met January 12.
- The Prevention Advisory Committee met January 16 and January 23 to provide input for the Texas Cancer Plan.
- The Advisory Committee on Childhood Cancer met January 22.

Operations and Finance Update

CPRIT posted a request for proposal (RFP) for an audit firm to conduct the statutorily required annual audit of CPRIT's financial statements. The initial year of the new contract will be FY 2025.

Upcoming Subcommittee Meetings

Listed below are the subcommittee meetings in advance of the February 21 Oversight Committee meeting. We will send instructions for signing onto the Microsoft Teams platform along with the subcommittee agenda and meeting materials one week prior to each meeting.

Board Governance	February 8 at 10:00 a.m.
Audit	February 12 at 10:00 a.m.
Prevention	February 13 at 12:00 p.m.
Academic Research	February 14 at 12:00 p.m.
Product Development	February 15 at 10:00 a.m.

******

CPRIT has awarded **1,909** grants totaling **$3.44 billion:**

- 291 prevention awards totaling $354.8 million
- 1,618 academic research and product development research awards totaling $3.09 billion

Of the $3.09 billion in academic research and product development research awards,

- 32.6% of the funding ($1.01 billion) supports clinical research projects
- 23.4% of the funding ($722.4 million) supports translational research projects
- 29.1% of funding ($897.4 million) supports recruitment awards
- 12.0% of the funding ($370.1 million) supports discovery stage research projects
- 2.9% of funding ($90.4 million) supports training programs.

CPRIT has three open Requests for Applications (RFAs)

- 3 Academic Research Recruitment

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	VINCE BURGESS, CHIEF COMPLIANCE OFFICER
SUBJECT:	COMPLIANCE PROGRAM UPDATE
DATE:	FEBRUARY 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 February 1, 15 entities had not filed 68 academic research reports, one product development report, and one prevention 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 519 second-level reviews of grantee Financial Status Reports (FSRs) in November, December, and January. Seventy-five FSRs (14%) 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 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, one grantee has not 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. Compliance staff is working with the grantee.

Desk Reviews

CPRIT staff performed eight enhanced desk-based financial monitoring reviews in November, December, and January. 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 have cleared all desk review findings.

Onsite Reviews

CPRIT completed 10 onsite reviews in November, December, and January. Onsite reviews are the most extensive monitoring activity conducted by CPRIT and include virtual or field visits led by compliance grant monitoring staff. The grantee's financial and administrative operations, subcontract monitoring, procurement and contracting procedures, inventory procedures, personnel policies and procedures, payroll and timesheet policies, travel policies and records, and compliance with single audits are all monitored during onsite reviews. Onsite monitoring enables CPRIT compliance staff to assess a grantees' capability, performance, and compliance with applicable laws, rules, and policies. Compliance specialists are collaborating with one grantee to address onsite review findings.

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. This opportunity to self-report, in the form of a checklist, provides a baseline of grantee compliance and allows compliance specialists to proactively work with grantees towards full compliance prior to a desk review or onsite review.

All grantees have submitted their annual compliance 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. Compliance specialists are collaborating with product development grantees to review documentation.

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 five annual match expenditure reviews in November, December, and January. The total amount of match expenses reviewed by compliance staff for FY 2024 is $16,664,839.23. The unallowable match expenses for FY 2024 total $221,364.79.

Training and Support

CPRIT staff conducted six new Authorized Signing Official (ASO) training webinars in November, December, and January for The University of Texas Health Science Center at Tyler, The University of Texas at Austin, Baylor Research Institute, Pulmotect, Asylia Therapeutics, and Stellanova Therapeutics. The ASO training covered grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. Pursuant to Texas Administrative Code §703.22, CPRIT requires new ASOs to complete compliance training within 60 days.

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:	FEBRUARY 21, 2024

ACTION ITEM: Proposed Academic Research Fiscal Year 2025 Cycle 1 (FY25.1) 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.

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 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 the 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

FY2024 Cycle 1 RFAs

The following FY24.1 RFAs were posted on February 17, 2023. CPRITs Application Receipt System (CARS) opened for applications on March 15, 2023, and closed on June 14, 2023. Virtual Peer Review was conducted in October 2023. Dr. Le Beau will present the Scientific Review Council's recommendations to the PIC and the Oversight Committee in February 2024.

- **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. Competitive renewal applications accepted.
Award: Up to $350,000 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 $400,000 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. Competitive renewal applications accepted.
  Award: Up to $350,000 per year. Applicants who plan on conducting a clinical trial as part of the project may request up to $500,000 in total costs. 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 $400,000 per year. Exceptions permitted if extremely well justified; maximum duration: 5 years.

- **Individual Investigator Research Awards for Clinical Translation (IIRACT)**
  Supports applications that propose innovative cancer clinical studies 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 contract is awarded.
Award: Up to $500,000 per year. Maximum duration: 4 years. Exceptions permitted if extremely well justified.

Table 1: Application Submission data for FY2024 Cycle 1

Mechanism	Submitted	Total Funding Requested	Recommended Awards	Funding
Individual Investigator Research Award (IIRA)	228	$233,894,288	27	$28,250,155
Individual Investigator Research Awards for Computational Systems Biology of Cancer (IIRACSBC)	18	$36,108,737	3	$3,599,999
Individual Investigator Research Awards for Cancer in Children and Adolescents (IIRACCA)	35	$47,815,216	5	$6,998,170
Individual Investigator Research Awards for Prevention and Early Detection (IIRAP)	15	$27,050,403	1	$1,920,007
Individual Investigator Research Awards for Clinical Translation (IIRACT)	19	$19,850,946	3	$5,921,344
Total	**315**	**$364,719,590**	**39**	**$46,689,675**

FY2024 Cycle 2 RFAs

The following FY24.1 RFAs were posted on September 14, 2023. CPRITs Application Receipt System (CARS) opened for applications on October 17, 2023, and closed on January 16, 2024. Virtual Peer Review will be conducted in late April 2024. Dr. Le Beau will present the Scientific Review Council's recommendations to PIC and the Oversight Committee in August 2024.

Core Facility Support Awards (R-24.2 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-24.2 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.

Multi-Investigator Research Awards (R-24.2 MIRA)

Supports highly integrated programs of collaborative and cross-disciplinary research among multiple Texas investigators and Institutions. Applications responding to this RFA that address one of the program priorities for academic research adopted by CPRIT's Oversight Committee are particularly encouraged.
Award: $4,500,000 in total costs for a maximum period of 4 years.

Clinical Investigator Award (R-24.2 CIA)

Supports mid-career clinician scientists with specialty training relevant to delivery of cancer care to devote more time to augment their capabilities in clinical cancer research, and to provide mentoring to early-stage investigators in the conduct of clinical research. The CIA will provide protected time from clinical responsibilities to provide physicians with the opportunity to expand clinical research skills, to develop investigator-initiated clinical trials, to develop external relations with industry and pharmaceutical company partners, and to expand partnerships with laboratory-based collaborators to design and conduct correlative studies needed to interpret the outcome of an interventional trial. The CIA initiative will increase the pool of clinical investigators at Texas academic institutions who are conducting patient-oriented studies, who will be able to compete successfully for peer-reviewed grants, and who will mentor the next generation of clinical investigators.
Award: $1,500,000 in total costs for a maximum period of 5 years.

Table 2: Application Submission data for FY2024 Cycle 2

Mechanism	Submitted	Total Funding Requested
Clinical Investigator Award	6	$6,624,889
Core Facility Support Awards	22	$58,593,485
High-Impact/High-Risk Research Awards	101	$25,065,092
Multi-Investigator Research Awards	18	$77,774,808
Total	**147**	**$168,058,274**

FY2024 Recruitment Update

Table 3 displays an overview of the status of CPRIT recruitment applications received for the third, fourth and fifth cycles of FY2024. CPRIT's Application Receipt System (CARS) opened for applications on June 21, 2023, and closed on November 20, 2023. The Scientific Review Council reviewed these applications on November 16, 2023, and December 14, 2023, and recommended applications will be presented to the Oversight Committee in February 2024.

FY2024

Table 3: Recruitment Application Submission data for Cycle 24.3, 24.4, 24.5

Mechanism	Number Received	Funds Requested	# SRC Recommended	SRC Recommended Funds
Recruitment of Established Investigators	3	$18,000,000	2	$12,000,000
Recruitment of First-Time, Tenure-Track Faculty Members	4	$8,000,000	3	$6,000,000
Recruitment of Rising Stars	6	$22,000,000	2	$8,000,000
TOTAL	**13**	**$48,000,000**	**7**	**$26,000,000**

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: RAMONA MAGID, CHIEF PREVENTION OFFICER

SUBJECT: PREVENTION PROGRAM UPDATE

DATE: FEBRUARY 21, 2024

Prevention FY 2024 Review Cycle 1 (24.1)

The Prevention Program released two RFAs, *Primary Prevention of Cancer and Cancer Screening and Early Detection*, on May 5, 2023, for the first cycle of FY 2024. CPRIT received 29 proposals totaling $46,657,038 by the August 30 deadline. Three applications were administratively withdrawn. Peer review took place on December 5-6, 2023, and the Prevention Review Council (PRC) met on January 12, 2024, 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 February 2024.

Mechanism	Apps Received	Funds Requested
Cancer Screening and Early Detection	16	$27,272,619
Primary Prevention of Cancer	13	$19,384,419
TOTAL	**29**	**$46,657,038**

Prevention FY 2025 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. CPRIT has scheduled peer review for August through October. Ms. Magid will present the Prevention Review Council's recommendations to the PIC and the Oversight Committee in November 2024.

Other Activities

- The Prevention Advisory Committee met on January 16 and January 23 to provide input for the Texas Cancer Plan.

- The Cancer Prevention and Research Institute of Texas has become a member of the American Cancer Society (ACS) National Breast Cancer Round Table (NBCRT). As a member of this roundtable, CPRIT will work together with other members to drive action sharing information, identifying needs and opportunities, and addressing gaps in research, programs, activities, and services relating to breast cancer care and control. Mr. Allen and Ms. Magid are the 2 representatives from CPRIT. https://nbcrt.org/
- Mr. Allen will serve on the Louisiana & East Texas - American Cancer Society Area Board. Board members develop and implement strategies to help deliver priority programs, elevate the ACS brand in LA & East Texas, help position the ACS as the leader in the fight against cancer, generate revenue and leverage relationships, and serve as the official ACS spokesperson within their respective communities.
- Mr. Carlton Allen, Program Manager for Prevention, has been recognized as one of the inaugural UT Tyler 40 Under 40 Alumni Awards recipients. This initiative celebrates and acknowledges the achievements of 40 outstanding young alumni leaders from The University of Texas Tyler. https://www.uttyler.edu/40-under-40-2024/finalists/

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: KEN SMITH, PH.D., CHIEF PRODUCT DEVELOPMENT OFFICER
SUBJECT: PRODUCT DEVELOPMENT PROGRAM UPDATE
DATE: FEBRUARY 21, 2024

Product Development Review FY 2024 Cycle 2 (24.2)

On November 29, 2023, CPRIT released four FY 2024 Product Development RFAs. Due to the limited award budget for cycle 24.2 (~$20 million), CPRIT instituted a $5 million budget cap for all non-Seed company awards. Seed company budgets remain capped at $3 million.

The portal for preliminary applications opened December 1, 2023. CPRIT received 63 preliminary applications requesting $240,414,212 by the December 11, 2023, deadline. More than a third of the applications (23) were submitted by companies currently located outside of Texas. CPRIT administratively withdrew three applications for non-compliance and assigned the remaining 60 applications to eight panels. Following individual peer review, each panel met to rank order their assigned applications. The Product Development Review Council (PDRC) met January 23 and considered the two highest ranking applications from each panel, ultimately recommending 11 companies to receive invitations to receive full applications. Prior to the PDRC meeting, five companies that received invitations to submit a full application following the FY 2024 Cycle 1 preliminary review notified CPRIT that they intended to submit full applications in the 24.2 review cycle.

CPRIT directed the 16 companies to submit full applications by the February 13 deadline. Fourteen companies submitted applications by the deadline, requesting $53,877,125. Four applicants are currently located out of state (Maryland, Massachusetts, Missouri, and Virginia). The companies will present their full applications to review panels March 18 - March 27. Following due diligence review, I will present the PDRC's award recommendations to the PIC and the Oversight Committee at the May meeting.

24.2 Grant Mechanisms	Prelim Apps	Prelim Apps $ Request	24.2 Invited Apps	24.2 Full Review*	Full App $ Request
Texas Therapeutic Company	19	$92,098,500	3	4	$19,999,618
Texas Device & Diagnostic Co.	3	$12,455,000	0	0	N/A
Texas New Technologies Company	10	$47,844,796	1	2	$9,940,969
Seed Company	31	$88,015,916	7	8	$23,936,538
TOTAL	**63**	**$240,414,212**	**11**	**14**	**$53,877,125**

* These include four companies that received invitations to submit full applications during the 24.1 preliminary review cycle. All non-Seed companies must abide by the $5 million budget cap for 24.2.

CPRIT Resource Guide

The Product Development Research program released the *Texas Resource Guide* (texasresourceguide.org) in October 2023. Product Development program staff receive multiple requests to add new entries each week and works with the CPRIT communications team to issue regular updates.

CPRIT Intellectual Property Database

CPRIT has contracted with Wellspring for the use of their Sophia system as the service provider for IP reporting. This system is already in use by approximately half of the grantee institutions, facilitating the integration process. The auditing and migration of existing IP data to the Sophia system were completed in January 2024. Organization leaders for IP reporting have been identified and set up with accounts across all 16 grantee institutions. The development of the grantee submission portal is in its final stages, expected to be operational by the end of February 2024. This step marks progress in centralizing and streamlining the process for managing the intellectual property generated from CPRIT-funded research.

The implementation of the Sophia system and the upcoming launch of the grantee submission portal are geared towards improving the efficiency of IP data management and analysis within CPRIT-funded projects.

Product Development Advisory Committee (PDAC)

The PDAC met January 11 to discuss CPRIT's product development program, including the FY 2024 review cycles, the *Texas Resource Guide*, biotech funding, and the CPRIT company portfolio.

FY 2025 Requests for Applications

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

- Texas Therapeutic Company Award (TTC)
- Texas Device and Diagnostics Company Award (TDDC)
- Texas New Technologies Company Award (TNTC)
- Texas Seed Company Award (SEED)

The FY 2025 RFAs will be the same as the those released for the FY 2024 review cycles, with updated information as appropriate. We plan to release these RFAs in late April/early May and open the portal for preliminary applications. The first full application deadline will be sometime in June/July, with award announcements planned for the November 2024 Oversight Committee meeting.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	CAMERON ECKEL, ASSISTANT GENERAL COUNSEL
SUBJECT:	APPOINTMENTS TO THE SCIENTIFIC RESEARCH AND PREVENTION PROGRAMS COMMITTEE
DATE:	FEBRUARY 12, 2024

Summary and Recommendation

The Chief Executive Officer has appointed five experts to CPRIT's Scientific Research and Prevention Programs Committee. CPRIT's statute requires Oversight Committee approval for the appointments. At their February 8 meeting, the Board Governance subcommittee reviewed the appointees to the Product Development Research peer review panels and recommends approval by the Oversight Committee.

Discussion

Scientific Research and Prevention Programs committee members (also referred to as "peer reviewers") are responsible for reviewing grant applications and recommending grant awards for meritorious projects addressing cancer prevention and research, including product development research. Peer reviewers perform a significant role for the state; all CPRIT grant awards must first be recommended by a Scientific Research and Prevention Programs committee. Individuals appointed to serve as CPRIT's Scientific Research and Prevention Programs committee members must be exceptionally qualified, highly respected, well-established members of the cancer research, product development research, and prevention communities.

Texas Health and Safety Code Section 102.151(a) directs the Chief Executive Officer to appoint members to the Scientific Research and Prevention Programs committees. The CEO's appointments are final once approved by a simple majority of the Oversight Committee. The Board Governance Subcommittee charter assigns the subcommittee with the responsibility "to circulate to Oversight Committee members in advance of a public meeting written notification of the committee's intent to make the nomination, along with such information about the nominee as may be relevant."

The Board Governance Subcommittee reviewed the five appointees at its February 8 meeting and recommends their approval by the Oversight Committee.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Scientific Research and Prevention Programs Committees ("Peer Reviewer")
Appointments
February 2024

Appointments to Product Development Research Peer Review Panels			
Name	**Organization**	**Title**	**Expertise**
Jijun Dong, Ph.D.	Salubris Biotherapeutics	Chief Scientific Officer	Immune-oncology, oncology, biological drug development, antibody, recombinant proteins, re-engineered cytokines, antibody-cytokine fusion
Armin Ghobadi, M.D.	Washington University School of Medicine	Associate Professor, Clinical Director	Oncology, cellular therapy, Hematologic malignancies
Min Li, Ph.D.	The University of Oklahoma Health Sciences Center	George Lynn Cross Professor of Medicine, Vice Chairman for Research, Assistant Dean for International Research Collaboration	Pancreatic cancer, immunotherapy, biomarkers, image-guided surgery
Tiao Xie, Ph.D.	Yokogawa	Regional Sales Manager, consultant	Imaging, high-throughput screening, data analysis
Yuqing Zhang, Ph.D.	The University of Oklahoma Health Sciences Center	Associate Professor	Cancer pathogenesis, pancreatic cancer, drug resistance in malignant cancers

Professor Richard Gorlick, M.D.

Dr. Richard Gorlick, M.D. is a professor, Division Head, and the H. Grant Taylor, M.D., W.W. Sutow, M.D., and Margaret P. Sullivan, M.D. Distinguished Chair of the Division of Pediatrics at the University of Texas MD Anderson Cancer Center Children's Cancer Hospital in Houston, TX. He also serves as *interim* Chair of Sarcoma Medical Oncology at the University of Texas MD Anderson Cancer Center.

