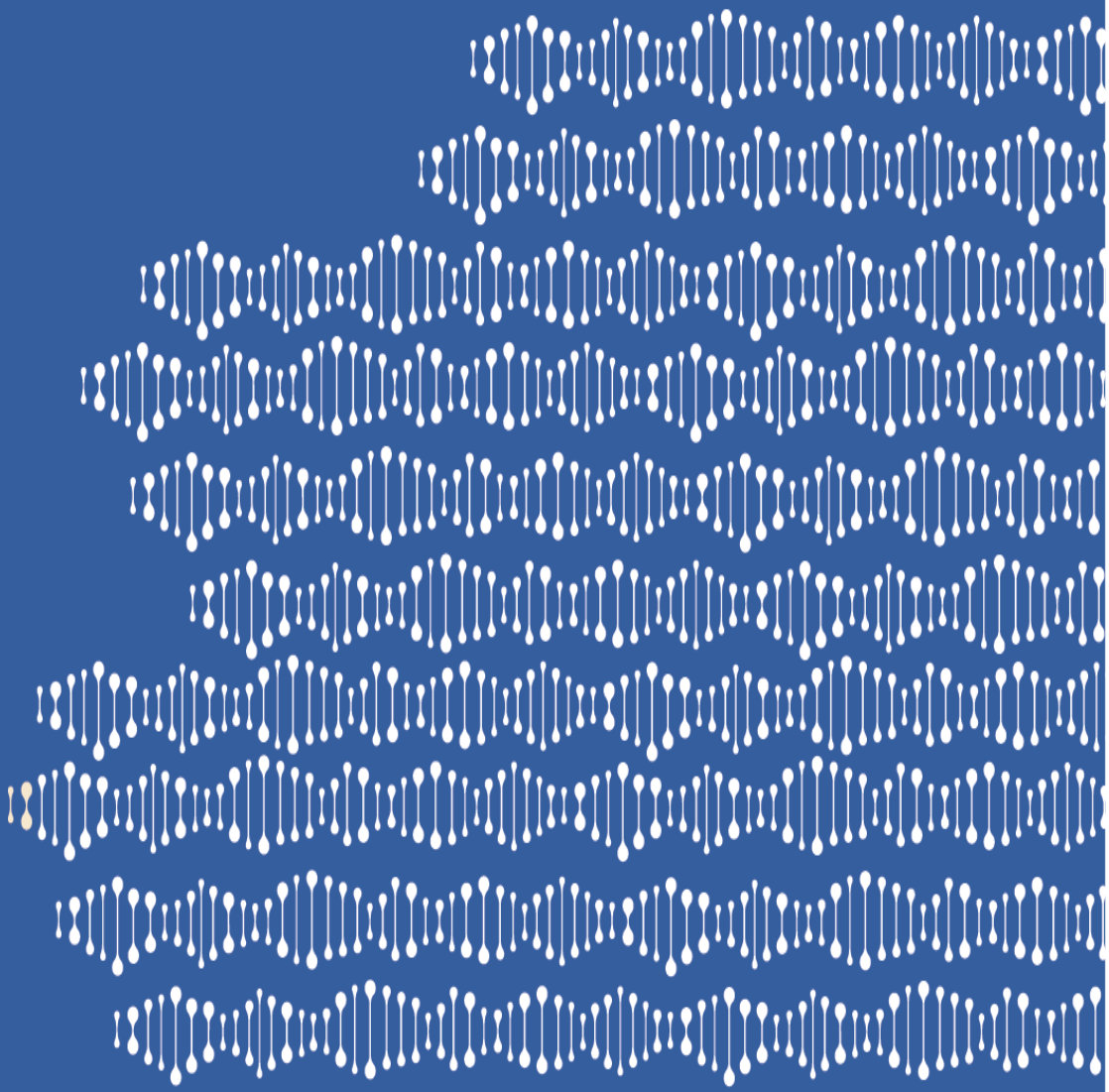
CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Meeting

August 16, 2023



CANCER PREVENTION & RESEARCH
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Summary Overview of the August 16, 2023, Oversight Committee Meeting

This summary provides an overview of major agenda items and background on key issues for Committee consideration at the August 16, 2023, Oversight Committee meeting.

CEO Report
Wayne Roberts will present the CEO's report and address issues including a personnel update, grant funds available for FY 2023 and other topics.

Chief Compliance Officer Report and Grant Award Certification
Vince Burgess will report on the status of required grantee reports, financial status report reviews, desk reviews and site visits, annual compliance attestation, audit tracking, and training. He will also certify that the proposed awards and review process 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) 20 award recommendations for the Texas CONNECT for Cancer Prevention Study Award, the TREC: Institutional Postdoctoral Training Award, the TREC: Major Instrument Awards, the TREC: Pilot Study Awards, Recruitment of Established Investigators and Recruitment of First-Time, Tenure-Track Faculty Members, totaling $36 million. She will also present FY 2024 requests for applications.

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

Chief Prevention Officer Report and Grant Award Recommendations
Ramona Magid and Program Manager Carlton Allen will update the Oversight Committee on the on the agency's prevention activities and present the PIC's nine award recommendations totaling $13,343,163. The recommended awards include Cancer Screening and Early Detection; Colorectal Cancer Screening Coordinating Center; Dissemination of CPRIT-Funded Cancer Control Interventions; and Primary Prevention of Cancer.

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

Chief Product Development Officer Report and Grant Award Recommendation
Dr. Ken Smith and Senior Program Manager Dr. Abria Magee will provide an update on the Product Development Program.

Internal Auditor Report
Weaver and Tidwell, CPRIT's internal auditor, will provide an internal audit update, as well as an update on the Internal Audit Report over Information Technology General Controls. The IT General Controls update will take place in closed session.

Appointments to the Scientific Research and Prevention Programs Committee
Mr. Roberts has provisionally appointed 25 new members to CPRIT's Scientific Research and Prevention Programs Committees. CPRIT's statute requires the Oversight Committee to approve the CEO's recommendations before the appointments are final. CPRIT has provided biographical sketches for the appointees for the Oversight Committee's consideration.

Advisory Committee Appointments and Annual Reports
Mr. Roberts will present four new appointments to the Advisory Committee on Clinical Trials and the Product Development Advisory Committee. Mr. Roberts will also provide a proposed schedule of presentations for the advisory committees' reports to the Oversight Committee in FY 2024. Two of the Oversight Committee's six advisory committees – the Clinical Trials Advisory Committee and the Geographic Diversity Advisory Committee - will present annual reports and answer Oversight Committee member's questions.

FY 2024 Honoraria Policy
Mr. Roberts will present CPRIT's FY 2024 honoraria policy for peer reviewers. There are no changes from the FY 2023 Honoraria Policy.

Health & Safety Code § 102.1062 Waivers
Mr. Roberts will present two conflict of interest waivers pursuant to Texas Health and Safety Code 102.1062. The FY 2022 waivers are for Don Brandy and the Review Council Members. The Oversight Committee approved the same waivers in FY 2023.

Proposed Amendments to 25 TAC Chapters 701 and 703
Ms. Eckel will present the final orders approving proposed amendments to the agency's Chapters 701 and 703 administrative rules, which the Oversight Committee provisionally approved at the May meeting. If approved, the amendment will become effective in September. She will also present proposed administrative rule changes to Chapter 701 for Oversight Committee consideration and approval to publish in the *Texas Register*.

Chief Operating Officer Report and Contract Approvals
Ms. McConnell will discuss the operating budget, performance measures, and debt issuance history for the third quarter of FY 2023. She will also present recommendations for contract approvals for the following services: an Economic Assessment of the Cost of Cancer in Texas, Due Diligence Services (contract renewal), and Peer Review Monitoring Services (contract renewal.)

Communications Report
Mr. 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.

Subcommittee Business
The Board Governance subcommittee recommends approval of new subcommittee assignments for all members for fiscal years 2024-2025. The Oversight Committee must vote to approve the changes to subcommittee membership.

Personnel
The Oversight Committee will consider salary adjustments for the Chief Executive Officer and the Chief Scientific Officer consistent with the authorization approved by the Texas Legislature.

FY 2023 DIR Texas Cybersecurity Framework Assessment
Mr. Emenike will present the FY 2023 DIR Texas Cybersecurity Framework Assessment in closed session. Due to the sensitive nature of IT security issues, CPRIT will provide the Oversight Committee with the report under a separate cover.

Election of Board Officers
The Board Governance subcommittee unanimously recommends a slate of officers for fiscal years 2024 – 2025 for the Oversight Committee's approval. The outgoing Oversight Committee Presiding Officer worked with the Board Governance subcommittee to develop the slate of officers.

FY 2024 Meeting Dates
Mr. Roberts will present the proposed dates for the FY 2024 Oversight Committee quarterly meetings and the regular subcommittee meetings for Oversight Committee approval.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

Oversight Committee Meeting Agenda

August 16, 2023
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 2.034A.

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

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

1. Call to Order
2. Roll Call/Excused Absences
3. Adoption of Minutes from the May 17, 2023, meeting — Tab 1
4. Public Comment
5. Chief Executive Officer Report — Tab 2
6. Chief Compliance Officer Report and Compliance Certification of Grant Award Process — Tab 3
7. Chief Scientific Officer Report — Tab 4
   - Grant Award Recommendations
   - FY 2024 Requests for Applications
8. Chief Prevention Officer Report — Tab 5
   - Grant Award Recommendations
9. Chief Product Development Officer Report — Tab 6
10. Internal Auditor Report — Tab 7
    - Internal Audit Report over Information Technology General Controls
11. Scientific Research and Prevention Program Committee Appointments — Tab 8
12. Advisory Committees — Tab 9
    - Appointments
    - Clinical Trial Advisory Committee Presentation
    - Geographic Diversity Advisory Committee Presentation
    - Schedule for FY 2024 Advisory Committee Annual Report Presentations
13. FY 2024 Honoraria Policy — Tab 10

14. Health & Safety Code Section 102.1062 Waivers — Tab 11
15. Amendments to 25 T.A.C. Chapters 701 and 703 — Tab 12
    - Final Order Approving Amendments to Chapters 701 and 703
    - Proposed Amendment to Chapter 701
16. Chief Operating Officer Report — Tab 13
17. Contract Approvals — Tab 14
    - Economic Assessment of the Cost of Cancer in Texas
    - Due Diligence Services (contract renewal)
    - Peer Review Monitoring Services (contract renewal)
18. Communications Report — Tab 15
19. Subcommittee Business — Tab 16
    - FY 2024 – 2025 Subcommittee Assignments
20. Personnel – Chief Executive Officer and Chief Scientific Officer
    - Salary Adjustment
21. FY 2023 DIR Texas Cybersecurity Framework Assessment
22. Election of Board Officers — Tab 17
23. Compliance Investigation Pursuant to Health & Safety Code § 102.2631
24. Consultation with General Counsel
25. Future Meeting Dates and Agenda Items — Tab 18
    - FY 2024 Meeting Dates
26. Adjourn

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Meeting Minutes
May 17, 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. Mahendra Patel announced a quorum present and called the meeting to order at 9:00 a.m.

Roll Call/Excused Absences – Agenda Item 2

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

Adoption of Minutes from the February 15, 2023, Meeting – Agenda Item 3, Tab 1

MOTION:
On a motion by Mr. Montgomery and seconded by Mr. Margo, the Oversight Committee voted unanimously to approve the minutes of the February 15, 2023, Oversight Committee meeting as presented.

Public Comment – Agenda Item 4

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

Chief Executive Officer Report – Agenda Item 5, Tab 2

Presiding Officer Dr. Patel recognized Chief Executive Officer Wayne Roberts to present his report. Mr. Roberts introduced Chief Strategic Initiatives and Intellectual Property Officer Tracey Davies. Ms. Davies gave a status update on the intellectual property database project. She expects to complete a contract with a third-party vendor by mid-summer.

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An Oversight Committee member asked if the information would be searchable on the internet. Ms. Davies responded that there is not an answer to that question yet; however, the software can make non-confidential information searchable.

An Oversight Committee member asked if the information is available by a request for information under the Texas Public Information Act. Ms. Davies responded that non-confidential information is available. If CPRIT receives a request for confidential information, the agency would assert applicable exceptions to production available under the Texas Public Information Act.

An Oversight Committee member asked about the need for the database. Ms. Davies responded that the database would allow CPRIT to have a more comprehensive view of the patents resulting from CPRIT funded IP and that this information may improve the ability to track revenue generated and stimulate further development.

An Oversight Committee member asked about IP ownership related to product development research. Ms. Davies responded that CPRIT has revenue sharing terms with each grantee, but CPRIT does not own the IP generated by the grantee's research.

Oversight Committee members thanked Ms. Davies for her work on the IP database project.

Mr. Roberts proceeded with his Chief Executive Officer report with an update on agency funds available and introduced new personnel. He provided a brief legislative update, reporting that there should not be any surprises in the state budget related to CPRIT and the committees included the 5 percent per year cost-of-living exempt salary adjustment to the chief scientific officer position but not the one for the chief executive officer.

Chief Compliance Officer Report and Compliance Certification for the Proposed Grant Awards – Agenda Item 6, Tab 3

Presiding Officer Dr. Patel recognized Chief Compliance Officer Vince Burgess and 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. There were no questions for Mr. Nance

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

Chief Scientific Officer Report and Grant Award Recommendations – Agenda Item 7, Tab 4

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

Dr. Le Beau directed Oversight Committee members to Table 1 on page 4 of the Proposed Grant Awards Book that displayed the Scientific Review Council (SRC) and Program Integration Committee (PIC) recommendations for the FY 2023 Recruitment, Cycle 23.4, including three awards from two grant mechanisms totaling $14,000,000.

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

Rank	ID	Mechanism	Score	Application Title	Candidate	Organization	Budget
1	RR230031	RFTFM	1.0	Nomination of Dian Yang, Ph.D. for a CPRIT Recruitment of a First-Time Tenure-Track Faculty Member Award Investigator	Dian Yang, Ph.D.	The University of Texas Southwestern Medical Center	$2,000,000
2	RR230032	REI	1.8	Nomination of Yuan Zhu, Ph.D. for a CPRIT Recruitment of an Established Investigator Award	Yuan Zhu, Ph.D.	The University of Texas Southwestern Medical Center	$6,000,000
3	RR230029	REI	2.0	Recruitment of Established Investigators - Dr. King	Michael King, Ph.D.	Rice University	$6,000,000

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

Following the award recommendation presentation, Dr. Le Beau provided a program update, including the second cycle of applications for FY 2023 and the open request for applications for FY 2024 awards. She also introduced three proposed FY 2024 requests for applications for Oversight Committee approval.

An Oversight Committee member congratulated Dr. Le Beau for the collaborative research noted between the approved recruitment applicants and TREC eligible institutions.

Compliance Certification

Presiding Officer Dr. Patel reminded members that Mr. Burgess previously certified compliance of the academic research awards process.

Conflict of Interest Notification

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

Approval Process – Academic Research Awards

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

MOTION:
On a motion made by Dr. Hernandez and seconded by Mr. Margo, 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.

Approval For Proposed Fiscal Year 2024 RFAs

MOTION:
On a motion made by Mr. Margo and seconded by Mr. Montgomery, the Oversight Committee members voted unanimously to approve the three proposed FY 2024 RFAs presented by Dr. Le Beau.

Chief Prevention Officer Report – Agenda Item 8, Tab 5

Presiding Officer Dr. Patel recognized Chief Prevention Officer Ramona Magid to present the prevention program update. Ms. Magid reported on activities related to the applications for the second cycle FY 2023 Cycle 2 and the newly released request for applications for FY 2024.

Lastly, Ms. Magid also reported that Mr. Carlton Allen, Program Manager for Prevention, is leading the revision of the *Texas Cancer Plan* and has begun meeting with multiple stakeholders to gather input.

In response to a question by an Oversight Committee member regarding the time necessary to solicit and approve prevention grants, Ms. Magid explained that timelines for the two prevention cycles each year have not changed.

An Oversight Committee member asked whether prevention grantees were reporting fewer cancer screenings and later stage cancer diagnoses. Ms. Magid responded that grantees had not reported major disruptions and that screening levels had returned to pre-pandemic levels.

An Oversight Committee member inquired about the expected publication date for the updated *Texas Cancer Plan* and whether it would be ready by CPRIT's conference. Ms. Magid clarified that the anticipated release date is June 2024 according to the schedule she developed based upon the 2012 and 2018 revisions. She explained the lengthy update and data-gathering process in more detail, including the need for significant input from many stakeholders, as well as the Department of State Health Services and its Texas Comprehensive Cancer Control Program, and work necessary for charting new goals.

In response to a question from an Oversight Committee member about whether CPRIT has prevention projects in all counties, Ms. Magid reported that CPRIT prevention projects are currently serving every Texas county.

An Oversight Committee member asked whether CPRIT had heard about insurance companies possibly increasing their co-pays for colonoscopies, Ms. Magid responded that no grantees have reported this issue. She explained that CPRIT-funded programs may use grant funds to cover co-pays.

Chief Product Development Officer Report – Agenda Item 9, Tab 6

Presiding Officer Dr. Patel recognized Chief Product Development Officer Dr. Ken Smith to present the Product Development Research update.

Dr. Smith presented the proposed product development grant awards.

FY 2023 Cycle 1 Award Recommendations

Rank	ID	RFA	Company	Project	Score	Budget
1	DP230079	TNTC FULL	Resilience Texas, LLC dba CTMC	Building Differentiated Cell Therapy Manufacturing Technologies to Attract Value-Added Biotech Partnerships	2.3	$9,100,000
2	DP230062	TTC FULL	7 Hills Pharma LLC	7HP349, a Small Molecule, Oral Integrin Activator to Treat Patients With anti-PD-1 Resistant Melanoma	2.6	$13,439,001
3	DP230064	SEED Ther.	OmniNano Pharmaceuticals LLC	IND-Enabling Studies of ONP-001: A Nano-Codelivery Formulation with Two Drugs of Distinct Mechanisms of Action for Treating Pancreatic Ductal Adenocarcinoma	3.3	$2,711,437
4	DP230076	TTC FULL	OncoResponse	OncoResponse OR502 anti-LILRB2 monoclonal antibody Phase 1-2 clinical study	3.6	$13,259,174
5	DP230066	TTC FULL	Pulmotect, Inc.	Improving Cancer Patient Outcomes by Activating Lung Innate ImmunityLutetium-177 for Use in Prostate Cancer Therapy	3.3	$8,851,165
6	DP230071	TTC FULL	Allterum Therapeutics, LLC	Clinical development of a novel CD127 antibody for treating patients with relapsed/refractory Acute Lymphoblastic Leukemia (ALL)	2.6	$11,721,150
					TOTAL	**$ 59,081,927**

TNTC – Texas New Technologies Company
TTC – Texas Therapeutics Company
SEED – Seed Company

He explained that each of the six companies recommended for awards worked with him to

reduce their proposed budgets to accommodate funding all projects recommended by the Product Development Review Council.

An Oversight Committee member asked Dr. Smith whether CPRIT guaranteed the company's remaining budget for goals and objectives that CPRIT cut during the budget negotiations. Dr. Smith responded that this was not the case.

Dr. Smith explained that the recommended companies reduced their requested budgets by approximately 30% in response to another member's question.

An Oversight Committee inquired whether Dr. Smith thought negotiating budgets before final award approval was a good exercise to use moving forward. Dr. Smith responded that he would continue this process as long as it works towards reasonable budgets so the program may fund more companies.

Another Oversight Committee member asked about the review committee's involvement in the budget negotiation process. Dr. Smith explained that the program conducts the negotiations after the review committee establishes contingencies for the project. CPRIT brings in a third-party due diligence and a clinical consulting firm to assist with budget review. Mr. Roberts added that CPRIT previously managed the contracting and budget negotiation process after OC approval. Ms. Doyle explained that the time invested negotiating the budgets prior to final approval will expedite the contract execution process.

When asked by an Oversight Committee member about whether he thought that applicants for grants may inflate the project budget because they know that the agency will cut the proposal, Dr. Smith responded that some companies may do so, but not all. Ms. Doyle added that the requirement of matching funds does discourage companies from inflating their budgets because they must provide a match for their budget request.

An Oversight Committee member asked if the Academic research program was considering pre-approval budget negotiations. Mr. Roberts responded that all staff have used this process before, and the academic research program has recently discussed the topic. He clarified that the other two programs do not initiate the budget reductions at this level of detail since the three CPRIT programs are different.

Referring to the Product Development Advisory Committee report included in the packet, an Oversight Committee member expressed concerns regarding the number of full applications that went through peer review in the FY 2023 cycle. The PDAC report mentioned applicants may race to apply in FY 2024. Dr. Smith explained that the request for applications for the FY 2024 product development applications notifies potential applicants of the application review restrictions and that companies are aware of the process. The program has created new panels, including one for device, diagnostics, and new technologies, to accommodate so many preliminary applications.

Mr. Roberts explained that available funds are a problem. By Oversight Committee direction, the program is now getting more quality applications going through the peer review process. The

program plans to focus on outreach to family foundations and other funds to invest in biotechnology research.

Dr. Smith discussed the release of FY 2024 requests for applications, and the number of preliminary applications received since the opening of the applications. The total request from the applications submitted at this point is over a quarter of a billion dollars. He indicated that the program would like to see more devices, diagnostic and new technology applications.

An Oversight committee member asked Dr. Smith about the company relocating from Washington. Dr. Smith responded that he would provide the company's proposed relocation plan to the committee member.

In response to a member's question about another recommended company, Dr. Smith clarified that CPRIT will fund projects that are cancer-related, such as ancillary therapeutics addressing side effects of cancer treatments. He explained that this is a longstanding policy of CPRIT, noting that this was the second award for the company.

Another Oversight committee member inquired whether CPRIT recoups funding through equity. Ms. Doyle mentioned that we have standard revenue sharing terms that are royalty-based no matter the indication.

An Oversight Committee member asked whether CPRIT will offer the relocation RFA in the future. Dr. Smith explained that any product development RFA could be a relocation award because the company may apply from outside of Texas, but must relocate to Texas to receive the award. Ms. Doyle added that CPRIT renamed the relocation RFA because prospective applicants did not understand that CPRIT does not pay for relocation costs.

Compliance Certification

Presiding Officer Dr. Patel reminded members that Mr. Burgess previously certified compliance of the process for product development awards.

Conflict of Interest Notification

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

Approval Process – Product Development Awards

MOTION:
On a motion made by Dr. Rice and seconded by Mr. Montgomery, the Oversight Committee members voted unanimously to approve the PIC's six recommendations for product development awards.

MOTION:

On a motion made by Mr. Margo 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.

MOTION:
On a motion made by Mr. Margo and seconded by Mr. Montgomery, the Oversight Committee members voted unanimously to approve the authorization of CPRIT to disburse grant funds via advance payments upon execution of the award contract and the successful completion of tranches to the six companies approved for awards today.

Scientific Research and Prevention Program Committee Appointments – Agenda Item 11, Tab 8

Mr. Roberts presented his appointments to the CPRIT's Scientific Research and Prevention Programs Committee:

- Nathanael S. Gray, Ph.D.
- Lourdes Baezconde-Garbanati, Ph.D., M.P.H.
- Erin Kobetz, Ph.D.
- Isabel Scarinci, Ph.D.
- Melissa Troester, Ph.D.
- Tristan Sissung, Ph.D.
- Felicitas L. Lacbawan, M.D.

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

Advisory Committees – Item 12, Tab 9

Presiding Officer Dr. Patel recognized Mr. Roberts to present the Presiding Officer's new appointments to the advisory committees.

Mr. Roberts presented Dr. Pavan Reddy's appointment to the Clinical Trials Advisory Committee and Laura Wood's appointment to the Prevention Advisory Committee.

He also noted the three new appointments to the University Advisory Committee.

MOTION:
On a motion made by Dr. Cummings and seconded by Mr. Montgomery, the Oversight Committee voted unanimously to approve the two advisory committee appointments.

University Advisory Committee Presentation:

Presiding Officer Dr. Patel called on Dr. Le Beau to introduce Dr. Peter Davies, Chair of the University Advisory Committee (UAC), to provide the UAC 2023 Annual Report.

Dr. Le Beau introduced Dr. Davies.

Dr. Davies presented the UAC 2023 Annual Report.

Oversight Committee members thanked Dr. Davies for his leadership on the University Advisory Committee.

In response to a question by an Oversight Committee member inquiring if there are any data on follow-up success on CPRIT grants, Dr. Davies clarified that Dr. Le Beau might know, but the information would help develop a comprehensive picture of the academic research program. Dr. Le Beau added that CPRIT has the data and can share it.

Another Oversight Committee asked about communicating the results of CPRIT grantee work and prioritizing CPRIT accomplishments on a national stage. Dr. Davies responded that the CPRIT program is nationally recognized. Dr. Le Beau added that groups from other states have approached CPRIT seeking to replicate what Texas is doing.

Presiding Officer Dr. Patel noted that he has attended UAC meetings and they are rigorous and to the point on how they can help CPRIT. He and the other Oversight Committee members thanked Dr. Davies for the presentation.

Chief Operating Officer Report – Agenda Item 14, Tab 11

Taking up Agenda Item 14 out of order, Presiding Officer Dr. Patel recognized Chief Operating Officer Heidi McConnell to present her report.

Ms. McConnell presented her report on the operating budget, performance measures, and debt issuance history. She said that, in the second quarter, the Texas Public Finance Authority issued $66 million in commercial paper notes on CPRIT's behalf. By the end of this fiscal year, $298.3 million in bond proceeds will be issued.

Ms. McConnell also updated the members on the upcoming CPRIT conference.

There were no questions for Ms. McConnell.

Fiscal Year 2024 Bond Issuance Resolution – Agenda Item 15, Tab 12

Presiding Officer Dr. Patel recognized Ms. McConnell to introduce the FY 2024 bond issuance resolution.

She presented the annual request seeking the Texas Public Finance Authority to issue debt on behalf of CPRIT in an amount not to exceed $300 million in FY 2024. Ms. McConnell projects $298.4 million in commercial paper notes over four separate issuances, and that bond proceeds will pay for grant costs associated with projects approved from FY 2016 to the present.

There were no questions for Ms. McConnell.

MOTION:
On a motion by Mr. Margo and seconded by Mr. Montgomery, the Oversight Committee voted unanimously to approve the resolution requesting financing for $300 million in bond proceeds by the Texas Public Finance Authority in FY 2024.

Contract Approval – Grant Management Services – Agenda Item 16, Tab 13

Presiding Officer Dr. Patel recognized Ms. McConnell to present the staff's recommendation regarding the grant management services contract. She explained that staff recommended exercising the second renewal option with General Dynamics Information Technology (GDIT) for $9,662,900 in FY 2024. The renewal includes an annual payment of $1.1 million for subscription to the grant management platform and an estimated $8,562,900 in time and materials expended by GDIT on labor and direct costs for grant application receipt, peer review meeting support, and post award grant management support.

There were no questions for Ms. McConnell.

MOTION:
On a motion by Mr. Margo and seconded by Mr. Montgomery, the Oversight Committee voted unanimously to approve the grant management support services contract renewal with General Dynamics Information Technology for an amount not to exceed $9,662,900.

Amendments to 25 T.A.C. Chapters 701 and 703 – Agenda Item 13, Tab 10

Presiding Officer Dr. Patel recognized assistant general counsel Cameron Eckel to present the proposed rule amendments. Ms. Eckel reviewed the proposed changes, located behind Tab 10. All changes relate to the use of the term "Scope of Work." A final vote on the proposed changes will take place at the August Oversight Committee meeting.

MOTION:
On a motion by Mr. Montgomery and seconded by Dr. Rice, the Oversight Committee voted unanimously to approve the publication of the proposed changes to Chapters 701 and 703 in the *Texas Register*.

Advisory Committees – Item 12, Tab 9

<u>Product Development Advisory Committee Presentation:</u>

Returning to Agenda Item 12, Presiding Officer Dr. Patel called on Dr. Smith to introduce the Product Development Advisory Committee co-chairs, Mr. Andrew Strong and Dr. Michele Park.

Following the Product Development Advisory Committee's presentation, an Oversight Committee member asked if CPRIT has made an impact in the early oncology investment market, since investments are traditionally on the east and west coasts. Dr. Park confirmed that the investment community was aware of CPRIT.

Mr. Strong commended the Oversight Committee for fully committing the PDR funds for FY 2022 and FY 2023. He reported that applicants now know they must not wait to submit their applications, that there is urgency to be one of the 15 applications presenting to the peer review panels. Mr. Strong expressed concerns regarding timing, noting that the program changes were supposed to shorten the timing to funding to three months, but that CPRIT pushed the FY 2023 award announcement from the February meeting to the May meeting.

Mr. Strong addressed a question that an Oversight Committee member asked earlier in the meeting. He explained that companies are not padding or inflating their budgets. Companies know that there are limited funds, and that they must defend their budgets. He strongly supported the budget negotiations that took place for FY 2023 Cycle 1. However, he noted his concerns about the timeline for review and negotiation of the budgets.

He suggested that the program handle the rush to apply by reviewing like venture capitalists, focusing on applications that are in the "sweet spot," meaning those companies that can raise matching funds. Mr. Strong proposed that there could be "dry powder" follow on funds for companies that CPRIT has previously funded, such as reinvesting in companies that are homegrown from a Texas academic institution. Mr. Strong also recommended capping the funding amount per award and continuing budget negotiations moving forward.

An Oversight Committee member and Mr. Strong discussed the potential for PDAC members serving as mentors/advisors for awarded companies.

Communication Report – Agenda Item 17, Tab 14

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

There were no questions for Mr. Loeffler.

Subcommittee Business – Agenda Item 18

Presiding Officer Dr. Patel informed the Oversight Committee members of the upcoming election of new officers in August as well new subcommittee assignments.

Internal Auditor Report – Agenda Item 10, Tab 7

Returning to Agenda Item 10, Presiding Officer Dr. Patel recognized Daniel Graves to present the internal auditor report. Mr. Graves updated the committee members on the FY 2023 Internal Audit Plan schedule. He directed the members to page 7-3 of the meeting book with the list of audits and audit advisory engagements, explaining that Weaver completed the contract risk

management assessment and was currently executing the post-award compliance program, purchasing, and IT general controls engagements.