Prior to moving to MD Anderson, Dr. Gorlick previously served as the Division Chief of Pediatric Hematology Oncology and the Vice Chairman of Pediatrics at The Children's Hospital at Montefiore, and Professor of Pediatrics and Molecular Pharmacology at The Albert Einstein College of Medicine. He earned his medical degree from State University of New York Downstate Medical Center. He completed his residency at Columbia Presbyterian Medical Center (now New York-Presbyterian Hospital). and his fellowship in pediatric hematology and oncology at Memorial Sloan Kettering Cancer Center.

For over twenty years, Dr. Gorlick has focused his research and clinical efforts on sarcomas, a type of malignant tumor. He currently serves as the director of the Pediatric Sarcoma Research Laboratory at MD Anderson Cancer Center where his lab focuses on targeted therapies for childhood cancers and understanding the mechanisms behind the development and progression of bone cancer (osteosarcoma).

A well-respected subject matter expert in the field of pediatric oncology, Dr. Gorlick has published over 325 peer-reviewed papers, reviews, and book chapters. He is an active member, advisor, and leader in several organizations, including the National Cancer Institute's Pediatric Preclinical Testing Consortium, now the Pediatric Preclinical in Vivo Testing (PIVOT) Program, the Sarcoma Alliance for Research through the Collaboration Consortium, and the Children's Oncology Group (COG). Dr. Gorlick has held several roles within COG, including past chairman of the Bone Tumour Disease Committee. His early involvement in COG led to his laboratory establishing a bone tumor bank, which is now considered a national resource and home to the world's largest osteosarcoma tissue bank.

Donald (Will) Parsons, MD, PhD

Texas Children's Cancer and Hematology Center
Baylor College of Medicine, Houston, Texas

Dr. Will Parsons MD, PhD, is a board-certified pediatric oncologist, Professor of Pediatrics at Baylor College of Medicine, and the Deputy Director of Texas Children's Cancer and Hematology Center. Dr. Parsons' work has been instrumental in characterizing the genetic landscapes of a variety of pediatric and adult cancers, including the first identification of IDH1 and IDH2 as critical oncogenes in gliomas. His current research primarily focuses on the clinical application of genomic technologies in pediatric cancer care. Dr. Parsons has a particular interest in the development and evaluation of molecularly targeted therapies and has a number of leadership roles in this area including serving as the Children's Oncology Group (COG) study chair for the NCI-COG Pediatric MATCH trial (the first nationwide precision oncology trial for children with relapsed and refractory solid tumors, lymphomas, and histiocytoses) and as a Steering Committee member for the NIH Pediatric Early Phase Clinical Trials Network. Dr. Parsons received his B.A. in chemistry from Princeton University and his M.D. and Ph.D. degrees from The Ohio State University College of Medicine. He completed his pediatric residency at Johns Hopkins University and his oncology/neuro-oncology fellowship training at Johns Hopkins and the Pediatric Oncology Branch of the National Cancer Institute. Dr. Parsons currently serves as Vice Chair for the Advisory Committee on Childhood Cancers.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

Advisory Committee on Childhood Cancer

Committee Annual Report

February 21, 2024

Presented By:

Richard Gorlick, M.D.

Chair, ACCC

Division Head and Department Chair, Pediatrics, The University of Texas MD Anderson Cancer Center Children's Cancer Hospital

H. Grant Taylor, M.D., W.W. Sutow, M.D., and Margaret P. Sullivan, M.D. Distinguished Chair in Pediatrics

Department Chair *ad interim*, Sarcoma Medical Oncology, Division of Cancer Medicine

Donald (Will) Parsons, M.D., Ph.D.,

Vice-Chair, ACCC

Professor, Pediatrics – Baylor College of Medicine

Deputy Director, Texas Children's Cancer and Hematology Center

THE UNIVERSITY OF TEXAS MD Anderson Cancer Center Children's Cancer Hospital®

Texas Children's Hospital®

Presentation Outline

- **Childhood Cancer in Texas, the US: a review**
- **Summary of CPRIT Pediatric Achievements**
- **ACCC Ongoing Steps**
  - Membership/Researchers Roundup
- **ACCC Strategy**
  - Ongoing goals
  - Vision for future
- **Summary/Next Steps**

Statement of the problem: Childhood Cancer

Childhood Cancer

- In the US, **nearly 15,000 children ages 0-19 will be diagnosed with cancer** this year
  - About 1 in 285 children will develop cancer before the age of 20
  - 47 children are diagnosed with cancer every day

- As of 2023, **the FDA has approved only three drugs** specifically developed for pediatric patients
  - Compared to the 290 drugs developed for adults, **a clear gap exists**
  - Poor cure rates remain for patients with metastatic **sarcomas,** high risk **brain cancers, acute myeloid leukemia**

- **Childhood cancer survivors represent a growing population, with unique challenges**
  - Late effects of treatments present additional health risks and concerns.

Childhood Cancer: A Texas-sized problem?

- Texas has the **second highest cancer population** in the United States
- **Cancer is still the leading cause of disease-related death in Texas** past infancy among children* and adolescents**
- In Texas, the age-adjusted incidence rate for children*** hovers around 16.5 cases per 100,000 population
  - within the national average
- **In Texas, over 1,800 children under age 20** are diagnosed with cancer+
- Each year, **~ 7,800 Adolescents and Young Adult (AYA) are diagnosed with cancer in Texas**

*birth to 14 years ** 15-19 years old *** birth to 19 years

+Calculated as Texans diagnosed with childhood and adolescent cancer between 1995–2019 who were alive as of January 1, 2020).

Adolescent & Young Adult Cancer (AYA)

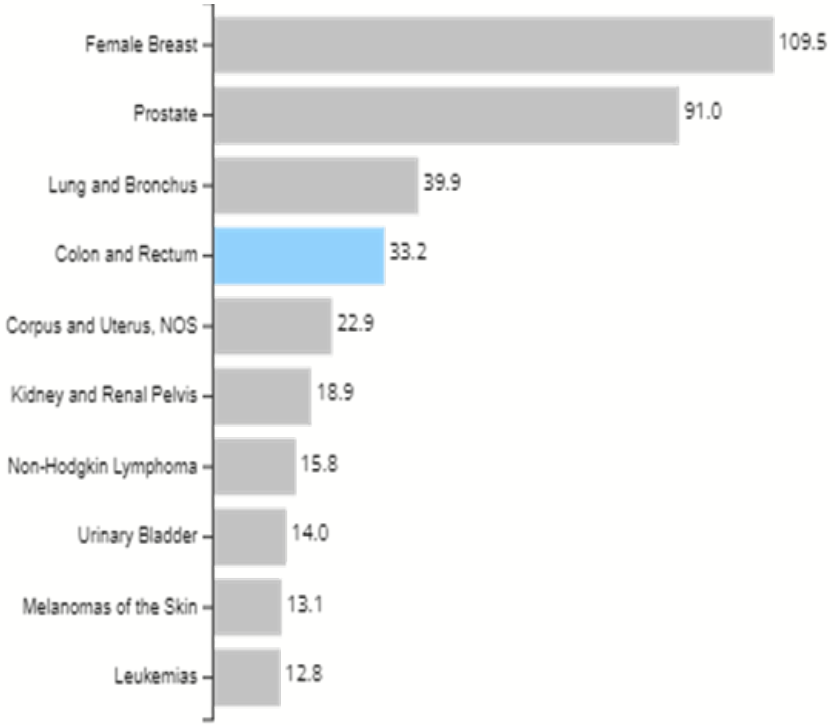
- The National Cancer Institute defines the AYA age range as 15-39

- The five-year overall survival for AYA is 85.8%, limited improvement in cure rates for many AYA diagnoses
  - **sarcoma**, CNS tumors, **early onset colorectal cancer,** breast cancer

- **Colorectal cancer (CRC) rates on the rise** for individuals under 50
  - In 2023: 19,550 cases and 3,750 deaths in individuals younger than 50 years of age

- There are few studies focused on AYA short and long-term survival and quality of life
  - 100,000+ childhood and AYA survivors live in Texas

Top 10 Cancers by Rates of New Cancer Cases
Texas, 2020*



*All Races, Ages, & Ethnicities, Male and Female

Cancer Among Adolescents and Young Adults (AYAs) — Cancer Stat Facts

An Investment in Our Future…

- The number of children in Texas is projected to **increase to over 8.5 million by 2060**
  - Investing in childhood cancer research and prevention is an investment in our future
- According to the U.S. Census Bureau, **Texas is the second youngest state in the nation** (35 = median age)
- The population of Texas children under age six is greater than OK, LA, FL and NM **combined**
  - Approximately 1 in 10 American children under age six live in TX

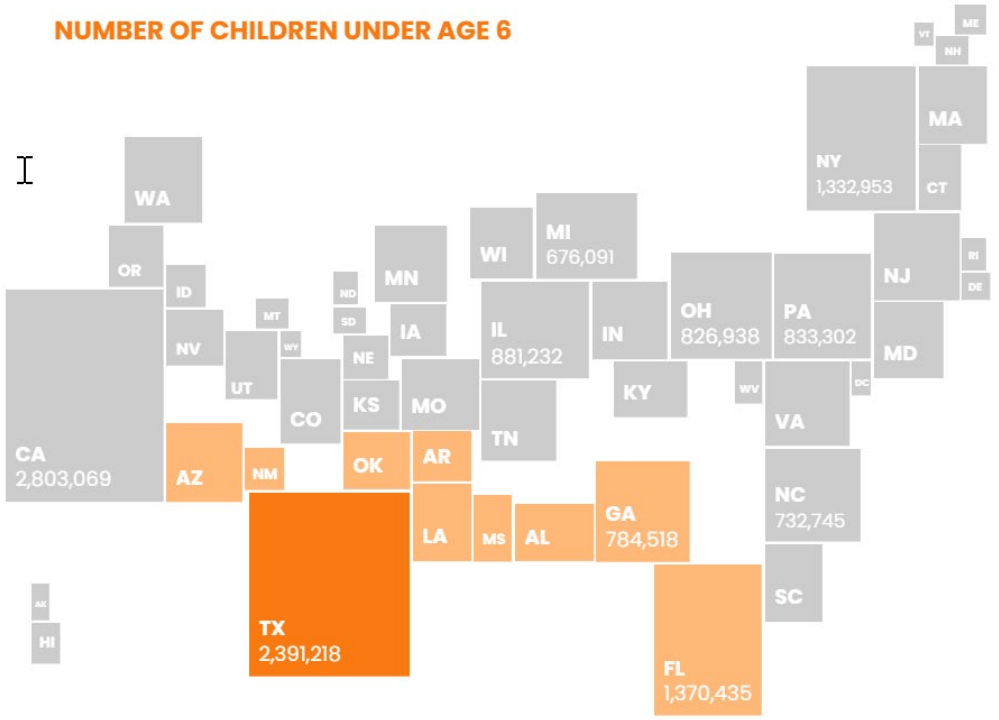


Image retrieved from TexasReadyKids website (2024)

Big and Bright: Texas is Leading the Nation

- National Cancer Institute – Children's Oncology Group Pediatric MATCH trial
  - **Will Parsons,** M.D., Ph.D.- BCM/Texas Children's Hospital

- Pediatric Preclinical in Vivo Testing (PIVOT) program contributions
  - **Richard Gorlick**, M.D., UTMDACC: osteosarcoma
  - **Peter Houghton,** Ph.D. **/Raushan Kurmasheva,** Ph.D., UTHCSA:
    - Ewing Sarcoma, rhabdomyosarcoma, kidney and liver cancers

- Childhood Cancer Data Initiative contributions
  - **Maria Gramatges,** M.D., Ph.D. & **Will Parsons,** M.D., Ph.D. -Texas Children's Hospital; **Gail E. Tomlinson**, M.D., Ph.D. - UTSA

- Osteosarcoma Specimen Bank - **Richard Gorlick,** M.D., UTMDACC

- Adolescent and Young Adult Program:
  - UTMDACC leads the largest and most comprehensive program in the nation- **Michael Roth**, M.D

Summary

- Incidence rates for childhood cancer rates in Texas are comparable to the national average
- Childhood/AYA cancers are significant public health issues
- Drug development for pediatric patients is a serious unmet need
- AYAs represent a unique population critical needs, often under-reported and under-studied
- As the second youngest state in the nation, investing in childhood cancer research/prevention is an investment in our future
- Texas leads the nation with dedicated and innovative research and cancer care

Summary of CPRIT Pediatric Accomplishments

CPRIT Funds Important Childhood Cancer Research: FY23

TITLE	PI	INSTITUTION	PEDIATRIC CANCER	MECHANISM
Identifying Clinical Methotrexate Toxicity Phenotypes Across Phases of Pediatric Leukemia Therapy	Bernhardt, Melanie	Baylor College of Medicine	Leukemia	IIRACCA
Neuronal Alterations in the Midbrain Dopaminergic System Function: A Novel Mechanism of Radiation-Induced Cognitive	Zhang, Die	The University of Texas M. D. Anderson Cancer Center	Brain	IIRACCA
Clonal Evolution and Chemoresistance of Hepatoblastomas With Hepatocellular Carcinoma	Sumazin, Pavel	Baylor College of Medicine	Liver	IIRACCA
Normalizing Membrane Homeostasis in Microglia/Macrophages of Pediatric High-Grade Gliomas	Hu, Jian	The University of Texas M. D. Anderson Cancer Center	Glioblastoma	IIRACCA
Integrate Whole-Slide Imaging and Genomic Data to Study Pediatric Rhabdomyosarcoma	Xiao, Guanghua	The University of Texas Southwestern Medical Center	Rhabdomyosarcoma	IIRACCA
TREC: Major Instrument Award	Min Kang, PharmD	Texas Tech University Health Science Center	neuroblastoma	TREC:MIA
TREC: Major Instrument Award	Wenshe Liu, Ph.D.	Texas A&M University	All Pediatric Cancers	TREC:MIA
TREC: Pilot Study Award	Hongjun Liang, Ph.D.	Texas Texas Unviersity Health Science Center	All Pediatric Cancers	TREC:PSA

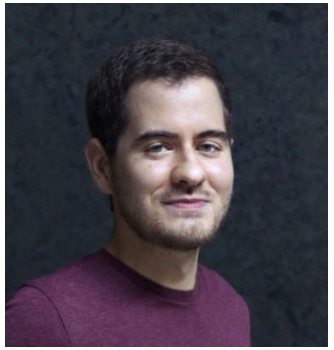
Core Facilities Support Awards create new resources

Provides financial support for a wide variety of projects relevant to cancer research in Texas, including for pediatric specific projects such as:

Title	PI	Institution	Award Year
The Adolescent and Childhood Cancer Epidemiology and Susceptibility Service (ACCESS) for Texas	Michael Scheurer, PhD, MPH	Baylor College of Medicine	2021
Center for Innovative Drug Discovery Enhancement of a Shared Cancer Resource for South Texas	Stanton McHardy, PhD	The University of Texas Health Science Center at San Antonio	2022
Patient-Derived Xenograft and Advanced In Vivo Models (PDX-AIM) Core Facility of Texas	Michael Lewis, PhD	Baylor College of Medicine	2022
West Texas Pharmacology Core	Min Kang, PharmD	Texas Tech University Health Sciences Center	2022
Advanced Protein Therapeutics Core	Jennifer Maynard, PhD	The University of Texas at Austin	2022
Texas Pediatric Cancer Testing (TPCT) Core	Peter J. Houghton, PhD	The University of Texas Health Science Center at San Antonio	2022

*CFSA were not offered in FY23; however, there was a 24.2 funding opportunity for this mechanism, which will be awarded August 2024.

CPRIT Recruits New Childhood Cancer Researchers to Texas



Michael Robertson, Ph.D.

- CPRIT First-Time, Tenure Track Faculty Member
- Recruited to Baylor College of Medicine from Stanford University
- Expertise: Cryogenic electron microscopy, structure-based drug discovery, computational chemistry, membrane protein biochemistry
- He brought a prestigious NIH K99/R00 Pathway to Independence Award from the NIH Childhood Health and Development to Texas, to investigate the basis of compound selectivity at somatostatin receptors & leverage these insights to develop improved compounds for childhood neuroendocrine tumors

Qian Zhu, Ph.D.

- CPRIT First –Time, Tenure Track Faculty Member
- Recruited to Baylor College of Medicine from Dana Farber Cancer Institute
- Interests include: clinical genomics annotation, reporting of germline variants identified in childhood cancer patients

Impact Data: CPRIT Childhood and Adolescent Awards

By CPRIT Program	# Awards	Total Follow on Funds	# Publications	# of Patents Filed	# of Clinical Trials	# of Patients Enrolled
Academic Research	182	$349,137,051	729	23	43	12,095
Prevention	47	$2,603,880	51	0	0	0
Product Development Research	7	$310,040,637	14	17	4	78
TOTAL	**236**	**$661,781,568**	**794**	**40**	**47**	**12,173**

Data Source: Annual Progress Reports as of 2/12/2024

Impact of CPRIT Funding Mechanisms

- **Impact**
  - Over 200 awards, $661M+ follow-on funds, 794 publications, 40 patents filed, 47 clinical trials with 12,000+ patients enrolled
  - **New, shareable childhood cancer models**
    - Texas Pediatric PDX facility (Houghton, UTHSCSA)
    - PDX-AIM (Lewis, BCM)
    - Cancer Animal Facility (Trasti, TTUHSC)
  - **New capacity for data storage and sharing**
    - Pediatric Cancer Data Core (Xie, UTSW)
    - Pediatric Solid Tumors Comprehensive Data Core (Gorlick, UTMDACC)
    - ACCESS for Texas (Scheurer, BCM)
- **Recommendations**
  - **Specific calls for proposals focused on childhood cancer**
    - Ensure impact extends beyond local institutions
    - Enlist ACCC to help prioritize Core Facilities
    - Invite competitive renewal of high-performing Cores that fill state-wide needs

Local grants make a national impact

- *IIRA RP170510 renewed as RP220460*
  - Resulted in incorporation of assays for telomere maintenance mechanisms into current (ANBL1531) and future (ANBL2131) Children's Oncology Group (COG) national phase III clinical trials for neuroblastoma.

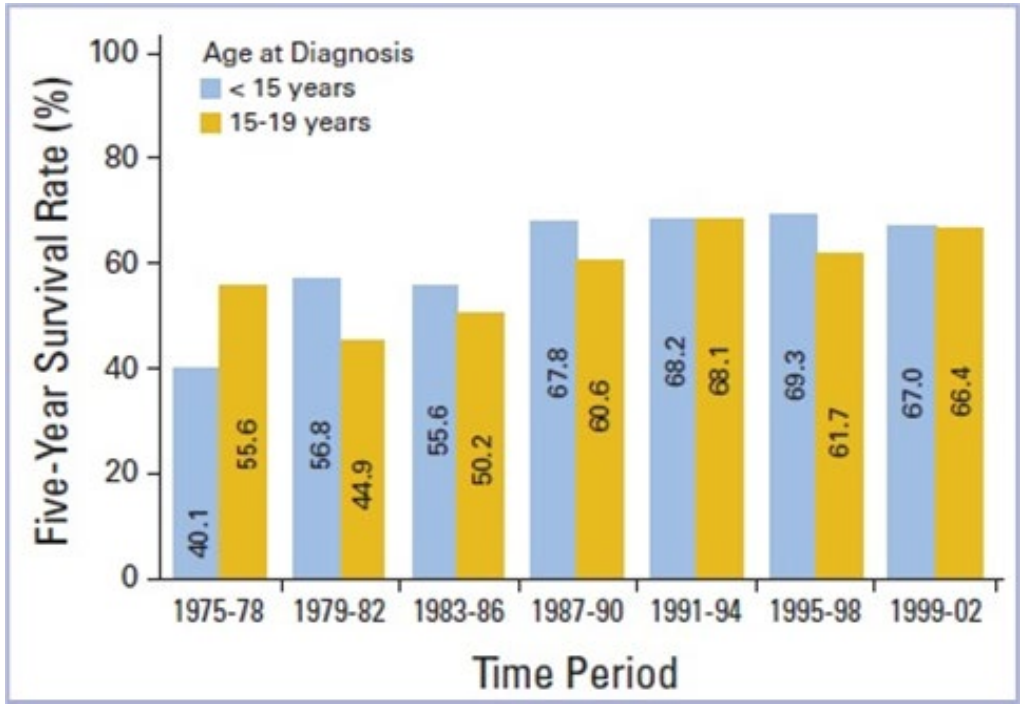
- *IIRA RP200432*
  - Developed assay to assess loss of binding of therapeutic antibody to identify cancer cell resistance to therapy with antibody used to treat neuroblastoma. Sending samples to Texas for that assay has been incorporated into the next COG national phase III neuroblastoma clinical trial (ANBL2131).

- *MIRA RP110763 and Core RP190524*
  - Partial support for COG repository for patient-derived cell lines and patient-derived xenografts of childhood cancer that are used by investigators across the USA and in 30 countries.

New drugs are needed

- New, effective, non-cytotoxic drugs are still needed to make progress in Sarcoma
- The INT0133 and EURAMOS studies failed to change the standard of care in North America
  - Refers to additional trials of cytotoxic chemotherapy but also has implications for needed level of evidence
- No progress has been made in improving the survival of osteosarcoma in the past 30 years

Smith, et al. Outcomes for children and adolescents with cancer. J Clin Oncol 2010.



A reinstated opportunity, incredible potential. . .

- A Core Facilities Support Award Call for Applications did not occur in 2023
  - Planned to award again in 2024. The announcement included one for anything, one for pediatrics or population science

- **An RFA R-24.2-MIRA was reinstated**
  - Award: Up to $4.5 Million over a period of four years
  - This reinstatement allowed for two application from each institution
    - One for anything, one for pediatrics or population

  - Multiple applications were likely submitted in response
    - Results way too early to be released
      - Anticipated funding in August 2024

Many thanks to CPRIT Leadership

- Incredible engagement in issues facing children with cancer
  - Michelle Le Beau
  - Wayne Roberts
  - David A. Cummings
  - Patty Moore
  - Myriam Casillas

Advisory Committee on Childhood Cancer
Ongoing Steps

CPRIT ACCC Organization

We continue to add new members to expand our network!

Leadership
Richard Gorlick, M.D., Chair
Donald (Will) Parsons, M.D., Ph.D., Vice Chair

Members
Karen Albritton, M.D.; Carl E. Allen, M.D.; Mohamad Al-Rahawan, M.D., MPH; Greg Aune, M.D., Ph.D., FAAP; Juan Carlos Bernini, M.D.; Smita Bhaskaran, M.D.; Tim Culliver; Stan Goldman, M.D.; ; Barkat Hooda, M.D.; Eugenie Kleinerma, M.D.; Andrew Y Koh, M.D.; Annette Leslie; Julie Luke, CPNP; Phillip Neff, M.D.; C Patrick Reynolds, M.D., Ph.D.; Stephen X. Skapek, M.D.; Lisa Tichenor; Gail Tomlinson, M.D., Ph.D., **Atul Varadhachary, MD, PhD**

SC1: AYA
Karen Albritton (Leader), Michael Roth, Chibuzo O'Suoji (Members)

SC2: Brain Tumors
Donald Parsons (Leader), Daniel Bowers, Holly Lindsay (Members)

SC3: Cell Therapy
Andrew Koh (Leader), Kris Mahadeo, Robin Parihar, Samuel John, Matthew Campbell, Meena Hegde (Members)

SC4: Epidemiology
Philip Lupo (Leader), Paul Scheet, Sandi Pruitt, Michael Scheurer, Michael Roth (Members)

SC5: Frontiers
Smita Bhaskaran, Mohamad Al-Rahawan, Phil Neff (Co-Leaders), Lisa Thicenor, Shannon Cohn (Members), Richard Gorlick (Advisor)

SC6: Genetic Predisposition & Risk
Gail Tomlinson (Leader), Laura Klesse (Member)

SC7: Leukemia / Lymphoma
Carl Allen (Leader), Rachel Rau (Member)

SC8: Solid Tumors
Nino Rainusso (Leader), Jessica Naiditch, Dinesh Rakheja, Gabriel Axelrud, Lorimar Ramirez (Members)

SC9: Survivorship
Greg Aune (Leader), Barbara Jones, Monica Gramatges, Chibuzo O'Suoji, Michael Roth (Members)

Welcome, Dr. Atul Varadhachary!

- Dr. Varadhachary, M.D, Ph.D. is the Managing Partner at Fannin, and a physician with a PhD in Physiology from Johns Hopkins University
- Dr. Varadhachary brings thirty years of experience in life sciences and healthcare in both corporate and entrepreneurial settings
- Before Fannin, Dr. Varadhachary served as President of U.S. Operations at Reliance Life Sciences, President & COO at Agennix, Inc., and Senior Manager at McKinsey & Co.
- Dr. Varadhachary has served on the faculties of Baylor College of Medicine, Rice Graduate School of Management, the UT School of Public Health and on multiple company and community boards
- In terms of CPRIT Support, Fannin-affiliated companies have received five CPRIT grants:
  - **Allterum Therapeutics, Inc.** have received two product development grants (DP190025, DP230071) aimed at the pediatric population
  - **Pulmotect, Inc**. has received two product development grants (CP120014, DP230066), aimed at pediatric population
  - Acelerox received a High Impact/High Risk grant (RP160813)

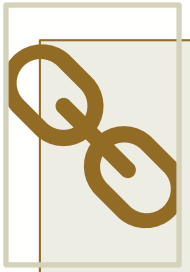
Researchers Roundup 2022 – Opportunity to develop and refine strategy – Many thanks to the Carson Leslie Foundation and CPRIT for their engagement

Strategy for advancing childhood cancer care in Texas will address the following issues

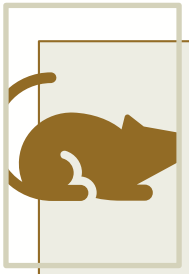
- Address gaps in pediatric drug development
- Continue to address variation in incidence rates and outcomes across Texas
  - They are not well understood with demographic details, environmental exposures not captured
- Address the needs of the AYA cancer patient population

Ongoing Steps

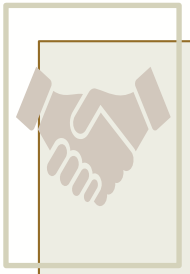
Enhanced website for Core information dissemination



Patient Derived Xenograft (PDX) sharing/homogenization



Pre-clinical testing/product development integration



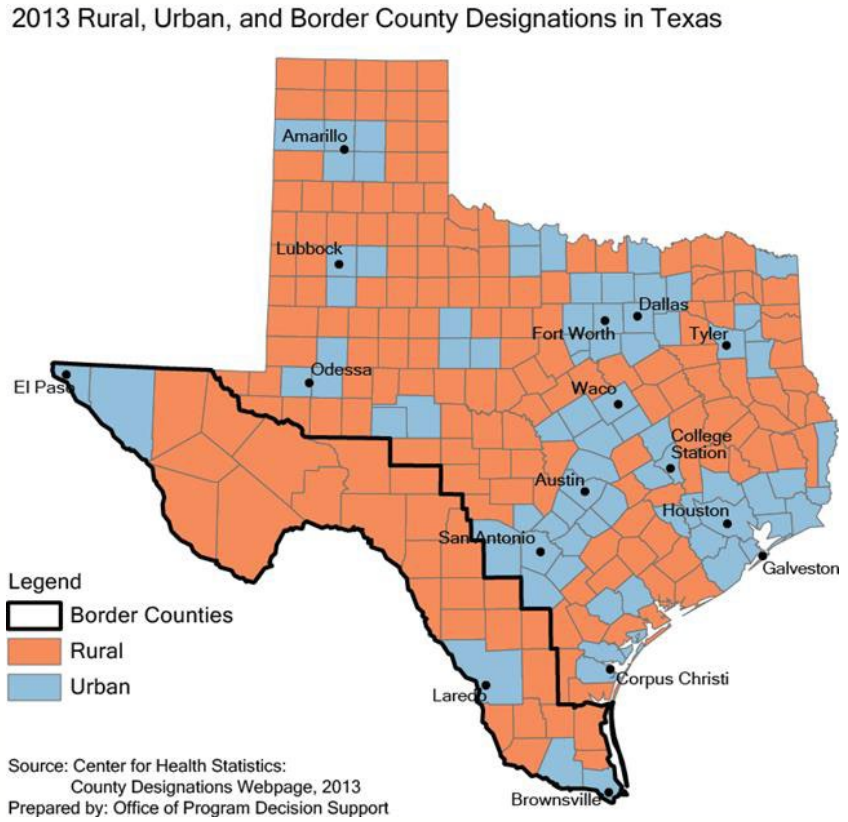
Data harmonization and sharing

RFAs should require use of Cores

We are considering a publication to share the results of the Researchers Roundup to share this strategy.

Ongoing goal: define childhood cancer throughout TX

- Focus remains on identifying primary, secondary and tertiary **referral pattern** of new/relapsed patients
- Continue to assess current **clinical trial accrual rate, especially among rural populations**
- Obtain data on the **capabilities** of rural pediatric oncology centers to conduct clinical trials



Create and continue funding mechanisms which would accrue patients throughout Texas

						
Enhance drug development in the state of Texas	Study sub-groups	Continue to grow membership of advisory council to increase collaboration	Provide interventions	Expand reach via technology	Include underserved populations	Provide services not often available outside large academic centers

The impact of expansion

- Consider specifically requesting applications for new projects focused on Childhood Cancer topics that are critical needs

- Consider specifically requesting applications for new researchers focused on Childhood Cancer drug development, novel therapies, clinical trials

- Areas of high priority include pediatric drug development and drug manufacturing experts

Advisory Committee on Childhood Cancer: Recommendations/Strategy

ACCC Recommendations to CPRIT

- Critical to continue pediatric applications including Core, MIRA, instrument, and research grants and recruitment awards
- Immediate opportunities:
  - Enhanced website for Core information dissemination and resource sharing
  - Model sharing with treatment development structure
  - Data harmonization/sharing
  - Enhanced ability to participate in Cores as well as encouragement of utilization
  - Consider a manuscript describing ACCC strategy and outcomes for publication in a scientific journal

ACCC Recommendations to CPRIT

- Longer-Term opportunities:
  - Utilize the Cores along with a new RFP to:
    - Enhance collaboration across Texas with emphasis on drug development expertise
    - Facilitate data sharing across the state
    - Increase access to trials
    - Implement best manufacturing practices throughout Texas
  - Explore ways to enhance development of drugs focused on childhood cancers to bring the possibility of a cure closer to Texans
  - Propose a common infrastructure for pediatric cancer research in Texas

CPRIT & The Carson Leslie Foundation proudly present:
Researchers RoundUp '24: Nov. 10 – Nov. 12, 2024

This event occurs bi-annually, alternating with CPRIT's "Innovations in Cancer Prevention and Research" Conference.

THANKS to the GENEROUS SUPPORT of our wranglers (aka sponsors)!

CLF CARSON LESLIE FOUNDATION
helping kids fight cancer

PEGASUS PARK BIOTECH+

what would Willie want
foundation
www.QuadW.org

LYDA HILL® PHILANTHROPIES

Summary/Next Steps

Summary

- The ACCC wants to extend their appreciation to Texans for their strategic development of CPRIT
- CPRIT has allowed remarkable innovation and scientific breakthroughs to occur, benefitting children with cancer in Texas.
- Thank you for supporting the visionary leadership that continues to move the needle for childhood cancer research!
- Continued support of pediatric-focused proposals remains critical

Q&A

Richard Gorlick, M.D.
Chair, CPRIT Advisory Committee on Childhood Cancers

Will Parsons, M.D., Ph.D.
Vice Chair, CPRIT Advisory Committee on Childhood Cancers

Sarah Williams-Blangero, Ph.D., is a genetic epidemiologist who received her Ph.D. in Biological Anthropology from Case Western Reserve University in 1987. She completed a postdoctoral fellowship in genetics at the Texas Biomedical Research Institute, and was then appointed to the faculty of Texas Biomed in 1990. Dr. Williams-Blangero became Chair of the Department of Genetics at Texas Biomed in 1999 and additionally Deputy Director of the Southwest National Primate Research Center in 2012. In 2014, she moved to the University of Texas Rio Grande Valley (UTRGV) to become the Founding Director of the South Texas Diabetes and Obesity Institute, and in 2017 was appointed Chair of the Department of Human Genetics in the UTRGV School of Medicine. Dr. Williams-Blangero's research has focused on the genetic determinants of risk for complex diseases in minority populations, including the Jirel ethnic group of Nepal and Mexican Americans.

Robert A. Kirken, Ph.D.

THE UNIVERSITY OF TEXAS AT EL PASO
DEAN, COLLEGE OF SCIENCE

Robert A Kirken, Ph.D, is currently the Dean of the College of Science at The University of Texas at El Paso (UTEP), America's leading Hispanic-serving university. In addition to his strong commitment to students and faculty, he has an extensive track-record as a scientific leader focused on cancer health disparities within the El Paso del Norte Region, shared between El Paso, Texas, New Mexico and Juarez, Mexico. As a research scientist, he has been working in the field of cytokine cell signaling, cancer biology and immunology. The aim of his current research has been to characterize the cell signaling pathways responsible for immune-cell derived pathologies to understand the mechanism by which certain diseases originate, thereby allowing for the development of new therapeutic strategies. Prior to his role as Dean, Dr. Kirken was the Professor and Chair of the Department of Biological Sciences at UTEP. He was also an Assistant and tenured Associate Professor in the Department of Pharmacology and Integrative Biology with a joint appointment in the Departmentof Surgery at UTHealth Houston and held a secondary appointment at MD Anderson Cancer Center. Prior to his academic positions, he was a postdoctoral fellow and then staff scientist at the NCI at Fort Detrick, Frederick, Maryland. Dr. Kirken received his B.A. in Chemistry from Olivet College in Southeastern Michigan and completed his Ph.D. in Biomedical Sciences at Wright State University in Ohio.

PRESENTATION PLACE HOLDER

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	SECTION 102.1062 WAIVER – CARLTON ALLEN FY 2024
DATE:	FEBRUARY 21, 2024

Waiver Request and Recommendation

I request that the Oversight Committee approve a FY 2024 conflict of interest waiver for Carlton Allen, CPRIT's program manager for prevention, pursuant to Health & Safety Code Section 102.1062 "Exceptional Circumstances Requiring Participation." Mr. Allen's wife, Kristie Allen, is a lecturer of psychology and counseling at The University of Texas at Tyler (UT Tyler). While it is unlikely that Kristie Allen would be part of team applying for a CPRIT grant, this waiver ensures transparency regarding her employment at a grantee institution. 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

Mr. Allen's spouse, Kristie Allen, is an employee and lecturer within the Department of Psychology and Counseling at UT Tyler, an institution that has applied for CPRIT grants in the past. UT Tyler includes the instructional site of The University of Texas Health Science Center at Tyler (UTHSC Tyler), which is an active grant recipient with two prevention awards (PP220035 and PP220034). In total, UTHSC Tyler has received five CPRIT prevention grant awards and one academic research grant award. Cumulatively, UT Tyler and UTHSC Tyler have submitted approximately 48 CPRIT grant applications with some submitted as recently as FY2023.