In response to a question by an Oversight Committee member inquiring if it is the compliance program's responsibility to follow up on the contract risk assessment, Mr. Graves responded that CPRIT's management is responsible for assigning follow up activities.

> **MOTION:**
> On a motion by Mr. Montgomery and seconded by Mr. Margo, the Oversight Committee voted unanimously to approve the Contract Risk Assessment Model Advisory Audit Report.

Presiding Officer Dr. Patel announced the committee would go into closed session at 12:12 p.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, Ms. Eckel, Shannon Cusick, Soma Emenike and Mr. Graves to join the members in closed session.

The Board reconvened in open session at 1:01 p.m.

Presiding Officer Dr. Patel stated that the Oversight Committee would not take up standing items 19 and 20.

Future Meeting Dates and Agenda Items – Agenda Item 21

Presiding Officer Dr. Patel reminded members that the CPRIT Oversight Committee will meet on August 16.

Adjournment – Agenda Item 22

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

The meeting adjourned at 1:01 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: AUGUST 9, 2023

The Chief Executive Officer Report will include the items listed below; I will address additional items as warranted. I have attached copies of the May/June 2023 and July 2023 CPRIT Activity Updates for your reference.

FY 2023 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 on August 16 at the Program Integration Committee's recommended level of $49.4 million, we will have $6.9 million unawarded in FY 2023. This balance remains with the agency for use in later fiscal years through legislative appropriation.

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

Personnel

CPRIT has 46 full-time equivalent positions filled and an accountant position is in progress. I will introduce new staff and discuss other pending personnel changes.

*****

CPRIT has awarded **1,874** grants totaling **$3.334 billion:**

- 282 prevention awards totaling $341.5 million
- 1,592 academic research and product development research awards totaling $2.99 billion

Of the $2.99 billion in academic research and product development research awards,

- 31.7% of the funding ($948.6 million) supports clinical research projects
- 24.0% of the funding ($716.8 million) supports translational research projects
- 29.0% of funding ($867.6 million) supports recruitment awards
- 12.3% of the funding ($369.5 million) supports discovery stage research projects
- 3.0% of funding ($90.4 million) supports training programs.

CPRIT has five open Requests for Applications (RFAs)

- 3 Academic Research Recruitment
- 2 Prevention

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FY 2023 GRANT AWARD FUNDS AVAILABLE

General Obligation Bond Proceeds

	Prevention	Academic / Product Development Research	1% Grant Funding Buffer	Operating Budget	Total Appropriations
Available Appropriated Bond Funds	**$ 27,660,780**	**$ 251,369,432**		**$ 20,969,788**	**$ 300,000,000**
Appropriations Transfer to DSHS		**$ (3,118,032)**		**$ 3,118,032**	
Adjusted Appropriations	**$ 27,660,780**	**$ 248,251,400**		**$ 24,087,820**	**$ 300,000,000**
Total Available for All Grants			**$ 275,912,180**		
0.42416249% of Total Available Grant Funding			**$ 1,170,316**		
Adjusted Grant Award Funding	**27,660,780**	**$ 247,081,084**			**$ 274,741,864**

	Prevention Grants	Academic Research Grants	PD Research Grants	
Total Available for Grant Awards (Total GO Bond Proceeds Less Operating Budget)	**$ 27,660,780**	**$ 173,775,980**	**$ 74,475,420**	**$ 275,912,180**
Total Available for Grant Awards Using $1,170,316 of Original $2,759,122 (1%) Grant Funding Buffer for PDR	**$ 27,660,780**	**$ 171,844,595**	**$ 75,236,489**	**$ 274,741,864**
Announced Grant Awards				
9/14/2022 Core Facility Support Awards (6)	$ -	$ 23,298,824	$ -	
9/14/2022 Clinical Trials Network Awards (1)	$ -	$ 3,000,000	$ -	
9/14/2022 Early Clinical Investigator Awards (2)	$ -	$ 2,994,784	$ -	
9/14/2022 High-Impact/High Risk Awards (14)	$ -	$ 3,474,906	$ -	
9/14/2022 Company Grant Award (1)	$ -	$ -	$ 16,154,562	
11/16/2022 Recruitment Awards (2)	$ -	$ 11,999,198	$ -	
2/15/2023 Prevention Grant Awards (8)	$ 13,577,257	$ -	$ -	
2/15/2023 IIR Awards (31)	$ -	$ 39,135,679	$ -	
2/15/2023 TREC Awards (3)	$ -	$ 17,998,422	$ -	
2/15/2023 Recruitment Awards (5)	$ -	$ 17,999,977	$ -	
5/17/2023 Recruitment Awards (3)	$ -	$ 14,000,000	$ -	
5/17/2023 Company Grant Awards (6)	$ -	$ -	$ 59,081,927	
Announced Grant Award Subtotal	**$ 13,577,257**	**$ 133,901,790**	**$ 75,236,489**	**$ - $ 222,715,536**
Grant Award Adjustments				
5/22/2023 Declined Recruit (UTSW-Yang) 5/2023 Slate	$ -	$ (2,000,000)	$ -	$ (2,000,000)
6/29/2023 Reduction for Overlap to MDACC RP230160	$ -	$ (17,284)	$ -	$ (17,284)
7/13/2023 UTHSC-Houston RP230222 Withdrawn	$ -	$ (1,046,680)	$ -	$ (1,046,680)
	$ -	$ -	$ -	$ -
Revised Grant Award Subtotal	**$ 13,577,257**	**$ 130,837,826**	**$ 75,236,489**	**$ 219,651,572**
Available Grant Funds as of July 17, 2023	**$ 14,083,523**	**$ 41,006,769**	**$ -**	**$ 55,090,292**
Pending Grants-PIC Recommendations				
Recruitment Awards (10)	$ -	$ 23,800,000	$ -	
TREC: Major Instrument Award (3)	$ -	$ 2,894,693	$ -	
TREC: Post-Doctoral Cancer Research Training Program (1)	$ -	$ 850,000	$ -	
TREC: Pilot Study Award (5)	$ -	$ 1,000,000	$ -	
Connect (1)	$ -	$ 7,499,998	$ -	
Prevention Grant Awards (9)	$ 13,343,163	$ -	$ -	
Pending Award Subtotal	**$ 13,343,163**	**$ 36,044,691**	**$ -**	**$ 49,387,854**
Total Potential Grant Funding Committed	**$ 26,920,420**	**$ 166,882,517**	**$ 75,236,489**	**$ 269,039,426**
Uncommitted Grant Funds as of August 2, 2023	**$ 740,360**	**$ 4,962,078**	**$ -**	**$ 5,702,438**
Grant Funding Buffer	**$ -**	**$ 1,170,316**	**$ -**	**$ 1,170,316**
Total Remaining Funds	**$ 740,360**	**$ 6,132,394**	**$ -**	**$ 6,872,754**

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

CPRIT MANAGEMENT DASHBOARD
FISCAL YEAR 2023

	SEPT	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	CUMULATIVE (ANNUAL)	CUMULATIVE (TO DATE)
ACCOUNTABILITY														
Announced Grant Awards	25		2			48			9				84	
New Grant Contracts Signed	10	11	15	13	4	3	5	17	19	3	7		107	
New Grant Contracts In Negotiation			8			30			9				47	
Grant Reimbursements Processed (#)	172	150	124	193	148	149	195	185	196	170	93		1775	
Grant Reimbursements Processed ($)	$ 16,461,776	$ 18,449,931	$ 9,059,403	$ 15,994,971	$ 25,810,994	$ 18,838,917	$ 20,938,739	$ 25,259,310	$ 21,928,601	$ 25,900,748	$ 17,560,466		$ 216,203,856	
Revenue Sharing Payments Received	$ 20,611	$ 10,783	$ 70,854	$ 3,100	$ 41,334	$ 1,020,317	$ 115,886	$ -	$ 260,511	$ 90,490	$ 196,000		$ 1,829,886	$ 9,555,425
Grants Awarded (#)/ Applications Rec'd (#)	18%	18%	18%	18%	18%	19%	19%	19%	19%	18%	19%			
Grantee Compliance Trainings	2	4	3	4	1	3	4	1	2	3	5		32	
Grantee Compliance Monitoring Visits	0	0	2	4	1	4	2	1	0	3	1		18	
Awards with Delinquent Reimbursement Submission (FSR)			0			1			1					
Awards with Delinquent Matching Funds Verification			3			13			1					
Awards with Delinquent Progress Report Submission			4			0			0					
MISSION														
Open RFAs	7	6	6	10	14	10	11	11	11	13	5			
Prevention Applications Received	0	0	0	0	0	25	0	0	0	0	0		25	988
Product Development Preliminary Applications Received	26	11	9	9	2	0	0	0	43	36	0		136	136
Product Development Full Applications Received	0	0	14	0	1	0	0	0	0	16	0		31	675
Academic Research Applications	4	3	0	4	0	7	0	36	0	327	2		383	9,056
Help Desk Calls/Emails	175	221	132	136	123	91	71	131	221	254	210		1,765	
Number of Research Grants Announced (Annual)	24		2			40			3				69	
Recruited Scientists Contracted														291
Number of Product Development Grants Announced (Annual)	1		0			0			6				7	
Life Science Companies Recruited (in TX)													0	14
Number of Product Development Jobs Created & Maintained														1,228
Number of Prevention Grants Announced (Annual)			0			8			0				8	
Total Number of Education, Navigation and Training Services			162,223			127,978			203,636				493,837	
Total Number of Clinical Services			46,301			40,140			47,601				134,042	
Published Articles on CPRIT-Funded Projects (#)														
Clinical Studies (#)														228
Number of Patent Applications														
Number of Patents Resulting from Research														
TRANSPARENCY														
Total Website Hits (Sessions)	10,994	9,456	9,086	6,474	10,576	32,480	10,971	9,066	14,521	11,623	9,923			
Total Unique Visitors to Website (Users)	8,280	7,276	7,070	5,081	8,142	29,224	8,115	6,508	8,317	6,608	6,433			

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	CPRIT ACTIVITIES UPDATE FOR MAY AND JUNE 2023
DATE:	JULY 7, 2023

Topics in this memo address CPRIT activities in May and June, including recent milestones in our fight against cancer, a staffing summary, outreach efforts, the 2023 Texas legislative regular session wrap up, and updates from Compliance, Programs, and Operations.

Recent Milestones in the Fight Against Cancer

CPRIT Grantees in the News

- The American Association of Immunologists (AAI) announced May 1 that a team from The University of Texas MD Anderson Cancer Center led by CPRIT Scholar Mauro Di Pilato, Ph.D., received a 2023 Intersect Fellowship for Computational Scientists and Immunologists. This prestigious fellowship program improves understanding and communication between immunology researchers and computational scientists by affording an opportunity to train in each other's discipline. The fellowship provides independent research scientists with one year of salary support for postdoctoral fellows already trained in basic bench research to undertake one year of cross-training in computational science, or postdoctoral fellows trained in computational science to spend one year in an immunology research lab. Dr. Di Pilato, assistant professor in the Department of Immunology, and Ziyi Li, Ph.D., assistant professor in the Department of Biostatistics at MD Anderson, will provide mentorship to trainee Fernanda Grande Kugeratski, Ph.D.

  MD Anderson recruited Dr. Di Pilato to Texas with a $2 million First-Time, Tenure-Track Faculty Member award in 2021 (RR210017). The Di Pilato Laboratory investigates the mechanisms that regulate T cell stability and infiltration in cancer to develop new treatment strategies for patients who do not respond to current cancer immunotherapies.

- Immatics, a clinical-stage biopharmaceutical company active in the discovery and development of T cell-redirecting cancer immunotherapies, announced May 1 that Bristol Myers Squibb exercised its option to enter an exclusive worldwide license for the first T cell receptor engineered T cell therapy (TCR-T) candidate from their research partnership. "The opt-in decision by Bristol Myers Squibb is an example of the success of our ongoing collaboration. The partnership's goal is to leverage Immatics' ability to develop innovative cell therapies that have the potential to deliver future breakthrough therapies for patients,"

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explained Immatics' CEO Dr. Harpreet Singh. CPRIT awarded the Houston-based Immatics US a $19.65 million CPRIT New Company Product Development Research grant (DP150029) in February 2015 to build a sustainable, world-class cancer immunotherapy company in Texas and translate the value of novel cancer targets into better and longer lives for cancer patients.

- Perimeter Medical Imaging AI initiated an additional clinical trial site at Baptist MD Anderson Cancer Center in Jacksonville, Florida, on May 2 under the direction of Laila Samiian, M.D., FACS. Dr. Samiian, director of the Breast Program at Baptist MD Anderson Cancer Center, remarked, "We are excited to become the newest active site with three investigators anticipated to participate in this clinical study to assess if the Perimeter B-Series with artificial intelligence demonstrates an improvement over the current standard of care. Combining optical coherence tomography with deep learning algorithms could assist us, as surgeons, to better identify regions of interest supporting 'real-time' decisions on margin status in the OR – potentially setting a new standard for specimen imaging technology during breast conservation surgery." The Dallas-based company received a $7.45 million CPRIT Product Development Research grant (DP190087) in August 2019 to develop and implement Perimeter's high-resolution imaging device.

- The American Cancer Society awarded CPRIT Scholar Shrikanth Gadad, Ph.D., M.Sc., a $792,000 grant on May 2 to support his ongoing efforts with cancer research. Dr. Gadad's research focuses on understanding the shift from hormone-sensitive to hormone-resistant breast cancer. Texas Tech University Health Sciences Center at El Paso recruited Dr. Gadad in 2017 with a $2 million CPRIT Recruitment of First-Time, Tenure-Track Faculty Members grant (RR170020.)

- On May 4 Susan G. Komen, one of the nation's leading breast cancer organizations, appointed two CPRIT grantees, Carlos L. Arteaga, M.D., and Jeffrey M. Rosen, Ph.D., as Komen Scholars. These world-renowned breast cancer experts will join a distinguished group whose expertise spans many areas, including breast cancer biology, genomics, biomarkers, health disparities, therapeutics, clinical trials and imaging. The Komen Scholars help guide Komen's research and scientific programs, with a focus on advancing discoveries to improve breast cancer outcomes for everyone.

  CPRIT Scholar Dr. Arteaga is the director of the Harold C. Simmons Comprehensive Cancer Center and associate dean of oncology programs, professor of internal medicine, and the Lisa K. Simmons Distinguished Chair in Comprehensive Oncology at The University of Texas Southwestern Medical Center. Internationally renowned for his work in laboratory-based translational research and advancing the care of breast cancer patients, he has earned numerous accolades from the American Cancer Society, the American Association for Cancer Research, Susan G. Komen, the Breast Cancer Research Foundation, and the American Society of Clinical Oncology. UT Southwestern recruited Dr. Arteaga to Texas from Vanderbilt University School of Medicine with a $6 million Established Investigator Award in 2017 (RR170061). He is Co-Chair of the CPRIT University Advisory Committee and a member of the Clinical Trials Advisory Committee.

Dr. Rosen is a Distinguished Service Professor and the Charles C. Bell Professor in the department of molecular and cellular biology, and leader of the Breast Cancer Program at Baylor College of Medicine's Dan L. Duncan Comprehensive Cancer Center. Dr. Rosen has received international acclaim for his work in hormonal regulation of mammary gland gene expression in development and breast cancer. Dr. Rosen's laboratory has created a series of extensively characterized and "credentialed" syngeneic mouse models of triple-negative breast cancer for use in preclinical studies to determine tumor-related effects on the tumor microenvironment of both targeted therapies using small molecule inhibitors and immunotherapy with the long-term goal of translating these studies into the clinic. CPRIT has supported Dr. Rosen's work with five research grants totaling $6.25 million (RP101499, RP130485, RP140102, RP170172, RP220468), as well as two research training program grants totaling $8 million (RP160283, RP210027).

- Hummingbird Bioscience will conduct molecular-matched patient trials of its clinical-stage anti-HER3 drug in Australia. George Clinical announced May 4 that the company has initiated preparations in Australia for two oncology Phase 1b trials that will examine Hummingbird's precision therapy program targeting HER3 in biomarker-selected patient populations, including lung cancer. HMBD-001 is a unique antibody engineered by Hummingbird to bind strongly and specifically to HER3, a potent driver of tumor growth and resistance against cancer drugs. Preclinical models show that HMBD-001 potently inhibits the activation of the MAPK/PI3K signaling pathway and consequently, prevents tumor growth and drug resistance. The Houston and Singapore-based company received a $13.1 million CPRIT Product Development Research grant (DP190027) in February 2019.

- Salarius Pharmaceuticals announced May 9 that the FDA removed its partial clinical hold on Salarius' Phase 1/2 Ewing sarcoma clinical trial evaluating seclidemstat, Salarius' novel oral, reversible, targeted LSD1 inhibitor. The FDA previously granted seclidemstat Fast Track Designation, Orphan Drug Designation and Rare Pediatric Disease Designation for Ewing sarcoma. Houston-based Salarius received a $16.1 million CPRIT New Company Product Development Award (DP160014) in May 2016 to develop novel drugs for rare pediatric cancers and other cancers by focusing on treatments that interrupt the final steps of the signaling cascade.

- The James P. Allison Institute at The University of Texas MD Anderson Cancer Center appointed its first members - CPRIT Scholar and Nobel laureate James P. Allison, Ph.D., CPRIT grantee Padmanee Sharma, M.D., Ph.D., CPRIT grantee Jennifer Wargo, M.D., Sangeeta Goswami, M.D., Ph.D., and Kenneth Hu, Ph.D – on May 10. In addition, Garry Nolan, Ph.D., will join the Allison Institute as an adjunct member. These members include pioneering researchers who have made notable contributions to science as well as rising stars on the path toward important breakthroughs.

  "We are proud to be joined by these stellar scientists, and we are confident that together we will set the tone for the exceptional research we aim to support at the Allison Institute," noted Dr. Allison, director of the Allison Institute and regental chair of Immunology at MD

Anderson. "Our collective expertise in areas that now will include immune-microbiome interactions, epigenetic mechanisms, and novel methods for spatial transcriptomics and proteomics fits well with our priority research areas, and we look forward to collaboratively advancing the field." The Allison Institute members will incorporate laboratory and clinical insights to develop novel and synergetic therapies that enable cures for more patients.

MD Anderson brought Dr. Allison to Texas from Memorial Sloan-Kettering Cancer Center in 2011 with a $10 million CPRIT Recruitment of Established Investigators grant (R1203). Dr. Sharma received a $1.4 million Individual Investigator Research Award in 2011 (RP120108) and Dr. Wargo received two CPRIT research awards in 2015 and 2020 totaling $1.15 million.

- Rice University and Texas Southern University (TSU) announced a partnership on May 10 to share resources, expertise and best practices to build bridges between their institutions and communities. The goal is to foster meaningful dialogue; seed new research partnerships; create additional opportunities for students, faculty and staff at both universities; and benefit Houston. Rice and TSU have collaborated for decades and are now working on various research-related projects and teaching partnerships, including a joint project aimed at producing more doctoral students of color in STEM fields. Another joint endeavor is the CPRIT-funded Gulf Coast Consortia (GCC) Center for Comprehensive PK/PD and Formulation at TSU, a state-of-the-art drug development core facility with experienced faculty from TSU's College of Pharmacy and Health Sciences, the University of Houston's College of Pharmacy and the GCC for Quantitative Biomedical Sciences at Rice University. CPRIT awarded TSU a $4.7 million CPRIT Core Facility Support Awards grant (RP190581) in 2019 to fund the GCC Center for Comprehensive PK/PD and Formulation.

- Texas A&M University selected CPRIT Grantee Sanjukta Chakraborty, Ph.D., as one of 12 faculty researchers to receive seed grants totaling $900,000 in the inaugural round of Research Leadership Fellowships. The Research Leadership Fellowship program is part of the collaborative research seed grant initiative ASCEND, which President M. Katherine Banks announced in her 2022 State of the University address. The grants, announced May 11, provide initial funding for fellows and their interdisciplinary research teams to pursue innovation that targets society's greatest problems. In addition, the program enhances Texas A&M's ability to secure research funding from external sources.

  Dr. Chakraborty, an assistant professor in the School of Medicine, will apply a chemical-biology approach toward developing new classes of therapeutics that selectively target metastatic cancers in lymph nodes, the route for spread of carcinomas. CPRIT awarded Texas A&M University Health Science Center and Dr. Chakraborty a $250,000 High Impact High Risk grant in 2021 (RP210213) for her project studying therapeutic inhibition of cholangiocarcinoma progression by targeting tumor-lymphatic crosstalk.

- On May 11 Austin's NPR station KUT 90.5 featured Dr. Michael Pignone's colorectal cancer FIT screening project, "Improving Colorectal Cancer Screening in Vulnerable Populations in Travis County." The NPR story, "One Way To Get More Austinites Screened

for Colon Cancer: Mail-In Poop Tests," highlighted the CPRIT-funded collaboration between the Dell Medical School at The University of Texas at Austin and Travis County's federally qualified health clinic system, CommUnityCare. After the story aired Dr. Pignone tweeted, "Not exactly a glamour shot but I'll take it! 😂😂 Many thanks to @CPRITTexas and @AmericanCancer for their support of this work!"

CPRIT awarded The University of Texas at Austin and Dr. Pignone $4.5 million since 2017 (PP170082, PP200066, PP210045) to create and disseminate Dr. Pignone's mailed stool testing program for colorectal cancer prevention in underserved communities in Texas.

- On May 16 Baylor College of Medicine recognized Dr. Maria Carmenza Mejia, M.D., M.P.H., FACPM, with the Clark Faculty Service Award. The Clark Faculty Service Award honors a Baylor College of Medicine faculty member whose exemplary service contributions represent their professions and Baylor's mission, vision and values at the highest level. Dr. Mejia, associate professor in the department of Family and Community Medicine at Baylor College of Medicine, is co-program director of the CPRIT-funded lung cancer screening projects, "Equitable Access to Lung Cancer Screening and Smoking Cessation Treatment: A Comprehensive Primary Care and Community Health Approach" (PP180016) and its expansion award, "Expansion of the Lung Cancer Screening and Tobacco Control Network to Rural and Medically Underserved Populations" (PP210044).

- Aravive announced May 16 that the company received guidance from the FDA regarding a registrational Phase 3 trial design for batiraxcept in clear cell renal cell carcinoma (ccRCC). The company designed the randomized, double-blind, registrational Phase 3 trial to evaluate efficacy and tolerability of batiraxcept at a dose of 15 mg/kg in combination with cabozantinib compared to cabozantinib alone. The primary endpoint is progression-free survival, and secondary endpoints include overall survival, duration of response, and objective response rates. The FDA granted batiraxcept Fast Track Designation for ccRCC in November 2022. Houston-based Aravive received a $20 million CPRIT New Company Product Development Award (DP150127) in November 2015.

- On May 17, Break *Through* Cancer awarded The University of Texas MD Anderson Cancer Center more than $5.7 million in grants to support two collaborative research teams working to address major roadblocks to preventing and improving patient outcomes in acute myeloid leukemia. CPRIT grantees participating in the Break *Through* Cancer projects include Michael Andreef, M.D., Ph.D., Pavan Bachireddy, M.D., Simona Colla, Ph.D.; Courtney DiNardo, M.D.; and Guillermo Garcia-Manero, M.D. The projects expand upon work initiated within MD Anderson's Myelodysplastic Syndromes and Acute Myeloid Leukemia Moon Shot.

  This funding is part of $20 million in grants awarded to the five cancer centers that comprise Break *Through* Cancer - MD Anderson, Dana-Farber Cancer Institute, the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, Memorial Sloan Kettering Cancer Center, and the Koch Institute for Integrative Cancer Research at MIT. Break *Through* Cancer launched in 2021 to bring together the nation's top cancer research institutions to find new solutions for some of cancer research's biggest challenges. Their TeamLab model allows researchers to work

collaboratively in real- time using new technology and systems to reduce barriers that often impact cross-institutional collaboration.

- Iterion Therapeutics, a leading Houston-based biopharmaceutical company dedicated to developing innovative treatments for cancer, announced May 18 its collaboration in a Phase 1 clinical trial for tegavivint in patients with relapsed or refractory c-Myc-overexpressing large B-cell lymphomas. Tegavivint is a first-in-class small molecule inhibitor of Transducin beta-like protein 1 (TBL1) that demonstrated safety, clinical and pharmacodynamic activity in a Phase 1 study of patients with desmoid tumors. The study has enrolled its first patient at The Ohio State University Comprehensive Cancer Center. Patients with relapsed/refractory c-MYC-overexpressing diffuse large B-cell lymphomas represent a significant unmet clinical as their prognosis is particularly poor with limited effective treatment options. Iterion received two CPRIT Product Development grants (CP130058, DP220019) in 2014 and 2022, totaling $18.9 million to achieve novel, structurally distinct drug candidates with improved pharmaceutical properties, including oral absorption.

- The Texas A&M University Health Science Center of Excellence in Cancer Research hosted its first cancer research symposium in College Station on May 22, bringing together cancer researchers from across the region. The symposium highlighted the outstanding cancer research throughout the Texas A&M University System and featured the newly established cancer center. Texas A&M University received a $6 million CPRIT Texas Regional Excellence in Cancer Award (RP230204) in February to bring together a critical mass of cancer researchers at Texas A&M University, facilitate collaborations within and outside the institution, and support innovative cancer research.

- The University of Texas Health Science Center at San Antonio announced May 26 that CPRIT Scholar Elizabeth Wasmuth, Ph.D., received the Max and Minnie Tomerlin Voelcker Fund Young Investigator Award for her project to uncover therapeutic vulnerabilities in androgen receptor signaling in treatment-resistant prostate cancer. Dr. Wasmuth, an assistant professor in the Department of Biochemistry and Structural Biology, is an accomplished junior investigator who focuses on understanding the structure and function of the androgen receptor, specifically the mechanism by which oncoproteins regulate androgen receptor activity, and how such functional interactions contribute to prostate cancer development, progression, and acquired resistance to current therapeutics. UT Health San Antonio recruited her to Texas with a $2 million First-time, Tenure-track Award in 2022 (RR220068.)

- On May 30, the William and Ella Owens Medical Research Foundation awarded $1.5 million to eight investigators at The University of Texas Health Science Center at San Antonio to support research projects that address cancer and Alzheimer's disease. Three CPRIT grantees - CPRIT Scholar Myron Ignatius, Ph.D.**,** Manjeet Rao, Ph.D., and Shaun Olsen, Ph.D. **-** were among the grant recipients.

- Fannin Partners received a $2 million Small Business Innovation Research (SBIR) Phase II grant in May from the National Cancer Institute (NCI) to advance its spin-out company Allterum Therapeutics' 4A10 monoclonal antibody for treating acute lymphoblastic leukemia

(ALL), the most frequently diagnosed cancer in children. The SBIR grant will support a Phase I clinical trial to assess the safety and activity of 4A10 as monotherapy. CPRIT funded Houston-based Allterum's early preclinical work with a $2.9 million Product Development Seed Company grant (DP190025) in 2019 and matched by a $1.8 million Series Seed financing led by Fannin. In May, CPRIT approved a $11.7 million CPRIT Product Development grant to advance the 4A10 antibody to an Investigational New Drug filing with the FDA and the first-in-human clinical trial.

- David Poplack, M.D., Director of Global HOPE (Hematology-Oncology Pediatric Excellence) and professor in the Hematology and Oncology Section of the Department of Pediatrics at Baylor College of Medicine, received the 2023 Excellence in Teaching Award from the American Society of Clinical Oncology (ASCO) during its annual meeting in early June. ASCO selects recipients of the Excellence in Teaching Award based on their outstanding ability to expand trainees' patient connection and communication skills, broaden their vision of patient-physician interaction and stimulate their personal and professional growth.

  Dr. Poplack authored 370 original articles and book chapters in the field of pediatric oncology, in addition to being a founding co-editor of *Principles and Practice of Pediatric Oncology*, the leading textbook for pediatric oncology. He also developed the CPRIT-funded "Passport for Care," an interactive website that addresses the need to provide long-term survivors of childhood cancer and their caregivers with screening guidelines and resources individualized to the survivor's treatment history. CPRIT awarded Baylor College of Medicine and Dr. Poplack four CPRIT Prevention grants (PP100090, PP130070, PP170036, PP210031) and two CPRIT Academic Research grants (RP101335-C1, RP140022-AC) totaling $4.6 million since 2010.

- *The New York Times* featured Dr. Michael Pignone, of the Dell Medical School at The University of Texas at Austin, in the June 12 article, *"*How A.I. Chatbots Are Helping Doctors Be More Human and Empathetic.*"* Dr. Pignone and his team used ChatGPT to assist developing a screening questionnaire on the CPRIT-funded project, "Screening and Treatment for Unhealthy Alcohol Use as a Means of Cancer Prevention." CPRIT awarded The University of Texas at Austin $1 million in 2020 (PP200036) to support this project.

- On June 15, the National Institute of Neurological Disorders and Stroke awarded its Outstanding Investigator Award to Benjamin Deneen, Ph.D., a professor and chair in neurosurgery and director of the Center for Cancer Neuroscience at Baylor College of Medicine. This is a highly competitive distinction and includes up to $7.4 million in funding over an eight-year period to support investigators and their labs. Dr. Deneen's research will focus on the role astrocytes play in brain circuit control. Astrocytes are a form of glial cells that make up most cells in the central nervous system and play essential roles in brain circuit activity. CPRIT awarded Baylor College of Medicine and Dr. Deneen two CPRIT Academic Research grants (RP150334, RP160192) in 2015 totaling $2.7 million to comprehensively define the cellular and functional heterogeneity of diverse cell populations in malignant glioma.

- On June 23, the American Society for Nutrition (ASN) and the American Society for Nutrition Foundation (ASFN) awarded Robert Chapkin, Ph.D., the Mary Swartz Rose Senior Investigator Award. This award recognizes an investigator conducting mechanistic, epidemiological, clinical and/or translational research contributing to the understanding of the benefits of a healthy dietary pattern. ASN and ASFN selected Dr. Chapkin, chair of Texas A&M College of Agriculture and Life Sciences' department of nutrition, for his outstanding research on the safety and efficacy of bioactive compounds for human health. Between 2010 and 2020, CPRIT awarded Texas Agrilife Research and Dr. Chapkin four awards totaling $1.8 million (RP100473, RP120028, RP160589, RP200604).