Mrs. Allen is not involved in current or past CPRIT grant projects or grant applications. 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. As his wife, Mrs. Allen falls within the second degree of affinity to Mr. Allen. She is employed by a grant recipient or applicant because CPRIT considers the institution as the grant applicant or recipient, in this case UT Tyler and UTHSC Tyler, 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 be recused from participating in the "review, discussion, scoring, deliberation and vote on all grant applications competing for the same grant mechanism in the entire grant review cycle, unless a waiver has been granted…"

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. While CPRIT staff are prohibited from participating in the grant review process, it is possible that Mr. Allen's role as prevention program manager would require him to field questions from grant applicants, including UT Tyler and UTHSC Tyler. Mr. Allen is the sole prevention program manager, which is especially important during an open grant review cycle because CPRIT's administrative rules prohibit the Chief Prevention Officer, who is a member of the Program Integration Committee, from communicating with a grant applicant regarding the substance of a pending grant application. Mr. Allen is the only CPRIT staff whose job is to communicate with prevention grant applicants in this way.

Day-to-day activities require Mr. Allen to work closely with prevention grantees and to aid in management and compliance of prevention grantees. Mr. Allen works with the Chief Prevention Officer to monitor the progress of each prevention grantee and ensure that grantee reports are submitted in a timely manner. A large part of the job for each of CPRIT's program managers is to communicate directly with grantee contacts at the various grantee institutions. Again, Mr. Allen is the only dedicated CPRIT staff to help the Chief Prevention Officer monitor and communicate with prevention grantees.

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. Allen to perform all duties assigned as prevention program manager subject to the limitations stated below:

1. Mr. Allen may answer questions from grant applicants including applicants from UT Tyler or UTHSC Tyler;
2. Mr. Allen may attend peer review meetings and PIC meetings as an observer, including meetings that include applications from UT Tyler or UTHSC Tyler;
3. Mr. Allen may have access to grant application information, including information related to UT Tyler or UTHSC Tyler, except as noted in item number 5;
4. Mr. Allen will inform the Chief Prevention Officer of any CPRIT grant application that includes his spouse;
5. CPRIT will prevent Mr. Allen from accessing application review data for any applications under review that include his wife as part of the grantee team;

6. In the event that an issue arises that is not addressed herein, the Chief Prevention Officer in conjunction with the Chief Executive Officer, Chief Compliance Officer, and Deputy Executive Officer and General Counsel, may review the circumstances and determine whether Mr. Allen should recuse himself from involvement in these or other regular job duties as appropriate.

Regarding item number 2, Mr. Allen will continue to follow CPRIT's established policy that prohibits CPRIT employees from actively participating in peer review committee meetings. As part of their CPRIT duties, program managers regularly attend peer review committee meetings as observers but do not participate in substantive discussion of any grant application, do not score any application, and do not vote on any application. CPRIT contracts with an independent third-party 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 but not limited to the list of approved activities and duties and the limitations on duties and activities. Approval for any change to the waiver granted shall be by a vote of the Oversight Committee in an open meeting.
- CPRIT limits this waiver to the conflict of interest specified in this request. To the extent that Mr. Allen has a conflict of interest with an application that is not the conflict identified in Section 102.106(c)(3), then Mr. Allen will follow the required notification and recusal process.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	KRISTEN PAULING DOYLE, DEPUTY EXECUTIVE OFFICER & GENERAL COUNSEL CAMERON ECKEL, ASSISTANT GENERAL COUNSEL
SUBJECT:	CHAPTERS 701 AND 703 - PROPOSED RULE CHANGES
DATE:	FEBRUARY 12, 2024

Summary and Recommendation

The Board Governance Subcommittee convened on February 8 to discuss the suggested rule changes to Texas Administrative Code §§ 701.3, 703.10, 703.21, and 703.23. Publication of the anticipated rule changes in the *Texas Register* is the first step in the agency rulemaking process. CPRIT Staff will bring back the proposed rule amendments and any public comments to the Oversight Committee in May 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 February 8 to discuss the proposed rule changes to Texas Administrative Code Chapters 701 and 703 related to CPRIT's use of the term "Tranche." The amendment proposes that CPRIT add its definition of "Tranche" to Chapter 701 and ensure that the term is capitalized throughout Chapter 703. The subcommittee voted to recommend that the Oversight Committee approve publication of the suggested changes in the *Texas Register*.

Next Steps

Once approved by the Oversight Committee, CPRIT will publish the proposed rule changes 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 May.

The Cancer Prevention and Research Institute of Texas ("CPRIT" or "the Institute") proposes amending 25 Tex. Admin. Code § 701.3 by adding a definition of "tranche" to the Institute's defined terms.

Background and Justification

The proposed rule change defines the term "tranche" used CPRIT's administrative rules to refer to the portion of total Grant Award funds that is released to the Grant Recipient upon a Grant Recipient's successful completion of predefined milestones or adherence to specific timelines as outlined in the Grant Contract.

Fiscal Note

Kristen Pauling Doyle, Deputy Executive Officer and 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

Ms. Doyle 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 defining a term used in CPRIT's administrative rules and grant contract.

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

Ms. Doyle 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 change to Ms. Kristen Pauling Doyle, General Counsel, Cancer Prevention and Research Institute of Texas, P. O. Box 12097, Austin, Texas 78711, no later than April 8, 2024. 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 kdoyle@cprit.texas.gov or by facsimile transmission to 512/475-2563.

Statutory Authority

The Institute proposes the rule change 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. Ms. Doyle has reviewed the proposed amendment and certifies the proposal to be within the Institute's authority to adopt.

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

<rule>

§701.3.Definitions.

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Advisory Committee--a committee of experts, including practitioners and patient advocates, created by the Oversight Committee to advise the Oversight Committee on issues related to cancer.

(2) Allowable Cost--a cost that is reasonable, necessary for the proper and efficient performance and administration of the project, and allocable to the project.

(3) Annual Public Report--the report issued by the Institute pursuant to Texas Health and Safety Code §102.052 outlining Institute activities, including Grant Awards, research accomplishments, future Program directions, compliance, and Conflicts of Interest actions.

(4) Approved Budget--the financial expenditure plan for the Grant Award, including revisions approved by the Institute and permissible revisions made by the Grant Recipient. The Approved Budget may be shown by Project Year and detailed budget categories.

(5) Authorized Expense--cost items including honoraria, salaries and benefits, consumable supplies, other operating expenses, contracted research and development, capital equipment, construction or renovation of state or private facilities, travel, and conference fees and expenses.

(6) Authorized Signing Official (ASO)--the individual, including designated alternates, named by the Grant Applicant, who is authorized to act for the Grant Applicant or Grant Recipient in submitting the Grant Application and executing the Grant Contract and associated documents or requests.

(7) Bylaws--the rules established by the Oversight Committee to provide a framework for its operation, management, and governance.

(8) Cancer Prevention--a reduction in the risk of developing cancer, including early detection, control and/or mitigation of the incidence, disability, mortality, or post-diagnosis effects of cancer.

(9) Cancer Prevention and Control Program--effective strategies and interventions for preventing and controlling cancer designed to reduce the incidence and mortality of cancer and to enhance the quality of life of those affected by cancer.

(10) Cancer Prevention and Research Fund--the dedicated account in the general revenue fund consisting of legislative appropriations, gifts, grants, other donations, and earned interest.

(11) Cancer Research--research into the prevention, causes, detection, treatments, and cures for all types of cancer in humans, including basic mechanistic studies, pre-clinical studies, animal model studies, translational research, and clinical research to develop preventative measures, therapies, protocols, medical pharmaceuticals, medical devices or procedures for the detection, treatment, cure or substantial mitigation of all types of cancer and its effects in humans.

(12) Chief Compliance Officer--the individual employed by the Institute to monitor and report to the Oversight Committee regarding compliance with the Institute's statute and administrative rules. The term may also apply to an individual designated by the Chief Compliance Officer to fulfill the duty or duties described herein, unless the context clearly indicates otherwise.

(13) Chief Executive Officer--the individual hired by the Oversight Committee to perform duties required by the Institute's Statute or designated by the Oversight Committee. The term may apply to an individual designated by the Chief Executive Officer to fulfill the duty or duties described herein, unless the context clearly indicates otherwise.

(14) Chief Prevention Officer--the individual hired by the Chief Executive Officer to oversee the Institute's Cancer Prevention program, including the Grant Review Process, and to assist the

Chief Executive Officer in collaborative outreach to further Cancer Research and Cancer Prevention. The term may also apply to an individual designated by the Chief Prevention Officer to fulfill the duty or duties described herein, unless the context clearly indicates otherwise.

(15) Chief Product Development Officer--the individual hired by Chief Executive Officer to oversee the Institute's Product Development program for drugs, biologicals, diagnostics, or devices arising from Cancer Research, including the Grant Review Process, and to assist the Chief Executive Officer in collaborative outreach to further Cancer Research and Cancer Prevention. The term may apply to an individual designated by the Chief Product Development Officer to fulfill the duty or duties described herein, unless the context clearly indicates otherwise.

(16) Chief Scientific Officer--the individual hired by the Chief Executive Officer to oversee the Institute's Cancer Research program, including the Grant Review Process, and to assist the Chief Executive Officer in collaborative outreach to further Cancer Research and Cancer Prevention. The term may apply to an individual designated by the Chief Scientific Officer to fulfill the duty or duties described herein, unless the context clearly indicates otherwise.

(17) Code of Conduct and Ethics--the code adopted by the Oversight Committee pursuant to Texas Health and Safety Code §102.109 to provide guidance related to the ethical conduct expected of Oversight Committee Members, Program Integration Committee Members, and Institute Employees.

(18) Compliance Program--a process to assess and ensure compliance by the Oversight Committee Members and Institute Employees with applicable laws, rules, and policies, including matters of ethics and standards of conduct, financial reporting, internal accounting controls, and auditing.

(19) Conflict(s) of Interest--a financial, professional, or personal interest held by the individual or the individual's Relative that is contrary to the individual's obligation and duty to act for the benefit of the Institute.

(20) Encumbered Funds--funds that are designated by a Grant Recipient for a specific purpose.

(21) Financial Status Report--form used to report all Grant Award related financial expenditures incurred in implementation of the Grant Award. This form may also be referred to as "FSR" or "Form 269-A."

(22) Grant Applicant--the public or private institution of higher education, as defined by §61.003, Texas Education Code, research institution, government organization, non-governmental organization, non-profit organization, other public entity, private company, individual, or consortia, including any combination of the aforementioned, that submits a Grant

Application to the Institute. Unless otherwise indicated, this term includes the Principal Investigator or Program Director.

(23) Grant Application--the written proposal submitted by a Grant Applicant to the Institute in the form required by the Institute that, if successful, will result in a Grant Award.

(24) Grant Award--funding, including a direct company investment, awarded by the Institute pursuant to a Grant Contract providing money to the Grant Recipient to carry out the Cancer Research or Cancer Prevention project in accordance with rules, regulations, and guidance provided by the Institute.

(25) Grant Contract--the legal agreement executed by the Grant Recipient and the Institute setting forth the terms and conditions for the Cancer Research or Cancer Prevention Grant Award approved by the Oversight Committee.

(26) Grant Management System--the electronic interactive system used by the Institute to exchange, record, and store Grant Application and Grant Award information.

(27) Grant Mechanism--the specific Grant Award type.

(28) Grant Program--the functional area in which the Institute makes Grant Awards, including research, prevention and product development.

(29) Grant Progress Report--the required report submitted by the Grant Recipient at least annually and at the close of the grant award describing the activities undertaken to achieve the Scope of Work of the funded project and including information, data and program metrics. Unless the context clearly indicates otherwise, the Grant Progress Report also includes other required reports such as a Historically Underutilized Business and Texas Supplier form, a single audit determination form, an inventory report, a single audit determination form, a revenue sharing form, and any other reports or forms designated by the Institute.

(30) Grant Recipient--the entire legal entity responsible for the performance or administration of the Grant Award pursuant to the Grant Contract. Unless otherwise indicated, this term includes the Principal Investigator, Program Director, or Company Representative.

(31) Grant Review Cycle--the period that begins on the day that the Request for Applications is released for a particular Grant Mechanism and ends on the day that the Oversight Committee takes action on the Grant Award recommendations.

(32) Grant Review Process--the Institute's processes for Peer Review, Program Review and Oversight Committee approval of Grant Applications.

(33) Indirect Costs--the expenses of doing business that are not readily identified with a particular Grant Award, Grant Contract, project, function, or activity, but are necessary for the general operation of the Grant Recipient or the performance of the Grant Recipient's activities.

(34) Institute--the Cancer Prevention and Research Institute of Texas or CPRIT.

(35) Institute Employee--any individual employed by the Institute, including any individual performing duties for the Institute pursuant to a contract of employment. Unless otherwise indicated, the term does not include an individual providing services to the Institute pursuant to a services contract.

(36) Intellectual Property Rights--any and all of the following and all rights in, arising out of, or associated therewith, but only to the extent resulting from the Grant Award:

(A) The United States and foreign patents and utility models and applications therefore and all reissues, divisions, re-examinations, renewals, extensions, provisionals, continuations and such claims of continuations-in-part as are entitled to claim priority to the aforesaid patents or patent applications, and equivalent or similar rights anywhere in the world in Inventions and discoveries;

(B) All trade secrets and rights in know-how and proprietary information;

(C) All copyrights, whether registered or unregistered, and applications therefore, and all other rights corresponding thereto throughout the world excluding scholarly and academic works such as professional articles and presentations, lab notebooks, and original medical records; and

(D) All mask works, mask work registrations and applications therefore, and any equivalent or similar rights in semiconductor masks, layouts, architectures or topography.

(37) Invention--any method, device, process or discovery that is conceived and/or reduced to practice, whether patentable or not, by the Grant Recipient in the performance of work funded by the Grant Award.

(38) License Agreement--an understanding by which an owner of Technology and associated Intellectual Property Rights grants any right to make, use, develop, sell, offer to sell, import, or otherwise exploit the Technology or Intellectual Property Rights in exchange for consideration.

(39) Matching Funds--the Grant Recipient's Encumbered Funds equal to one-half of the Grant Award available and not yet expended that are dedicated to the research that is the subject of the Grant Award. For public and private institutions of higher education, this includes the dollar amount equivalent to the difference between the indirect cost rate authorized by the federal

government for research grants awarded to the Grant Recipient and the five percent (5%) Indirect Cost limit imposed by §102.203(c), Texas Health and Safety Code.

(40) Numerical Ranking Score--the score given to a Grant Application by the Review Council that is substantially based on the final Overall Evaluation Score submitted by the Peer Review Panel, but also signifies the Review Council's view related to how well the Grant Application achieves program priorities set by the Oversight Committee, the overall Program portfolio balance, and any other criteria described in the Request for Applications.

(41) Overall Evaluation Score--the score given to a Grant Application during the Peer Review Panel review that signifies the reviewers' overall impression of the Grant Application. Typically it is the average of the scores assigned by two or more Peer Review Panel members.

(42) Oversight Committee--the Institute's governing body, composed of the nine individuals appointed by the Governor, Lieutenant Governor, and the Speaker of the House of Representatives.

(43) Oversight Committee Member--any person appointed to and serving on the Oversight Committee.

(44) Patient Advocate--a trained individual who meets the qualifications set by the Institute and is appointed to a Scientific Research and Prevention Programs Committee to specifically represent the interests of cancer patients as part of the Peer Review of Grant Applications assigned to the individual's committee.

(45) Peer Review--the review process performed by Scientific Research and Prevention Programs Committee members and used by the Institute to provide guidance and recommendations to the Program Integration Committee and the Oversight Committee in making decisions for Grant Awards. The process involves the consistent application of standards and procedures to produce a fair, equitable, and objective evaluation of scientific and technical merit, as well as other relevant aspects of the Grant Application. When used herein, the term applies individually or collectively, as the context may indicate, to the following review process(es): Preliminary Evaluation, Individual Evaluation by Primary Reviewers, Peer Review Panel discussion and Review Council prioritization.

(46) Peer Review Panel--a group of Scientific Research and Prevention Programs Committee members conducting Peer Review of assigned Grant Applications.

(47) Prevention Review Council--the group of Scientific Research and Prevention Programs Committee members designated as the chairpersons of the Peer Review Panels that review Cancer Prevention program Grant Applications. This group includes the Review Council chairperson.

(48) Primary Reviewer--a Scientific Research and Prevention Programs Committee member responsible for individually evaluating all components of the Grant Application, critiquing the merits according to explicit criteria published in the Request for Applications, and providing an individual Overall Evaluation Score that conveys the general impression of the Grant Application's merit.

(49) Principal Investigator, Program Director, or Company Representative--the single individual designated by the Grant Applicant or Grant Recipient to have the appropriate level of authority and responsibility to direct the project to be supported by the Grant Award.

(50) Product Development Prospects--the potential for development of products, services, or infrastructure to support Cancer Research efforts, including but not limited to pre-clinical, clinical, manufacturing, and scale up activities.

(51) Product Development Review Council--the group of Scientific Research and Prevention Programs Committee Members designated as the chairpersons of the Peer Review Panels that review Grant Applications for the development of drugs, drugs, biologicals, diagnostics, or devices arising from earlier-stage Cancer Research. This group includes the Review Council chairperson.

(52) Program Income--income from fees for services performed, from the use or rental of real or personal property acquired with Grant Award funds, and from the sale of commodities or items fabricated under the Grant Contract. Except as otherwise provided, Program Income does not include rebates, credits, discounts, refunds, etc. or the interest earned on any of these items. Interest otherwise earned in excess of $250 on Grant Award funds is considered Program Income.

(53) Program Integration Committee--the group composed of the Chief Executive Officer, the Chief Scientific Officer, the Chief Product Development Officer, the Commissioner of State Health Services, and the Chief Prevention Officer that is responsible for submitting to the Oversight Committee the list of Grant Applications the Program Integration Committee recommends for Grant Awards.

(54) Project Results--all outcomes of a Grant Award, including publications, knowledge gained, additional funding generated, and any and all Technology and associated Intellectual Property Rights.

(55) Project Year--the intervals of time (usually 12 months each) into which a Grant Award is divided for budgetary, funding, and reporting purposes. The effective date of the Grant Contract is the first day of the first Project Year.

(56) Real Property--land, including land improvements, structures and appurtenances thereto, excluding movable machinery and equipment.

(57) Relative--a person related within the second degree by consanguinity or affinity determined in accordance with §§573.021 - 573.025, Texas Government Code. For purposes of this definition:

(A) examples of an individual within the second degree by consanguinity are a child, grandchild, parent, grandparent, brother, sister;

(B) a husband and wife are related to each other in the first degree of affinity. For other relationship by affinity, the degree of relationship is the same as the degree of the underlying relationship by consanguinity;

(C) an individual adopted into a family is considered a Relative on the same basis as a natural born family member; and

(D) an individual is considered a spouse even if the marriage has been dissolved by death or divorce if there are surviving children of that marriage.

(58) Request for Applications--the invitation released by the Institute seeking the submission of Grant Applications for a particular Grant Mechanism. It provides information relevant to the Grant Award to be funded, including funding amount, Grant Review Process information, evaluation criteria, and required Grant Application components. The Request for Applications includes any associated written instructions provided by the Institute and available to all Grant Applicants.

(59) Review Council--the term used to generally refer to one or more of the Prevention Review Council, the Product Development Review Council, or Scientific Review Council.

(60) Scientific Research and Prevention Programs Committee--a group of experts in the field of Cancer Research, Cancer Prevention or Product Development, including trained Patient Advocates, appointed by the Chief Executive Officer and approved by the Oversight Committee for the purpose of conducting Peer Review of Grants Applications and recommending Grant Awards. A Peer Review Panel is a Scientific Research and Prevention Programs Committee, as is a Review Council.

(61) Scientific Research and Prevention Programs Committee Member--an individual appointed by the Chief Executive Officer and approved by the Oversight Committee to serve on a Scientific Research and Prevention Programs Committee. Peer Review Panel Members are Scientific Research and Prevention Programs Committee Members, as are Review Council Members.

(62) Scientific Review Council--the group of Scientific Research and Prevention Programs Committee Members designated as the chairpersons of the Peer Review Panels that review Cancer Research Grant Applications. This group includes the Review Council chairperson.

(63) Scope of Work--the goals and objectives or specific aims and subaims, if appropriate, of the Cancer Research or Cancer Prevention project, including the timeline and milestones to be achieved.

(64) Senior Member or Key Personnel--the Principal Investigator, Project Director or Company Representative and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not the individuals receive salary or compensation under the Grant Award.

(65) Technology--any and all of the following resulting or arising from work funded by the Grant Award:

(A) Inventions;

(B) Third-Party Information, including but not limited to data, trade secrets and know-how;

(C) databases, compilations and collections of data;

(D) tools, methods and processes; and

(E) works of authorship, excluding all scholarly works, but including, without limitation, computer programs, source code and executable code, whether embodied in software, firmware or otherwise, documentation, files, records, data and mask works; and all instantiations of the foregoing in any form and embodied in any form, including but not limited to therapeutics, drugs, drug delivery systems, drug formulations, devices, diagnostics, biomarkers, reagents and research tools.

(66) Texas Cancer Plan--a coordinated, prioritized, and actionable framework that helps to guide statewide efforts to fight the human and economic burden of cancer in Texas.

(67) Third-Party Information--generally, all trade secrets, proprietary information, know-how and non-public business information disclosed to the Institute by Grant Applicant, Grant Recipient, or other individual external to the Institute.

(68) Tobacco--all forms of tobacco products, including but not limited to cigarettes, cigars, pipes, water pipes (hookah), bidis, kreteks, electronic cigarettes, smokeless tobacco, snuff and chewing tobacco.

(69) Tranche—the portion of the Grant Award disbursed to the Grant Recipient in a sequential and conditional manner based upon the successful completion of predefined milestones as specified in the Grant Contract.

The Cancer Prevention and Research Institute of Texas ("CPRIT" or "the Institute") proposes amending 25 Tex. Admin. Code §§ 703.10, 703.21, and 703.23 to consistently use the term "Tranche" as defined in § 701.3.

Background and Justification

The proposed changes to Chapter 703 capitalize "Tranche" to consistently refer to the term as written and defined in 701.3. The proposed amendments do not change any substantive requirements in Chapter 703.

Fiscal Note

Kristen Pauling Doyle, Deputy Executive Officer and 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

Ms. Doyle 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 defining a term used in the agency's administrative rules.

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

Ms. Doyle 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 Ms. Kristen Pauling Doyle, General Counsel, Cancer Prevention and Research Institute of Texas, P. O. Box 12097, Austin, Texas 78711, no later than April 8, 2024. 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 kdoyle@cprit.texas.gov or by facsimile transmission to 512/475-2563.

Statutory Authority

The Institute proposes the rule change 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. Ms. Doyle has reviewed the proposed amendment and certifies the proposal to be within the Institute’s authority to adopt.

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

<rule>

§703.10. Awarding Grants by Contract.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(10) An agreement that, to the extent possible, the Grant Recipient will evaluate whether any new or expanded preclinical testing, clinical trials, Product Development, or manufacturing of

any real or intellectual property resulting from the award can be conducted in this state, including the establishment of facilities to meet this purpose;

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

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

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

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

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

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

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

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

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

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

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

(19) Requirements for closing out the Grant Contract at the termination date, including the submission of a Financial Status Report, a final Grant Progress Report, an equipment inventory, a HUB and Texas Business report, a revenue sharing form, a single audit determination report form and a list of contractual terms that extend beyond the termination date;

(20) A certification of dedicated Matching Funds equal to one-half of the amount of the Research Grant Award that includes the name of the Research Grant Award to which the matching funds are to be dedicated, as specified in Section §703.11 of this chapter (relating to Requirement to Demonstrate Available Funds for Cancer Research Grants);

(21) The project deliverables as described by the Grant Application and stated in the Scope of Work for the Grant Contract reflecting modifications, if any, approved during the Peer Review process or during Grant Contract negotiation;

(22) An agreement that the Grant Recipient shall notify the Institute and seek approval for a change in effort for any of the Senior Members or Key Personnel of the research or prevention team listed on the Grant Application, including any proposed temporary leave of absence of a Principal Investigator, Program Director, or Company Representative;

(23) An agreement that the Grant Recipient is legally responsible for the integrity of the fiscal and programmatic management of the organization; and

(24) An agreement that the Grant Recipient is responsible for the actions of its employees and other research collaborators, including third parties, involved in the project. The Grant Recipient is responsible for enforcing its standards of conduct, taking appropriate action on individual infractions, and, in the case of financial conflict of interest, informing the Institute if the infraction is related to a Grant Award.

(d) The Grant Recipient's failure to comply with the terms and conditions of the Grant Contract may result in termination of the Grant Contract, pursuant to the process prescribed in the Grant Contract, and trigger repayment of the Grant Award funds.

§703.21.Monitoring Grant Award Performance and Expenditures.

(a) The Institute, under the direction of the Chief Compliance Officer, shall monitor Grant Awards to ensure that Grant Recipients comply with applicable financial, administrative, and

programmatic terms and conditions and exercise proper stewardship over Grant Award funds. Such terms and conditions include requirements set forth in statute, administrative rules, and the Grant Contract.

(b) Methods used by the Institute to monitor a Grant Recipient's performance and expenditures may include:

(1) Financial Status Reports Review--The Institute shall review Grant Award expenditures reported by Grant Recipients on the quarterly Financial Status Reports and supporting documents to determine whether expenses charged to the Grant Award are:

(A) Allowable, allocable, reasonable, necessary, and consistently applied regardless of the source of funds; and

(B) Adequately supported with documentation such as cost reports, receipts, third party invoices for expenses, or payroll information.

(2) Timely submission of Grant Award Reports--The Institute shall monitor the submission of all required reports and implement a process to ensure that Grant Award funds are not disbursed to a Grant Recipient with one or more delinquent reports.

(3) Grant Progress Reports--The Institute shall review Grant Progress Reports to determine whether sufficient progress is made consistent with the Scope of Work set forth in the Grant Contract.

(A) The Grant Progress Reports shall be submitted at least annually, but may be required more frequently pursuant to Grant Contract terms or upon request and reasonable notice of the Institute.

(B) Unless specifically stated otherwise herein, the annual Grant Progress Report shall be submitted within sixty (60) days after the anniversary of the effective date of the Grant Contract. The annual Grant Progress Report shall include at least the following information:

(i) An affirmative verification by the Grant Recipient of compliance with the terms and conditions of the Grant Contract;

(ii) A description of the Grant Recipient's progress made toward completing the Scope of Work specified by the Grant Contract, including information, data, and program metrics regarding the achievement of the Scope of Work;

(iii) The number of new jobs created and the number of jobs maintained for the preceding twelve month period as a result of Grant Award funds awarded to the Grant Recipient for the project;

(iv) An inventory of the equipment purchased for the project in the preceding twelve month period using Grant Award funds;

(v) A verification of the Grant Recipient's efforts to purchase from suppliers in this state more than 50 percent goods and services purchased for the project with grant funds;

(vi) A Historically Underutilized Businesses report;

(vii) Scholarly articles, presentations, and educational materials produced for the public addressing the project funded by the Institute;

(viii) The number of patents applied for or issued addressing discoveries resulting from the research project funded by the Institute;

(ix) A statement of the identities of the funding sources, including amounts and dates for all funding sources supporting the project;

(x) A verification of the amounts of Matching Funds dedicated to the research that is the subject of the Grant Award for the period covered by the annual report, which shall be submitted pursuant to the timeline in §703.11 of this title (relating to Requirement to Demonstrate Available Funds for Cancer Research Grants). In order to receive disbursement of grant funds, the most recently due verification of the amount of Matching Funds must be approved by CPRIT;

(xi) All financial information necessary to support the calculation of the Institute's share of revenues, if any, received by the Grant Recipient resulting from the project; and

(xii) A single audit determination form, which shall be submitted pursuant to the timeline in §703.13 of this title (relating to Audits and Investigations).

(C) Notwithstanding subparagraph (B) of this paragraph, in the event that the Grant Recipient and Institute execute the Grant Contract after the effective date of the Grant Contract, the Chief Program Officer may approve additional time for the Grant Recipient to prepare and submit the outstanding reports. The approval shall be in writing and maintained in the Institute's electronic Grants Management System. The Chief Program Officer's approval may cover more than one report and more than one fiscal quarter.

(D) In addition to annual Grant Progress Reports, a final Grant Progress Report shall be filed no more than ninety (90) days after the termination date of the Grant Contract. The final Grant Progress Report shall include a comprehensive description of the Grant Recipient's progress made toward completing the Scope of Work specified by the Grant Contract, as well as other information specified by the Institute.

(E) The Grant Progress Report will be evaluated pursuant to criteria established by the Institute. The evaluation shall be conducted under the direction of the Chief Prevention Officer, the Chief Product Development Officer, or the Chief Scientific Officer, as may be appropriate. Required financial reports associated with the Grant Progress Report will be reviewed by the Institute's financial staff. In order to receive disbursement of grant funds, the final progress report must be approved by CPRIT.

(F) If the Grant Progress Report evaluation indicates that the Grant Recipient has not demonstrated progress in accordance with the Grant Contract, then the Chief Program Officer shall notify the Chief Executive Officer and the General Counsel for further action.

(i) The Chief Program Officer shall submit written recommendations to the Chief Executive Officer and General Counsel for actions to be taken, if any, to address the issue.

(ii) The recommended action may include termination of the Grant Award pursuant to the process described in §703.14 of this chapter (relating to Termination, Extension, and Close Out of Grant Contracts, and De-Obligation of Grant Award Funds).

(G) If the Grant Recipient fails to submit required financial reports associated with the Grant Progress Report, then the Institute financial staff shall notify the Chief Executive Officer and the General Counsel for further action.

(H) In order to receive disbursement of grant funds, the most recently due progress report must be approved by CPRIT.

(I) If a Grant Recipient fails to submit the Grant Progress Report within 60 days of the anniversary of the effective date of the Grant Contract, then the Institute shall not disburse any Grant Award funds as reimbursement or advancement of Grant Award funds until such time that the delinquent Grant Progress Report is approved.

(J) In addition to annual Grant Progress Reports, Product Development Grant Recipients shall submit a Grant Progress Report at the completion of specific Tranches [~~tranches~~] of funding specified in the Award Contract. For the purpose of this subsection, a Grant Progress Report submitted at the completion of a Tranche [~~tranche~~] of funding shall be known as "Tranche Grant Progress Report."

(i) The Institute may specify other required reports, if any, that are required to be submitted at the time of the Tranche Grant Progress Report.

(ii) Grant Funds for the next Tranche [~~tranche~~] of funding specified in the Grant Contract shall not be disbursed until the Tranche Grant Progress Report has been reviewed and approved pursuant to the process described in this section.

(K) A Grant Award in the prevention program with a Grant Contract effective date within the last quarter of a state fiscal year (June 1-August 31) will have an initial reporting period beginning September 1 of the following state fiscal year.

(4) Desk Reviews--The Institute may conduct a desk review for a Grant Award to review and compare individual source documentation and materials to summary data provided during the Financial Status Report review for compliance with financial requirements set forth in the statute, administrative rules, and the Grant Contract.

(5) Site Visits and Inspection Reviews--The Institute may conduct a scheduled site visit to a Grant Recipient's place of business to review Grant Contract compliance and Grant Award performance issues. Such site visits may be comprehensive or limited in scope.

(6) Audit Reports--The Institute shall review audit reports submitted pursuant to §703.13 of this chapter (relating to Audits and Investigations).

(A) If the audit report findings indicate action to be taken related to the Grant Award funds expended by the Grant Recipient or for the Grant Recipient's fiscal processes that may impact Grant Award expenditures, the Institute and the Grant Recipient shall develop a written plan and timeline to address identified deficiencies, including any necessary Grant Contract amendments.

(B) The written plan shall be retained by the Institute as part of the Grant Contract record.

(c) All required Grant Recipient reports and submissions described in this section shall be made via an electronic grant portal designated by the Institute, unless specifically directed to the contrary in writing by the Institute.

(d) The Institute shall document the actions taken to monitor Grant Award performance and expenditures, including the review, approvals, and necessary remedial steps, if any.

(1) To the extent that the methods described in subsection (b) of this section are applied to a sample of the Grant Recipients or Grant Awards, then the Institute shall document the Grant Contracts reviewed and the selection criteria for the sample reviewed.

(2) Records will be maintained in the electronic Grant Management System as described in §703.4 of this chapter (relating to Grants Management System).

(e) The Chief Compliance Officer shall be engaged in the Institute's Grant Award monitoring activities and shall notify the General Counsel and Oversight Committee if a Grant Recipient fails to meaningfully comply with the Grant Contract reporting requirements and deadlines, including Matching Funds requirements.

(f) The Chief Executive Officer shall report to the Oversight Committee at least annually on the progress and continued merit of each Grant Program funded by the Institute. The written report shall also be included in the Annual Public Report. The report should be presented to the Oversight Committee at the first meeting following the publication of the Annual Public Report.

(g) The Institute may rely upon third parties to conduct Grant Award monitoring services independently or in conjunction with Institute staff.

(h) 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.

§703.23.Disbursement of Grant Award Funds.

(a) The Institute disburses Grant Award funds by reimbursing the Grant Recipient for allowable costs already expended; however, the nature and circumstances of the Grant Mechanism or a particular Grant Award may justify advance payment of funds by the Institute pursuant to the Grant Contract.

(1) The Chief Executive Officer shall seek authorization from the Oversight Committee to disburse Grant Award funds by advance payment.

(A) A simple majority of Oversight Committee Members present and voting must approve the Chief Executive Officer's advance payment recommendation for the Grant Award.

(B) Unless specifically stated at the time of the Oversight Committee's vote, the Oversight Committee's approval to disburse Grant Award funds by advance payment is effective for the term of the Grant Award.

(2) Unless otherwise specified in the Grant Contract, the amount of Grant Award funds advanced in any particular Tranche [~~tranche~~] may not exceed the budget amount for the corresponding Project Year.

(3) The Grant Recipient receiving advance payment of Grant Award funds must maintain or demonstrate the willingness and ability to maintain procedures to minimize the time elapsing between the transfer of the Grant Award funds and disbursement by the Grant Recipient.

(4) The Grant Recipient must comply with all financial reporting requirements regarding use of Grant Award funds, including timely submission of quarterly Financial Status Reports.

(5) The Grant Recipient must expend at least 90% of the Grant Award funds in a Tranche [~~tranche~~] before Institute will advance additional grant funds or reimburse additional costs. To the extent possible, the Institute will work with the Grant Recipient to coordinate the

advancement of Grant Award fund Tranches [~~tranches~~] in such a way as to avoid affecting work in progress or project planning.

(6) Nothing herein creates an entitlement to advance payment of Grant Award funds; the Institute may determine in its sole discretion that circumstances justify limiting the amount of Grant Award funds eligible for advance payment, may restrict the period for the advance payment of Grant Award funds, or may revert to payment on a reimbursement-basis. Unless specifically stated in the Grant Contract, the Institute will disburse the last ten percent (10%) of the total Grant Award funds using the reimbursement method of funding, and will withhold payment until the Grant Recipient has closed its Grant Contract and the Institute has approved the Grant Recipient's final reports pursuant to §703.14 of this chapter relating to Termination, Extension, Close Out of Grant Contracts, and De-Obligation of Grant Award funds.