- The American Society of Mechanical Engineers (ASME) honored CPRIT-grantee Zhenpeng Qin, Ph.D., naming him an ASME fellow on June 28. Dr. Qin, associate professor of mechanical engineering at The University of Texas at Dallas, leads several projects, including developing a more accurate rapid test for diagnosing infectious diseases, a technique to open the blood-brain barrier temporarily to deliver medication to the brain, and tools that make it possible to study how neuropeptides affect brain circuits and behavior in real time. ASME previously awarded Dr. Qin the Y.C. Fung Early Career Award in 2022. UT Dallas and Dr. Qin received four CPRIT Academic Research grants (RP160770, RP180846, RP190278, RP210236) since 2016 totaling $1.55 million.

Notable CPRIT-Supported Research and Prevention Accomplishments

- **Assessing the Use of Digital Health Technology in Older Adults with Cancer.** A recent study reported in the May issue of the *Journal of Medical Internet Research* examined the use of digital health technology in adults 65 and older diagnosed with cancer. Despite the benefits of digital health technology, older adults report challenges in adopting these technologies. To better understand the impact of the COVID-19 pandemic on their use of digital health technology, a research team led by Youmin Cho, Ph.D., in the School of Biomedical Informatics at The University of Texas Health Science Center at Houston, analyzed data from the National Health and Aging Trends Study.

  Dr. Cho and her team found that the prevalence of digital health technology use among older adults with cancer increased from 36% in 2015 to 45% in 2019. During the COVID-19 pandemic in 2020-2021, the cohort's usage rate increased to ~52%. However, despite the gradual increase in digital health technology use among older adults with cancer, particularly during the pandemic, physical health and socioeconomic and racial disparities exist in digital health technology use among older cancer survivors. Understanding these usage patterns and barriers is crucial to improving oncology care for older adults with cancer, ensuring that they have equitable access to digital health technologies and benefiting from their potential in enhancing healthcare delivery.

  The $4 million CPRIT training grant, "Collaborative Training of a New Cadre of Innovative Cancer Prevention Researchers," awarded to UT Health Houston in 2021 (RP210042) supported Dr. Cho's work.

- On May 2, Immatics announced an interim clinical data update for 11 patients with recurrent and/or refractory solid cancers treated with ACTengine IMA203 TCR-T monotherapy in the ongoing Phase 1b dose expansion Cohort A. IMA203 TCR-T cells act against an HLA-A*02-presented peptide derived from PRAME, a broadly expressed solid cancer target. Overall, IMA203 showed a high rate of deep and durable objective responses across multiple tumor types. Heavily pre-treated patients continue to tolerate IMA203 monotherapy well and scientists did not observe any aggressive immune response in Cohort A by data cut-off. Immatics believes that these results further validate PRAME as one of the most promising solid tumor targets for TCR-based therapies. Houston-based Immatics US received a $19.65 million CPRIT New Company Product Development Research grant (DP150029) in February 2015 to build a sustainable, world-class cancer immunotherapy company in Texas and translate the value of novel cancer targets into better and longer lives for cancer patients.

- **Addressing "Long-Distance" Tumor Effects.** Breast cancer can have a profound impact on the body even before it spreads to other organs. Researchers have discovered that tumors can disrupt the bone marrow, where the body produces immune cells, in a way that promotes tumor growth instead of fighting it. Xiang H.F. Zhang, Ph.D., the William T. Butler, M.D., Endowed Chair for Distinguished Faculty, Professor of Molecular and Cellular Biology, and member of the Dan L. Duncan Comprehensive Cancer Center at Baylor College of Medicine, conducted a study to understand this process better by examining animal models of breast cancer before the tumors had spread.

  As reported in the May 4 edition of *Cell Stem Cell*, Dr. Zhang's team found that remote tumors caused changes in the bone marrow, leading to the expansion of certain cells involved in bone formation and immune cell production. These changes resulted in the accumulation of immune cells called granulocytes and monocytes, which then infiltrated the tumors, aiding their growth. The researchers discovered that a molecule called HTRA1, carried by small extracellular vesicles released by the tumor, played a role in this process by affecting the expression of a protein called MMP-13 on the surface of specific cells in the bone marrow.

  Importantly, the study revealed that these negative effects persisted even after excising the tumor, impairing the immune system's ability to fight cancer. This has significant implications for the treatment of patients because immunotherapy, a common approach after tumor removal, relies on a functioning immune system. The findings suggest that additional therapies targeting tumor-induced systemic effects on the immune response may be necessary for optimal treatment outcomes.

  These findings also shed light on the process of metastasis, where cancer spreads to other parts of the body. Metastasis may arise years or even decades after surgeons remove the primary tumor, seeded by residual cancer cells left behind, or by cells that had metastasized prior to surgery. Lingering immunosuppressive effects after tumor removal may create an environment that facilitates the growth and spread of residual cancer cells.

  Two CPRIT Core Facility Support Awards to Baylor College of Medicine totaling $9.2 million provided essential technologies and research services for this study - RP200504

Comprehensive Cancer Epigenomics Core led by Dr. Rui Chen; and RP180672 Advanced Multiparameter Cytometry and Cell Sorting Core led by Dr. Christine Beeton.

- **"Dangerous Liaisons" - Reorganizing the Genome in Cancer.** In the early 1900s, Theodor Boveri, a pioneer in cytology, proposed that imbalances in chromosomes could cause cancer. This sparked a long-lasting controversy that eventually led to identifying recurring chromosomal abnormalities in human leukemias in the 1970s. Today, analyzing chromosomal profiles and identifying changes in genes and proteins are crucial for diagnosing and predicting the prognosis of many types of cancer. As reported on-line in the May 10 edition of *Nature*, new findings by CPRIT Scholar Peter Ly, Ph.D., assistant professor of pathology and cell biology at The University of Texas Southwestern Medical Center, shed light on how errors occur during cell division, resulting in chromosomal abnormalities found in cancer. Understanding these processes can have important implications for diagnosing, predicting outcomes, and developing new therapies for various types of cancer.

  During the process of cell division, called mitosis, chromosomes sometimes fail to separate correctly, leading to the loss or gain of entire chromosomes. Additionally, complex rearrangements in the genome can occur when mis-segregated chromosomes shatter and form structures known as micronuclei. Dr. Ly and his research team used live-cell imaging to observe these micronucleated chromosomes and found that the fragments of chromatin cluster closely together throughout mitosis. As a result, a single daughter cell inherits the clustered fragments asymmetrically, and later, DNA repair processes incorrectly reassemble the pieces, forming rearranged chromosomes. A protein complex called CIP2A-TOPBP1 plays a role in this process by prematurely associating with the broken DNA ends in ruptured micronuclei. Disruption of this protein complex caused fragments to disperse during cell division, leading to cell death.

  This crucial process of clustering chromatin fragments during mitosis allows the reassembly of acentric fragments into rearranged chromosomes. These rearranged chromosomes contain most or all the original chromosomes but in a different order. Interestingly, Dr. Ly and his research team discovered that this process is common in cancers. Analysis of cancer genomes from various types of cancer revealed clusters of rearranged DNA sequences, termed balanced chromothripsis, which result in the acquisition of oncogenic driver events. This suggests that targeting the CIP2A-TOPBP1 protein complex is a potential cancer treatment approach, especially for tumors with chromosomal instability and DNA repair deficiencies.

  UT Southwestern recruited Dr. Ly to Texas from the Ludwig Institute for Cancer Research and University of California, San Diego, School of Medicine with a $2 million First-Time, Tenure-Track Award in 2018 (RR180050).

- **Zebrafish Provide Novel Insights into Drug Resistance in Childhood Rhabdomyosarcoma.** A recent CPRIT-supported study identifies potential targets for treating a devastating form of pediatric cancer. Rhabdomyosarcoma (RMS) is a type of soft tissue sarcoma that affects around 250-300 children in the US each year. Clinicians can

control localized RMS with surgical, chemotherapy, and radiation treatments, but there are no effective options for relapsed or metastatic RMS - resulting in survival rates of less than 30% over three years.

Researchers led by Lin Xu, Ph.D., assistant professor in the Peter O'Donnell Jr. School of Public Health and the Simmons Comprehensive Cancer Center at The University of Texas Southwestern Medical Center, examined the underlying biology of therapy-resistant RMS stem cells in response to the standard chemotherapy drug vincristine. To study the stem cells, which are sparse in RMS tissue, the team developed RMS spheres grown in the lab and utilized a zebrafish model.

As reported in the May 17 issue of *Cancers*, they discovered that treatment with vincristine caused an increase in CD133-positive stem-like resistant cells. Analysis revealed the significant expression of MYC and YBX1, encoding transcription factors, in these genes. MYC is a crucial regulator of embryonic stem cell identity and cellular functions such as growth and metabolism. The expression of MYC and YBX1 in RMS patients correlated positively, and high MYC expression was associated with poor survival. The researchers used CRISPR/Cas9 genome editing to target MYC and YBX1, resulting in a reduction in stem-like characteristics and viability of the vincristine-resistant cells. They also found that the MYC protein regulated the YBX1 gene and that inhibiting MYC, in combination with vincristine, reduced tumor growth and stem-like cells in the zebrafish model.

These findings suggest that targeting the MYC-YBX1 axis is a promising therapeutic strategy to overcome therapy resistance and improve survival in RMS patients. By understanding the underlying mechanisms and identifying these potential therapeutic targets, researchers are one step closer to developing more effective treatments for difficult-to-treat pediatric cancers like RMS.

CPRIT awarded UT Southwestern grants totaling $8.7 million since 2018 to support this research, including RP180319 (PI: Stephen Skapek), RP200103 (PI: Eric Olson), and RP180805 (The Pediatric Cancer Data Core, PI: Yang Xie).

- **T Cell "Stressed" State Linked to Resistance to Immunotherapy.** A new study led by CPRIT grantee Linghua Wang, M.D., Ph.D., at The University of Texas MD Anderson Cancer Center, and published May 29 in *Nature Medicine*, provides important insights into the diversity and roles of immune T cells within tumors, which could impact the effectiveness of cancer immunotherapy. The study also demonstrates the power of big data in unraveling the complexity of T cells in tumors and highlights the importance of integrating large datasets in cancer research.

  Dr. Wang and her team of investigators developed a comprehensive T cell atlas by analyzing data from 27 single-cell RNA sequencing datasets covering 16 types of cancer. This atlas reveals previously unknown states and subpopulations of T cells within the tumor microenvironment. One significant finding is the identification of a unique group of T cells called T cell stress response (T_{STR}) cells, characterized by the expression of heat shock genes. In previous studies, scientists overlooked these cells or dismissed them as artifacts, but the extensive data in this study

allowed the researchers to recognize them as a distinct group. Dr. Wang's research team also found that T cell states correlated with various clinical and genomic features, including the response to immune checkpoint blockade therapy. Understanding the mechanisms behind T cell stress response and finding ways to reverse this state could potentially improve the efficacy of immunotherapy and overcome resistance to treatment.

The research team shared their T cell atlas with the wider research community through their *Single-Cell Research Portal* (https://singlecell.mdanderson.org/), a user-friendly, interactive web portal, and developed a tool, *TCellMap* (https://singlecell.mdanderson.org/TCM/), which enables researchers to automatically annotate T cells from their datasets by aligning with the high-resolution T cell maps generated by this study.

Multiple CPRIT grants to Dr. Wang (RP200385), and co-authors (RP220101, PI: Dr. Humam Kadara; RP150079, PI: Dr. Paul Scheet), totaling $2.62 million, supported this work.

- **Bypassing Human Behavior to Improve Cancer Outcomes.** CPRIT Scholar and bioengineer Kevin McHugh, Ph.D., is working on a solution to a significant problem in treating chronic diseases – human behavior. Every year, more than 100,000 deaths in the United States occur due to incorrect medication use or missing essential doses. Dr. McHugh, an assistant professor in the bioengineering department at Rice University, and his research team are tackling the issue of missing doses by developing advanced biomaterial microdevices for drug delivery that will improve medication adherence and address challenges in healthcare accessibility.

  As described in the June 1 volume of *Advanced Materials*, the technology, dubbed PULSED (Particles Uniformly Liquified and Sealed to Encapsulate Drugs), uses 3D printing and soft lithography to create arrays of tiny polymer cylinders filled with medication. Clinicians can inject these cylinders, which are biodegradable and safe, using standard needles. Depending on the specific properties of the polymer coating, the cylinders release the encapsulated drug after delays ranging from 10 to 36 days when inside the body. This platform shows promise for creating long-acting drug formulations that could improve treatment outcomes for cancer and other diseases.

  The system developed by Dr. McHugh overcomes a common problem known as "first-order release" seen in current drug encapsulation methods. With PULSED, clinicians can release the same amount of drug consistently throughout the treatment period, avoiding uneven dosing. This technology has the potential for various applications, including delivering multiple doses of vaccines over months, which could address accessibility issues in low- and middle-income countries.

  Rice University recruited Dr. McHugh to Texas from the Massachusetts Institute of Technology with a $2 million First-Time, Tenure-Track Faculty Award in 2019 (RR190056).

- **Improving the Efficacy of the Oncotype Dx Biomarker test for Diverse Populations.** A recent study by CPRIT Scholars Chao Cheng, Ph.D., and Christopher Amos, Ph.D., provides

a method for more accurately calibrating multigene molecular tests, like the Oncotype DX test, in racially and ethnically diverse patients with cancer.

The Oncotype DX test predicts cancer recurrence and determines the benefit of adjuvant chemotherapy based on a patient's genetic profile. Breast cancer is the most common type of cancer in women, and biomarker measurements have revolutionized its treatment by providing individualized information about the tumor. Clinicians rely on the Oncotype DX test to guide prognosis and treatment decisions for breast cancer. However, a previous study revealed that the Oncotype DX test has lower prognostic accuracy in Black women, suggesting the need to calibrate these tests for ethnically diverse populations.

In response, Dr. Cheng and Dr. Amos, both of Baylor College of Medicine's Section of Epidemiology and Population Science at the Dan L. Duncan Comprehensive Cancer Center, developed a model using a large dataset of breast cancer patients to determine chemotherapy benefit thresholds for different racial groups. The study highlighted racial differences in the efficacy of chemotherapy indicating that White, Black, and Asian women with early-stage breast cancer benefited from chemotherapy at different Oncotype DX scores, including some at lower threshold scores than current guidelines suggest. Their results, reported June 16 in *Cancers*, identified key chemotherapy sensitivity thresholds for the Oncotype DX test, providing a method to better tailor multigene molecular tests for treatment decisions in diverse patient populations.

Baylor College of Medicine recruited Dr. Amos and Dr. Cheng to Texas from Geisel School of Medicine at Dartmouth with a $6 million Established Investigator grant to Dr. Amos in 2017 (RR170048) and a $4 million Rising Star grant to Dr. Cheng in 2018 (RR180061).

- Plus Therapeutics, Inc. reported positive interim updates from the ReSPECT-LM clinical studies at the Society of Nuclear Medicine & Molecular Imaging Annual Meeting, held June 24-27 in Chicago. Interim results from 10 patients in the Phase 1 trial evaluating the company's lead radiotherapeutic, rhenium (186Re) obisbemeda, for the treatment of leptomeningeal metastases (LM) show a single treatment with rhenium (186Re) obisbemeda decreased cerebrospinal fluid tumor cell count and was well-tolerated in patients with LM. Scientists did not observe any dose limiting toxicities and any safety issues were generally minor and resolved. Phase 1/Part B, for continued dose escalation (Cohorts 4-7), will open following review by the FDA, and scientists will explore the potential for repeated dosing. An expansion in Cohort 3 is enrolling eligible patients.

  The Austin-based company received a three-year $17.6 million CPRIT Product Development grant in August 2022 (DP220039) to fund the ReSPECT-LM study.

Personnel

CPRIT has filled all 45 full-time equivalent positions and has several positions in progress including Grant Accountant, Systems Support Specialist and Grant Compliance Specialist positions.

- Dr. Myriam Casillas accepted the position of Program Manager for Academic Research effective June 1. Dr. Casillas comes to us from Texas Tech University Health Sciences Center El Paso, where she served as Managing Director for the Office of Research, and Senior Director, Office of the Vice President. She has more than 15 years of operational and leadership experience in research, compliance, and epidemiology. She created the Division of Biostatistics at Texas Tech HSC El Paso and managed several research projects including the Hispanic Center of Excellence grant and Project AMIGAS: "Increasing Cervical Cancer Screening in Mexican Women."

- Cathy Harkness accepted the permanent position of Grant Accountant effective June 1. She has worked at CPRIT as a contract accounting employee since November 2022.

88th Texas Legislature Update and Activities

The 88th Texas Legislature convened in Austin at noon on January 10 and adjourned *sine die* for its regular session on May 29. Legislators filed a record-breaking 8,276 bills in the regular session. The information reported below on CPRIT's budget and legislation of interest reflects the status after the expiration of Governor's veto period on June 18. The legislature is currently in its second special session; we do not anticipate any CPRIT-related legislation.

General Appropriations Bills (Senate Bill 1 and House Bill 1)

House Bill 1 signed by the Governor provides CPRIT's full, constitutionally authorized annual appropriation of $300 million less the required transfer of $3.1 million per year to the Cancer Registry at the Texas Department of State Health Services. There are no changes to the specific rider provisions governing our funding.

House Bill 1 includes a five percent (5%) per year cost-of-living-adjustment (COLA) specifically shown in our bill pattern for non-exempt employees. Since CPRIT is a special fund agency, the legislature did not provide additional general revenue to fund the COLA; instead, the budget writers transferred the money from (and thereby reduced) the money available for CPRIT's research and prevention programs. Senate Bill 30, the supplemental appropriations act for FY 2023, provides funding authorization for the FY 2024 5% COLA to begin in July of this fiscal year but did not increase funds to CPRIT to implement the pay increase.

As per our budget request testimony and my direct intervention during the session, the bill includes the 5% COLA for the Chief Scientific Officer exempt salary. House Bill 1 includes a

negligible adjustment to the CEO position of $402 attributed to a "market compensation report" used by the Legislative Budget Board staff in December.

The CEO position is one of only a few, perhaps the only position not to receive the 5% COLA among some 330,000 general state agencies and institutions of higher education employees. This disparate treatment results from misleading LBB staff work and not critical action by the chairs of the conference committee. However, this decision will cause serious salary compression issues going forward.

CPRIT-Related Legislation

- Senate Bill 1838/House Bill 4160 (companions) – Both bills died in committee without receiving a hearing.

  Senator Juan "Chuy" Hinojosa and Representative Ryan Guillen filed companion legislation to make significant changes to CPRIT's enabling legislation, including imbedding within CPRIT an Oversight Committee for Neurodegenerative Diseases as the governing body of the Alzheimer's Research Collaborative of Texas, and altering the use of CPRIT bond proceeds from cancer prevention and research grants to Alzheimer's disease research.

  The legislation appeared to violate the terms of the bond covenants related to CPRIT debt issuance by the Texas Public Finance Authority and would likely be unconstitutional. I reached out to both authors' offices, and I had a brief initial discussion with Senator Hinojosa about the bill. I never heard back from Representative Guillen's staff. We also notified staff of the Senate Committee on Health and Human Services, the House Committee on Public Health and the Lt. Governor's Office of our concerns.

- House Bill 3914 - The bill died in committee without receiving a hearing.

  Representative Oliverson filed legislation to prohibit CPRIT from awarding a grant to an applicant whose proposed research requires the applicant to procure or otherwise obtain from a hospital located in China an organ for organ transplantation or another purpose. The bill also required CPRIT to add a written contract certification that the grantee will not use grant funds to buy organs from a hospital in China for all awards, including those made prior to the effective date of the bill. Rep. Oliverson proposed the same legislation in 2021, which did not receive a hearing.

  CPRIT grantees do not procure organs for transplant as part of CPRIT-funded grant projects. However, we had concerns related to the administrative burden of documenting compliance with the prohibition. We worked with Rep. Oliverson's office last session to address those issues, which he incorporated into a committee substitute. We discussed with his staff making the same changes if the current bill had been set for a hearing.

Other Notable Legislation

- House Bill 15/House Joint Resolution 135 – Both bills passed the House but died in the Senate after failing to attract a Senate sponsor.

  Representative Senfronia Thompson filed legislation, jointly authored by Representatives Tom Craddick and Brad Buckley, to establish the Mental Health and Brain Research Institute of Texas (MBRIT), modeled on CPRIT. These proposed bills were among Speaker Phelan's priorities for the session, and both passed the House on April 11 with a vote of 116 yeas and 29 nays (2 present, not voting, and 3 absent).

  The legislation proposed to fund the new agency through a constitutional dedication of $3 billion of general revenue. We worked with Rep. Thompson and her staff on the introduced language. As a result, Deputy Executive Officer and General Counsel Kristen Doyle testified March 20 on the bills during the House Committee on Higher Education hearing. Ms. Doyle articulated that the proposed institute would have the same compliance, peer review, conflict of interest, match requirements, and contract revenue sharing terms as CPRIT. Other witnesses frequently compared the new agency favorably to CPRIT.

- Senate Bill 989/House Bill 3188 (companions) – Senate Bill 989 passed, effective date September 1.

  Senator Huffman's legislation requires health insurance companies to cover biomarker testing in the diagnosis and treatment of cancer and rare diseases. The "Biomarker Bill" was a legislative priority for the American Cancer Society's Cancer Action Network so that patients and their physicians have better access to new and innovative treatments and therapies, like those developed by CPRIT grantees. Representative Greg Bonnen filed the companion legislation in the House.

- Senate Bill 704 (Paxton), Senate Bill 1014 (Hughes), Senate Bill 2086 (Kolkhorst), Senate Bill 1544 (Johnson)/House Bill 2545 (Capriglione) (companions) – House Bill 2545 passed, effective date September 1; all other bills died in committee.

  Several legislators filed bills this session relating to the use of an individual's genetic data. These bills addressed direct-to-consumer genetic testing companies that use the data for commercial purposes, e.g., 23&Me, incorporating restrictions on retention of the genetic data, requiring heightened procedures for informed consent, and introducing civil or criminal penalties for violations.

  Some CPRIT grantees expressed concern that the legislation as filed could affect genetic data used for research purposes, including de-identified data maintained in research databases. Rep. Capriglione introduced an amended version of HB 2545 to address these issues. As adopted, HB 2545 creates an exclusive property right in the individual's biological sample provided to or used by a direct-to-consumer genetic testing company. The direct-to-consumer genetic testing company may not share that information with third parties,

including insurance providers, employers, or law enforcement (without a warrant.) If the direct-to-consumer genetic testing company shares the individual's genetic data contrary to the statute, it is liable for a civil penalty up to $2,500 for each violation. The enacted legislation is not applicable to entities engaged only in the collecting, using, or analyzing genetic data or biological samples in the context of research conducted in accordance with federal law or good clinical practice guidelines. In addition, the legislation explicitly states that it does not apply to institutions or higher education or a private or independent institution of higher education.

CPRIT Outreach

Staff Outreach

Staff outreach activities during May and June include:

- Senior Program Manager for Product Development Dr. Abria Magee and Program Manager for Product Development Dr. Waye Leeuwon attended the JLABS Investor Day events held May 3-4 at the Texas Medical Center.

- Chief Scientific Officer Dr. Michelle Le Beau received the 2023 Charles M Rubin, M.D., Lectureship at the University of Chicago, and delivered a seminar on May 4 entitled "Therapy-Related Myeloid Neoplasms: When Genetics and Environment Collide" at the Department of Pediatrics Grand Rounds.

- On May 8, several CPRIT staff, including Deputy Executive Officer and General Counsel Kristen Doyle, Chief Strategic Initiatives and Intellectual Property Officer Tracey Davies, Chief Product Development Officer Dr. Ken Smith, Dr. Le Beau, Dr. Magee, Dr. Leeuwon, and I met with the senior team from BrightEdge, the philanthropic impact fund of the American Cancer Society, to discuss possible collaboration opportunities.

- Dr. Magee was a panelist representing CPRIT at the Illumina User Group Meeting held May 16 in Houston.

- I attended the celebration of the 75th Anniversary of the Independence of the State of Israel held in Houston on May 18 at the invitation of Consular General of Israel to the Southwest Livia Link-Raviv.

- Dr. Le Beau serves as a member of the national Board of Directors for the American Cancer Society, and participated in a virtual quarterly Board meeting May 22, focusing on evaluating the ACS' integrated strategic and financial plan for its mission of advocacy, discovery science, and patient support.

- Dr. Smith, Dr. Magee, Dr. Leeuwon, and Ms. Doyle attended the BIO International Convention held in Boston on June 4 – 8 as part of the Texas delegation coordinated by the Texas Healthcare and Bioscience Institute (THBI.)

  More than 18,000 executives, investors and companies in the life science industry attended the annual convention. During the conference, Ms. Doyle participated in a panel discussion with a representative of the California Institute of Regenerative Medicine (CIRM) discussing the impact these two large state research funds have on the health and economies of their states. The CPRIT team met with more than 40 representatives of companies, investors, and other life science organizations in one-on-one scheduled meetings and in more informal discussions held at the Texas Pavilion on the convention floor.

- Ms. Davies represented CPRIT at a June 6 meeting in Houston with Innovate UK hosted by the British Consulate-General Houston. Ms. Davies talked with Innovate UK representatives and a delegation of life science companies that are part of an incubation program coordinated by the Texas Medical Center about CPRIT funding priorities and future partnering opportunities. Innovate UK Oncology and several members of CPRIT held a follow up meeting on June 20 to discuss each organization's prioritization of research and development areas to explore shared goals.

- As a member of the NCI Board of Scientific Advisors, Dr. Le Beau participated in an in-person joint meeting of the NCI's National Cancer Advisory Board and Board of Scientific Advisors held June 14-15 to review new and renewal RFA concepts for NCI's research portfolio.

- On June 23, Dr. Le Beau led a mentoring and career development session for high school and undergraduate students enrolled in several summer STEM programs offered by the University of Chicago Medicine Comprehensive Cancer Center, discussing her career pathway and opportunities for aspiring scientists in cancer research.

- Director of Research Dr. Patty Moore attended the State Agency Council (SAC) Quarterly meeting held June 28 at the Barbara Jordan Building. As SAC Vice Chair, she introduced keynote speaker Trent Thurman, assistant dean and director of executive education at the LBJ School of Public Affairs at The University of Texas at Austin, who spoke about the Governor's Center for Management Development and opportunities for state employees.

- Dr. Moore attended a virtual NCI webinar, "Using the Childhood Cancer Data Initiative Hub and Childhood Data Catalog," held June 29.

- In addition to meetings at the BIO International Convention and continued follow up, Dr. Magee and Dr. Leeuwon met with several companies in May and June, including Metaclipse Therapeutics, Savran Technologies, Stimulus Bio, Eikonizo Therapeutics, Bracane Company and Vitria to discuss the CPRIT product development program.

Compliance Program Update

Submission Status of Required Grant Recipient Reports

As of June 21, eight entities had not filed eight academic research 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 249 second-level reviews of grantee Financial Status Reports (FSRs) in May and June. Sixteen FSRs (6%) 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 29 enhanced desk-based financial monitoring reviews in May and June. Desk reviews confirm financial, administrative, and programmatic compliance using data from CGMS/CARS with additional focus on an organization's internal controls, current and previous fiscal audits, and grantee report submission timeliness. Desk reviews also aid in the identification of potential problems and technical assistance issues for follow-up during an onsite visit, as well as areas of non-compliance and grantee performance issues. Compliance specialists are collaborating with three grantees to address desk review findings.

Onsite Reviews

CPRIT completed four onsite reviews in May and June. 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 two 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, two grantees have 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 actively working with the two grantees to submit the required audit.

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 May. The total amount of match expenses reviewed by compliance staff for FY 2023 is $18,249,543.46. The unallowable match expenses for FY 2023 total $24,617.10.

Training and Support

CPRIT staff conducted one new Authorized Signing Official (ASO) training webinar in May for Invectys USA Inc. The 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 of the change.

CPRIT staff conducted a series of annual compliance training webinars on June 14-15 for 90 grantee staff. These training webinars are specific to each program area (Academic Research, Product Development Research, and Prevention) and allow for an interactive experience and opportunity to focus on topics relevant to each program. The trainings covered grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. This was the second training series offered this year for the annual compliance training requirement, which requires the ASO and at least

one other employee from each grantee organization to attend an annual compliance training by December 31 of each year.

Academic Research Program Update

Recruitment FY 2023 Review Cycle 5

CPRIT's Scientific Review Council (SRC) reviewed recruitment applications for the fourth quarter of FY 2023 on May 18. Dr. Le Beau will present the SRC's award recommendations for recruitment awards to the Program Integration Committee (PIC) and the Oversight Committee in August.

FY 23 Mechanism	Received	Funds Requested	Recommended	Recommended Funds
Recruitment of Established Investigators	1	$6,000,000	0	N/A
Recruitment of First-Time, Tenure Track Faculty Members	9	$18,000,000	5	$10,000,000
TOTAL	**10**	**$24,000,000**	**5**	**$10,000,000**

Academic Research FY 2023 Review Cycle 2 (23.2)

CPRIT released several RFAs for the second cycle of FY 2023 (23.2) on January 17 and accepted applications January 25 – April 18. CPRIT received 26 applications by the deadline. Peer review panels met virtually June 13 and 16 to consider the applications. Dr. Le Beau will present the SRC's recommendations to the PIC and the Oversight Committee in August.

Three of the four cycle 23.2 RFAs are first-time grants and will support research, training, and instrumentation at TREC-eligible institutions. The fourth RFA, also offered by CPRIT for the first time, will support the Texas CONNECT for Cancer Prevention Study in collaboration with the NCI CONNECT Study.

FY 23 Mechanism	Received	Funds Requested
TREC: Pilot Study Award	14	$2,800,000
TREC: Major Instrument Award	5	$4,700,000
TREC: Institutional Postdoctoral Training Award	3	$2,500,000
Texas Connect for Cancer Prevention Study Awards	4	$29,500,000
TOTAL	**26**	**$39,500,000**

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. Peer review will take place in

October. 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**

Product Development Research Program Update

Product Development FY 2024 Review Cycle

On May 1 CPRIT released four FY 2024 Product Development Research RFAs and opened the portal to receive preliminary and full applications on a rolling basis. As described in more detail below, CPRIT received the total number of full applications (15) allocated for the first cycle of FY 2024 by June 30, one month before the August 1 deadline. Given the quality of the full applications and the requested project budget totaling $149 million, it is likely that this will be the only review cycle for FY 2024 product development grants.

The overwhelming interest and response to the product development program RFAs validate CPRIT's efforts to overhaul the review process in FY 2023. Dr. Smith will continue to work with the Oversight Committee, the Product Development Review Council, the Product Development Advisory Committee, and the Texas life science community to refine details to ensure that CPRIT is attracting high-quality applicants with an efficient and fair review process.

- Preliminary Application Review: CPRIT received 79 FY 2024 preliminary applications on a rolling basis between May 1 and June 30. Like the FY 2023 review cycle, five standing review panels evaluated the FY 2024 preliminary applications on a rotating basis. CPRIT issued weekly invitations to submit full applications to companies that presented meritorious preliminary applications, based on application scores as determined by the preliminary application peer review panel.

  As discussed in the section below, CPRIT received the total number of full applications for the 15 review slots for FY 2024 on June 30. The preliminary review panels had completed reviews of 45 preliminary applications and issued invitations to 19 companies to submit a full application for FY 2024 by June 30. Because there are no more spots available for full application review, CPRIT returned 34 preliminary applications to applicants without review. Should the applicants submit these unreviewed applications in future cycles, they will not count against the resubmission limit.

  The table below provides information about the FY 2024 preliminary applications.

FY 2024 RFA	Preliminary Applications			Total Prelim Budget Request	Invited to Submit Full Applications
	Submitted	Reviewed	Returned - no review		
TTC	34	23	11	$353 M	10
TDDC	4	2	2	$27 M	1
TNTC	9	5	4	$39 M	2
Seed	32	15	17	$48 M	6
TOTAL	**79**	**45**	**34**	**$467 M**	**19**

TTC = Texas Therapeutics Company
TDDC = Texas Device and Diagnostic Company
TNTC – Texas New Technologies Company

Full Application Review (July and August): For the FY 2024 review cycle, we planned to convene 15 review panels, an increase of five panels over the FY 2023 cycle, with an August 1 deadline for submission of full applications. The RFAs notified applicants that CPRIT would continually monitor the number of submissions and would stop accepting full applications before the August 1 deadline if we received more than 15 applications.

In addition to the 19 invitations issued by June 30, CPRIT allowed four companies that submitted full applications in the FY 2023 cycle to resubmit their full applications for review in the FY 2024 cycle. (CPRIT did not review these four full applications in FY 2023 because of time and resource limitations.)

By 4:00 p.m. CST on June 30, CPRIT received its 16th full application submittal (including four FY 2023 full applications.) Accordingly, we closed the portal for full application submission at 5:00 p.m. on June 30. We separately notified the seven companies with invitations for FY 2024 who had not submitted full applications by June 30 that CPRIT was no longer accepting full applications at this time.

Although we planned for 15 spots, Dr. Smith decided to increase the number of review slots by one (16 full application review panels) to accommodate the 16th full application received by CPRIT on June 30. As a result, unlike the FY 2023 review cycle, CPRIT will not return any full applications to applicants without a review, and we will not carry over submitted but unreviewed full applications into the FY 2025 cycle.

The table below provides information about the FY 2024 full applications.

FY 2024 RFA	Invited Apps (including FY 2023 carry overs)	Full Apps Submitted by June 30 (including FY 2023 carry overs)	Submitted Budget Request
TTC	**12** (10 FY 2024 + 2 FY 2023)	**8** (6 FY 2024 + 2 FY 2023)	$112,760,268
TDDC	**2** (1 FY 2024 + 1 FY 2023)	**2** (1 FY 2024 + 1 FY 2023)	$9,026,687
TNTC	**2**	1	$12,600,000
Seed	**7** (6 FY 2024 + 1 FY 2023)	**5** (4 FY 2024 + 1 FY 2023)	$14,989,952
TOTAL	**23** (19 FY 2024 + 4 FY 2023)	**16** (12 FY 2024 + 4 FY 2023)	**$149,376,907**

- Panel Presentations and Due Diligence Review (August – October): The 16 companies will present their full applications to review panels in August and September. Based upon the review panels' recommendations, some companies will proceed to due diligence review in October.

- Final Recommendations and Budget Negotiation (November - through early 2024): The Product Development Review Council (PDRC) will meet in November to recommend companies for product development awards. Once the PDRC finalizes its recommendations, CPRIT will use the same process we successfully employed for the FY 2023 review cycle to negotiate the proposed project budgets to identify ways to decrease CPRIT-funded project expenses while maintaining the goals and objectives of the recommended projects. As we learned from the FY 2023 review process, this is a crucial step to ensuring that CPRIT can fund as many meritorious projects as possible with the estimated $74 million allocated for FY 2024 Product Development awards. Dr. Smith will present the companies recommended for product development awards to the Program Integration Committee and the Oversight Committee in early 2024.

  If CPRIT does not award all product development award funds allotted for FY 2024 in this first cycle, the product development program will reopen the RFAs in early 2024 for a second round of awards for Oversight Committee approval in August 2024.

Prevention Program Update

Prevention FY 2023 Review Cycle 2 (23.2)

CPRIT released four prevention RFAs on November 17, 2022, for the second review cycle of FY 2023. CPRIT received 25 proposals by the February 23 deadline, including two for the new *Colorectal Cancer Coordinating Center* grant award. Together, the submitted applications seek $37 million in grant funds. Peer reviewers convened via teleconference on May 24-25 to evaluate the applications. The Prevention Review Council met June 19 to review the two applications responding to the Colorectal Cancer Coordinating Center and to conduct programmatic review for the Cycle 23.2 applications. Chief Prevention Officer Ramona Magid will present the Prevention Review Council's recommendations to the PIC and the Oversight Committee in August.

Cycle 23.2 Mechanism	Applications	Funds Requested
Primary Prevention of Cancer	15	$21,748,129
Cancer Screening and Early Detection	5	$7,995,375
Dissemination of CPRIT-Funded Cancer Control Interventions	3	$1,348,397
Colorectal Cancer Coordinating Center	2	$5,999,936
TOTAL	**25**	**$37,091,837**

Prevention FY 2024 Review Cycle 1 (24.1)

The Prevention Program released two prevention RFAs (*Primary Prevention of Cancer* and *Cancer Screening and Early Detection*) on May 5 for the first cycle of FY 2024. CPRIT will accept applications through August 30, with peer review scheduled for October – December. Ms. Magid will present the PRC's recommendations to the PIC and the Oversight Committee in February 2024.

CPRIT Grantee IP Database Project

Chief Strategic Initiatives and Intellectual Property Officer Tracey Davies is leading an internal CPRIT team to implement a streamlined and standardized reporting process and system to better track and understand the amount and nature of intellectual property (IP) generated from CPRIT grant activity and the commercialization paths taken by that IP. Implementation of the first phase of this project (collection and standardization of IP data) is substantially complete for the 15 research institutions receiving the most CPRIT academic research grants. This will be an ongoing process as academic research grantees generate new IP and related documentation and information.

For the second phase of the project (database selection), CPRIT has identified a database and software as a service (SaaS) provider that will store the IP information and underlying documentation reported by grantees and negotiated contract terms. The proposed database will enable searching, tracking, and data analysis, and will issue reports across a variety of parameters. We anticipate finalizing the contract with the database/SaaS provider in August.

The third phase of the project (data migration) will begin once CPRIT executes the contract with the database/SaaS provider. We expect that it will take approximately four to six months to fully transfer CPRIT grantee IP data into the newly acquired database and management system. CPRIT plans to roll-out the IP database system and its related capabilities by early 2024.

We will keep you updated on the project status.

Advisory Committee Meetings

- The Clinical Trial Advisory Committee met June 9.

Operations, Finance, and Conference Update

- CPRIT finalized the conference schedule and speakers for CPRIT's Innovations VI Conference. The abstract submission system and the conference registration portal, available through the dedicated website for the conference (www.texascancerconference.org), are both live. Currently, 225 people have paid and registered. The regular registration rates end July

31, with late registration rates in effect on August 1. CPRIT has secured Scorpius BioManufacturing as conference sponsor for lunch on October 2, as well as two exhibit sponsors, Levitas Bio and Collaborative Drug Discovery.

- CPRIT's internal auditor, Weaver and Tidwell, is conducting a purchasing compliance internal audit of CPRIT's procurement processes and procedures. CPRIT's contract specialist, Don Brandy, and Chief Operating Officer Heidi McConnell are working with the auditors.

- CPRIT has posted a request for proposal (RFP) for internal audit services and another for economic impact of cancer analysis services for FY 2024. Ms. McConnell will present vendor recommendations to the Oversight Committee in the upcoming months.

Upcoming Subcommittee Meetings

Listed below are the subcommittee meetings in advance of the August 16 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 the meeting.

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

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CPRIT has awarded **1,874** grants totaling **$3.334 billion:**

- 282 prevention awards totaling $341.5 million
- 1,592 academic research and product development research awards totaling $2.99 billion

Of the $2.99 billion in academic research and product development research awards,

- 31.7% of the funding ($948.6 million) supports clinical research projects
- 24.0% of the funding ($716.8 million) supports translational research projects
- 29.0% of funding ($867.6 million) supports recruitment awards
- 12.3% of the funding ($369.5 million) supports discovery stage research projects
- 3.0% of funding ($90.4 million) supports training programs.

CPRIT has five open Requests for Applications (RFAs)

- 3 Academic Research Recruitment
- 2 Prevention

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	CPRIT ACTIVITIES UPDATE FOR JULY 2023
DATE:	AUGUST 1, 2023

Topics in this memo address CPRIT activities in July, including preparations for the upcoming August 16 Oversight Committee meeting, recent milestones in our fight against cancer, a staffing summary, outreach efforts, and updates from Compliance, Programs, and Operations.

Planning for the August 16 Oversight Committee Meeting

The Oversight Committee will meet in person on Wednesday, August 16, in the Barbara Jordan Building. The meeting will begin at 8:30 a.m. due to possible quorum concerns. We will have a full agenda with grant award recommendations, contract approvals and annual reports from the Geographic Diversity and Clinical Trials advisory committees. Please notify me as soon as possible if you are unable to attend the August 16 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 August 4 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 August 8. Oversight Committee members will receive an electronic copy of the agenda packet by August 9. Hard copies of the agenda and proposed award packet will be available at the meeting.

Recent Milestones in the Fight Against Cancer

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

- Houston-based ImmunoGenesis announced on July 3 that Cancer Focus Fund LP, an investment fund partnered with The University of Texas MD Anderson Cancer Center to advance cancer therapies, invested $4.5 million in the company. The money will support the Phase 1a/1b trial of ImmunoGenesis candidate IMGS-001, an antibody that targets cancer

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cells that resist immunotherapy. The investment will coincide with an upcoming Series A funding round for ImmunoGenesis, which the company expects to complete in the third quarter. CPRIT awarded ImmunoGenesis a $15 million CPRIT Product Development Research grant (DP200094) in 2020. The company develops novel drugs with technology spun out of MD Anderson Cancer Center.

- The European Molecular Biology Organization elected CPRIT Scholar and stem cell biologist Sean J. Morrison, Ph.D., as an associated member on July 4. Dr. Morrison, Howard Hughes Medical Institute Investigator and founding director of the Children's Medical Center Research Institute at The University of Texas Southwestern Medical Center, studies the cellular and molecular mechanisms that regulate stem cell function and the role these mechanisms play in cancer. His laboratory pioneered methods to purify stem cells from multiple tissues and discovered mechanisms that allow stem cells to persist throughout life to regenerate tissues after injury. He discovered key mechanisms that regulate stem cell self-renewal as well as the location and cellular composition of specialized microenvironments that promote the maintenance of hematopoietic stem cells in blood-forming tissues.

  UT Southwestern recruited Dr. Morrison to Texas in 2011 from the University of Michigan with a $10 million CPRIT Established Investigator Award (R1109). CPRIT has awarded Dr. Morrison an additional $7.6 million since 2016 (RP170114, RP170633, RP180778, RP220492) to support his groundbreaking research.

- The UT Health Houston School of Public Health newsletter featured the CPRIT-funded liver cancer prevention program, GRASSROOTS HEALTH, on July 6. The program, co-led by Vanessa Schick, Ph.D., associate professor in the Department of Management, Policy and Community Health, and Jack Tsai, Ph.D., professor and regional dean of The University of Texas Health Science Center at Houston School of Public Health in San Antonio, provides access to testing, vaccines and treatment for hepatitis B and C to those experiencing homelessness in Houston and San Antonio. CPRIT awarded UT Health Houston more than $3 million in 2018 and 2022 (PP180086, PP220022) to create and expand this program.

- On July 6, the Leukemia & Lymphoma Society announced the Equity in Access Research Program's second cohort of award recipients, a group of outstanding health services researchers who have received $3.8 million in combined funding, to ensure that all patients with and survivors of a blood cancer achieve access to the cancer care and services they need throughout their lives. Among the recipients is CPRIT Scholar Christopher Flowers, M.D., M.S., chair of the department of lymphoma-myeloma at The University of Texas MD Anderson Cancer Center. Together with Meng Li, Ph.D., Sc.M., Dr. Flowers is investigating how financial hardship affects quality of life and survival in patients with non-Hodgkin lymphoma (NHL). This work highlights the role insurance coverage plays in access to care, survival, and financial hardship among patients with NHL and to what extent insurance coverage influences racial disparities in access and outcomes. The University of Texas MD Anderson Cancer Center recruited Dr. Flowers to Texas from Emory University School of Medicine with the support of a $6 million CPRIT Recruitment of Established Investigators grant (RR190079) in May 2019.

- On July 11 Salarius Pharmaceuticals, a clinical-stage biopharmaceutical company using protein inhibition and protein degradation to develop cancer therapies for patients in need of new treatment options, announced FDA clearance of the company's investigational new drug application for a Phase 1 clinical trial. Salarius expects to begin treating patients with relapsed/refractory non-Hodgkin lymphoma in the dose-escalation portion of the trial in the second half of 2023 to evaluate safety, clinical activity, pharmacokinetics and pharmacodynamics of SP-3164, an oral small molecule protein degrader. Salarius will also assess the applicability of the gene signature in predicting response to SP-3164. Previous research with similar agents indicates that patients with an identifiable gene signature may be more likely to respond to SP-3164 treatment. Houston-based Salarius received a $16.1 million CPRIT New Company Product Development Award (DP160014) in May 2016 to develop novel drugs for rare pediatric cancers and other cancers by focusing on treatments that interrupt the final steps of the signaling cascade.

- Kytopen announced July 11 that it selected CPRIT Scholar Omid Veiseh, Ph.D., an eminent scientist in bioengineering and associate professor of bioengineering at Rice University, for a strategic collaboration to drive cutting-edge research in genome engineering and expedite the discovery of novel cell therapies. Dr. Veiseh's renowned translational medical research laboratory will host the placement of Kytopen's new high-throughput gene editing instrument, Flowfect Discover, along with Kytopen's manufacturing-scale platform, Flowfect Tx, at his laboratory. Kytopen, a Massachusetts Institute of Technology startup biotechnology company specializing in scalable gene editing platforms, created the Flowfect platforms to reduce the time of therapeutic development from years to months reducing the overall costs of creating and manufacturing therapies.

  Rice University recruited Dr. Veiseh to Texas from MIT in 2016 with a $2 million First Time, Tenure-Track recruitment award (RR160047); CPRIT also supported his research with a $250,000 High-Impact, High-Risk research award in 2021 (RP210205)

- The July 11 Texas Tech Health Check podcast released by Texas Tech University Health Sciences Center featured the CPRIT-funded project "Get FIT to Stay Fit" and its project director, Dr. Izi Obokhare, M.D., F.A.C.S., F.I.C.S. The project provides colorectal cancer screening and diagnostic testing in 26 counties in the Texas Panhandle. Dr. Obokhare is a Texas Tech Physicians surgeon, associate professor in general and colorectal surgery, and associate dean for faculty development at Texas Tech University Health Sciences Center in Amarillo. CPRIT awarded Texas Tech University Health Sciences Center nearly $5.5 million since 2014 (PP150031, PP180031, PP210017) to establish and extend this program.

- Invectys, a clinical-stage immuno-oncology company developing novel therapies for the treatment of advanced cancers, announced on July 13 that it started the Phase 1/2 clinical trial of its lead CAR-T program, IVS-3001, in solid tumors. IVS-3001 targets the rarely exploited immune checkpoint and tumor specific antigen known as HLA-G. The company initiated the clinical trial in late June at The University of Texas MD Anderson Cancer Center for patients with HLA-G-positive solid tumor patients, particularly those with kidney and ovarian cancers.

The company also announced the appointment of Dr. Jake Kushner, M.D., as its new Chief Executive Officer. Dr. Kushner is a renowned endocrinologist who also serves as the Medical Director for McNair Interests, where he evaluates and manages medical investments. CPRIT awarded the Paris and Houston-based company a $14.2 million Product Development Company Relocation grant (DP200034) in 2020.

- Molecular Templates, a clinical-stage biopharmaceutical company developing proprietary engineered toxin bodies announced July 13 that it entered into a definitive securities purchase agreement with healthcare investors that will provide the company up to $40 million in gross proceeds. Existing investor BVF Partners LP is leading the financing, which includes current investors BB Biotech AG and Adage Capital Management, and other leading institutional investors. CPRIT awarded Austin-based Molecular Templates two Product Development grants (CC121020, DP160071) in 2011 and 2016, committing up to $26 million.

- Rice University announced July 17 that CPRIT Scholar Han Xiao, Ph.D., received a $3.2 million research grant from the National Cancer Institute. The grant aims to develop a groundbreaking treatment for bone metastasis that specifically targets the cancer cells in the bone while leaving the normal cells in other parts of the body unaffected. This targeted approach could significantly improve the treatment's effectiveness and reduce side effects.

  Although the research initially focuses on breast cancer patients, bone metastasis is a major problem for other cancers like prostate, lung, kidney, and thyroid cancers. Current treatments for primary cancers are not very effective for bone metastasis, which often leads to poor outcomes. More than two-thirds of bone metastases are associated with subsequent spread to other organs, which is a major cause of cancer-related deaths. Dr. Xiao's research aims to interrupt this process known as "metastasis-to-metastasis" by focusing on the cancer cells in the bone.

  Rice University recruited Dr. Xiao to Texas in 2017 from Stanford University with a $2 million First-Time, Tenure-Track Faculty Member recruitment award (RR170014).

- Baylor College of Medicine announced July 19 that CPRIT Scholar S. Gail Eckhardt, M.D. will join the institution as associate dean for experimental therapeutics in September and serve as associate director for translational research at the Dan L. Duncan Comprehensive Cancer Center.

  The University of Texas at Austin Dell Medical School recruited Dr. Eckhardt to Texas from the University of Colorado in 2016 with a $6 million Established Investigator recruitment award (RR160093). She is an internationally renowned translational leader in oncology and developed the oncology clinical and research programs at Dell Medical School as well as serving as the inaugural director of the Livestrong Cancer Institutes. Dr. Eckhardt is the principal investigator on grants involving early clinical trials and colorectal cancer research, has published 200+ manuscripts, and conducted numerous early phase clinical trials.

- The Damon Runyon Cancer Research Foundation awarded CPRIT Scholar Pavan Bachireddy, M.D., the Damon Runyon Clinical Award on July 20. Recipients of this prestigious award are outstanding, early-career physician-scientists conducting patient-oriented cancer research at major research centers under the mentorship of the nation's leading scientists and clinicians. Dr. Bachireddy will receive $600,000 over three years; Damon Runyon will also retire up to $100,000 of his medical school loan debt.

  The University of Texas MD Anderson Cancer Center recruited Dr. Bachireddy to Texas in 2020 with a $2 million First-Time, Tenure-Track Faculty Member recruitment award (RR210008). At MD Anderson, Dr. Bachireddy is using cutting-edge machine learning approaches to identify immunosuppressive mechanisms that target measurable residual disease (MRD) cells—cancer cells that remain after treatment and eventually spread. MRD cell persistence and progression is a major cause of relapse after therapy. Jeffrey J. Molldrem, M.D., an international leader in stem cell transplantation and cellular therapies and focuses on the pathogenesis and treatment of blood cancers, mentors Dr. Bachireddy.

- On July 24, Immatics US, Inc, announced that Bristol Myers Squibb made a $35 million equity investment in the company. Bristol Myers Squibb purchased 2,419,818 ordinary shares in a private placement transaction at a subscription price per share of $14.46. “This investment is further testimony to the strength of the relationship and of our differentiated platform technologies that are the foundation of our TCR-based cell therapies and bispecifics,” explained Harpreet Singh, Ph.D., CEO and Co-Founder of Immatics. The Houston-based Immatics US, Inc. received a $19.65 million CPRIT New Company Product Development Research grant (DP150029) in February 2015 to build a sustainable, world-class cancer immunotherapy company in Texas and translate the value of novel cancer targets into better and longer lives for cancer patients.

- In July, The University of Texas MD Anderson Cancer Center named 10 early career faculty members to the 2023 class of Andrew Sabin Family Fellows. Established by philanthropist Andrew Sabin through a generous $30 million endowment in 2015, the Sabin Family Fellowship program nurtures brilliant rising clinicians and scientists to deliver cancer breakthroughs. Six of the new fellows are CPRIT grantees, including CPRIT Scholar Jihye Yunv, Ph.D. (RR170039), CPRIT Early Clinical Investigator Carl Gay, M.D., Ph.D. (RP210159), CPRIT Scholar Robert Jenq, M.D. (RR160089), CPRIT Scholar Pavan Bachireddy, M.D. (RR210008), Anil Korkut, Ph.D. (RP170640), and CPRIT Scholar Nidhi Sahni, Ph.D. (RR160021). Each Sabin Family Fellow will receive $100,000 over two years. This funding frees researchers to pursue novel or high-risk, high-reward scientific endeavors early in their careers. The work of the Sabin Family Fellows spans the cancer care continuum, from basic science to translational research to survivorship, and is already impacting the lives of patients at MD Anderson.

- The International Society for Computational Biology (ISCB) inducted CPRIT Scholar Bissan Al-Lazikani, Ph.D., professor of genomic medicine at The University of Texas MD Anderson Cancer Center, into the 2023 Class of ISCB Distinguished Fellows. The ISCB Fellows Program honors members who have distinguished themselves through outstanding

contributions to the fields of computational biology and bioinformatics. The University of Texas MD Anderson Cancer Center recruited Dr. Al-Lazikani to Texas from the Institute of Cancer Research in 2020 with the support of a $6 million CPRIT Recruitment of Established Investigators grant (RR210007).

Notable CPRIT-Supported Research and Prevention Accomplishments

- **Oncology Field Advocates for Expanding Eligibility in Clinical Trials to Cancer Survivors**. A recent study published June 15 in *JAMA Oncology* by The University of Texas Southwestern Medical Center researchers CPRIT Scholar Sandi Pruitt, Ph.D., and CPRIT grantee David Gerber, M.D., suggests a significant change in the eligibility criteria for cancer clinical trials. The number of cancer survivors in the United States has been increasing, with an estimated 18 million survivors in 2023. However, current practices exclude a portion of these survivors from participating in clinical trials, limiting their access to potentially life-saving experimental treatments.

  Dr. Pruitt and Dr. Gerber, working with Caitlyn Murphy, M.D., Ph.D. from The University of Texas Health Science Center at Houston, analyzed data from cancer patients diagnosed in 2019 and found that about 19.4% of them had a history of prior cancer. This means that almost one in five newly diagnosed cancer patients had previously battled cancer, either of the same or different type. Interestingly, the research revealed that cancer survivors with a different type of previous cancer were more common among older patients, men, and White patients compared to younger patients, women, and Black patients, respectively.

  It has been common practice to exclude patients with a history of prior cancer from clinical trials. However, this study's findings challenge that approach. Over the six-year interval from 2013 to 2019, there was approximately a 15% increase in cancer survivors diagnosed with a new cancer. Moreover, growing evidence suggests that cancer survivors newly diagnosed with a different type of cancer have similar survival rates compared to those without a history of prior cancer.

  These results indicate that the long-standing recommendation of excluding patients with a history of prior cancer from clinical trials may no longer be appropriate. The growing population of cancer survivors and the evidence supporting their equivalent survival rates provide compelling reasons to reconsider the eligibility criteria for cancer clinical trials. By revising these criteria, more cancer patients, including those with a history of prior cancer, could gain access to experimental treatments, potentially leading to improved outcomes and advancing cancer research.

  UT Southwestern recruited Dr. Pruitt to Texas from the Washington University School of Medicine in 2012 with a $900,000 First-Time, Tenure-Track Faculty Member award (R1205). Dr. Gerber has received multiple CPRIT grants totaling $6 million since 2016 (RP160030, RP210115, RP220542), including a Clinical Trials Network Award to expand access to clinical trials for underserved patients with cancer in Texas.

- **"Y" Are Some Cancers More Frequent and Aggressive in Men?** Recent findings published June 21 in the scientific journal *Nature* by CPRIT grantee Ronald DePinho, M.D., shed light on why certain types of cancer, such as bladder and colorectal cancer, are more common in men and often have worse outcomes compared to women. While scientists have linked lifestyle factors and sex hormones to these differences, differences in cancer between men and women persist even when accounting for such factors.

  Dr. DePinho and his team at The University of Texas MD Anderson Cancer Center have identified a gene on the Y chromosome, called KDM5D, that plays a significant role in colorectal cancer with mutations in a specific protein called KRAS. KRAS mutations, commonly found in human tumors, can increase the aggressiveness of cancer cells and reduce the body's ability to fight the cancer.

  Through their research using advanced techniques and a specially engineered mouse model, the team discovered that the KDM5D gene produces a protein that alters the activity of certain genes, promoting the spread of cancer cells and weakening their connection to each other. This weakening of connections allows the cancer cells to break away and spread to other parts of the body, the process known as metastasis. The research team found that KDM5D also hinders the immune system's ability to recognize and attack cancer cells. Normally, the immune system can identify abnormal cells and eliminate them, but KDM5D represses the genes that help the immune system detect these cancerous cells, allowing them to evade detection and continue growing.

  Interestingly, when the researchers removed the KDM5D gene from cancer cells in the mouse model, the cancer became less invasive, and the immune system was better able to kill the cancer cells. This suggests that targeting KDM5D could be a potential therapeutic strategy to reduce the risk of metastasis in men with colorectal cancer.

  In addition to the $1 million Individual Investigator grant awarded to Dr. DePinho in 2022 (RP220364), the $4 million "The Future of Cancer Research: Training Program for Basic and Translational Scientists" CPRIT Training Grant (RP210028) supported the work of several members of Dr. DePinho's team on this project.

- Appendix cancer is a rare gastrointestinal cancer with limited available treatment options due to the lack of preclinical models. Surgery and heated intraperitoneal (IP) chemotherapy is the current standard of care, but it is not appropriate for patients with a large tumor burden. Researchers led by CPRIT Scholar John Paul Shen, M.D., hypothesized that IP paclitaxel, which is safe and effective in other cancers, would also be effective in appendix cancer, since these tumors are in the peritoneal space. In three different lab models of appendix cancer, weekly IP paclitaxel significantly reduced tumor growth and had fewer side effects than intravenous chemotherapy. The study, published in *Cancer Research* on July 11 demonstrated the promising therapeutic potential of IP paclitaxel. Given the established safety record of IP paclitaxel in gastric and ovarian cancers, and lack of effective chemotherapeutics, these data support the evaluation of IP paclitaxel in a prospective clinical trial patients with metastatic appendix cancer. The University of Texas MD Anderson Cancer

Center recruited Dr. Shen in 2018 from the University of California, San Diego with the support of a $2 million CPRIT Recruitment of First-Time, Tenure-Track Faculty Members grant (RR180035.)

- **Elucidating Mechanisms of Metastasis in Estrogen Receptor-Positive Breast Cancer**. CPRIT-supported research available in the July 18 edition of *Cell Reports* sheds new light on the cellular processes leading to metastasis of estrogen receptor-positive (ER+) breast cancer. In ER+ breast cancer, the estrogen receptor plays a crucial role in regulating genes that control the growth of normal breast tissue as well as cancerous cells.

  Treatment for ER+ breast cancer typically involves endocrine therapy, like tamoxifen, which targets the estrogen receptor. However, many patients eventually develop resistance to this treatment, leading to disease progression and poor outcomes. In most cases of endocrine resistance, the estrogen receptor remains active, albeit in a modified form, and continues to drive the progression of breast cancer.

  A multi-investigator research team led by Xiaoyong Fu, M.D., Ph.D., and Rachel Schiff, Ph.D. of the Departments of Medicine, and Molecular and Cellular Biology at Baylor College of Medicine and the Dan L. Duncan Comprehensive Cancer Center focused on a specific protein, FOXA1, which regulates how the estrogen receptor binds to the genetic material (chromatin) in cells. FOXA1 plays a critical role in controlling the activation of certain genes, including those involved in cancer development. Scientists have observed abnormal activation of FOXA1 in advanced hormone-related cancers, but scientists do not fully grasp the exact factors responsible for its high activity.

  Through experiments using mice with human breast cancer, the researchers found that high levels of FOXA1 promoted the spread of ER+ breast cancer to other parts of the body. Mechanistically, FOXA1 caused changes in how the estrogen receptor interacts with chromatin, leading to alterations in the activated genes. This change in gene activation resulted in the production of proteins that drive cancer metastasis, which is the process of cancer cells spreading to other organs.

  One of the proteins strongly associated with poor outcomes in ER+ breast cancer is Secretome14. The researchers discovered that high FOXA1 activity led to increased production of Secretome14 and other pro-metastatic proteins. This indicates that FOXA1 influences the expression of genes involved in promoting cancer spread.

  The study's findings suggest that inhibiting the interaction between FOXA1 and the estrogen receptor could be a potential strategy to prevent and treat endocrine-resistant ER+ breast cancer. Developing more potent drugs that target the estrogen receptor and potential epigenetic interventions (modifying how genes expression without changing the underlying DNA sequence) may be promising approaches for future treatments.