(A) A Grant Recipient receiving advance payment may request in writing that the Institute withhold less than ten percent (10%) of the total Grant Award funds. The Grant Recipient must submit the request and reasonable justification to the Institute no sooner than the start of the final year and no later than the start of the final financial status reporting period of the grant project.

(B) The Chief Executive Officer may approve or deny the request. If approved, the Chief Executive Officer will provide written notification to the Oversight Committee. The Chief Executive Officer's decision to approve or deny a request is final.

(b) The Institute will disburse Grant Award funds for actual cash expenditures reported on the Grant Recipient's quarterly Financial Status Report.

(1) Only expenses that are allowable and supported by adequate documentation are eligible to be paid with Grant Award funds.

(2) A Grant Recipient must pay their vendors and subcontractors prior to requesting reimbursement from CPRIT.

(c) The Institute may withhold disbursing Grant Award funds if the Grant Recipient has not submitted required reports, including quarterly Financial Status Reports, Grant Progress Reports, Matching Fund Reports, audits and other financial reports. Unless otherwise specified for the particular Grant Award, Institute approval of the required report(s) is necessary for disbursement of Grant Award funds.

(d) All Grant Award funds are disbursed pursuant to a fully executed Grant Contract. Grant Award funds shall not be disbursed prior to the effective date of the Grant Contract.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: KRISTEN DOYLE, DEPUTY EXECUTIVE OFFICER & GENERAL COUNSEL
CAMERON ECKEL, ASSISTANT GENERAL COUNSEL

SUBJECT: TEXAS OPEN MEETINGS ACT AND PUBLIC INFORMATION ACT UPDATES – T.A.C. § 702.21 TRAINING

DATE: FEBRUARY 5, 2024

Summary

Texas Administrative Code § 702.21 requires that Oversight Committee members receive training on the Texas Public Information Act (PIA) and the Texas Open Meetings Act (TOMA) after each regular session of the legislature. This memo summarizes notable changes made to the PIA and TOMA during the 88th Legislative Session that are applicable to state agencies or CPRIT activities. The information supplements the comprehensive overview of the TOMA (attached), provided to Oversight Committee members in November 2021.

CPRIT legal staff reviewed the recent changes to the PIA and TOMA and consulted a 2023 legislative session update prepared by the Attorney General's Office (attached). Most of the recent amendments to the PIA do not directly impact Oversight Committee members or the agency. However, House Bill 3033 contains several amendments to the PIA, some of which affect CPRIT.

Legal staff reviewed the legislative changes and determined that the amendments to TOMA made in the 2023 session do not affect Oversight Committee open meetings. While there is not a comprehensive legislative update from the Attorney General regarding TOMA, CPRIT will continue to monitor any publications and relay relevant information to the Oversight Committee.

A review of this memo and the attachments fulfill the training required by § 702.21. CPRIT legal staff and Oversight Committee members may meet in closed session for legal advice and counsel on these issues.

Notable Changes to the Texas Public Information Act Affecting CPRIT

HB 3033 (Author: Landgraf): House Bill 3033 was the PIA omnibus bill of the 88th Legislative Session and it includes several amendments to Texas Government Code Chapter 552. Relevant issues for CPRIT include:

- Clarifies that an employee's status as a remote worker does not affect the designation of a "business day" for purposes of calculating due dates under the PIA.

- Updates requirements regarding when and how a governmental body must provide information to a requestor after the governmental body receives an Attorney General's opinion.
- Authorizes the Attorney General to require a public official to complete training if the Attorney General determines that the governmental body has not complied with a requirement in the PIA. Public officials must complete training no later than the 60th day after the public official receives the written notice.
- Allows governmental bodies to set limits on the amount of time personnel may dedicate to providing records to a requestor for inspection or duplication before receiving payment for that time and provides for restrictions on inspecting records for requestors with unpaid invoices.
- Requires the governmental body to use the OAG's electronic filing system for submitting request for Attorney General rulings unless the agency staff hand delivers the request for ruling. A governmental body must pay a fee for each request for ruling filed via the OAG's electronic filing system: $15 for each initial request for a ruling and then $5 for any supplemental documents related to the original request. CPRIT legal staff uses the OAG's electronic filing system to request previous rulings.

2023 Texas Legislative Session Update

The Texas Legislative Session resulted in several amendments to the Public Information Act (the "Act"), chapter 552 of the Government Code. To help familiarize governmental bodies and members of the public with these changes, the Office of the Attorney General (the "OAG") is providing the following list of significant or broadly applicable amendments to Texas public information law. This list does not encompass all changes impacting public information. It is also important to note some of these amendments are only applicable to requests received by a governmental body on or after September 1, 2023. This update is provided as a courtesy and should not be relied upon as legal advice. To learn more about these amendments or recent amendments to other relevant laws, please check the Texas Legislature Online Webpage.

2023 Texas Legislative Session Update

AMENDED STATUTE(S)	RELEVANT BILL	EFFECTIVE DATE	SUMMARY
Educ. Code §§ 12.104, 37.108	**HB 3**	9/1/23	Amends provisions relating to a school's Multihazard Emergency Operations Plan and Safety and Security Audit.

AMENDED STATUTE(S)	RELEVANT BILL	EFFECTIVE DATE	SUMMARY
Gov't Code § 552.108	**HB 30**	9/1/23	Adds section 552.108(d) which limits the applicability of section 552.108(a)(2) law enforcement exception in certain circumstances.
Tax Code § 25.025	**HB 1911**	Immediately	Amends provisions relating to the confidentiality of certain information for certain university healthcare providers.
Various Codes	**HB 2190**	9/1/23	Amends the terminology used to describe transportation-related accidents from "accident(s)" to "collision(s)" throughout Texas Codes.
Util. Code § 182.054	**HB 2644**	Immediately	Amends provision to provide an additional exception to disclosure prohibition found in section 182.052.

[continued on next page]

AMENDED STATUTE(S)	RELEVANT BILL	EFFECTIVE DATE	SUMMARY
Gov't Code §§ 552.0031, .012, .103, .108, .163, .271, .3031, .306, .310	**HB 3033**	9/1/23	(1) Defines business days for purposes of the Act. (2) Adds new training requirement for public officials if the OAG determines the governmental body has failed to comply with a requirement under the Act. (3) Excludes certain information related to elections from section 552.103 litigation exception . (4) Requires a governmental body to promptly release basic information responsive to a request under the Act regardless even if the governmental body seeks a ruling under the Act regarding other information subject to the request. (5) Adds an exception to disclosure for certain OAG settlement communications. (6) Amends section 552.271 to require payment of unpaid statements if the requestor has exceeded the limit established under section 552.275 and seeks to review information on behalf of another requestor. (7) Amends procedures for requestors who have exceeded the limit established under section 552.275, including procedures for photo identification of requestors to determine if they have exceeded time limits. (8) Mandates electronic submission of requests for an OAG decision under the Act unless the governmental body requesting the decision has fewer than 16 full-time employees, is located in a county with a population of less than 150,000, or use of the electronic filing system is impractical or impossible (9) Amends section 552.306 to add procedures and certain notice requirements after a governmental body has received a letter ruling decision from the OAG. (10) Requires OAG to make a publicly accessible and searchable database of letter ruling requests and corresponding decisions issued under the Act. The database must be available on January 1, 2024.

AMENDED STATUTE(S)	RELEVANT BILL	EFFECTIVE DATE	SUMMARY
Gov't Code § 552.138	**HB 3130**	9/1/23	Amends provision relating to the confidentiality of certain occupational licensing information.
Educ. Code § 22.0835(f); Gov't Code Ch. 411	**HB 4123**	Immediately	Relates to access to and use of certain criminal history record information. Updates and reorganizes, as applicable, Texas' criminal background check requirements relating to access to and use of the information and clarifies the duties and responsibilities of an applicable entity with regard to that information and criteria.
Elec. Code § 66.058	**HB 5180**	9/1/2	Amends provision and adds sections concerning the availability of certain election records and procedures related to the production of the records.
Gov't Code § 552.108	**SB 435**	Immediately	Amends provision and adds sections concerning the permissive inspection of a medical examiner's report and/or video evidence of a crime by crime victims and/or victim family members in certain circumstances.
Educ. Code § 51.971	**SB 336**	Immediately	Amends provision to expand the definition of "compliance program".
Gov't Code §§ 552.1176, .11765	**SB 510**	9/1/23	Amends provisions relating to the confidentiality of certain information, including license application and specified personal information, maintained by the State Bar and state licensing agencies.
Tax Code § 25.025	**SB 617**	Immediately	Amends provisions relating to the confidentiality of certain information for a customs and border protection officer or border patrol agent of United States Customs and Border Protection and certain family members.

AMENDED STATUTE(S)	RELEVANT BILL	EFFECTIVE DATE	SUMMARY
Gov't Code § 552.133	**SB 983**	9/1/23	Amends provision relating to disclosure of information related a competitive matter involving the provision of cable, internet, or broadband services by a public power utility.
Gov't Code § 552.1345	**SB 1179**	9/1/23	Adds provision relating to the confidentiality of certain information relating to civilly committed sexually violent predators.
Occ. Code §§ 1701.167, .168, .205	**SB 1445**	9/1/23	Requires TCOLE to set and enforce minimum standards for law enforcement agencies, requires law enforcement agencies to access a national law enforcement database before hiring, and eliminates discharge categories from the F-5 separation form.
Tax Code § 25.025	**SB 1525**	Immediate	Amends provisions relating to the confidentiality of certain information for a current or former attorney for the Department of Family and Protective Services.

Back to Top

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Texas Public Information Act Overview

Background

The Texas Public Information Act (PIA), Government Code Chapter 552, gives the public the right to request government records. The law presumes that the public has access to official information unless the information falls under an exception that allows the governmental body to withhold the requested information. When CPRIT receives a request for information under the PIA, staff must follow the specific procedures and requirements. CPRIT staff may ask Oversight Committee members for official CPRIT-related information that is responsive to a request.

Below is a general overview of the PIA as it relates to CPRIT's Oversight Committee.

What does Texas law consider public information?

The PIA defines public information as information that someone has written, produced, collected, assembled, or maintained under law or ordinance in connection with official business by or for a governmental body. (Tex. Gov't Code § 552.002)

Does CPRIT make the final decision about what information the agency should disclose publicly and what information it can keep information confidential under the PIA?

No. The Office of Attorney General (OAG) determines if an exception to public disclosure applies that allows CPRIT to withhold information from a requestor.

What is the general process CPRIT follows when the agency receives a PIA request?

When CPRIT receives a request under the PIA, legal staff asks agency staff and others (e.g. contractors, Oversight Committee members), if applicable, to collect information responsive to the request that exists at the time of the request. The information may include e-mails, reports, agency documents, etc.

After CPRIT staff has compiled all information potentially responsive to the request, legal staff reviews the information to determine 1.) if the information is responsive to the request, and 2.) whether any of the information should be withheld from public disclosure pursuant to the PIA.

Once legal staff determines that information is responsive to the request and not excluded from public disclosure under the PIA, CPRIT provides the information to the requestor to conclude the request. If the amount of information is voluminous, CPRIT can ask for the requestor to pay reasonable costs for copying the information before CPRIT fulfills the request.

If CPRIT identifies information that is responsive but should be withheld from public disclosure pursuant to the PIA, legal staff notifies the Office of the Attorney General and submits a brief and a copy of the information at issue explaining why CPRIT should not publicly disclose the information. If a third party created the requested information held by CPRIT, legal staff are required by law to notify the third party of the request. The PIA permits the third party to submit their own brief to the Attorney General explaining why CPRIT should not disclose the requested information.

After reviewing the briefs and the information at issue, the Office of the Attorney General issues an opinion directing CPRIT to either provide the information at issue to the requestor or to withhold or redact certain information from public disclosure. The requestor, the agency, or a third party may appeal the Attorney General's opinion.

Is CPRIT required to create information to answer a PIA request?

No. State law requires the agency to provide only information that already exists. For example, a person may request information comparing Texas' cancer rates to cancer rates in France and an explanation for any differences between the two rates. The PIA does not require CPRIT to research and draft a report to respond to the request. CPRIT would respond to the requestor that the agency does not have any responsive information.

Does the PIA apply to Oversight Committee members?

Yes, the PIA is applicable to information that an officer of a governmental body produces or maintains as part of official business. Oversight Committee members are officers of CPRIT and are subject to the PIA as it relates to information maintained or produced in their role as governing board members.

What is the responsibility of an Oversight Committee member under the PIA?

When CPRIT receives a request for information that may be applicable to information held by Oversight Committee members, legal staff will ask Oversight Committee members if they have information responsive to a request.

The responsibility of an Oversight Committee member is to search his or her files (electronic and physical) and devices for responsive information. If an Oversight Committee member is unsure if information in his or her possession is subject to the PIA, the member should reach out to legal staff for guidance rather than withholding the information.

The PIA imposes strict timelines on agencies for complying with requests for public information. Legal staff will provide a deadline when they request responsive information from an Oversight Committee member. It is critical that the Oversight Committee member inform legal staff as soon as possible if the Oversight Committee member is unable to meet the deadline.

What information held by Oversight Committee members may fall under the PIA?

The information the Oversight Committee member receives from CPRIT falls under the PIA. However, CPRIT staff will not ask Oversight Committee members to provide information that the agency already maintains.

An Oversight Committee may generate information as part of their official role that CPRIT does not possess but nonetheless may be responsive to the PIA request. One example is an e-mail sent or received by an Oversight Committee member addressing issues that are part of the member's official duties and does not include a CPRIT employee in the communication.

Is information maintained on an Oversight Committee member's personal device(s) subject to the PIA?

Yes. If an Oversight Committee member holds public information connected to, created, or maintained as part of their official duties as a CPRIT board member, the information is subject to the PIA even if the information is only on his or her personal devices (e.g., laptop, tablet, or cell phone). It is the nature of the information, not the type or ownership of the device that determines if the information is subject to the PIA. The Texas legislature amended the PIA recently to specifically state that public information includes, "any electronic communication created, transmitted, received, or maintained on any device if the communication is in connection with the transaction of official business."[1]

[1] Tex. Gov't Code § 552.002(a-2)

Texas Open Meetings Act – An Overview

Texas Government Code Chapter 551, often referred to as the Texas Open Meetings Act (TOMA or "the Act"), mandates that meetings of governmental bodies such as the Oversight Committee be open to the public, except for specific situations. This summary addresses scenarios when the Act applies to meetings of Oversight Committee members.

Background – Texas Open Meetings Act

For five decades, state law has mandated that, "Every regular, special, or called meeting of a governmental body shall be open to the public, except as provided by [Chapter 551 of the Texas Government Code]."[1] The purpose of the Act, as interpreted by the Texas Supreme Court, is "to safeguard the public's interest in knowing the workings of its governmental bodies."[2] That interest is not served solely by informing the public of the outcome of a governing body's decision on a particular issue. Instead, satisfying public interest occurs only when the public is able "to observe how and why every decision is reached."[3]

Determining whether the Act applies is important because a meeting subject to the Act must comply with specific requirements. A governing board for a state agency like CPRIT must conduct deliberations and discussions in public pursuant to an agenda posted publicly for seven days before the day of the meeting. Texas law limits the governing body's discussion and action to the items listed on the published agenda. The meeting location must be open and accessible to the public. Actions taken at a meeting subject to the Act that fails to comply with these requirements are voidable, and if done with the intention of evading the statutory mandates, can result in criminal penalties for governing board members.

The Office of the Attorney General (OAG) reports that most cases involving open government violations result from public officials simply not knowing what the law requires. The OAG provides the free video training courses as well as publishing several guides to assist governmental bodies in understanding their obligations under the Act. State law requires elected and appointed public officials receive at least two hours of Open Government training within 90 days of the member's appointment; one hour dedicated to Open Meetings and one hour related to the Public Information Act.[4]

---

[1] Tex. Gov't. Code Ann. § 551.002
[2] *Cox Enter., Inc. v. Bd. of Trs. of Austin. Indep. Sch. Dist.*, 706 S.W.2d 956, 960 (Tex. 1986).
[3] *Acker v. Tex. Water Comm'n*, 790 S.W.2d 299, 300 (Tex. 1990).
[4] Tex. Govt. Code §§ 551.005 and 552.012. According to the Attorney General, "The law imposes no specific penalty on officials who fail to attend open government training. The purpose of the law is not to punish public officials, but to foster open government by making open government education a recognized obligation of public service." https://www.texasattorneygeneral.gov/open/og_training.shtml#3, "Frequently Asked Questions about Open Government Training."

When Does the Act Apply to Communications Between Members?

With few exceptions, the Act's requirements (e.g. public notice, posted agenda, meeting open to the public) apply whenever a quorum of the governmental body meets to deliberate the governmental body's public business.

- What is a quorum? For most governmental bodies, including the Oversight Committee, the presence of a simple majority of the appointed members makes up a quorum. The Act requires a quorum of members to convene a meeting. The governmental body cannot bind the agency without a quorum.

  The Attorney General and Texas courts have determined that a quorum may exist even if the members are not physically present in the same location. For example, circulating a group letter among the governmental body members for signatures may constitute a quorum subject to the Act even though the members were not physically together.[5]

- What constitutes a "meeting"? Texas law regards an opportunity to deliberate about the governmental body's public business as a "meeting" subject to the Act. Courts have broadly construed the act of deliberating when interpreting the Act; no action or vote is necessary for a court to find that the governmental body deliberated. Listening to information conveyed by another person may be enough to invoke the Act, even if the governmental body does not discuss or act on the information.[6] For this reason, the Act applies to staff briefings and work sessions if a quorum attends, whether discussion or binding action takes place.

Are There Any Situations When the Act Does Not Apply?