  CPRIT supported this research through a $900,000 Individual Investigator grant to Dr. Schiff (RP190398) and two CPRIT Core Facility Support Awards to Baylor College of Medicine

(RP200504, Comprehensive Cancer Epigenomics Core Facility, PI: Dr. Rui Chen, $4 million and RP180672, Advanced Multiparameter Cytometry and Cell Sorting Core, PI: Dr. Christine Beeton, $5.2 million).

- Uterine fibroids are non-cancerous tumors that grow in the uterus and are quite common in women of reproductive age. Various factors, including exposure to harmful substances like endocrine-disrupting chemicals (EDCs), contribute to their development. However, scientists do not fully understand the specific ways in which these chemicals disrupt biological processes and lead to uterine fibroids. Unfortunately, there are limited treatment options for uterine fibroids, with hysterectomy being the most common one.

  In a recent study reported in the *International Journal of Molecular Sciences* on July 19, researchers report evidence showing that exposure to EDCs during development affects a specific type of stem cells, called myometrial stem cells (MMSCs), which are responsible for uterine fibroid formation. They found that these chemicals alter the activity of certain genes related to inflammation in these stem cells. By targeting specific regulators in the cells' epigenome (the chemical tags that influence gene activity), such as MLL1 and HDAC, the researchers were able to reverse some of these changes in the MMSCs of rats exposed to EDCs. Understanding these mechanisms is crucial for researchers to comprehend how developmental exposures can impact human health.

  CPRIT supported this research with a $6 million grant that enhanced the Molecular Biology Facility Core at The University of Texas MD Anderson Cancer Center. This facility houses advanced equipment like the Illumina HiSeq 1000 to support next-generation sequencing, which aids researchers in conducting cutting-edge studies.

- **Ultra-sensitive, Cryogenic Electron Microscopy Enables Scientists to Visualize DNA Repair.** A collaborative team of leading biochemists and structural biologists, including four CPRIT Scholars at The University of Texas Health Science Center at San Antonio, report the structure of DNA repair complexes for the first time in the July 20 issue of *Nature*. DNA repair is a process through which cells identify and correct damage to their genetic material. Failure to repair this damage can lead to cell death or genomic instability, which may cause cells to become cancerous.

  Many effective cancer treatments work by blocking DNA repair or inducing so many DNA lesions that the damage overwhelms the cell's ability to correct, leading to tumor cell death. One particularly harmful type of DNA damage is double-strand breaks, which can result in chromosomal rearrangements linked to various cancers, including leukemias, lymphomas, and sarcomas.

  In a tour-de-force of structural biology, a team of scientists led by Dr. Shaun K. Olsen focused on a critical DNA repair process called homologous recombination (HR), which repairs double strand breaks and collapsed replication forks. They studied a complex of four proteins (RAD51B, RAD51C, RAD51D, and XRCC2) known as BCDX2, which plays a key role in HR by helping repair proteins bind to single-stranded DNA during the repair process.

Using advanced imaging techniques, the scientists revealed the structures of BCDX2 both alone and when bound to single-stranded DNA. This allowed them to understand how the individual components of BCDX2 interact to form the repair complex and specifically bind to single-stranded DNA. They also studied how certain mutations in one of the proteins found in some cancer patients, RAD51C, impact its ability to bind to DNA and mediate DNA repair.

These findings shed light on the role of BCDX2 in DNA repair and provide valuable insights into how alterations in BCDX2 can affect genome repair. Understanding these processes could lead to more effective treatments for cancer, as targeting specific DNA repair mechanisms could potentially make cancer cells more vulnerable to treatment.

UT Health San Antonio recruited Dr. Patrick Sung (RR180029) and Dr. Alexander Mazin (RR210023) from Yale University and Drexel University College of Medicine, respectively, with $6 million Established Investigator awards in 2018 and 2021. The institution recruited Dr. Shaun Olsen from the Medical University of South Carolina with a $4 million CPRIT Rising Star Award (RR200030) in 2020, and Dr. Elizabeth Wasmuth, an expert in cryoEM technology, from the Memorial Sloan Kettering Cancer Center in 2022 with a $2 million Recruitment of First-Time, Tenure-Track Faculty Award (RR220068,). In addition, UT Health San Antonio and Dr. Robert Hromas received a $890,000 Individual Investigator award in 2022 to support this work (RP220269).

- **Therapy Resistant Acute Myeloid Leukemia Cells Display Unexpected Heterogeneity.** Acute myeloid leukemia (AML) is a type of blood cancer characterized by various subgroups with disrupted development of certain blood cells. Clinicians further classify AML based on specific genetic mutations and abnormalities to determine the prognosis and treatment options. In adults, AML can be a devastating disease with a high resistance to therapy, leading to short survival rates.

  To understand why therapy resistance occurs in AML, researchers from The University of Texas MD Anderson Cancer Center led by Hussein Abbas, M.D., Ph.D., and CPRIT Scholar Andy Futreal, Ph.D., analyzed 22 bone marrow samples from eight patients with AML who had become resistant to treatment. They studied the developmental pathway of AML cells at the time of therapy resistance using advanced single-cell analysis.

  Their findings, published July 21 in *Communications Biology*, revealed a complex lineage architecture of therapy-resistant AML cells. These cells showed characteristics of stem and progenitor cells, which are early stages of blood cell development, as well as features of more mature blood cells. The resistant AML cells had a range of characteristics spanning different stages of cell development.

  Interestingly, even after subsequent therapy, the lineage composition of AML cells remained heterogeneous, with some cells maintaining characteristics associated with unfavorable outcomes. The researchers suggested that the acquisition of a spectrum of different cell lineages in therapy-resistant AML not only contributes to the generation and maintenance of

leukemia stem cells (which are hard to treat), but also creates barriers for therapeutic responses, leading to treatment resistance and persistence of the disease.

Based on these findings, the researchers proposed that using drugs that reprogram AML cells into a uniformly differentiated state (a state resembling more mature blood cells) as a potential approach to overcome therapy resistance. By better understanding the cellular pathways involved in AML resistance, there could be new opportunities for developing more effective treatments for patients with progressive or treatment-resistant AML.

MD Anderson recruited Dr. Futreal to Texas from the Wellcome Trust Sanger Institute with a $7 million Established Investigator award in 2011 (R1205). CPRIT also supported this work through a $4.4 million Core Facilities award to The University of Texas Health Sciences Center at Houston Cancer Genomics Core (RP180734, PI: Dr. Zhongming Zhao).

Personnel

CPRIT has filled 46 full-time equivalent positions and an accountant position is in progress.

- CPRIT hired four grant compliance specialists; two part-time employees will join in August, and two full-time employees will join in September.

- The new Information Technology Support Specialist will start September 1.

CPRIT Outreach

Staff outreach activities during July include:

- CPRIT Program Manager for Prevention Carlton Allen attended the 7th Annual Southeastern Colorectal Cancer Consortium (SCCC) Conference on June 21-23 in Norfolk, Virginia. The SCCC includes individuals and organizations from 13 southeastern states and Puerto Rico who are working on colorectal cancer issues, including raising screening rates.

- On July 7, Deputy Executive Officer and General Counsel Kristen Doyle and I met with representatives of the Texas Higher Education Coordinating Board to discuss their efforts to develop a statewide Technology Innovation and Commercialization Plan focused on maximizing tech transfer and commercialization activities at Texas institutions of higher education and strengthening regional innovation ecosystems across the state.

- Senior Program Manager for Product Development Dr. Abria Magee met with Laurie Fernandez from ICON on July 13. ICON is a global provider of outsourced drug and device development, and commercialization services to pharmaceutical, medical device, government, and public health organizations. Dr. Magee and Ms. Fernandez discussed ICON’s participation in the CPRIT resource guide and the CPRIT conference in October.

- On July 17, Dr. Magee met with Adam Labaff from Fortis Life Sciences, a contract development firm that partners with diagnostics and life science companies to custom design proprietary solutions for solving development problems. They discussed the CPRIT resource guide and the upcoming CPRIT conference.

- Dr. Magee met with several representatives from Tonix Pharma, including CEO Seth Ledermen, Mary Kelley, Siobhan Fogarty, and Bruce Daugherty, on July 24 to discuss CPRIT product development funding opportunities. Tonix is a clinical-stage biopharmaceutical company developing novel therapies and vaccines to prevent and treat central nervous system disorders.

- On July 26 I met with Dr. David Lakey, Vice Chancellor for Health Affairs and Chief Medical Officer at The University of Texas System, to discuss the System's interest in establishing a training, coaching, and mentoring program to facilitate successful applications by junior researchers for competitive research awards, especially from the National Institutes of Health.

- Oversight Committee member Dee Margo, Chief Scientific Officer Dr. Michelle Le Beau, Director of Academic Research Dr. Patty Moore, Dr. Myriam Casillas, Program Manager for Academic Research, Communications Director Mark Loeffler, Mr. Allen and I participated in a press briefing on July 28 spotlighting the recent TREC Award to the Texas Tech University Health Sciences Center El Paso.

- The National Colorectal Cancer Roundtable (NCCRT) asked Mr. Allen to join its 2023 Annual Meeting Planning Committee. Houston will host the 2023 NCCRT annual meeting in mid-November. The NCCRT, established by the American Cancer Society and the Centers for Disease Control and Prevention in 1997, is a national coalition of public and private organizations and invited individuals. NCCRT's goal is to increase the use of proven colorectal cancer screening tests among the entire population for whom screening is appropriate.

Compliance Program Update

Submission Status of Required Grant Recipient Reports

As of July 24, 11 entities had not filed 10 academic research reports, four product development reports, and two 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 68 second-level reviews of grantee Financial Status Reports (FSRs) in July. Seven FSRs (10%) 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 six enhanced desk-based financial monitoring reviews in July. 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 eight grantees to address desk review findings.

Onsite Reviews

CPRIT completed one onsite review in July. 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 one grantee 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, three grantees have 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 actively working with the three grantees to submit the required audit.

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 July. The total amount of match expenses reviewed by compliance staff for FY 2023 is $18,737,340.33. The unallowable match expenses for FY 2023 total $24,617.10.

Training and Support

CPRIT staff conducted one new Authorized Signing Official (ASO) training webinar in July for Marker Therapeutics. The 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 of the change.

CPRIT staff conducted three new grantee training webinars in July for 7 Hills Pharma, OncoResponse, and OmniNano Pharmaceuticals. New grantee training covers grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. Pursuant to Texas Administrative Code §703.22, CPRIT requires new grantees to complete the initial compliance training program prior to receiving disbursement of grant award funds.

The compliance program held an ad hoc training July 31 with Baylor College of Medicine to provide technical assistance with required reporting, specifically financial status reports. The training covered reporting timelines, cost allowability/allocability by category, and quality of support documentation.

Academic Research Program Update

Recruitment FY 2023 Review Cycle 5 and 6

CPRIT's Scientific Review Council (SRC) reviewed recruitment applications for the fourth quarter of FY 2023 on May 18 and July 13. Dr. Le Beau will present the SRC's award recommendations for recruitment awards to the Program Integration Committee (PIC) and the Oversight Committee in August.

FY 23 Mechanism	Received	Funds Requested	Recommended	Recommended Funds
Recruitment of Established Investigators	5	$28,610,776	1	$6,000,000
Recruitment of First-Time, Tenure Track Faculty Members	17	$33,800,000	9	$17,800,000
TOTAL	**22**	**$62,410,776**	**10**	**$23,800,000**

Academic Research FY 2023 Review Cycle 2 (23.2)

CPRIT released several RFAs for the second cycle of FY 2023 (23.2) on January 17 and accepted applications January 25 – April 18. CPRIT received 26 applications by the deadline. Peer review panels met virtually June 13 and 16 to consider the applications. Dr. Le Beau will present the SRC's recommendations to the PIC and the Oversight Committee in August.

Three of the four cycle 23.2 RFAs are first-time grants and will support research, training, and instrumentation at TREC-eligible institutions. The fourth RFA, also offered by CPRIT for the first time, will support the Texas CONNECT for Cancer Prevention Study in collaboration with the NCI CONNECT Study.

FY 23 Mechanism	Received	Funds Requested
TREC: Pilot Study Award	14	$2,800,000
TREC: Major Instrument Award	5	$4,700,000
TREC: Institutional Postdoctoral Training Award	3	$2,500,000
Texas Connect for Cancer Prevention Study Awards	4	$29,500,000
TOTAL	**26**	**$39,500,000**

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. Peer review will take place in October. 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**

Recruitment FY 2024 Review Cycle 1

CPRIT opened the portal to receive FY 2024 recruitment applications on June 21. The SRC will meet in September to review the two Recruitment of First-Time, Tenure Track Faculty Member applications received by July 20. Dr. Le Beau will present the SRC's recruitment award recommendations for the first quarter of FY 2024 to the PIC and the Oversight Committee in November.

Product Development Research Program Update

Product Development FY 2024 Review Cycle

On May 1 CPRIT released four FY 2024 Product Development Research RFAs and opened the portal to receive preliminary and full applications on a rolling basis. As described in more detail below, CPRIT received the total number of full applications (15) allocated for the first cycle of FY 2024 by June 30, one month before the August 1 deadline. Given the quality of the full applications and the requested project budget totaling $149 million, it is likely that this will be the only review cycle for FY 2024 product development grants.

- Preliminary Application Review: CPRIT received 79 FY 2024 preliminary applications on a rolling basis between May 1 and June 30. Like the FY 2023 review cycle, five standing review panels evaluated the FY 2024 preliminary applications on a rotating basis. CPRIT issued weekly invitations to submit full applications to companies that presented meritorious preliminary applications, based on application scores as determined by the preliminary application peer review panel.

  As discussed in the section below, CPRIT received the total number of full applications for the 15 review slots for FY 2024 on June 30. The preliminary review panels had completed reviews of 45 preliminary applications and issued invitations to 19 companies to submit a full application for FY 2024 by June 30. Because there are no more spots available for full application review, CPRIT returned 34 preliminary applications to applicants without review. Should the applicants submit these unreviewed applications in future cycles, they will not count against the resubmission limit.

  The table below provides information about the FY 2024 preliminary applications.

FY 2024 RFA	Preliminary Applications			Total Prelim Budget Request	Invited to Submit Full Applications
	Submitted	Reviewed	Returned - no review		
TTC	34	23	11	$353 M	10
TDDC	4	2	2	$27 M	1
TNTC	9	5	4	$39 M	2
Seed	32	15	17	$48 M	6
TOTAL	**79**	**45**	**34**	**$467 M**	**19**

TTC = Texas Therapeutics Company
TDDC = Texas Device and Diagnostic Company
TNTC – Texas New Technologies Company

Full Application Review (July and August): In addition to the 19 invitations issued by June 30, CPRIT allowed four companies that submitted full applications in the FY 2023 cycle to resubmit their full applications for review in the FY 2024 cycle. (CPRIT did not review these four full applications in FY 2023 because of time and resource limitations.)

The FY 2024 RFAs notified applicants that CPRIT would continually monitor the number of submissions and would stop accepting full applications before the August 1 deadline if we received more than 15 applications. By 4:00 p.m. CST on June 30, CPRIT received its 15th and 16th full application submittal (including the four FY 2023 full applications.) Accordingly, we closed the portal for full application submission at 5:00 p.m. on June 30. We separately notified the seven companies with invitations for FY 2024 who had not submitted full applications by June 30 that CPRIT was no longer accepting full applications at this time.

Although we planned for 15 spots, Dr. Smith decided to increase the number of review slots by one (16 full application review panels) to accommodate the 16th full application received by CPRIT on June 30. As a result, unlike the FY 2023 review cycle, CPRIT will not return any full applications to applicants without a review, and we will not carry over submitted but unreviewed full applications into the FY 2025 cycle.

The table below provides information about the FY 2024 full applications.

FY 2024 RFA	Invited Apps (including FY 2023 carry overs)	Full Apps Submitted by June 30 (including FY 2023 carry overs)	Submitted Budget Request
TTC	**12** (10 FY 2024 + 2 FY 2023)	**8** (6 FY 2024 + 2 FY 2023)	$112,760,268
TDDC	**2** (1 FY 2024 + 1 FY 2023)	**2** (1 FY 2024 + 1 FY 2023)	$9,026,687
TNTC	**2**	1	$12,600,000
Seed	**7** (6 FY 2024 + 1 FY 2023)	**5** (4 FY 2024 + 1 FY 2023)	$14,989,952
TOTAL	**23** (19 FY 2024 + 4 FY 2023)	**16** (12 FY 2024 + 4 FY 2023)	**$149,376,907**

- Panel Presentations and Due Diligence Review (August – October): The 16 companies will present their full applications to review panels in August and September. Based upon the

review panels' recommendations, some companies will proceed to due diligence review in October.

- Final Recommendations and Budget Negotiation (November - through early 2024): The Product Development Review Council (PDRC) will meet in October to recommend companies for product development awards. Once the PDRC finalizes its recommendations, CPRIT will use the same process we successfully employed for the FY 2023 review cycle to negotiate the proposed project budgets to identify ways to decrease CPRIT-funded project expenses while maintaining the goals and objectives of the recommended projects. As we learned from the FY 2023 review process, this is a crucial step to ensuring that CPRIT can fund as many meritorious projects as possible with the estimated $74 million allocated for FY 2024 Product Development awards. Dr. Smith will present the companies recommended for product development awards to the Program Integration Committee and the Oversight Committee in early 2024.

  If CPRIT does not award all product development award funds allotted for FY 2024 in this first cycle, the product development program will reopen the RFAs in early 2024 for a second round of awards for Oversight Committee approval in August 2024.

Prevention Program Update

Prevention FY 2023 Review Cycle 2 (23.2)

CPRIT released four prevention RFAs on November 17, 2022, for the second review cycle of FY 2023. CPRIT received 25 proposals by the February 23 deadline, including two for the new *Colorectal Cancer Coordinating Center* grant award. Together, the submitted applications seek $37 million in grant funds. Peer reviewers convened via teleconference on May 24-25 to evaluate the applications. The Prevention Review Council met June 19 to review the two applications responding to the Colorectal Cancer Coordinating Center and to conduct programmatic review for the Cycle 23.2 applications. Chief Prevention Officer Ramona Magid will present the Prevention Review Council's recommendations to the PIC and the Oversight Committee in August.

Cycle 23.2 Mechanism	Applications	Funds Requested
Primary Prevention of Cancer	15	$21,748,129
Cancer Screening and Early Detection	5	$7,995,375
Dissemination of CPRIT-Funded Cancer Control Interventions	3	$1,348,397
Colorectal Cancer Coordinating Center	2	$5,999,936
TOTAL	**25**	**$37,091,837**

Prevention FY 2024 Review Cycle 1 (24.1)

The Prevention Program released two prevention RFAs (*Primary Prevention of Cancer* and *Cancer Screening and Early Detection*) on May 5 for the first cycle of FY 2024. CPRIT will accept applications through August 30, with peer review scheduled for October – December. Ms. Magid will present the PRC's recommendations to the PIC and the Oversight Committee in February 2024.

Advisory Committees

Many members of CPRIT's Prevention Advisory Committee (PAC) successfully championed a rider to the FY 2024 – 2025 biennium budget recently approved by the Legislature. The rider appropriates $5,000,000 in general revenue in each fiscal year to the Health and Human Services Commission for a pilot program to fund colorectal treatment for uninsured and underinsured Texans. Several PAC members and staff from the Family Health Services division of the Health and Human Services Commission will meet to discuss implementation of this program.

The Product Development Advisory Committee met July 13.

Texas Cancer Plan

CPRIT Program Manager for Prevention Carlton Allen is leading the revision of the *Texas Cancer Plan*. The *Texas Cancer Plan* aims to reduce the cancer burden across the state and improve the lives of Texans. As the statewide call to action for cancer research, prevention, and control, it identifies the challenges and issues that affect our state and presents a set of goals, objectives, and strategies to help inform and guide communities in the fight against cancer. The report provides a coordinated, prioritized, and actionable framework that will help guide efforts to mitigate the cancer burden.

The Texas legislature charged CPRIT with facilitating the development of the *Texas Cancer Plan*. CPRIT released the first plan developed under its leadership in 2012. The most recent version, issued in 2018, reflects changes, progress, and advances in cancer prevention and control efforts since 2012.

CPRIT's strategic direction and funding opportunities align with the *Texas Cancer Plan*. However, the overall outcome and success of efforts to reduce the state's cancer burden will continue to depend on the cooperation, collaboration, and resources of the many stakeholders in Texas.

Mr. Allen is engaging an array of stakeholders to gather input and enhance the plan's effectiveness. He is also working with the Texas Cancer Registry and Behavioral Risk Factor Surveillance System to gather updated data on screening and treatment statistics. CPRIT is collaborating with the Department of State Health Services to facilitate data integration. To

ensure the *Texas Cancer Plan* reflects the state's needs, CPRIT will host town halls and forums to elicit open feedback and encourage community involvement. We will continue to update you on the progress of this project.

Operations, Finance, and Conference Update

FY 2024 Bond Funding Approval

I attended the July 6 meeting of the Board of Directors of the Texas Public Finance Authority (TPFA) and provided them with a brief update about CPRIT's progress. The TPFA board approved CPRIT's request for financing of $300 million in general obligation debt for FY 2024.

Ms. Doyle, Ms. McConnell, CPRIT accountant Uzoamaka Nwachukwu, and I attended the Bond Review Board (BRB) planning session on July 11. There were no questions regarding CPRIT's FY 2024 request for financing. Ms. McConnell and I attended the BRB board meeting on July 20. The board approved the $300 million request for financing on a vote of two to one, with the Office of the Comptroller's representative voting "no".

CPRIT's Innovations VI Conference

The abstract submission system and the conference registration portal, available through the dedicated website for the conference (www.texascancerconference.org), are both live. Currently, 263 people have paid and registered. The regular registration rates ended July 31, with late registration rates in effect on August 1. CPRIT sent out a reminder of the registration price change to the agency listservs.

Confirmed conference sponsor and exhibitors include:

- Scorpius BioManufacturing (Day 1 conference lunch sponsor)
- Levitas Bio (Exhibitor)
- Collaborative Drug Discovery (Exhibitor)
- Agilent Technologies, Inc. (Exhibitor)
- The Greater Houston Partnership (Exhibitor)
- Metabolon (Exhibitor)
- Shimadzu Scientific Instruments (Exhibitor)
- H2Ocean (Exhibitor)

Internal Auditor

CPRIT's internal auditor, Weaver and Tidwell, is conducting a purchasing compliance internal audit of CPRIT's procurement processes and procedures. CPRIT's contract specialist, Don Brandy, and Ms. McConnell are working with the auditors.

Contract Procurement

CPRIT issued two solicitations earlier this year requesting proposals for FY 2024 internal audit services and for economic impact of cancer analysis services. Both requests for proposals closed in July. CPRIT staff is evaluating the proposals. Ms. McConnell will present vendor recommendations to the Oversight Committee in the upcoming months.

Upcoming Subcommittee Meetings

Listed below are the subcommittee meetings in advance of the August 16 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 the meeting.

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

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CPRIT has awarded **1,874** grants totaling **$3.334 billion:**

- 282 prevention awards totaling $341.5 million
- 1,592 academic research and product development research awards totaling $2.99 billion

Of the $2.99 billion in academic research and product development research awards,

- 31.7% of the funding ($948.6 million) supports clinical research projects
- 24.0% of the funding ($716.8 million) supports translational research projects
- 29.0% of funding ($867.6 million) supports recruitment awards
- 12.3% of the funding ($369.5 million) supports discovery stage research projects
- 3.0% of funding ($90.4 million) supports training programs.

CPRIT has five open Requests for Applications (RFAs)

- 3 Academic Research Recruitment
- 2 Prevention

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	VINCE BURGESS, CHIEF COMPLIANCE OFFICER
SUBJECT:	COMPLIANCE PROGRAM UPDATE
DATE:	AUGUST 7, 2023

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 July 28, four entities had not filed five academic research reports, 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 496 second-level reviews of grantee Financial Status Reports (FSRs) in May, June, and July. Thirty-five FSRs (7%) needed resubmission due to insufficient or inaccurate documentation sent by the grantee. CPRIT's grant accounting staff completes the first review of the FSRs and supporting documentation before routing them to the compliance specialists for final review and disposition.

Single Audit Tracking

Compliance specialists track the submission of grantees' independent audit reports and the resolution of issues named in these reports. Grantees who spend $750,000 or more in state awards in the grantee's fiscal year must undertake a single independent audit, a program specific audit, or an agreed upon procedures engagement. The grantee sends the independent audit report with findings to CPRIT within 30 days of receipt, but no later than nine months after the grantee's fiscal year end.

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Currently, two grantees have not submitted the required audits. 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 actively working with the two grantees to submit the required audits.

Desk Reviews

CPRIT staff performed 35 enhanced desk-based financial monitoring reviews in May, June, and July. Desk reviews are intended to confirm financial, administrative, and programmatic compliance using data from CGMS/CARS with additional focus on an organization's internal controls, current and previous fiscal audits, and grantee report submission timeliness. Desk reviews also aid in the identification of potential problems and technical assistance issues for follow-up during an onsite visit, as well as areas of non-compliance and grantee performance issues. Compliance specialists are collaborating with eight grantees to address desk review findings.

Onsite Reviews

CPRIT completed four onsite reviews in May, June, and July. 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.

Match Expenditures Review

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

Product development grantees plus those academic research grantees whose indirect cost rate credit does not fully offset the required match must supply a detailed match expenditure report that includes the amount and date paid, vendor, description, and budget category. Compliance staff review grantees' match expenditures for appropriateness and allowability and work with CPRIT's grant accountants and the grantee to address any deficiencies. Compliance staff

performed five annual match expenditure reviews in May, June, and July. The total amount of match expenses reviewed by compliance staff for FY 2023 is $18,737,340.33. The unallowable match expenses for FY 2023 total $24,617.10.

Training and Support

CPRIT staff conducted three new Authorized Signing Official (ASO) training webinars in May, June, and July for University of Houston - Downtown, Invectys, and Asylia. The trainings covered grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. Pursuant to Texas Administrative Code §703.22, CPRIT requires new ASOs to complete compliance training within 60 days of the change.

CPRIT staff conducted a series of annual compliance training webinars on June 14-15 for 78 grantee staff. Trainings are specific to each program area (Academic Research, Product Development Research, and Prevention) and allow for an interactive experience and opportunity to focus on topics relevant to each program. The trainings covered grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. This was the second training series offered this year for the annual compliance training requirement which requires the Authorized Signing Official and at least one other employee from each grantee organization to attend an annual compliance training by December 31 of each year.

CPRIT staff conducted three new grantee training webinars in May, June, and July for 7 Hills Pharma, OncoResponse, and OmniNano Pharmaceuticals. The trainings covered grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. Pursuant to Texas Administrative Code §703.22, CPRIT requires new grantees to complete the initial compliance training program prior to receiving disbursement of grant award funds.

An ad hoc training was conducted on July 31 with Baylor College of Medicine to provide technical assistance with required reporting, specifically financial status reports. The training covered reporting timelines, cost allowability/allocability by category, and quality of support documentation.

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:	AUGUST 16, 2023

Proposed Academic Research Fiscal Year 2024 Cycle 2 (FY24.2) RFAs

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

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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.

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 will be conducted in October 2023. Dr. Le Beau will present the Scientific Review Council's recommendations to 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 that 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
Individual Investigator Research Award (IIRA)	228	$233,894,288
Individual Investigator Research Awards for Computational Systems Biology of Cancer (IIRACSBC)	18	$36,108,737
Individual Investigator Research Awards for Cancer in Children and Adolescents (IIRACCA)	35	$47,815,216
Individual Investigator Research Awards for Prevention and Early Detection (IIRAP)	15	$27,050,403
Individual Investigator Research Awards for Clinical Translation (IIRACT)	19	$19,850,946
Total	**315**	**$364,719,590**

Recruitment Update

Table 2 displays an overview of the status of CPRIT recruitment applications received for the first cycle of FY2024. CPRITs Application Receipt System (CARS) opened for applications on June 21, 2023 and closed on July 20, 2023. The Scientific Review Council will review these applications in September 2023, and recommended applications will be presented to the Oversight Committee in November 2023.

FY2024

Table 2: Recruitment Application Submission data for Cycle 24.1

Mechanism	Number Received	Funds Requested
Recruitment of Established Investigators	0	–
Recruitment of First-Time, Tenure Track Faculty Members	2	$3,990,000
TOTAL	**2**	**$3,990,000**

Table 3: FY23 Recruitment data, by all cycles, by mechanism, by number of submissions and number recommended.

Mechanism	Number Received	SRC Recommended	FY23 Success Rate
Recruitment of Established Investigators	16	7	44%
Recruitment of First-Time, Tenure Track Faculty Members	26	15	58%
TOTAL	**42**	**22**	**52%**

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: RAMONA MAGID, CHIEF PREVENTION OFFICER

SUBJECT: PREVENTION PROGRAM UPDATE

DATE: AUGUST 16, 2023

FY 2023 Review Cycle 2 (23.2)

The Prevention Program released four RFAs on November 17, 2022, for the second cycle of FY 2023. CPRIT received 25 proposals totaling $37,091,837 by the August 31 deadline. Five applications were research projects and were administratively withdrawn. Of the remaining twenty applications requesting a total of $31,166,458, thirteen were discussed during peer review on May 22, 2023, by teleconference. The Prevention Review Council (PRC) met on June 19 to review the two applications responding to the Colorectal Cancer Screening Coordinating Center mechanism and to conduct programmatic review. The programmatic review included two applications from FY 2023 Cycle 1. The Program Integration Committee (PIC) met on August 2 to consider the PRC's recommendations. Ms. Magid presents the PIC's award recommendations to the Oversight Committee on August 16, 2023.

FY 2023.2 (23.2) Application Data by Mechanism

Mechanism	Apps Received	Funds Requested
Primary Prevention of Cancer	15	$21,748,129
Cancer Screening and Early Detection	5	$ 7,995,375
Dissemination of CPRIT-Funded Cancer Control Interventions	3	$ 1,348,397
Colorectal Cancer Screening Coordinating Center	2	$ 5,999,936
TOTAL	**25**	**$37,091,837**

FY 2024 Review Cycle 1 (24.1)

CPRIT released two prevention RFAs, *Primary Prevention of Cancer and Cancer Screening and Early Detection*, on May 5. Applications will be accepted through August 30, 2023. CPRIT has scheduled peer review for October – December 2023. Ms. Magid will present the Prevention Review Council's recommendations to the PIC and the Oversight Committee in February 2024.

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Texas Cancer Plan

- The Plan is a statewide action plan for cancer research, prevention, and control initiatives. Multiple entities are involved with the revision, execution, and evaluation of the Texas Cancer Plan.
    - By statute, Texas Health and Safety Code Chapter 102 Section 102.002(3), The Cancer Prevention and Research Institute of Texas is charged with facilitating the development of the Plan and supporting its implementation.
    - The Texas Comprehensive Cancer Control Program (TCCCP) and Chronic Disease Epidemiology Branch (CDE) at the Department of State Health Services conduct the evaluation of the Plan. The evaluation of the plan is to inform CPRIT, TCCCP, the Cancer Alliance of Texas (CAT), public health professionals, and other cancer prevention and control stakeholders in Texas of the current measures and progress that has been made towards the Plan's goals and objectives. TCCCP receives funding, guidance, and technical assistance from the Centers for Disease Control and Prevention's (CDC) National Comprehensive Cancer Control Program (NCCCP) to coordinate cancer prevention and control interventions, and to support the CAT. TCCCP is responsible for routinely informing members of CAT, partners, and the public on trends in cancer burden. It also assists in coordinating the implementation and periodic revision of the Plan.
    - CAT is the state's comprehensive cancer control coalition and is administered by TCCCP. Since 1998, DSHS has received funding from the CDC's NCCCP to implement the state's cancer control plan and convene a statewide cancer control coalition. Its mission is to engage organizations, agencies, institutions, and individuals to work collaboratively to reduce the impact of cancer in Texas and promote the Plan.
    - Mr. Carlton Allen, Program Manager for Prevention, is leading the revision of the Texas Cancer Plan and has begun meeting with multiple stakeholders to gather input. He has engaged an array of stakeholders, using their input to enhance the plan's effectiveness. He is working with the Texas Cancer Registry and Behavioral Risk Factor Surveillance System, gathering updated data relevant to the Plan. Collaborating closely with the Department of State Health Services (DSHS), he has worked towards data integration. Lastly, he is actively planning community involvement by hosting townhalls/forums to elicit input on goals, objectives, and strategic actions to inform and guide communities and stakeholders in the fight against cancer.

Other Activities

- Carlton Allen attended the 7th Annual Southeastern Colorectal Cancer Consortium (SCCC) Conference on June 21-23 in Norfolk, Virginia. The SCCC is diverse group of individuals and organizations from 13 Southeast states and Puerto Rico who are working on colorectal cancer issues, including raising screening rates.

- Carlton has also been asked to join the 2023 National Colorectal Cancer Roundtable (NCCRT) Annual Meeting Planning Committee. The Annual meeting will take place in-

person in Houston, Texas in mid-November. The NCCRT, established by the American Cancer Society (ACS) and the Centers for Disease Control and Prevention (CDC) in 1997, is a national coalition of public and private organizations and invited individuals. The goal of the NCCRT is to increase the use of proven colorectal cancer screening tests among the entire population for whom screening is appropriate.

- The Legislature approved a rider to HB 1, establishing a pilot program to fund colorectal treatment for uninsured and underinsured Texans. This initiative was championed by the Prevention Advisory Committee (PAC). Several PAC members and staff from the Family Health Services division of the Health and Human Services Commission will meet to discuss implementation of this program.

86. Texas Colorectal Cancer Initiative. Included in the amounts appropriated above to the Health and Human Services Commission in D.1.10, Additional Specialty Care, is $5,000,000 in General Revenue in each fiscal year for the Health and Human Services Commission for a pilot program to fund the treatment of colorectal cancer for uninsured and underinsured Texas residents with household incomes at or below 200 percent of the federal poverty level. HHSC shall identify and pursue opportunities to use any available federal funding to implement this pilot program.

Any unexpended balances remaining as of August 31, 2024, are appropriated for the same purpose for the fiscal year beginning September 1, 2024.

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: AUGUST 10, 2023

Product Development Review FY 2024

CPRIT released four FY 2024 Product Development Research RFAs and opened the portal to receive preliminary applications on May 1, 2023. The portal for receipt closed on June 30, 2023. CPRIT received 79 preliminary applications and invited 19 companies to submit full applications. The deadline for full application receipt was August 1, 2023, however by June 30, 2023, CPRIT received 16 full applications and closed the full application portal. Sixteen companies, requesting $149,376,907 are moving forward to the next stage of the review process. Four companies from FY2023, that were deferred to this cycle, will present full applications to review panels on August 10 and 11. The twelve additional companies will present their full applications to review panels September 10 – 18. Following due diligence review, I will present the Product Development Review Council's (PDRC) award recommendations to the PIC and the Oversight Committee in early 2024.

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

Preliminary Applications

The PDRC reviews preliminary applications to determine those that demonstrate sufficient scientific merit and a compelling premise for more extensive review. This fiscal year, the preliminary review process was scheduled from May 1 to June 30 and generally takes 3 – 5 weeks. During the preliminary review process, CPRIT received 79 preliminary applications requesting $650,373,231. An additional 13 preliminary applications were started in the system but not submitted. On June 30, 2023, the preliminary application portal closed and at the same time, CPRIT received 16 full applications and closed the full application portal. Due to this closure, CPRIT halted the review of preliminary applications, and 34 preliminary applications were withdrawn without review. Thirty-one companies submitting preliminary applications are currently located in states/countries outside of Texas, including California, Connecticut, Florida, Georgia, Indiana, Massachusetts, Missouri, North Carolina, New Jersey, New York, Oklahoma, Virginia, Wisconsin, Canada, Israel, and Germany.

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FY 2024 RFA	Invited	Withdrawn w/o Review	Total Apps Submitted
Texas Therapeutics Company (TTC)	10	11	34
Texas Device and Diagnostics Company (TDDC)	1	2	4
Texas New Technologies Company (TNTC)	2	4	9
Seed Company	6	17	32
TOTAL	**19**	**34**	**79**

Invitation to Submit a Full Application

CPRIT invites companies that score favorably in preliminary review to submit a full application and present their proposal to a review panel. CPRIT invited 19 companies to submit full applications.

Due to scheduling and resource constraints, CPRIT stated in the FY2024 RFAs that we are limiting the number of full applications that the review panels will consider in Review Cycle 1 to the first fifteen applications received on or before the August 1 deadline, this included the four applications that were deferred from FY2023 Cycle 1. CPRIT received 16 full applications by June 30. Instead of deferring or withdrawing the additional application, I decided to include the company in the full review process. The 16 companies that CPRIT will review in the first cycle are requesting $149,376,907 and include 3 applicants that are currently located outside of Texas (CA (1), MD (1) and Israel (1)).

The table below reflects the information about the preliminary and full applications CPRIT has received in FY2024 Cycle 1.

RFA	Prelim Apps	Prelim Apps $ Request	Invited Apps	Invited Apps $ Request	Full Apps	Full Apps $ Request	Full Apps Review Cycle 1	Review Cycle 1 $ Request
TTC	34	$454,989,328	10	$146,407,890	8	$112,760,268	8	$112,760,268
TDDC	4	$36,892,333	1	$5,141,000	2	$9,026,687	2	$9,026,687
TNTC	9	$72,186,626	2	$23,850,000	1	$12,600,000	1	$12,600,000
Seed	32	$86,304,944	6	$17,999,903	5	$14,989,952	5	$14,989,952
TOTAL	**79**	**$650,373,231**	**19**	**$193,398,793**	**16**	**$149,376,907**	**16**	**$149,376,907**

Due Diligence Review

Like previous years, a full application that the review panel considers exceptional after the in-person presentation review will also undergo due diligence review. Due diligence review will include IP reports from third-party law firms and, if necessary, non-IP reports from Boyds Consulting. At the conclusion of due diligence review, the panel will decide whether to recommend the application for funding. The PDRC will submit the recommendation(s) to the PIC and the Oversight Committee for approval.

CPRIT Resource Guide

The Product Development Research program staff has developed content for a "Texas Resource Guide". The program receives many inquiries for information and life sciences connections from companies looking to relocate to Texas with or without CPRIT funding. To address the needs of our potential grantees, the program has collected information from various sources, including PDAC members to develop a guide for companies. The guide will provide contact information and more for various resources within the state. The resources chosen for this guide are split into multiple categories including but not limited to, capital, accelerators/incubators and CROs/CDMOs. The layout and design of this guide is being developed by the CPRIT Communications team. The guide will be made available online and in print.

Product Development Grantees: On-site Visits Scheduled

The Product Development Research program staff has scheduled approximately 20 in-person company meetings between October 4 and 24. We will be meeting with active grantees to tour their facilities and receive updates on their projects. These initiatives are an important step in building relationships with our active grantees and is a proactive step in managing potential project delays and difficulties before they arise. I will update you at the November 2023 OC meeting of the outcomes of these meetings.

Product Development Advisory Committee (PDAC)

The PDAC met via zoom on July 13 to discuss agenda items related to CPRIT's product development program. We provided an update on the FY 2023 award recommendations and budget negotiations as well as the FY2024 application process. Overall, the PDAC members were enthusiastic about the number of preliminary applications received for FY2024 Cycle 1. The members will be meeting to make recommendations for the enhancing the process for FY 2025. The PDAC also discussed participation in the Texas Cancer Conference and suggested additional resources for the CPRIT Resource Guide.

<u>Product Development Outreach</u>

- Senior Program Manager for Product Development Dr. Abria Magee met with Laurie Fernandez from ICON on July 13. ICON is a global provider of outsourced drug and device development, and commercialization services to pharmaceutical, medical device, government, and public health organizations. Dr. Magee and Ms. Fernandez discussed ICON's participation in the CPRIT resource guide and the CPRIT conference in October.

- On July 17, Dr. Magee met with Adam Labaff from Fortis Life Sciences, a contract development firm that partners with diagnostics and life science companies to custom design proprietary solutions for solving development problems. They discussed the CPRIT resource guide and the upcoming CPRIT conference.
- Dr. Magee met with several representatives from Tonix Pharma, including CEO Seth Ledermen, Mary Kelley, Siobhan Fogarty, and Bruce Daugherty, on July 24 to discuss CPRIT product development funding opportunities. Tonix is a clinical-stage biopharmaceutical company developing novel therapies and vaccines to prevent and treat central nervous system disorders.

Internal Auditor Report

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:	AUGUST 4, 2023

Summary and Recommendation

The Chief Executive Officer has appointed 25 experts to CPRIT's Scientific Research and Prevention Programs Committee. CPRIT's statute requires Oversight Committee approval for the appointments. At their August 3 meeting, the Board Governance subcommittee reviewed the appointees to the Academic Research and 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 25 appointees at its August 3 meeting and recommends their approval by the Oversight Committee.

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CANCER PREVENTION & RESEARCH
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Scientific Research and Prevention Program Committee ("Peer Reviewer") Appointments
August 2023

Appointments to Academic Research Peer Review Panels		
Nominee	**Panel Assignment**	**Expertise**
Tulia Bruno, Ph.D. Assistant Professor Department of Immunology University of Pittsburgh Pittsburgh, PA	Basic Cancer Research-1 (BCR-1)	Translational cancer immunology; spatial biology techniques; Tumor Immunology; B cells; Tertiary lymphoid structures
William Murphy, Ph.D. Professor Department of Dermatology and Internal Medicine University of California Davis Health System Sacramento, CA	Basic Cancer Research-1 (BCR-1)	Translational studies involving modeling cancer-immune system interactions; Cancer immunotherapy; Cancer Immunotherapy and graft vs host disease.
Verena Staedtke, M.D., Ph.D. Associate Professor Department of Neurology Johns Hopkins University Baltimore, MD	Basic Cancer Research-1 (BCR-1)	Gene and cell therapy; innovative immunotherapy strategies involving bacteria; therapeutics for the treatment of malignant brain tumors and neurofibromatosis
Jing Chen, Ph.D. Professor Division of Medicine and Biological Sciences University of Chicago Chicago, IL	Basic Cancer Research-2 (BCR-2)	Cancer Metabolism, Diet and nutrition, Drug discovery and development, Leukemia, Metabolites as signaling molecules, Signal Transductions
Yibin Deng, M.D., Ph.D. Professor Department of Urology The University of Minnesota Medical School Minneapolis, MN	Basic Cancer Research-2 (BCR-2)	Prostate cancer medical treatment, pathology, androgen receptor (AR) biology, genetic mouse models, and computational bioinformatics
Eileen White, Ph.D. Professor The Cancer Institute of New Jersey Rutgers University New Brunswick, NJ	Basic Cancer Research-2 (BCR-2)	Cancer metabolism, identifying mechanisms required for tumor cells and tumors to survive, proliferate, and evade surveillance by the immune system

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Appointments to Academic Research Peer Review Panels		
Nominee	**Panel Assignment**	**Expertise**
Lisa Coussens, Ph.D. Professor and Chair Department of Cell and Developmental Biology Oregon Health & Sciences University Portland, OR	Cancer Biology (CB)	Cancer, inflammation, tumor immunology, preclinical mouse models
Stephanie Oesterreich, Ph.D. Professor Department of Pharmacology and Chemical Biology University of Pittsburgh Pittsburgh, PA	Cancer Biology (CB)	Endocrine resistance in breast cancer; translational breast cancer research
Abby Overacre, Ph.D. Assistant Professor University of Pittsburgh, Pittsburgh, PA Abby Overacre, Ph.D. Assistant Professor University of Pittsburgh, Pittsburgh, PA	Cancer Biology (CB)	Cancer Immunology; Interactions between the microbiota and immune system during cancer progression; Immunoregulation in the tumor microenvironment
Bettina Drake, Ph.D., M.P.H. Assistant Professor Washington University School of Medicine St. Louis, MO	Cancer Prevention Research (CPR)	Cancer epidemiology; reducing disparities in cancer by focusing on cancer-prevention strategies through nutritional and community-based approaches.
Drew Pardoll, M.D., Ph.D. Professor Department of Oncology Johns Hopkins University School of Medicine Baltimore, MD	Imaging Technology and Informatics (ITI)	Cancer immunology and immunotherapy, gene and cell therapy
Robert Lee, Ph.D. Professor Division of Pharmaceutics, Pharmacology	Clinical and Translational Cancer Research (CTCR)	Design and development of novel drug delivery systems for cancer and other disease; targeted drug delivery systems based on nanoparticles

Appointments to Academic Research Peer Review Panels		
Nominee	**Panel Assignment**	**Expertise**
The Ohio State University College of Pharmacy Columbus, OH		

Appointments to Product Development Research Peer Review Panels			
Name	**Organization**	**Title**	**Expertise**
Ho Man Chan, Ph.D.	AstraZeneca	Head of Epigenetics, Early Oncology	Cancer epigenetics, intellectual property and clinical regulatory strategies
Shuibing Chen, Ph.D.	Weil Medical College, Cornell University	Kilts Family Professor of Surgery, Director of Center of Genomics Health, Vice Chair of Innovation	Chemical biology, genomics, regenerative medicine, diabetes, stem cell and tissue biology, high-throughput drug discovery, tissue regeneration,
Eric M. Brustad, Ph.D.	Illumina	Associate Director of Scientific Research	Protein Engineering, next generation sequencing,
Steven M. Ferguson, CLP, MBA	NIH	Special Advisor	Intellectual property management, technology valuation, drug discovery, vaccine
Karen R. Stein, M.D., MPH	Molecular Templates	Vice President Clinical Development and Medical Affairs	Oncology drug development
Brian D. Strahl, Ph.D.	University of North Carolina School of Medicine	Interim Assistant Dean of Research, Professor	Epigenetics, chemical biology, high-throughput synthesis and arraying
Ronak Savla, Pharm.D., Ph.D., MBA	Catalent Pharma Solutions	Director of Strategic Ventures	Business and investment strategies, platform technology discovery and

Appointments to Product Development Research Peer Review Panels			
Name	**Organization**	**Title**	**Expertise**
			assessment, technology and business valuation
Pengyu Yang, Ph.D.	Plexium, Inc.	Director	Synthetics chemistry, chemical biology, chemical proteomics, medicinal chemistry, targeted protein degradation, structure-based drug design, drug target selection and evaluation
Carles Monterrubio, Ph.D.	Johnson & Johnson Innovation	Associate Director of Early Innovation Partnering	Business strategy and transaction, technology valuation, pharmaco-oncology
David L. McCormick, Ph.D.	IIT Research Institute	President	Environmental medicine, physiology, toxicology and carcinogenesis
Suraj Kachgal, Ph.D.	EXUMA Biotech	Director of Business Development	Next generation Car-T development, technology and marketing strategies and due diligence, asset evaluation and transaction
Ho Man Chan, Ph.D.	AstraZeneca	Head of Epigenetics, Early Oncology	Cancer epigenetics, intellectual property and clinical regulatory strategies
Shoutian Zhu, Ph.D.	PhenoTarget Biosciences, Inc.	Co-founder & CEO	Chemical biology, biopharmaceutical discovery and development
Ming Zhao, Ph.D.	Arizona State University	Associate Professor, Director of Research Laboratory for Virtualized Infrastructures, Systems, and Applications	Distributed/cloud/edge computing, Big data/machine learning systems, high-performance computing, virtualization, storage systems, operation systems

Appointments to Academic Research Peer Review Panels		
Nominee	**Panel Assignment**	**Expertise**
Tulia Bruno, Ph.D. Assistant Professor Department of Immunology University of Pittsburgh Pittsburgh, PA	Basic Cancer Research-1 (BCR-1)	Translational cancer immunology; spatial biology techniques; Tumor Immunology; B cells; Tertiary lymphoid structures
William Murphy, Ph.D. Professor Department of Dermatology and Internal Medicine University of California Davis Health System Sacramento, CA	Basic Cancer Research-1 (BCR-1)	Translational studies involving modeling cancer-immune system interactions; Cancer immunotherapy; Cancer Immunotherapy and graft vs host disease.
Verena Staedtke, M.D., Ph.D. Associate Professor Department of Neurology Johns Hopkins University Baltimore, MD	Basic Cancer Research-1 (BCR-1)	Gene and cell therapy; innovative immunotherapy strategies involving bacteria; therapeutics for the treatment of malignant brain tumors and neurofibromatosis
Jing Chen, Ph.D. Professor Division of Medicine and Biological Sciences University of Chicago Chicago, IL	Basic Cancer Research-2 (BCR-2)	Cancer Metabolism, Diet and nutrition, Drug discovery and development, Leukemia, Metabolites as signaling molecules, Signal Transductions
Yibin Deng, M.D., Ph.D. Professor Department of Urology The University of Minnesota Medical School Minneapolis, MN	Basic Cancer Research-2 (BCR-2)	Prostate cancer medical treatment, pathology, androgen receptor (AR) biology, genetic mouse models, and computational bioinformatics
Eileen White, Ph.D. Professor The Cancer Institute of New Jersey Rutgers University New Brunswick, NJ	Basic Cancer Research-2 (BCR-2)	Cancer metabolism, identifying mechanisms required for tumor cells and tumors to survive, proliferate, and evade surveillance by the immune system
Lisa Coussens, Ph.D. Professor and Chair Department of Cell and Developmental Biology	Cancer Biology (CB)	Cancer, inflammation, tumor immunology, preclinical mouse models

Appointments to Academic Research Peer Review Panels		
Nominee	**Panel Assignment**	**Expertise**
Oregon Health & Sciences University Portland, OR		
Stephanie Oesterreich, Ph.D. Professor Department of Pharmacology and Chemical Biology University of Pittsburgh Pittsburgh, PA	Cancer Biology (CB)	Endocrine resistance in breast cancer; translational breast cancer research
Abby Overacre, Ph.D. Assistant Professor University of Pittsburgh, Pittsburgh, PA Abby Overacre, Ph.D. Assistant Professor University of Pittsburgh, Pittsburgh, PA	Cancer Biology (CB)	Cancer Immunology; Interactions between the microbiota and immune system during cancer progression; Immunoregulation in the tumor microenvironment
Bettina Drake, Ph.D., M.P.H. Assistant Professor Washington University School of Medicine St. Louis, MO	Cancer Prevention Research (CPR)	Cancer epidemiology; reducing disparities in cancer by focusing on cancer-prevention strategies through nutritional and community-based approaches.
Drew Pardoll, M.D., Ph.D. Professor Department of Oncology Johns Hopkins University School of Medicine Baltimore, MD	Imaging Technology and Informatics (ITI)	Cancer immunology and immunotherapy, gene and cell therapy
Robert Lee, Ph.D. Professor Division of Pharmaceutics, Pharmacology The Ohio State University College of Pharmacy Columbus, OH	Clinical and Translational Cancer Research (CTCR)	Design and development of novel drug delivery systems for cancer and other disease; targeted drug delivery systems based on nanoparticles

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	CAMERON ECKEL, ASSISTANT GENERAL COUNSEL
SUBJECT:	APPOINTMENTS TO ADVISORY COMMITTEES REQUIRING OVERSIGHT COMMITTEE APPROVAL
DATE:	AUGUST 4, 2023

Summary

At its August 3 meeting, the Board Governance subcommittee reviewed Presiding Officer Dr. Mahendra Patel's proposed appointments to the Clinical Trials Advisory Committee (CTAC) and Product Development Advisory Committee (PDAC). The subcommittee recommends that the Oversight Committee approve the four appointments.

Discussion

Texas Health & Safety Code § 102.155 allows the Oversight Committee to create ad hoc committees of experts to advise the Oversight Committee. The presiding officer of the Oversight Committee is responsible for appointing experts to serve on CPRIT's advisory committees. The appointments must be approved by the Oversight Committee.

The primary purpose of the CTAC is to advise the Oversight Committee on important issues of clinical trials. The CTAC gives their expert opinion on the impact of current CPRIT mechanisms supporting clinical trials; gives advice on opportunities to increase CPRIT's impact on translating basic discoveries to clinical trials; and advises on mechanisms that would address barriers to patient enrollment in therapeutic clinical trials.

The PDAC provides targeted advice to the Oversight Committee concerning the agency's product development program. Examples of issues include general contractual revenue sharing provisions that provide a fair return for the State of Texas while not discouraging follow-on funding from other sources; appropriate portfolio mix of product development awards by stage of company and size of award; and strategies to expand and encourage relocation of high quality companies to Texas.

The Board Governance subcommittee reviewed the appointments to the CTAC and PDAC at its August 3 meeting and voted to recommend approval to the Oversight Committee.

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CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Advisory Committee Appointments
August 2023

Advisory Committee	Nominee	Institution
Clinical Trials Advisory Committee	Ruma Bhagat, M.D., MPH, Principal Science Leader	Genentech, Inc. (A Member of the Roche Group)
Clinical Trials Advisory Committee	Suzanne Cole, M.D., FACP, FASCO, Hematologist & Medical Oncologist, Medical Director, Assistant Professor	The University of Texas Southwestern Medical Center
Clinical Trials Advisory Committee	David E. Gerber, M.D., Professor	The University of Texas Southwestern Medical Center
Product Development Advisory Committee	Emily Reiser, Ph.D.	*Associate Director, Innovation,* Texas Medical Center, Houston TX

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M.D., MPH
Principal Science Leader ,
Global Health Equity and Population Sciences at Genentech

Ruma is a physician by training and holds a Master's in Public Health in International health systems from Tulane University.

She is a clinical research professional with over 20 years of experience in the pharmaceutical industry and currently works as a Principal Portfolio Leader in the Global Health Equity and Population Science team at Genentech. She has a breadth of experience through her work in various roles in Clinical science, Clinical Operations and Process Excellence.

Ruma leads cross organizational efforts that advance health equity and inclusive research by broadening scientifically driven representation of understudied patients in clinical trials.

She is an intrapreneur, passionate about leading change in the organization and bringing innovation to our work and processes.

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: Suzanne Cole, MD FACP

eRA COMMONS USER NAME (credential, e.g., agency login): S42296

POSITION TITLE: Staff Physician, Departments of Hematology & Oncology, University of Texas Southwestern Medical Center, Parkland Health and Hospital System, Clements University Hospital

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

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of Texas at Dallas	BS	05/1999	Biology
University of Texas at Dallas	BA	05/1999	Modern Dance
University of Texas Southwestern Medical School	MD	05/2003	Medicine
University of Texas Southwestern Medical Center	Residency	06/2006	Internal Medicine
University of Texas MD Anderson Cancer Center	Fellowship	06/2010	Medical Oncology & Hematology

A. Personal Statement

I am a community-academic medical oncologist with a clinical focus on GU malignancies. I serve as Medical Director of the UT Southwestern Community Oncology Program overseeing Regional UT Southwestern Cancer Clinics in Richardson (North Dallas suburbs), Redbird (South Dallas suburbs), and Moncrief (Fort Worth), which range from 15 to 45 miles from the main university campus. I bring experience, expertise, and passion to my efforts to increase access to clinical trials in local community settings, thereby rendering research opportunities to more patients. Immediately following my oncology post-doctoral training, I worked for four years in Charleston, WV, providing cancer care to an underserved rural area with a robust community clinical trials program through the National Cancer Institute Community Oncology Research Program (NCORP). Having learned the nuances and challenges of implementing and conducting clinical trials in a community setting, I joined the staff of Mercy Hospital in Oklahoma City in 2014. There, I capitalized on an affiliation with the University of Oklahoma to enhance our community oncology clinical trials program. I attended urologic oncology research meetings and tumor boards to collaborate with colleagues and consolidate the care of patients across our two clinical systems. I became an honorary community member of the University Genitourinary team. Similarly, I collaborated with thoracic surgeons at the Oklahoma City Heart Hospital to develop a City-Wide Lung Cancer Case Conference, which attracted attendance from pathologists, pulmonologists, interventional radiologists, radiation oncologists, medical oncologists, and thoracic surgeons from three medical systems: Mercy Hospital, Oklahoma City Heart Hospital, and the University of Oklahoma. In 2016, Mercy Hospital transitioned its community clinical trial research program to align with Cancer Research of the Ozarks, an NCI Community Oncology Research Program (NCORP). This transition allowed Mercy Hospital to open clinical trials complementary to the clinical trial profile at the University of Oklahoma. In recognition of the effects of my efforts on cancer clinical trial availability and enrollment, I received an NCI Outstanding Clinical Trial Accrual Silver Physician Award in 2018. I also became highly involved in the National Clinical Trials Network (NCTN), becoming the National Community Chair for the PROSPER kidney cancer clinical trial in 2018. Within the Southwest Oncology Group (SWOG), I serve as SWOG Thoracic Committee Community Engagement Co-Chair. In this position, I review clinical trial concepts and protocols for the feasibility of execution in the community setting. 9-4

In 2018, I accepted a position at UT Southwestern Simmons Comprehensive Cancer Center to serve as the Medical Director of the community oncology clinic in Richardson-Plano. In this role, I have developed and launched a clinical trials program serving the community of North Texas. In the last five years, I have enrolled more patients in clinical trials than any other faculty member within the Division of Hematology and Oncology. I have also joined the ECOG-ACRIN GU Committee, where I serve as protocol champion for a SWOG study of neoadjuvant chemotherapy for urothelial cancer. I am the ECOG-ACRIN Medical Oncology Co-Chair for the SOAR trial utilizing stereotactic radiation for metastatic kidney cancer. In 2022, I became the Medical Director of the UT Southwestern Community Oncology Program and the Leader of Community Oncology Research. Since these appointments, I have launched a cancer clinical trials program in our new clinic, Redbird, predominantly caring for patients in an underserved area in south Dallas. My extensive experience establishing clinical trial programs, activating protocols, and enrolling patients onto clinical trials in community settings throughout the U.S. ideally positions me to serve as Principal Investigator in our endeavor to obtain real-world evidence leveraging our existing cooperative group model to conduct Phase IV evaluations of new therapies.

B. Positions and Honors

Faculty Academic Appointments

2010-14	Clinical Assistant Professor, Department of Medicine West Virginia University, School of Medicine, Charleston Division
2018-Present	Assistant Professor, Internal Medicine (Division of Hematology/Oncology) University of Texas Southwestern Medical Center

Professional Positions

2010-14	Hematologist & Medical Oncologist, Clinical Investigator, Charleston Area Medical Center, David Lee Cancer Center, Charleston, WV
2014-18	Hematologist & Medical Oncologist, Principal Investigator, Mercy Hospital, Coletta Cancer Center, Oklahoma City, OK
2018-present	Hematologist & Medical Oncologist, Principal Investigator, UT Southwestern Medical Center, UT Southwestern Simmons Comprehensive Cancer Center Richardson-Plano, TX
2022-present	Medical Director, UT Southwestern Community Oncology Program

Other Experience and Professional Memberships

2007-Present	Member, American Society of Hematology
2007-Present	Member, American Society of Clinical Oncology
2015-Present	Fellow, American College of Physicians - FACP
2018-2023	Co-Chair, SWOG Community Engagement Core, National Clinical Trial Network
2019-2020	Chair, ASCO Care Delivery and Practice Management & Regulatory Policy
2019-Present	Member, ECOG-ACRIN Genitourinary Committee
2020-Present	Member, Institutional Review Board for Human Research, UT Southwestern
2022-Present	Experimental Therapeutics Liaison for Community Outreach Engagement Equity
2022-Present	Leader of Cancer Research, UT Southwestern Community Oncology Program
2023-Present	Fellow, American Society of Clinical Oncology - FASCO

Selected Honors

2004-05	Outstanding Clinical Medicine Resident Teaching Award, UT Southwestern Medical Center
2011	Letter of Commendation for Patient Care Services, Charleston Area Medical Center
2017	Congressional Commendation for Medical Relief during Hurricane Harvey, Ralph Abraham, Louisiana 5th Congressional District, United States House of Representatives
2018	Silver Physician Award for Outstanding Clinical Trial Accrual, NCI-NCORP
2022	Distinguished Alumni UT Dallas

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C. Contributions to Science

1. Increasing access to clinical trials for community-residing patients

I am passionate about promoting access to clinical trials for cancer patients who reside in geographic areas removed from large academic medical centers. In addition to the scholarly and clinical conference contributions listed below, I have created a cancer clinical trials research program in the UT Southwestern Regional Cancer Centers in Richardson (est. 2018) and Redbird (est. 2022). I also serve as an institutional PI at UT Southwestern to open trials that provide additional cancer treatment options curated for community-residing patients. Since launching our clinical trial program, I hand-selected more than 40 clinical trials for activation at our community oncology cancer centers based on their feasibility. I am recognized as having the highest number of patients accruing to cancer clinical trials at UT Southwestern in the division of Hematology/Oncology. Last year, I successfully enrolled more than 50 patients in clinical trials from the community setting.