Yes. The Act does not apply to certain situations even though a quorum of the governmental body is present. In these cases, mandates such as notifying the public, posting an agenda, and opening the meeting room to the public are not necessary because the Act does not apply. Exceptions to the Act recognized by state law are:

- social functions unrelated to the board's public business;
- conventions or workshops;
- ceremonial events;
- press conferences;
- public testimony or comments at legislative agency meetings or legislative committee meetings; and
- political forums [added in 2017].

[5] Tex. Att'y Gen. Op. No. DM-95 (1992).
[6] S*ee Bexar Medina Atascosa Water Dist. v. Bexar Medina Atascosa Landowners' Ass*'*n*, 2 S.W.3d 459, 462 (Tex. App.--San Antonio 1999, pet. denied) (deliberations took place at informational gathering of water district board with landowners in board member's barn, where one board member asked questions and another board member answered questions, even though board members did not discuss business among themselves).

The exception applies only if the governmental body does not act on public business during the gathering.

Does the Act Apply to Closed Sessions?

Yes. The Act authorizes governing bodies to hold closed meetings (also referred to as "executive sessions"). Although the requirement that board deliberations take place in public does not pertain these specific topics, the Act still applies. The Oversight Committee may convene in closed session for one or more of the following eight reasons:

1. Consideration of specific personnel matters (this should be a specific individual or individuals, not a job category);
2. Consultations with its attorney;
3. Discussions about the value or transfer of real property;
4. Discussions about security personnel, security devices, or a security audit;
5. Discussions about a prospective gift or donation to a governmental body;
6. Discussions of certain economic development matters;
7. Certain information regarding emergencies and disasters; and
8. Discussion of an ongoing compliance investigation related to fraud, waste, or abuse of state resources.

CPRIT must list the items discussed in closed session on the meeting agenda and the meeting must convene first in open session. Governing bodies may use closed sessions only for deliberations. Any vote related to a matter discussed in closed session must take place in an open meeting.

Does the Act Apply to Oversight Committee Subcommittee Meetings?

No. Meetings of Oversight Committee subcommittees need not comply with the requirements of the Act because there is not a quorum of members and the Oversight Committee does not authorize any of the subcommittees to act in a way that binds the agency.

In most cases, a meeting of a quorum of members is necessary for the Act to apply. However, the Act will apply to a subgroup of governmental body members if the subgroup has the authority to make final decisions on behalf of the governmental body. No subcommittee currently constituted under the Oversight Committee Bylaws is authorized to take decisive action on behalf of the Oversight Committee. The bylaws limit subcommittee activity to recommending an action for the Oversight Committee's consideration. The board discusses the subcommittee's recommendations in the open meeting before acting; the recommendations are not simply rubberstamped.

Similarly, the Act does not apply to a group of Oversight Committee members that meets with a public or private group so long as there is not a quorum of Oversight Committee members. For

example, the Act does not apply to a meeting of three Oversight Committee members and CPRIT's University Advisory Committee.

Is a Conference Call or an Email Between Members Considered a "Meeting"?

[*This section addresses discussions between Oversight Committee members that occur by telephone or by email. Guidance regarding participation in an open meeting via telephone or videoconference is a different issue addressed in the section, "Can an Oversight Committee Member Participate in Open Meeting by Phone or Video Conference?" The section, "Are There Other Ways for a Quorum of the Oversight Committee to Communicate Electronically?" provides guidance related to the statutory provision permitting electronic communication among board members via an online message board.*]

In most cases, there must be a quorum of members present when a discussion of public business occurs for requirements of the Act to apply. However, physical presence in the same location is not necessary to invoke the Act. Discussing public business by phone or email with a quorum of members may be a violation of the Act. This can occur when one Oversight Committee member sends an email about public business to four or more board members or forwards an email discussion about public business between some Oversight Committee members to other members. Whether certain phone conversations or emails between members constitute a violation of the Act is a fact issue.[7]

Even if a quorum is not part of the call or email, using telephone conversations or electronic communication (including texting) with the intention to conduct deliberations about public business in private may result in criminal violations.[8] Members of a governmental body should be wary because technology makes it easier to hold serial private discussions among members about public business. See the discussion about "walking" quorums for more guidance.

What is a "Walking" Quorum?

A walking quorum occurs when:

(1) a series of smaller group meetings (less than a quorum) occur; and
(2) members use the smaller group meetings to intentionally avoid constituting a quorum and evade the requirements of the Act.[9]

[7] *See Hitt v. Mabry*, 687 S.W.2d 791 (Tex. App. B San Antonio 1985, no writ) (school trustees violated Act by telephone conferencing). *But see Harris County Emergency Serv, Dist. #1 v. Harris County Emergency Corps*, 999 S.W.2d 163 (Tex. App. B Houston [14th Dist.] 1999, no writ) (evidence that one board member of a five-member county emergency service district occasionally used telephone to discuss agenda for future meetings with one other board member did not amount to Act violation).
[8] Tex. Gov't Code Ann. § 551.143.
[9] Tex. Govt. Code Ann. § 551.143.

Texas courts have not limited their interpretation of a walking quorums to physical meetings. It may be a criminal violation if the members meet or communicate by phone, memo, text, or email in numbers less than a quorum if the specific intent for doing so is to hold secret deliberations and circumvent the Act.

In February 2019, the Texas Court of Criminal Appeals struck down the provision relating to the "walking quorum" stating the law was too vague.[10] After this ruling, Senator Watson introduced SB 1640 to revise the "walking quorum" provision in TOMA with the goal to clearly prohibit the practice. Senate Bill 1640 passed both chambers with near-unanimous votes; Governor Abbott signed it to take effect immediately. Notably, state law now defines "deliberation" include both verbal and written exchanges between a quorum of members or a quorum and another person on an issue under the body's jurisdiction.

Can an Oversight Committee Member Participate in an Open (or Closed) Meeting by Phone or Video Conference?[11]

Yes, in limited circumstances. Participation by phone may occur in the event of an emergency when convening a quorum is difficult or impossible. The Act also permits a governing board member to participate in an open or closed meeting by video conference even when there is no emergency.

- Participating in a Meeting by Phone – A governing body may not conduct meetings subject to the Act by phone unless it meets the following two requirements:

  (1) an emergency or public necessity exists;

  An emergency or public necessity exists only if the governmental body must take immediate action resulting from an imminent threat to public health or safety or a reasonably unforeseeable situation. Whether an emergency exists is a fact-based question subject to judicial review.

  AND

  (2) convening a quorum in one location is difficult or impossible.[12]

  A member may not participate by phone even in an emergency scenario if a quorum of the governing body is able to meet in one location. A requirement to justify participation by telephone is that it is difficult or impossible for the agency to convene a quorum in one location.

[10] *See State v. Doyal*, No. PD-0254-18 (Tex. Crim. App. Feb. 27, 2019).
[11] During the COVID pandemic, Governor Abbott issued an executive order suspending some provisions of the Texas Open Meetings Act, including the provision that members of the governing body meet in person. The governor's executive order expired August 31, 2021.
[12] Tex. Govt. Code Ann. §§ 551.121 - .126.

If the governing body properly convenes an open meeting where one or more members participate by phone, then the meeting must be audible to the public at the location specified in the notice with two-way communication available during the entire meeting. The governing body must record the meeting, with every party identified before speaking.

- Participating by Video Conference – A governing body may hold an open or closed meeting by video conference.[13] The Attorney General provided in guidance late 2019 that clarifies the statutory requirements for videoconference participation. One principal issue of confusion related to whether the governing board's elected/appointed presiding officer must physically attend the open meeting. The Attorney General's interpretation is that the person presiding over the open meeting must attend the meeting in person; however, that role is not exclusive to the elected presiding officer if there is a process in place to delegate the presiding officer's role to another member. Texas law also allows a member of the public to testify at a meeting from a remote location by video conference.

  How is quorum determined when members are participating via videoconference?
  Members participating by videoconference will count toward the number of members needed for quorum. For the nine-member Oversight Committee, a quorum is five members present in person or participating via live videoconference.

  If the member participating by videoconference loses audio and/or video connection with the meeting site, then that member does not count for purposes of the quorum. If the remote member's attendance via videoconference is necessary to achieve quorum, the Oversight Committee may take no action until the remote member restores the connection. The meeting may recess up to six hours to allow time for resolving technical issues. If the remote member is not back online within six hours, then the presiding officer must adjourn the meeting.

  Who must be physically present at the open meeting when one or more members are participating by videoconferencing?
  At least one member of governmental body must be physically present to preside over the open meeting at the location specified in the published meeting notice.

  Is the member attending by videoconference required to be visible to the public?
  Yes. The video and audio quality must be such that the public and other board members must be able to see the facial expressions of the member participating by videoconference as well as hear the member's questions and input. State law requires the governing body to have a monitor (at least 27-inches) at the physical location for each member participating remotely. The monitor's screen should be fully visible to the public at the meeting site and on the meeting livestream, with the volume loud enough to hear the remote member.
  Are there any special notice requirements to hold a meeting via videoconference?

[13] Tex. Govt. Code Ann. 551.127

Yes. In addition to following the regular open meeting notice requirements, the meeting notice must state that one or more members may participate via videoconference and that the member presiding over the meeting will be present at the location listed in the notice. Governing body members may not participate via videoconference if the meeting notice does not contain the required notice.

Should the Oversight Committee decide that videoconference participation may be an option for its members, Legal will include a standing notice in all future published meeting agendas regarding the possibility of videoconference participation.

May the governmental body's elected or appointed presiding officer attend a meeting by videoconference?
Yes, but TOMA prohibits any member that participates in a meeting by videoconference from presiding over that meeting. According to the Attorney General, the governing body's presiding officer may delegate the role to another member who is physically present at the meeting site if the presiding officer is unable to attend the meeting in person and will participate by videoconference instead.

Oversight Committee bylaws allow for the delegation of the chairperson's role to another member when the chairperson participates by videoconference.

Are There Other Ways for the Entire Oversight Committee to Communicate Electronically?

Yes. The Act permits communications about public business between members of a governmental body and its staff to take place electronically so long as the governmental body posts the written communication to an online message board that is accessible to the public. Such a discussion "does not constitute a meeting or deliberation," under the Act.

An electronic message board is an example of using technology to aid effective functioning of the governmental body without sacrificing transparency. It provides a forum for governing board members to discuss agency business in between traditional meetings. The governmental body must own or control the online message board, which must be publicly accessible within one click from the governmental body's home page. The message board should display the communication in real time, attributable by the name and title of the member or staff. The governmental body may not vote or take any action via posting to the online message board. The communication should be viewable for at least 30 days and retained as an agency record for six years.

The Austin City Council uses an electronic message board to communicate among the members and staff. You can see the city's bulletin board here (click on "View Active Topics" on the message board landing page to see discussion topics.)

Does the Act Apply to Social Media?

Yes, although the Act does not provide much guidance specifically addressing social media. Modern technologies such as Twitter, Facebook, Instagram, texting, and instant messaging make it easier for governmental body members to inadvertently (or intentionally) conduct a meeting that is subject to the Act's requirements. Other than authorizing the online electronic message board, the Texas Legislature has not addressed social media issues affecting open meetings. The Senate Committee on State Affairs' Interim Report to the 82nd Legislature opined, "…under the current interpretations of the Act, a quorum would exist if a majority of the governmental body discusses public business on a Facebook wall…A similar situation could arise with Twitter where members can have public or private accounts."[14]

What are the Consequences for Violating the Act?

Actions taken in violation of the Act are voidable. Certain violations of the Act may result in criminal penalties for board members if prosecutors prove an intent to evade or violate the Act's requirements. Criminal violations include knowing participation in a walking quorum or an unauthorized closed meeting.

[14] SENATE COMMITTEE ON STATE AFFAIRS, INTERIM REPORT TO THE 82D LEGISLATURE at 59 (Dec. 2010).

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	HEIDI MCCONNELL, CHIEF OPERATING OFFICER
SUBJECT:	CHIEF OPERATING OFFICER REPORT
DATE:	FEBRUARY 7, 2024

CPRIT Financial Overview for FY 2024, Quarter 1

FY 2024, Quarter 1 Operating Budget

CPRIT has an appropriated budget of $4.9 million in Indirect Administration and approximately $16.1 million budgeted in Grant Review and Award Operations. The Grant Review and Award Operations budget includes the majority of the agency's vendor contracts which support grant award and administration, including the $9.7 million contract for grant management support services with GDIT.

CPRIT carried forward $614,401 from FY 2023 to FY 2024. This amount includes $113,401 in contracts carried forward to cover contract extensions for Weaver and Tidwell LLP ($1,901), Swift Solutions ($99,000) for conference planning and coordinating services, and Wellspring Worldwide, Inc. ($12,500) for the implementation of the intellectual property tracking and reporting system, Sophia Knowledge Management System (KMS). There is also $501,000 carried forward from the IT budget to complete multiple IT projects and hardware renewals originally planned in FY 2023.

In addition, the 88th Texas Legislature appropriated $182,351 in FY 2024 out of CPRIT's general obligation proceeds to cover the across-the-board 5% salary increase for state employees. From this amount, CPRIT apportioned 75%, or $136,763, to Grant Review and Award Operations to cover CPRIT employees allocated to this budget strategy and the remaining 25%, or $45,588, to Indirect Administration to cover the employees allocated in this strategy.

The combination of the amounts carried forward and appropriated for the salary adjustment increased Indirect Administration to approximately $5.8 million and Grant Review and Award Operations to approximately $16.3 million.

CPRIT received approximately $146,180 in revenue sharing payments during the first quarter. This amount includes the receipt of a quarterly royalty payment for $80,902 from Merck & Co., Inc. from the sales revenue of WELIREG™ (belzutifan).

Revenue sharing payment deposits from CPRIT's inception total approximately $9.7 million through the end of November 2023.

FY 2024, Quarter 1 Performance Measure Report

In the first quarter, CPRIT reported to the Legislative Budget Board a total of 195,607 people served through CPRIT prevention and control grants and no company relocations.

Debt Issuance History

The Texas Public Finance Authority (TPFA) issued $92.8 million in commercial paper notes on CPRIT's behalf in October 2023. This was the first tranche of issuances against the $298.4 million projected to be issued in FY 2024.

TPFA then proceeded to issue $298.4 million in long-term CPRIT Series 2023A bonds in November 2023, the entire amount of funding that CPRIT projected for issuance. Of that $92.8 million refunded the commercial paper notes issued the month before, and the rest was new money. As a result, there will be no more transactions in FY 2024.

Cancer Prevention and Research Institute of Texas
Quarterly Financial Report
As of November 30, 2023

Indirect Administration (B.1.1.)

		2024 Appropriated	2024 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
1001	Salaries and Wages	$ 1,847,425	$ 1,862,286		$ 480,872	1,381,415	26%	$ 480,872	$ 1,381,415
1002	Other Personnel Costs	38,785	38,785		6,158	32,628	16%	6,158	32,628
2001	Professional Fees and Services	1,808,662	2,118,039		552,395	1,565,644	26%	552,395	1,565,644
2003	Consumable Supplies	24,000	24,000		839	23,161	3%	839	23,161
2004	Utilities	58,600	58,600		40,567	18,033	69%	40,567	18,033
2005	Travel	45,000	45,000		24,132	20,868	54%	24,132	20,868
2006	Rent-Building	11,000	11,000		2,334	8,666	0%	2,334	8,666
2007	Rent-Machine and Other	32,172	32,172		7,460	24,712	23%	7,460	24,712
2009	Other Operating Expenses	1,045,249	1,645,249		557,250	1,087,999	34%	557,250	1,087,999
	Subtotal - Indirect Administration (B.1.1.)	**$ 4,910,893**	**$ 5,835,132**	**1.96%**	**$ 1,672,006**	**$ 4,163,125**	**29%**	**$ 1,672,006**	**$ 4,163,125**

Grant Review and Award Operations (A.1.3.)