A. **Cole S.** The Intersection of Academia, Community Oncology & Clinical Trials. Evolution Conference, Boston, MA, Sep 24, 2022.
B. **Cole S.** Addressing the Cost of Cancer Treatment in Advanced Kidney Cancer. International Kidney Cancer Symposium, Virtual Meeting, Nov 7, 2020.
C. **Cole S.** Engaging the Community Oncologist in Lung Cancer Research. SWOG Spring Meeting San Francisco, CA. Oct 3, 2019.
D. **Cole S.** Engaging Clinical Trialists in the Community Setting – International Kidney Cancer Symposium, Miami, FL. Nov 3, 2018.

2. Addressing hospital system gaps in a rapidly changing medical landscape

I am a recognized leader in helping hospital systems respond to emergent needs in the rapidly changing medical landscape. This work has been focused on two areas. First, I spearheaded a movement to help institutions recognize and appropriately intervene when patients present with immunotherapy-related toxicity. My work has been reported at scholarly and clinical conferences and peer-reviewed journals. Second and more recently, during the COVID-19 pandemic, I led efforts to convert in-person care for our region's cancer patients to virtual care using synchronous video telehealth platforms. This work led to receipt of a collaborative grant from the Community Engaged Research Pilot Program investigating best practices for implementing telehealth cancer care among older adults during COVID-19.

A. Higashi, R, Etingen, B, **Cole, S**, Mansour, J, Sweetenham, J, Lee, J, Hogan, T. Responses to telehealth expansion for older adults with cancer during COVID-19 pandemic. *Journal Clinical Oncology*. Jun 2022. 40:16, 1591 meeting abstract.
B. **Cole S.** Rapid Rollout of Telehealth at UT Southwestern: A Physician's Perspective. UT Southwestern President's Advisory Board, Dallas, Texas, Apr 21, 2020.
C. **Cole S.** Immuno-Oncology Toxicity, Top 10 Innovative Institutional Initiatives – Invited Lecture at the ASCO Annual Meeting Chicago, IL, Jun 3, 2019.
D. **Cole S**, Zibelman M, Bertino E, Yucebay F, Reynolds K. Managing Immuno-Oncology Toxicity: Top 10 Innovative Institutional Solutions. *American Society of Clinical Oncology Education Book*, 2019: 39, 96-104. PMID:31099682

3. Bridging academic and community medical gaps through research

Beyond increasing access to clinical trials in community settings, I actively work to connect stakeholders and facilitate collaborative research efforts across traditional academic environments and community settings. I chair relevant community engagement committees as part of more extensive clinical trial networks. My role as the SWOG Lung Committee Co-Chair of Community Engagement allows community oncology input to vet clinical trial concepts for feasibility to be conducted in community research settings. By serving as the community oncology research advocate for cooperative group clinical trials such as PROSPER, RADICAL, SWOG-GAP, MAINCAV, and SOAR within the National Clinical Trial Network, I have been able to shape the protocols to be friendly to community oncology settings and increase accrual. These experiences have led to the dissemination of lessons learned from these efforts at scholarly and clinical conferences and journal publications.

A. Pal, S, Somford, D, Grivas, P, Sridhar, S, Gupta S, Bellmut, J, Sonpavde, G, Fleming, M, Lerner, S, Loriot, Y, Hoffman-Censits, J, Valderrama, BP, Andersen, C, Schabel, M. **Cole, S**, Daneshmand, S. Targeting FGFR3 alterations with adjuvant infigratinib in invasive urothelial carcinoma: the phase III PROOF 302 trial. *Future Oncology*. Jul 2022. V. 18 No. 21. 2599-2614. DOI: 10.2217/fon-2021-1629
B. Pal S, Miller M, Agarwal N, Chang SM, Chavez-MacGregor M, Cohen E, **Cole S**, Dale, W, Diefenbach CM, Disis M, Dreicer R, Graham D. Clinical Cancer Advances 2019: Annual Report on Progress Against Cancer from the American Society of Clinical Oncology. *Journal of Clinical Oncology.* 2019 37:10, 834-849. PMID:30702028; doi: 10.1200/JCO.18.02037
C. **Cole S.** Founder of City-Wide Lung Cancer Case Conference. Community Oncologist, Presentation of patient cases to a Collaborative Conference of stakeholders from Mercy Hospital, Oklahoma Heart Hospital, University of Oklahoma Stephenson Cancer Center to provide multidisciplinary lung cancer care for patients across hospital systems. OKC 2014-2018.
D. Patel HD, Puligandla M, Shuch BM, Leibovich BC, Kapoor A, Master VA, Drake CG, Heng DY, Lara, PN, Choueiri TK, Maskens D, Singer EA, Eggener SE, Svatek RS, Stadler WM, **Cole S**, Signoretti S, Gupta RT, Michaelson MD, McDermott DF, Cella D, Wagner LI, Haas, NB, Carducci MA, Harshman LC, Allaf ME. The future of perioperative therapy in advanced renal cell carcinoma: how can we PROSPER? *Future Oncology.* 2019 15:15, 1683-1695. doi.org/10.2217/fon-2018-0951

E. Publications Demonstrating Collaborative Research in Academic-Community Setting:

A. Goksu, S, Ozer, M, Goksu B, Wang, R, Khatib, J, Patel, P, Vusirikala, M, **Cole, S**, Seyhanli, A, Collins, R. The impact of race and ethnicity on outcomes of patients with myelodysplastic syndromes: a population-based analysis. *Leukemia & Lymphoma*. June 2022. 63:7. 1651-1659. DOI: 10.1080/10428194.2022.2032034
B. Merfeld, E, Blitzer, G, Kuczmarska-Haas, A, Pitt, S, Chino, F, Le, T, Allen-Rhoades, W, **Cole, S**, Marshall, A, Carnes, M. Women Oncologists' Perceptions and Factors Associated with Decisions to Pursue Academic vs Nonacademic Careers in Oncology. *JAMA Open Network*. Dec 2021. 4:12. DOI: 10.1001/jamanetworkopen.2021.41344
C. Graff S, Close J, **Cole S**, Matt-Amaral L, Beg R, Markham MJ. Impact of Closed Facebook Group Participation on Female Hematology/Oncology Physicians. *Journal Oncology Practice* 2018 14:12, e758-e769 PMID: 30537459 DOI: 10.1200/JOP.18.00448
D. Marcus, C, Butler, P, Bagrodia, A, **Cole S**, Subramaniam, RM. Fluorine-18-Labeled Fluciclovine PET/CT in Primary and Biochemical Recurrent Prostate Cancer Management. *American Journal of Roentgenology* 2020 215:2, 267-276 DOI:10.2214/AJR.19.22404
E. Park JM, Reed GD, Liticker J, Putnum WC, Chandra A, Yaros K, Afzal A, MacNamara JP, Raza J, Hall RG, Baxter J, Derner K, Pena S, Kallem RR, Subramanyan I, Edpuganti V, Harrison C, Reddy S, Unni N, Klemow D, Syed S, Li H, **Cole S**M, Froehlich T, Ayers CR, de Lemos JA, Malloy CR, Haley B, Zaha VG. Effect of Doxorubicin on Myocardial Bicarbonate Production from Pyruvate Dehydrogenase in Women with Breast Cancer. *Circulation Research*. 14 Oct 2020. 127:12. 1568-1570. PMID: 33054563 DOI: 10.1161/CIRCRESAHA.120.317970

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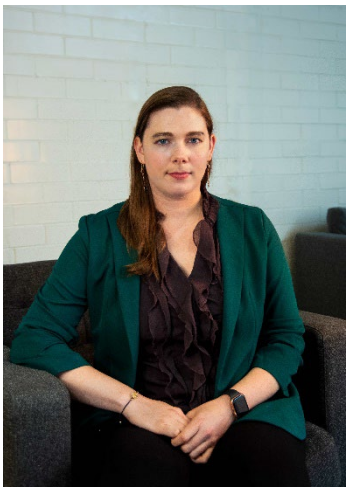
David E. Gerber, M.D.
University of Texas Southwestern Medical Center
5323 Harry Hines Blvd.
Dallas, Texas 75390-8852
214-648-4180

July 2023

Dr. Gerber is Tenured Professor in the Department of Internal Medicine (Hematology-Oncology) and the Peter J. O'Donnell Jr. School of Public Health at UT Southwestern Medical Center. Within the Harold C. Simmons Comprehensive Cancer Center at UT Southwestern, Dr. Gerber previously served as Associate Director of Clinical Research and as Co-Leader of the Experimental Therapeutics Program. He currently serves as Co-Director of the Office of Education and Training. He is an active thoracic medical oncology clinical investigator with more than 220 publications and continuous federal and foundation research funding for more than 13 years. Dr. Gerber currently serves as PI of three CPRIT grants, including a Clinical Trials Network Award and a Clinical Trials Participation Program Award. Dr. Gerber's extensive research on the design, implementation, and conduct of lung cancer clinical trials has resulted in widespread policy changes at the U.S. FDA and NCI, and has been featured in the *New York Times, Washington Post,* and on National Public Radio. In 2022, he received the NCI Director's Merit Award for his work expanding the role of advanced practice providers in NCI-sponsored clinical trials.

Short Bio



Dr. Emily Reiser is the Associate Director of Texas Medical Center Innovation, spearheading the Accelerators for Cancer Therapeutics, Healthtech, and international BioBridge programs. Since joining TMC in 2019, she has evolved from direct engagement with startup founders to overseeing a vast stakeholder network and now leading the recruitment of entrepreneurs in residence. Prior to joining TMC, Emily lead Eventure, an entrepreneurial community organization empowering the next generation of talent in Houston. She also contributed to the successful launch of local medtech startup, Noleus Technologies.

Emily earned her bachelor's degree in Biology from Emory University and a PhD in Bioengineering from Rice University, where her research focused on drug delivery for cancer immunotherapy.

Long Bio

Dr. Emily Reiser is the Associate Director of Texas Medical Center Innovation, spearheading the Accelerators for Cancer Therapeutics, Healthtech, and international BioBridge programs. Emily began with TMC Innovation began in 2019, and since then, she has evolved from direct engagement with startup founders to overseeing a vast stakeholder network and now leading the recruitment of entrepreneurs in residence. Prior to joining TMC, Emily lead Eventure, an entrepreneurial community organization fostering the next generation of talent in Houston. She also contributed to the successful launch of local medtech startup, Noleus Technologies.

Emily earned her bachelor's degree in Biology from Emory University and a PhD in Bioengineering from Rice University, where her research focused on drug delivery for cancer immunotherapy.

Throughout her career, Emily has skillfully blended her scientific expertise with business acumen to drive transformative changes in the fields of cancer therapeutics, medtech, and healthtech. Her unwavering dedication to advancing innovation, coupled with her adeptness at forging strong partnerships, has cemented her as a leader in her field.

At the heart of Dr. Reiser's mission lies a deep-seated desire to facilitate meaningful improvements in health outcomes at a scale that directly impacts the lives and well-being of countless individuals. Her ultimate goal is to enable a vibrant and thriving innovation community, where purposeful conversations lead to impactful collaborations, culminating in clinically significant milestones and ultimately enhancing patient outcomes.

S. Gail Eckhardt, MD, FASCO

S. Gail Eckhardt is a tenured Professor, inaugural Director of the Livestrong Cancer Institutes, Chair of the Department of Oncology, and Associate Dean of Cancer Programs at the University of Texas at Austin's Dell Medical School. Dr. Eckhardt has served on numerous committees and study sections, including the ASCO Molecular Oncology Task Force, the ASCO Board of Directors, the FDA Oncology Drugs Advisory Committee, and the National Cancer Institute (NCI) Cancer Centers Study Section. She is a member of the NCI Investigational Drug Steering Committee and serves on 11 external advisory boards of NCI-designated cancer centers. She was a lead mentor in ASCO's Leadership Development Program, is a past member of the Board of Directors of the Association of American Cancer Institutes (AACI) and Chair of the Cancer Prevention and Research Institute of Texas' Clinical Trials Advisory Committee. Dr. Eckhardt was awarded ASCO's 2022 Women Who Conquer Cancer Mentorship Award and is currently a member of the National Academies of Sciences, Engineering, and Medicine's National Cancer Policy Forum.

Dr. Eckhardt is the Principal Investigator on grants involving early clinical trials and colorectal cancer research, has conducted numerous early phase clinical trials and has published over 200 manuscripts. Her area of interest is in the preclinical and early clinical development of combinations of molecularly targeted compounds, with a disease focus on colorectal cancer. Dr. Eckhardt earned her undergraduate degree in chemistry from Stephen F. Austin State University and her medical degree from the University of Texas Medical Branch in Galveston. She conducted her internship and residency in Internal Medicine at the University of Virginia Medical School, followed by a post-doctoral research fellowship in Experimental and Molecular Medicine at Scripps Research Institute in La Jolla, California, and a fellowship in Medical Oncology at the University of California San Diego.

William Kelly, M.D., Assistant Professor in Hematology/Oncology, University of Texas Health Science Center of San Antonio

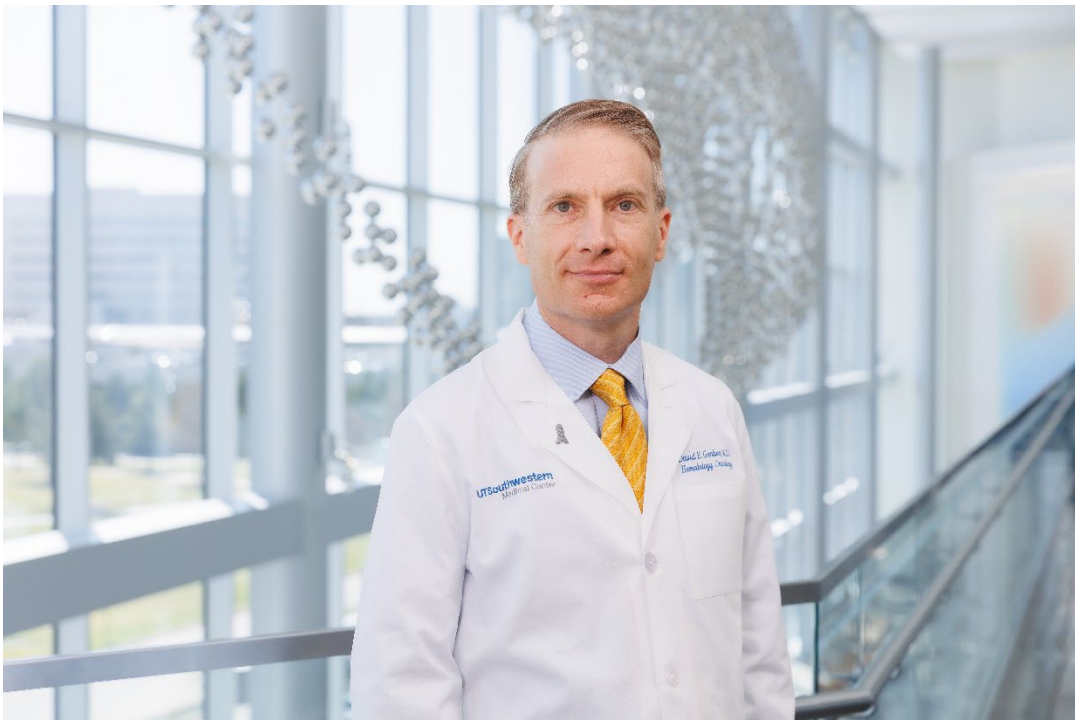
As an early clinical investigator, I feel my involvement in the proposed research is well-qualified and highly conducive for growth as a physician scientist. My interest in translational research began during my postbaccalaureate training at the National Cancer Institute. As the recipient of a research training award, I investigated the Trim 32 and Carp-1 genes in the myc apoptotic pathways while honing basic laboratory skills such as DNA extraction, PCR amplification and sequencing. As my capstone project at Georgetown School of Medicine, I returned to NIH in the Laboratory of Molecular Pharmacology to conduct genetic analysis on a case of suspected Reifenstein syndrome.

My scope broadened to include clinical research during my residency at University of Texas Medical Branch of Galveston, where I analyzed more than two thousand patients to identify high-risk women for referral to breast cancer prevention and early detection services. This project fostered an appreciation for the need for better prognostic biomarkers in oncology.

After residency, I continued my training as an oncology fellow at Medstar Georgetown University Hospital. I was struck by the devastation caused by these malignancies of the central nervous system, diseases which deprived patients of even the most vital and intrinsic functions. At the same time, I recognized the challenges of neuro-physiology and the immune sanctuary effect of the blood brain barrier. I resolved to dedicate myself toward the translation of basic scientific discoveries into novel therapeutics.

With this aim in mind, I participated in an analysis of samples of chordomas, a rare and aggressive bone tumor. We evaluated sixty-eight cases using next generational sequencing, immunohistochemistry and in situ hybridization to determine expression and mutational data. We identified several oncogenic drivers representing potentially druggable pathways. During my third year of medical oncology fellowship, I trained in the laboratory of Translational Immunology at the National Cancer Institute where I gained experience in flow cytometry and developed a protocol to investigate the impact of corticosteroids on patients with CNS tumors treated with checkpoint inhibitors. Following this, I completed a one-year neuro-oncology fellowship to facilitate this study's completion as the lead associate investigator and to gain additional expertise in the care of rare CNS malignancies.

As an assistant professor at the UT Health Science Center of San Antonio, I hope to shed light on promising neuro-oncologic biomarkers and immunotherapeutics so that one day I can look my glioma patient in the eye and give hope for a successful outcome. To this end I recently reported favorable safety and efficacy results of the FASN inhibitor, TVB-2640, in relapsed high-grade astrocytoma. Finally, there are multiple other clinical trials, for which I am PI, currently recruiting patients. This includes investigator-initiated studies such as a phase II, multicenter, prospective study of sacituzumab govitecan in recurrent glioblastoma (NCT04559230) and a phase II, investigator-initiated study of imipramine hydrochloride and lomustine in recurrent glioblastoma (NCT04863950).



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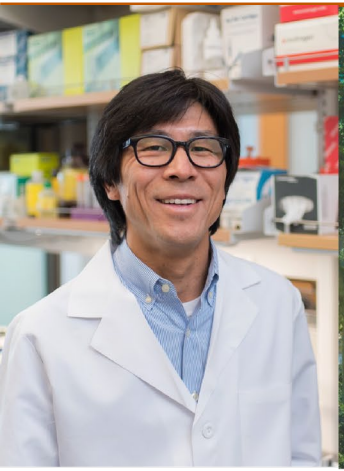
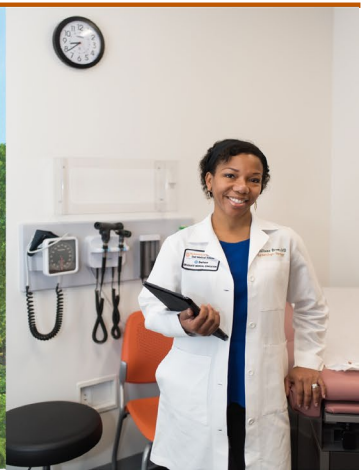
Dallas, Texas 75390-8852

August 2023

Dr. Gerber is Professor in the Department of Internal Medicine (Hematology-Oncology) and the Peter J. O'Donnell Jr. School of Public Health at UT Southwestern Medical Center. Within the Harold C. Simmons Comprehensive Cancer Center at UT Southwestern, Dr. Gerber serves as Co-Director of the Office of Education and Training and previously served as Associate Director of Clinical Research and as Co-Leader of the Experimental Therapeutics Program. He is an active thoracic medical oncology clinical investigator with more than 220 publications and continuous federal, state, and foundation research funding for more than 13 years. Dr. Gerber serves as PI of a CPRIT Clinical Trials Network Award and a CPRIT Clinical Trials Participation Program Award. Dr. Gerber's extensive research on the design, implementation, and conduct of cancer clinical trials has resulted in widespread policy changes at the U.S. FDA and NCI, and has been featured in the *New York Times, Washington Post,* and on National Public Radio. In 2022, he received the NCI Director's Merit Award for his work expanding the role of advanced practice providers in NCI-sponsored clinical trials.





CPRIT Clinical Trials Advisory Committee Fiscal Year 2023 Annual Report

CPRIT Oversight Committee Meeting
August 16, 2023
S. Gail Eckhardt M.D.

CTAC Membership: Expanded

- **S. Gail Eckhardt, MD**, Livestrong Cancer Institute, DMC, UT Austin
- **Carlos Arteaga, MD**, Harold Simmons Comprehensive Cancer Center, UTSWMC
- **Ruma Bhagat MD, MPH**, Genentech, Inc.
- **Suzanne Cole, MD, FACP, FASCO**, Community Oncology Program UTSWMC
- **David Gerber, MD,** Clinical Cancer Research, UTSWMC
- **David S. Hong, MD**, UTMDACC
- **Ronan Kelly, MD,** Baylor Scott and White
- **Pavan Reddy, MD**, Director, Dan L Duncan Comprehensive Cancer Center, Baylor College of Medicine
- **C. Patrick Reynolds, MD, PhD,** Cancer Center, TTUHSC

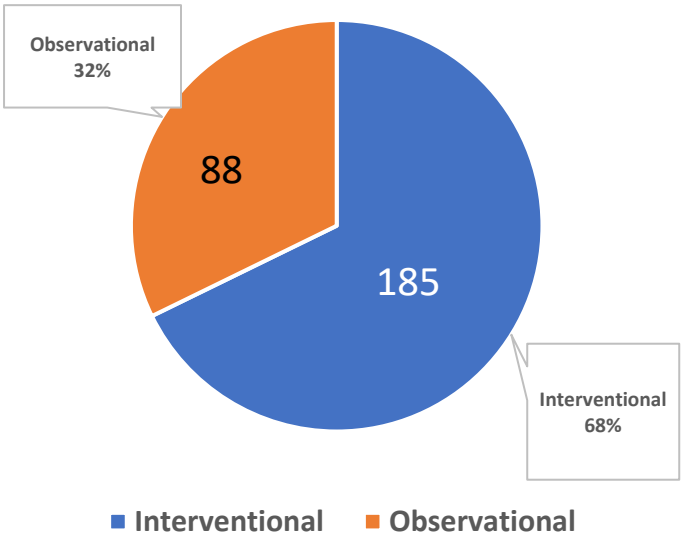
Completed 2022 CTAC Goals

1. Membership Expansion:
    - Added new Director of the Dan Duncan Comprehensive Cancer Center, Baylor College of Medicine
    - Added a Community Oncologist and a Community Clinical Researcher/Trialist members
    - Added an industry member with expertise in engaging diverse communities as well as regulatory knowledge of telehealth, consenting and local labs in early clinical trials
2. Dr. Pat LoRusso (Yale/expertise in early clinical trials and underserved populations) was a CTAC guest speaker and discussed lessons learned from her recently launched *"hybrid decentralization model"*—mechanism to expand trials to community sites
3. Dr. Beg, Vice President, Oncology for *Science 37* presented an overview of services they provide to expand access to clinical trials globally via a centralized digital platform

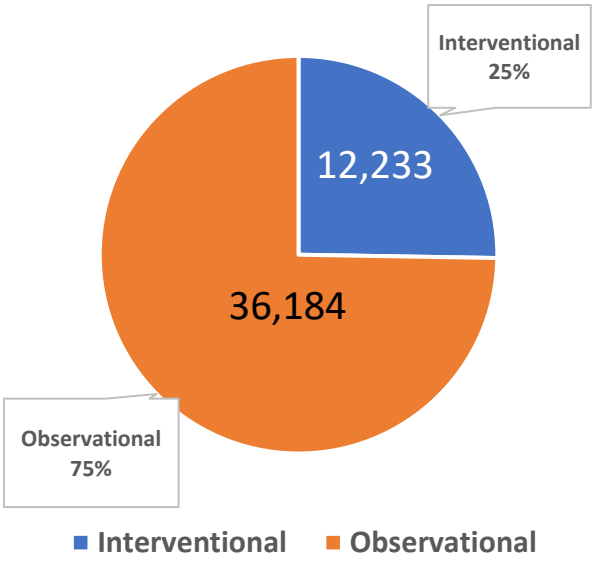
Cumulative Clinical Research Data

CPRIT Research Programs: 273 clinical trials; **48,417** patients enrolled; **8258** publications

Clinical Trials by Type of Trial



Patients Enrolled by Type of Trial



CTAC Recommendations to CPRIT

1. **Continue to refine the CTNA RFA to ensure we are diversifying the spectrum of patients enrolled in clinical trials across Texas**
   - Including rural patients
   - Utilize telehealth
2. **Consider partnering with NCI/CTEP on developing new initiatives that can be launched in Texas**
3. **Potential new RFAs to consider:**
   - K24-like mechanism to provide support for mentors (RFA for new Clinical Investigator Award)
   - Grand Challenge-like Awards
   - SU2C Catalyst-like awards
4. **Initiate regular meetings of cancer center leadership with rotating venue to discuss recruitment awards and new initiatives**

A Phase II, Multicenter, Prospective Study of Sacituzumab Govitecan in Recurrent Glioblastoma

Presented by William Kelly MD

9-18

Mays Cancer Center

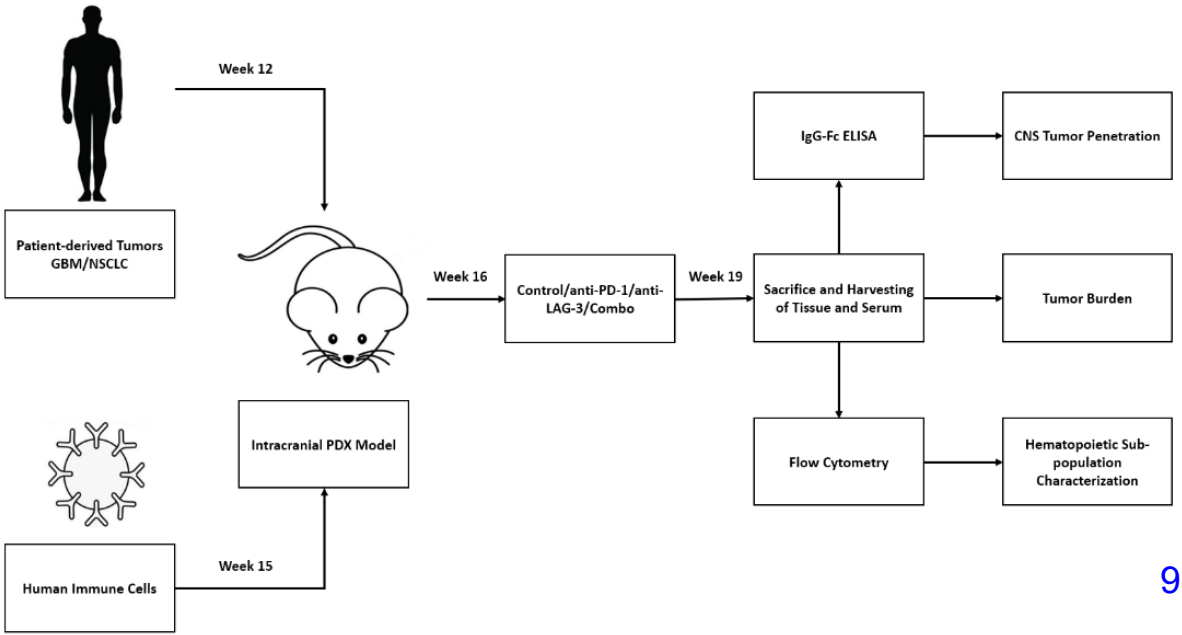
Disclosures: I have no personal, professional or financial relationships that would constitute a conflict of interest.

Clinical Research

- Principal Investigator for 'A Phase II, Multicenter, Prospective Study of Sacituzumab Govitecan in Recurrent Glioblastoma' (NCT04559230). Recruiting 12/9/21.
- Principal Investigator for 'A Phase II, Investigator-initiated Study of Imipramine Hydrochloride and Lomustine in Recurrent Glioblastoma' (NCT04863950). Recruiting 11/5/21.
- Principal Site Investigator for 'A Phase II, Open-label, Multicenter Study Evaluating the Safety and Efficacy of Neoadjuvant and Adjuvant Tiragolumab Plus Atezolizumab, with or without Platinum-based Chemotherapy, in Patients with Previously Untreated Locally Advanced Resectable Stage II, IIIA or Select IIIB Non-small Cell Lung Cancer' (NCT04832854). Recruiting 7/28/23.
- Principal Site Investigator for 'Phase II Trial of SMO/AKT/NF2/CDK Inhibitors in Progressive Meningiomas with SMO/AKT/NF2/CDK Pathway Mutations' (NCT02523014). Recruiting 11/3/22.

Basic Science Research

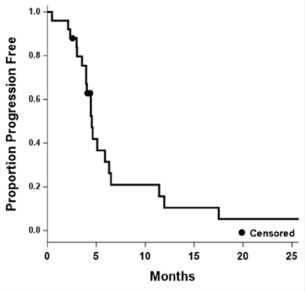
- PDX Model of PD-1 and LAG-3 Blockade in Glioma. Relatlimab and Nivolumab obtained from BMS 12/13/22. Awaiting IACUC protocol.