		2024 Appropriated	2024 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
1001	Salaries and Wages	$ 3,505,873	3,332,230		$ 1,049,153	$ 2,283,077	31%	$ 1,049,153	$ 2,283,077
1002	Other Personnel Costs	45,000	45,000		11,609	33,391	0%	11,609	33,391
2001	Professional Fees and Services	12,419,373	12,520,777		10,971,478	1,549,299	88%	10,971,478	1,549,299
2003	Consumable Supplies	-	-		-	-	0%	-	-
2004	Utilities	12,000	12,000		-	12,000	0%	-	12,000
2005	Travel	45,000	45,000		7,763	37,237	17%	7,763	37,237
2009	Other Operating Expenses	71,649	342,148		6,458	335,691	2%	6,458	335,691
	Subtotal - Grant Operations (A.1.3.)	**$ 16,098,895**	**$ 16,297,155**	**5.47%**	**$ 12,046,460**	**$ 4,250,695**	**74%**	**$ 12,046,460**	**$ 4,250,695**

Grants

		2024 Appropriated	2024 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
4000	Grants - Prevention (A.1.2)	$ 27,671,780	$ 27,544,573		$ -	$ 27,544,573	0%	$ -	$ 27,544,573
4000	Grants - Research (A.1.1.)	248,251,400	$ 248,251,400		63,196,634	$ 185,054,766	25%	63,196,634	185,054,766
	Subtotal - Grants	**$ 275,923,180**	**$ 275,795,973**	**92.57%**	**$ 63,196,634**	**$ 212,599,339**	**23%**	**$ 63,196,634**	**$ 212,599,339**
	Grand Totals	**$ 296,932,968**	**$ 297,928,260**	**100.00%**	**$ 76,915,101**	**$ 221,013,159**	**26%**	**$ 76,915,101**	**$ 221,013,159**

Cancer Prevention and Research Institute of Texas

Cancer Prevention and Research Institute Fund Account - 5136

As of November 30, 2023

	11/01/2023-11/30/2023	AY 23 Year to Date as of 11/30/2023
Beginning Balance : 9/01/2023		**$ 600,506**
Increases:		
(1)	$ -	$ -
(2)	-	
Total Increases	**$ -**	**$ 600,506.00**
Reductions:		
Expenditures - Appropriated	$ -	$ -
	$ -	$ -
	$ -	$ -
Total Reductions	**$ -**	**$ -**
Ending Balance: 11/30/2023		**$ 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 November 30, 2023

		11/01/2023-11/30/2023	AY 23 Year to Date as of 11/30/2023
Beginning Balance : 9/01/2023			**$ 101,766.48**
Increases:			
(1)	License Plate Revenue Received	$ 339.16	$ 1,325.48
	Interest	$ 168.81	$ 514.65
Total Increases		**$ 507.97**	**$ 103,606.61**
Reductions:			
	Expenditures - Appropriated	$ -	$ -
		-	-
Total Reductions		**$ -**	**$ -**
Ending Balance: 11/30/2023			**$ 103,606.61**

Note:

Balance forward from 2023 License Plate $101,766.48

Cancer Prevention and Research Institute of Texas

Appropriated Receipts - 666

As of November 30, 2023

		11/01/2023-11/30/2023	AY 23 Year to Date as of 11/30/2023
Beginning Balance : 9/01/2023			**$ 243,044.65**
Increases:			
(1)	Product Development Application Fees Received	$ -	$ -
(2)	Conference Registration Fees	$ -	$ 80,940.00
(3)	Conference Registration Fees-Credit Card	$ -	$ 1,761.70
Total Increases		**$ -**	**$ 82,701.70**
Reductions:			
	Conference Expenditures - Appropriated	$ -	$ -
	Credit Card Fees Expended	$ (1,124.54)	$ (1,124.54)
	Refund-Application Fees	$ -	$ -
	Legal Services Expenses (Application Fees)	$ -	$ -
Total Reductions		**$ (1,124.54)**	**$ (1,124.54)**
Ending Balance: 11/30/2023			**$ 324,621.81**

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 November 30, 2023

		11/01/2023-11/30/2023	AY 23 Year to Date as of 11/30/2023
Beginning Balance : 9/01/2023			**$ 6,390,606.01**
Increases:			
(1)	Revenue Sharing / Royalties	$ 104,746.30	$ 138,189.00
		$ -	$ -
Total Increases		**$ 104,746.30**	**$ 6,528,795.01**
Reductions:			
	Expenditures - Appropriated	$ -	$ -
		$ -	
		$ -	$ -
Total Reductions		**$ -**	**$ -**
Ending Balance: 11/30/2023			**$ 6,528,795.01**

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

Cancer Prevention and Research Institute of Texas
FY 2024, Quarter 1 Performance Measure Report

Measure	Targeted Performance	QTR 1	QTR 2	QTR 3	QTR 4	Sum of QTRs	% of Mandate Attained
Number of People Served by Institute Funded Prevention and Control Activities	750,000	195,607	0	0	0	195,607	26.08%
Number of Entities Relocating to TX for Cancer Research Related Projects	3	0	-	-	-	0	0.00%
Annual Age-adjusted Cancer Mortality Rate	138.0	N/A	N/A	N/A	N/A	0.0	0.00%
Number of Published Articles on CPRIT-Funded Research Projects	1,000	N/A	N/A	N/A	N/A	0	0.00%
Number of New Jobs Created and Maintained	3,000	N/A	N/A	N/A	N/A	0	0.00%

Variance Explanations

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 two companies who received a CPRIT award were able to complete this process.

CPRIT Commercial Paper and G.O. Bond Issuance

Fiscal Year	Amount Appropriated	Dated Issued	Amount Issued	Amount Issued for Fiscal Year	Commercial Paper or GO Bond Issuance	Series	Comments	Interest Rate
2010	$ 225,000,000	September 9, 2009	$ 9,100,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2010		September 9, 2009	$ 3,600,000		Commercial Paper Notes	Series B, Tax-Exempt	Defeased with cash July 2011	
2010		March 12, 2010	$ 63,800,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2010		August 26, 2010	$ 148,500,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
				$ 225,000,000				
2011	$ 225,000,000	September 7, 2010	$ 11,800,000		Commercial Paper Notes	Series A, Taxable		
2011		August 10, 2011	$ 51,000,000		G.O. Bonds	Taxable Series 2011	Par amount of new money	Fixed Rate Bonds All-In-True Interest Cost 4.0144%
2011		August 10, 2011	$ 232,045,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2011	Par amount of refunding; Refunded $233.2M of GOCP CPRIT Series A (9/9/09, 3/12/09, 8/26/09, 9/7/10)	Fixed Rate Bonds All-In-True Interest Cost 4.0144%
				$ 62,800,000				
2012	$ 300,000,000	September 7, 2011	$ 3,200,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2012		December 8, 2011	$ 3,200,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2012		March 2, 2012	$ 12,300,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2012		June 21, 2012	$ 15,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2012		August 16, 2012	$ 42,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
				$ 75,700,000				
2013	$ 300,000,000	September 6, 2012	$ 9,600,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2013		May 16,2013	$ 13,400,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
				$ 23,000,000				
2014	$ 300,000,000	November 25, 2013	$ 55,200,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2014		March 13, 2014	$ 47,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2014		June 17, 2014	$ 60,300,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2014		July 8, 2014	$ 233,280,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2014	Par amount of refunding; Refunded $237.88M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 3.327184%
				$ 162,500,000				
2015	$ 300,000,000	November 5, 2014	$ 57,600,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2015		April 29, 2014	$ 112,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2015		June 26, 2015	$ 75,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
				$ 244,600,000				

CPRIT Commercial Paper and G.O. Bond Issuance

Fiscal Year	Amount Appropriated	Dated Issued	Amount Issued	Amount Issued for Fiscal Year	Commercial Paper or GO Bond Issuance	Series	Comments	Interest Rate
2016	$ 300,000,000	September 22, 2015	$ 55,400,000		Commercial Paper Notes	Series A, Taxable		
2016		October 29, 2015	$ 300,000,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2015C	Par amount of refunding; Refunded $300M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 3.299867%
2016		October 29, 2015	$ 69,800,000		G.O. Bonds	Taxable Series 2015C	Par amount of new money: Disbursed to CPRIT January 2016	Fixed Rate Bonds All-In-True Interest Cost 3.299867%
2016		May 16, 2016	$ 92,100,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2016		August 29, 2016	$ 60,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
				$ 277,300,000				
2017	$300,000,000	October 19, 2016	$ 58,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2017		January 5, 2017	$ 58,900,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2017		February 8, 2017	$ 269,000,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2017	Par amount of refunding: Refunded $269M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 3.4622%
2017		February 8, 2017	$ 106,000,000		G.O. Bonds	Taxable Series 2017	Par amount of new money	Fixed Rate Bonds All-In-True Interest Cost 3.4622 %
				$ 222,900,000				
2018	$300,000,000	September 29, 2017	$ 68,200,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2018		March 8, 2018	$ 99,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2018		July 11, 2018	$ 55,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
				$ 222,200,000				
2019		September 21, 2018	$ 222,200,000		G.O. Bond (Refunding Bonds)	Taxable Series 2018	Par amount of refunding: Refunded $222.2M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 3.720632%
2019	$300,000,000	September 21, 2018	$ 75,975,000		G.O. Bonds	Taxable Series 2018	Par amount of new money	Fixed Rate Bonds All-In-True Interest Cost 3.720544%
2019		March 28, 2019	$ 77,725,000		Commercial Paper Notes	Series A, Taxable		Interest rates between 1.90% - 2.55%
2019		July 12, 2019	$ 54,000,000		Commercial Paper Notes	Series A, Taxable		Interest rates between 1.95% - 2.35%
				$ 207,700,000				

CPRIT Commercial Paper and G.O. Bond Issuance

Fiscal Year	Amount Appropriated	Dated Issued	Amount Issued	Amount Issued for Fiscal Year	Commercial Paper or GO Bond Issuance	Series	Comments	Interest Rate
2020		September 16, 2019	$ 64,300,000		Commercial Paper Notes	Series A, Taxable		Interest rate of 2.10%
2020		January 9, 2020	$ 52,000,000		Commercial Paper Notes	Series A, Taxable		
2020		April 23, 2020	$ 237,720,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2020	Par amount of refunding: Refunded $248.025M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 2.644360%
2020		April 23, 2020	$ 115,000,000		G.O. Bonds	Taxable Series 2020	Par amount of new money	Fixed Rate Bonds All-In-True Interest Cost 2.644360%
2020		April 23, 2020	$ 119,750,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2020	Par amount of refunding. Refunded $120.525M of Taxable Series 2011	
				$ 231,300,000				
2021	$300,000,000	September 11, 2020	$ 75,000,000		Commercial Paper Notes	Series A, Taxable		
2021		January 14, 2021	$ 59,000,000		Commercial Paper Notes	Series A, Taxable		
2021		April 29, 2021	$ 68,900,000		Commercial Paper Notes	Series A, Taxable		
2021		August 12, 2021	$ 57,400,000		Commercial Paper Notes	Series A, Taxable		
				$ 260,300,000				
2022	$300,000,000	September 28, 2021	$ 87,000,000		Commercial Paper Notes	Series A, Taxable		
2022		November 18, 2021	$ 334,745,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2021B	Par amount of refunding: Refunded $347.300M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 2.191715%
2022		November 18, 2021	$ 139,565,000		G.O. Bonds	Taxable Series 2021B	New money proceeds of $144.800M	Fixed Rate Bonds All-In-True Interest Cost 2.191715%
2022		November 18, 2021	$ 108,005,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2021B	Par amount of refunding: Refunded $108.660M of Taxable Series 2014B	Fixed Rate Bonds All-In-True Interest Cost 2.191715%
2022		July 14, 2022	$ 66,300,000		Commercial Paper Notes	Series A, Taxable		Interest rate of 2.30%
				$ 298,100,000				
2023	$300,000,000	September 20, 2022	$ 79,500,000		Commercial Paper Notes	Series A, Taxable		Interest rate of 3.15%
2023		March 2, 2023	$ 66,000,000		Commercial Paper Notes	Series A, Taxable		Interest rate of 4.80%
2023		April 6, 2023	$ 79,000,000		Commercial Paper Notes	Series A, Taxable		Interest rate of 5.10%
2023		June 15, 2023	$ 59,200,000		Commercial Paper Notes	Series A, Taxable		Interest rate of 5.40%
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		Interest rate of 5.45%
		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				
TOTAL ISSUED TO DATE				**$ 3,110,100,000**				

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	KRISTEN DOYLE, DEPUTY EXECUTIVE DIRECTOR AND GENERAL COUNSEL
SUBJECT:	OUTSIDE COUNSEL CONTRACT AMENDMENTS
DATE:	FEBRUARY 13, 2024

Summary and Recommendation

CPRIT staff recommend that the Oversight Committee approve a $60,000 increase to the fiscal year 2024 outside counsel contracts with Norton Rose Fulbright and McDermott Will & Emery. This increase, which would bring the total of each contract to $155,000 for FY 2024, is necessary to conduct intellectual property due diligence review for companies that advance to due diligence review in product development research cycle 24.2.

Background

CPRIT contracts with outside counsel to conduct intellectual property (IP) due diligence for companies under consideration for product development research awards. CPRIT uses multiple outside counsel firms to distribute the workload and avoid potential conflicts of interest. In FY 2024, CPRIT has contracts with two law firms to serve as outside counsel, Norton Rose Fulbright and McDermott Will & Emery.

The outside counsel contract budget amendment is necessary because the amount remaining for outside counsel services after the first cycle of review for FY 2024 will not be adequate to cover the expected workload for the second review cycle this year. CPRIT has invited 16 companies to submit full applications for product development review cycle 24.2. With Oversight Committee approval, CPRIT will increase the original $95,000 contract for each firm by $60,000, bringing each contract amount to $155,000. This results in a not-to-exceed outside legal service budget for FY 2024 of $310,000.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	MARK DALLAS LOEFFLER
SUBJECT:	COMMUNICATIONS UPDATE
DATE:	FEBRUARY 12, 2024

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

Annual Report

The Communications team compiled and released the 2023 CPRIT Annual Report. Pursuant to Health and Safety Code § 102.052, CPRIT provided its annual report to state legislators, leadership, and the public on January 31. The Annual Report is available in an online format. This year's report featured almost 40 new articles and briefs highlighting CPRIT-funded grantees and programs, a new interactive map displaying prevention grants per legislative districts, and a recap and photo gallery from the 2023 CPRIT Innovations VI conference. Notification of the release was provided via email, online news, and social media. The 2023 CPRIT Annual Report can be accessed from the CPRIT home page, or visiting this address: https://2023annualreport.cprit.texas.gov/

Scholars Letter

The Communications team coordinated the release of CEO Wayne Roberts' February 8th letter to state legislators highlighting several recent achievements, in particular the recruitment of the 300th CPRIT Scholar to Texas. CPRIT provided the hardcopy letter to all state legislators, the Governor, Lieutenant Governor, and Speaker of the Texas House.

Direct Communication

The communications team distributed listserv notifications regarding:

- Press release for November OC meeting
- ACS CAN North Texas Policy Forum 2023
- Product Development Research RFAs (24.2)
- Updates to Academic Research Program Cycle 24.2 RFAs
- Updates to CPRIT Policies and Procedures Guide December
- Event Announcement - BioNTX at Texas Tech
- 2023 CPRIT Annual Report (to public and legislative audiences)

- CPRIT Grantee Training Webinars - MARCH 6-7, 2024
- New Prevention Program RFAs February 9, 2024

Media Relations

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

- Press Release (November 15, 2023): CPRIT illustrates global impact with $63 million in research grants
- Press Release (February 6, 2024): CPRIT receives major public service award from state science organization

Newsclips

We shared 568 articles and social media posts through CPRIT ENews from November 6th to February 9th.

Social Media Statistics

Social Media from November 6, 2023, to February 9th, 2024

Facebook	X	LinkedIn
7.94% post engagement rate	**3.06%** engagement rate	**4.37%** engagement rate
1,276 Fans (**+2**)	**3,534** followers (**+9**)	**3,338** followers (**+176**)
Top Post: **12.13%** engagement (11/15/23)	Top Tweet: **404** impressions (11/15/23)	Top Post: **4,022** impressions (11/15/23)

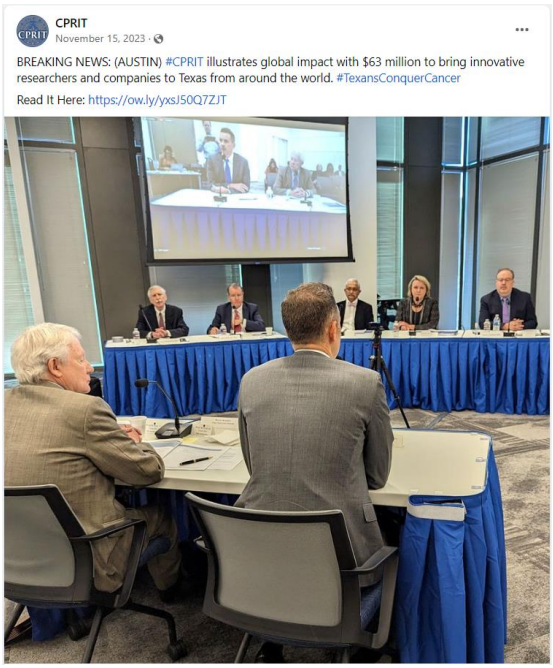
Website Hits and Visitors November 6, 2023, to February 9th, 2024

Users	New Users	Sessions (Visits)	Pageviews	Engage Rate
21,064	**19,751**	**33,738**	**61,384**	**52.09%**

Top Performing Posts

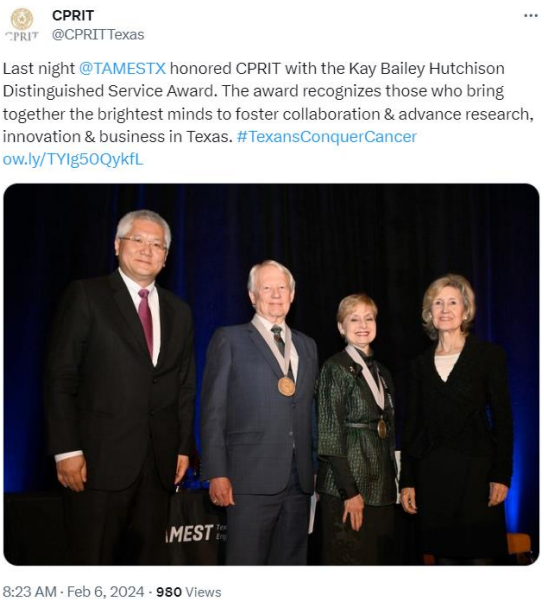
FACEBOOK: 11/15/23

BREAKING NEWS: (AUSTIN) #CPRIT illustrates global impact with $63 million to bring innovative researchers and companies to Texas from around the world. #TexansConquerCancer
Read It Here: https://ow.ly/yxsJ50Q7ZJT



X: 2/6/24

Last night @TAMESTX honored CPRIT with the Kay Bailey Hutchison Distinguished Service Award. The award recognizes those who bring together the brightest minds to foster collaboration & advance research, innovation & business in Texas. #TexansConquerCancer
https://ow.ly/TYIg50QykfL



LINKEDIN: 11/15/23

BREAKING NEWS: (AUSTIN) #CPRIT illustrates global impact with $63 million to bring innovative researchers and companies to Texas from around the world. #TexansConquerCancer Read It Here: https://ow.ly/IZkQ50Q7ZJU

Cancer Prevention and Research Institute of Texas' Post