Recent Peer Reviewed Publications

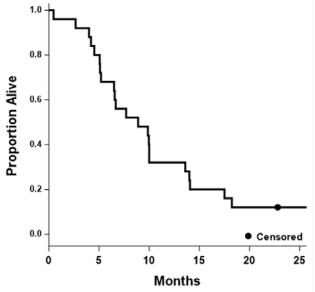
- **Kelly WJ**, Diaz Duque AE, Michalek J, Konkel B, Caflish L, Chen Y, Pathuri SC, Madhusudanannair-Kunnuparampil V, Floyd J, Brenner A. Phase II Investigation of TVB-2640 with Bevacizumab in Patients with First Relapse of High-Grade Astrocytoma. Clin Cancer Res. 2023 Jul 5;29(13):2419-2425.
- Tripathy S, Alvarez N, Jaiswal S, Williams R, Al-Khadimi M, Hackman S, Phillips W, Kaur S, Cervantez S, **Kelly W**, Taverna J. Hypermetabolic Lymphadenopathy Following the Administration of COVID-19 Vaccine and Immunotherapy in a Lung Cancer Patient. J Med Case Rep 2022 Nov 25;16(1):445.
- Kapoor V, **Kelly WJ**. Biomarkers for Immune Checkpoint Inhibitors in Solid Tumors. Clin Transl Oncol. 2022 Sep 14.

Figure 1



Kaplan-Meier Estimate of Progression (All patients, N=25), median=4.5, 95% CI 4.0, 6.3

Figure 2



Kaplan-Meier Estimate of Overall Survival (All patients, N=25) Median=8.9 95% CI 5.2, 13.6

Manuscripts in Progress

- **Kelly WJ**, Balinda H, Michalek J, Surapaneni, P, Floyd J, Brenner A. A Phase 0 Clinical Trial of Sacituzumab Govitecan in Patients with Breast Cancer Brain Metastases and Recurrent Glioblastoma. Manuscript preparation.
- **Kelly WJ**, Gruslova A, Ricardo R, Brenner A. VB-1111 Modulates Macrophage-specific Cytokines in Glioblastoma. In progress.

Abstract Presentations

- **Kelly W**, Balinda H, Ghamasaee P, Gilbert A, Michalek J, Surapaneni P, Floyd J, Brenner A. Sacituzumab Govitecan for Recurrent Glioblastoma. Accepted for presentation by William Kelly at the Society for NeuroOncology Annual Meeting 11/15/23.
- Ghamasaee P, Balinda H, **Kelly W**, Gruslova A, Floyd J, Chiou J, Lodi A, Tiziani S, Brenner A. A Phase 0 Clinical Trial of Sacituzumab Govitecan in Patients with Breast Cancer Brain Metastases. Presented by Henriette Balinda at the San Antonio Breast Cancer Symposium 12/7/22.

Academic Performance and Mentorship

- Master of Science in Clinical Investigation and Translational Science Program. 15/30 credits earned to date
- Weekly lab meetings and mentoring with Dr. Brenner

Seminars and Journal Clubs

- Spotlight on Research Integrity 5/24/22
- Thoracic tumor board, neuro-oncology tumor board, grand rounds
- Brenner Lab Journal Club: Bimonthly attendance, presented 5/20/22

Contributions to Scientific Review

- Member of DoD CDRMP Peer Review Panel for Brain Tumors 11/3/22-11/4/22
- Review Editor for Frontiers in Oncology since 7/14/23
- Peer review for Clinical Translational Oncology, Cancer Immunology an Targeted Oncology

Teaching

- Monthly didactic lectures to neurology residents and fellows
- Four chemotherapy lectures to medical students per year

Quality Improvement

- QI Project with Dr. Salazar and Student Nurse Practitioner Martinez. 'Reducing Anxiety in Medical Oncology Patients via a Mindfulness Approach'. Presented by April Martinez at the 26th Annual Oncology Symposium by the Association of Physician Assistants in Oncology 8/24/23. First Place Winner.

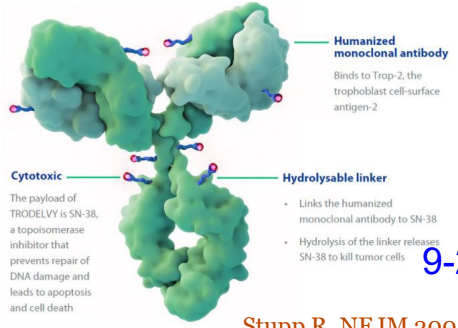
Leadership

- Neuro-Oncology CDST Leader

Background

- Glioblastoma is the most common and aggressive primary malignant brain tumor
- Standard of care is surgery followed by radiation with concurrent and adjuvant TMZ
  - OS of ~14 months
- There are no systemic therapies with proven survival benefit in the recurrent setting
- Trop2 is a transmembrane glycoprotein that participates in calcium signaling
- In glioma, Trop2 expression is highly expressed (95%) but not normal brain tissue
  - This expression correlates with grade, proliferation rate, microvessel density and worsened survival
- Sacituzumab Govitecan is an ADC that is FDA approved in mUC and mTNBC
  - Anti-Trop2 antibody
  - Ph-dependent cleavage site (CL2A)
  - Topoisomerase I inhibitor (SN38)

rGBM: Recurrent Glioblastoma
TMZ: Temozolomide
OS: Overall Survival
Trop2: Trophoblast cell-surface antigen 2 (TACSTD2)
ADC: Antibody-drug conjugates
mUC: Metastatic Urothelial Cancer
mTNBC: Metastatic Triple Negative Breast Cancer



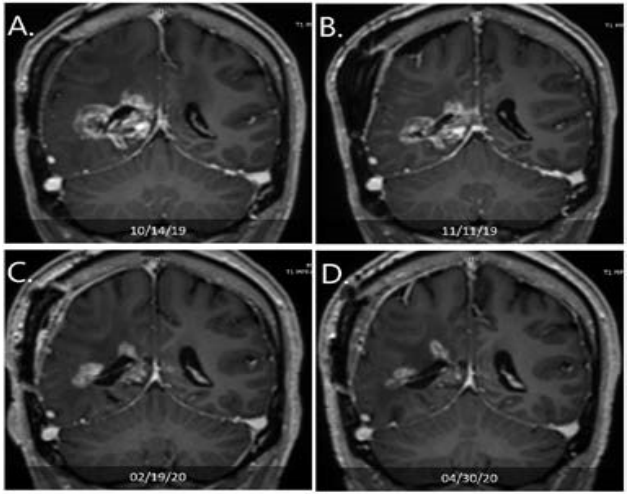
9-26

Stupp R, NEJM 2005.
Ning S, Neurol Sci 2013.

Background

- We initiated a single center, prospective, window-of-opportunity trial of 10 patients with rGBM and 11 breast cancer patients with BM
  - Administered single dose SG (10mg/kg IV) on D-1 of surgery
  - Undergo elective craniotomy with intraoperative tumor and serum collection
  - Continued on SG D1 and 8 q21 days
  - Among first 14 patients 2 PR were observed
  - Among sufficient rGBM samples, SN-38 tissue concentrations varied from 39.7 nM to 259.1 nM/g (median 176.85 nM/g)

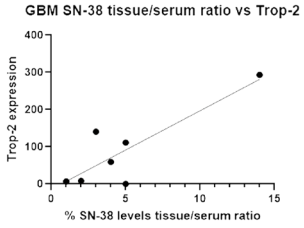
SG: Sacituzumab Govitecan



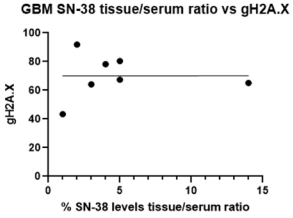
Brenner AJ, Cancer Res 2021.

Background

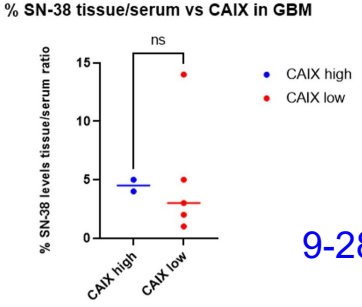
- As expected, Trop-2 expression correlates with % SN-38 tissue/serum ratio indicating deliver of payload by antibody
- γ-H2AX, a surrogate marker of DNA damage, did not correlate with % SN-38 tissue/serum ratio
  - This had been looked at as a marker of direct deliver
  - However, a lack of correlation could be explained by prior alkylating therapy causing high levels of preexisting DNA damage or a failure of the SN-38 to sufficiently impact DNA in the 1 day interval between dosing and surgery
- CAIX, a surrogate marker of intratumoral hypoxia, did not correlate with % SN-38 tissue/serum ratio, suggesting hypoxia does not appreciably drive indirect SN-38 release



Pearson r	
r	0.8575
95% confidence interval	0.2948 to 0.9786
R squared	0.7353
P value	
P (two-tailed)	0.0136
P value summary	*
Significant? (alpha = 0.05	Yes
Number of XY Pairs	7



Pearson r	
r	0.001923
95% confidence interval	-0.7522 to 0.7539
R squared	3.699e-006
P value	
P (two-tailed)	0.9967
P value summary	ns
Significant? (alpha = 0.05	No
Number of XY Pairs	7



γ-H2AX: Gamma H2A histone family member X
CAIX : Carbonic anhydrase IX

Design

- Multicenter, open-label, single-arm therapeutic trial
  - Mays Cancer Center at UT Health San Antonio
  - Texas Oncology Austin
  - Cleveland Clinic Cancer Center
- Sacituzumab Govitecan 10mg/kg IV, D1 and D8 q21 days

IDHwt: Isocitrate dehydrogenase wild-type

Hypothesis

- That treatment with SG will improve PFS in patients with IDHwt rGBM as compared with a historical control of lomustine monotherapy (EORTC 26101)

Two-stage phase II Bayesian Adaptive Design

- Initial phase
  - Assuming PFS6 with unfavorable and favorable probabilities of 0.17 and 0.34 respectively
  - Assuming posterior probability of 0.95 as threshold for efficacy and 5% cutoff of the predictive probability to stop the trial
  - Interim analysis with trial stopped for futility if ≤2 responses
  - Calculate n=20

9-29

Wick W, NEJM 2017

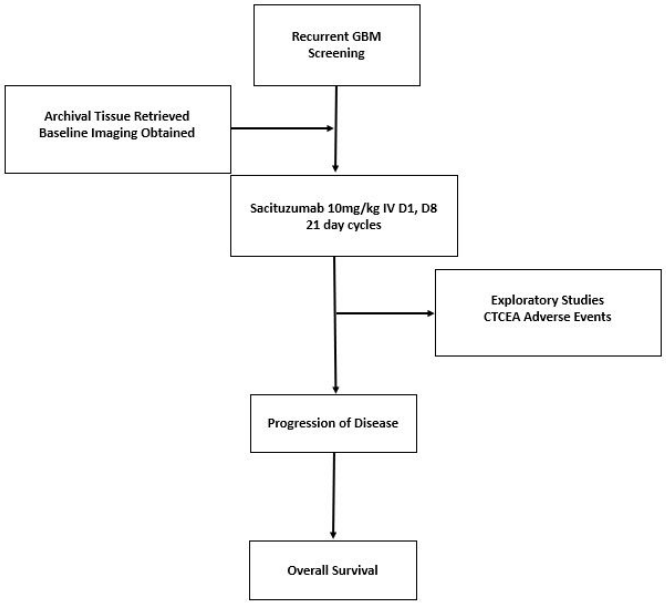
Exploratory Studies

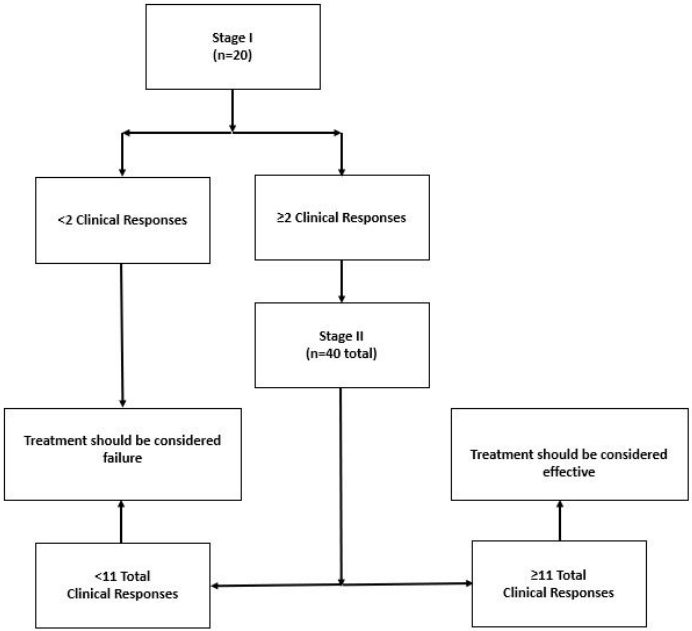
- **Hypoxia via oxygen-enhanced MRI**
  - Collaborative effort with University of Manchester
  - Measures longitudinal relaxation rates (R_{1air}, R_{1O2}) to classify voxels as oxygen enhancing or refractory to oxygen challenge
- **Metabolic Analysis**
  - Collaborative effort with UT Austin
  - Polar metabolites will be analyzed using UHPLC-MS and NMR
  - Fatty acids will be analyzed by GC-MS
  - Complex lipids will be characterized by shotgun lipidomics in conjunction with direct infusion MS

UHPLC-MS: Ultra-high Performance Liquid Chromatography-Mass Spectrometry

GC-MS: Gas Chromatography-Mass Spectrometry

NMR: Nuclear Magnetic Resonance


Recurrent GBM
Screening
Archival Tissue Retrieved
Baseline Imaging Obtained
Sacituzumab 10mg/kg IV D1, D8
21 day cycles
Exploratory Studies
CTCEA Adverse Events
Progression of Disease
Overall Survival


Stage I
(n=20)
<2 Clinical Responses
≥2 Clinical Responses
Stage II
(n=40 total)
Treatment should be considered
failure
Treatment should be considered
effective
<11 Total
Clinical Responses
≥11 Total
Clinical Responses

Thank You

Clinical Trials Network Award (RP220542)

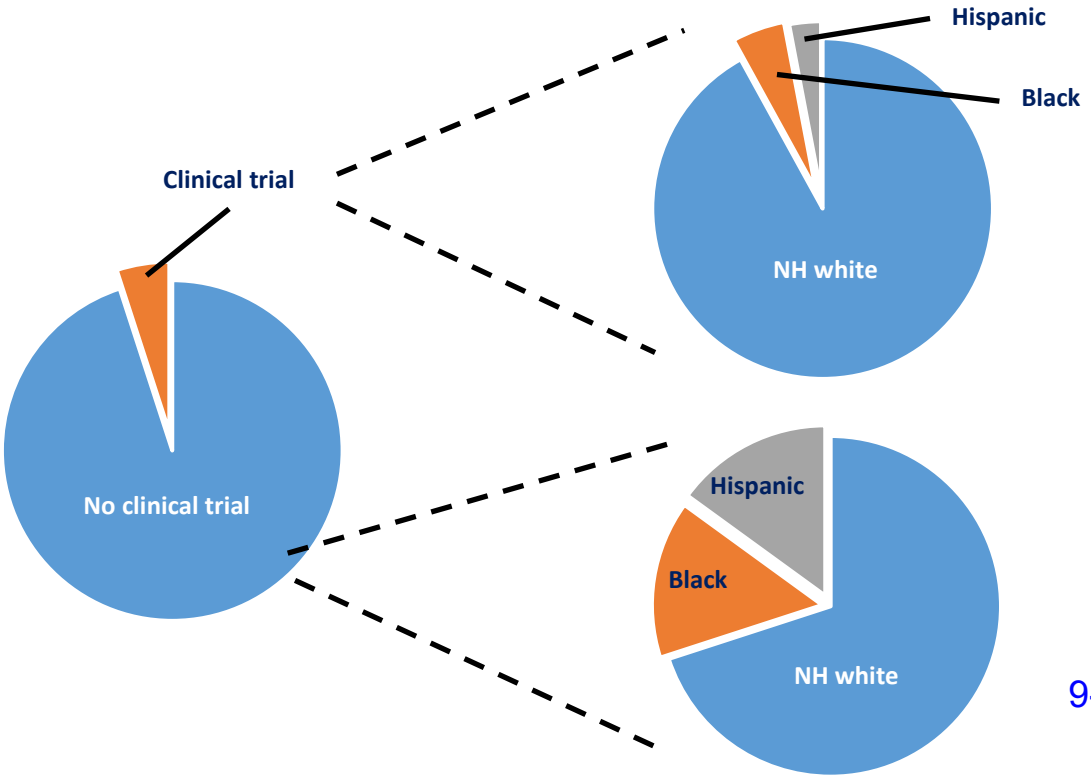
Clinical Trials Participation Award (RP210115)

David E. Gerber, MD
Professor, Department of Internal Medicine and O'Donnell School of Public Health
Harold C. Simmons Comprehensive Cancer Center
UT Southwestern Medical Center
Dallas, Texas

CPRIT Oversight Committee
August 16, 2023

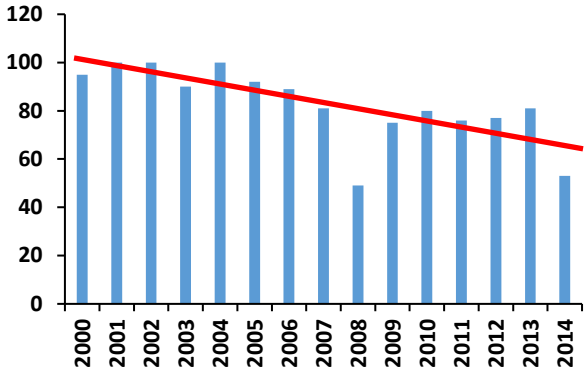
Cancer Prevention & Research Institute of Texas

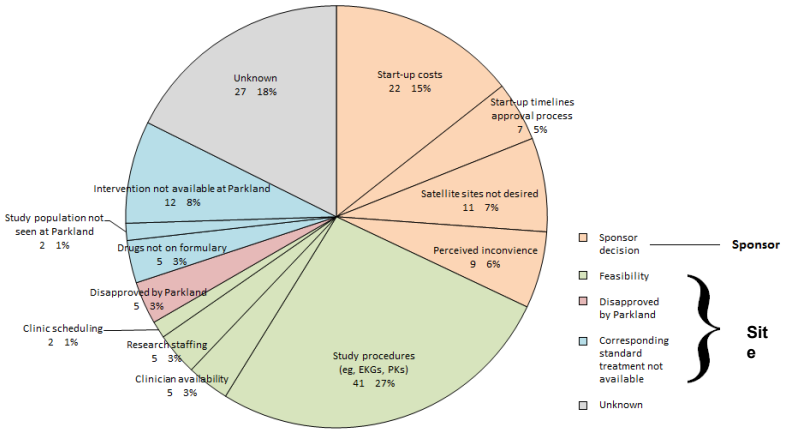
These efforts address a persistent challenges and disparities in accessing cancer clinical trials



Over time, it has become more difficult to offer cancer clinical trials at many clinical sites

A declining proportion of trials in our cancer center could be open at the safety-net clinical site





Diverse reasons underlie this trend

Gerber DE et al. *Oncologist* 2015;20:674-82.

The Texas Clinical Trials Network offers sponsors access to diverse settings and populations

North-Central Texas

Lead institution:

UT Southwestern (Dallas)

Affiliates:

John Peter Smith (Fort Worth)*

Baylor-Scott & White (Temple)

Southeast Texas

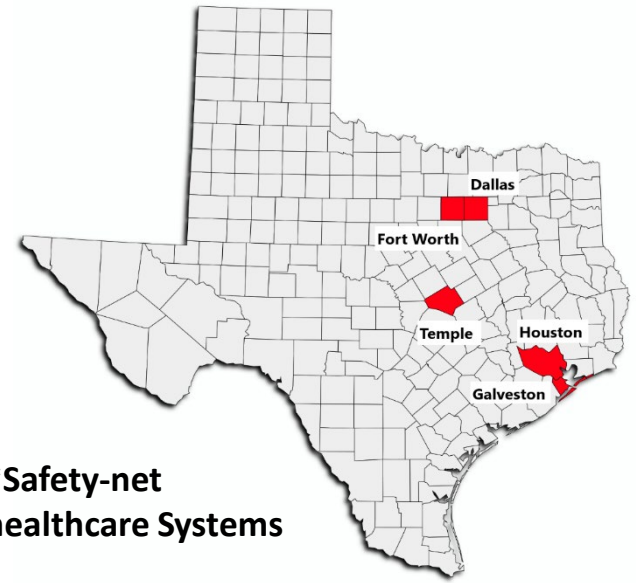
Lead institution:

MD Anderson (Houston)

Affiliates:

Lyndon B. Johnson (Houston)*

UT Medical Branch (Galveston)



***Safety-net healthcare Systems**

The Network is designed to optimize the activation, conduct, and oversight of clinical trials

- CPRIT-supported infrastructure/personnel enhance sites' capabilities
- Critical review of protocols to match sites' populations and needs
- IRB reliance (within regions) to expedite activation
- Shared strategies to enhance awareness of and enrollment to activated trials
- Oversight and *bidirectional* education to support protocol management, data collection, and other trial activities
- Future growth into additional regions of Texas

We introduced the Texas CTNA to clinical trial sponsors in a May 2023 webinar

67 organizations invited

27 organizations attended
- 24 pharma companies
- 3 CROs†

14 organizations have followed up‡
- 12 pharma companies
- 2 CROs

7 trials forwarded for possible activation

Areas of interest / points of clarification
- prioritized phase of trials
- use of central IRB
- consideration of non-therapeutic trials
- potential use of shared contract templates
- future expansion to non-covered regions of Texas
- capacity for hematologic malignancy trials
- time to trial activation
- specific tumor-type expertise within individual Network sites
- planned evaluation measures and intervals
- suggested steps for interested sponsors

†Contract research organizations

‡Including two in-person visits

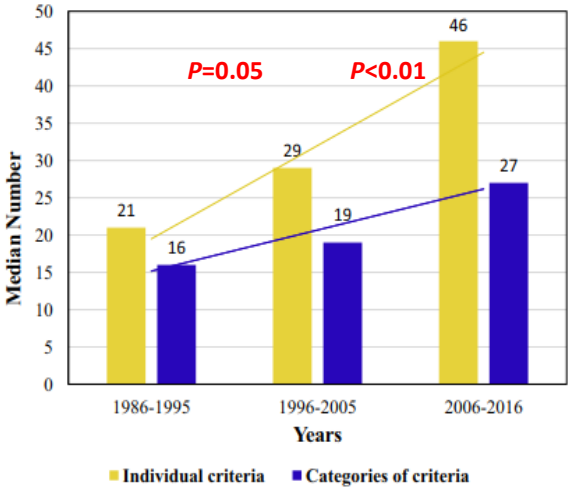
Ultimately, successful enrollment to cancer clinical trials requires clinician and institutional interest and support

How medical oncology trainees benefit from enrolling patients on clinical trials

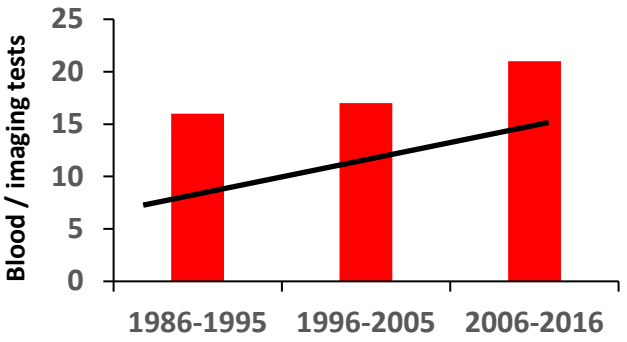
- Skills learned: RECIST, CTCAE, etc
- Authorship opportunities
- Opportunities to participate in related research: secondary data analyses, correlative studies
- Experience valued for multiple future research paths: private practice, academics, industry, regulatory
- Gain experience with new/experimental therapies

Cancer clinical trials add to the substantial burden of standard cancer therapy

Ongoing increase in eligibility criteria



Ongoing increase in screening procedures



Garcia S et al. *J Thorac Oncol* 2017;12:1489-95.

The CTPA provides reimbursement of out-of-pocket costs associated with more frequent (and possibly more distant) travel

Program reimbursement rates.

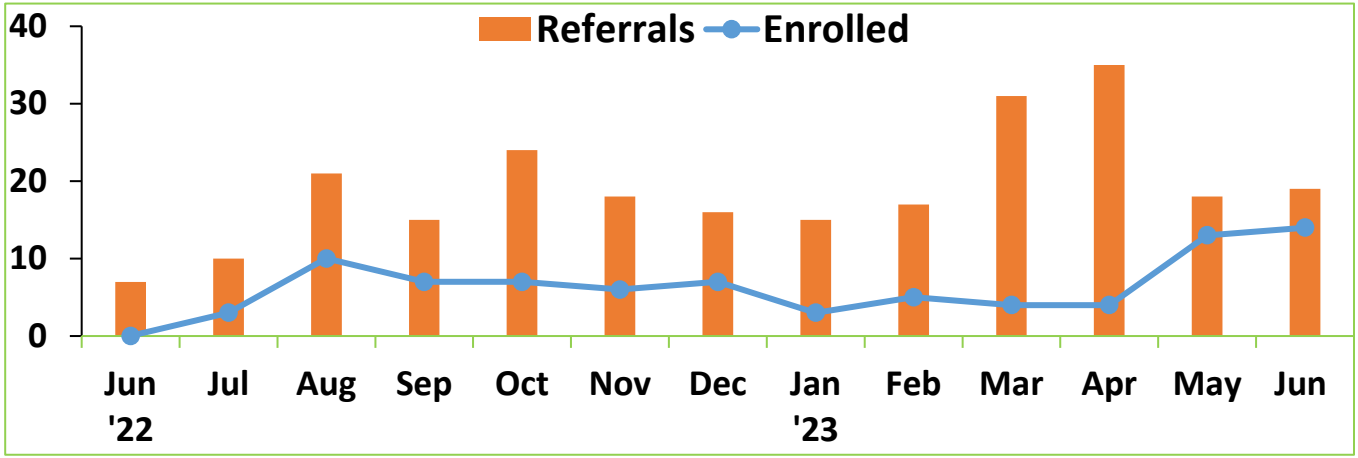
Number in household	Income 0–400%	Income 401%–550%	Income 551% - 700%
1	<$51,040	$51,041 - $70,180	$70,181 - $89,320
2	<$68,960	$68,961 - $94,820	$94,821 - $120,680
3	<$86,880	$86,881 - $119,460	$119,461 - $152,040
4	<$104,800	$104,801- $144,100	$144,101 - $183,400
5	<$122,720	$122,721- $168,740	$168,741 - $214,760
6	<$140,640	$140,641 - $193,380	$193,381 - $246,120
7	<$158,560	$158,561 - $218,020	$218,021 - $277,480
8	<$176,480	$176,481- $242,660	$242,661 - $308,840
REIMBURSEMENT RATE:	100%	75%	50%

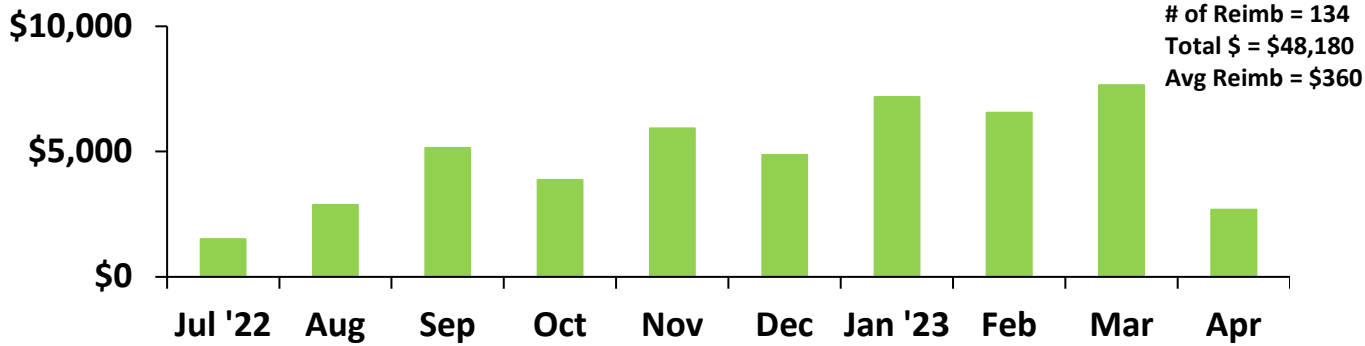
- **Travel**
- **Lodging**
- **Food**
- **Childcare***
  *Depends on available documentation
- **Internet (for telehealth encounters)**

NOT considered inducement or coercion:

- Texas Health & Safety Code, Section 50.0005
- U.S. FDA, "Payment and reimbursement to study subjects" (January 2018)

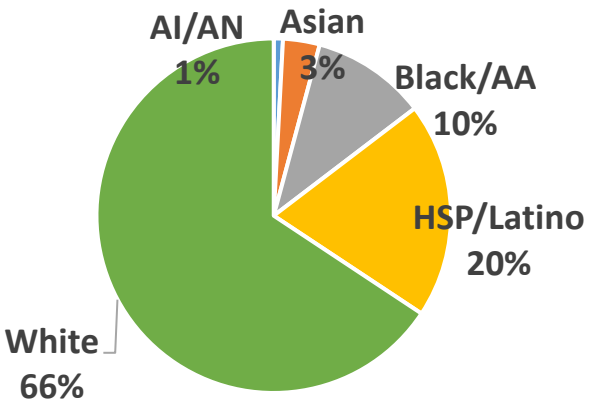
We have been enrolling patients and providing reimbursements for one year



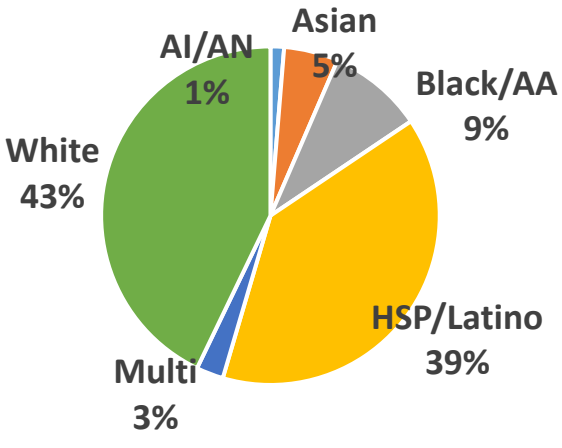


Demographic differences between referred and enrolled populations reveal potential process improvements

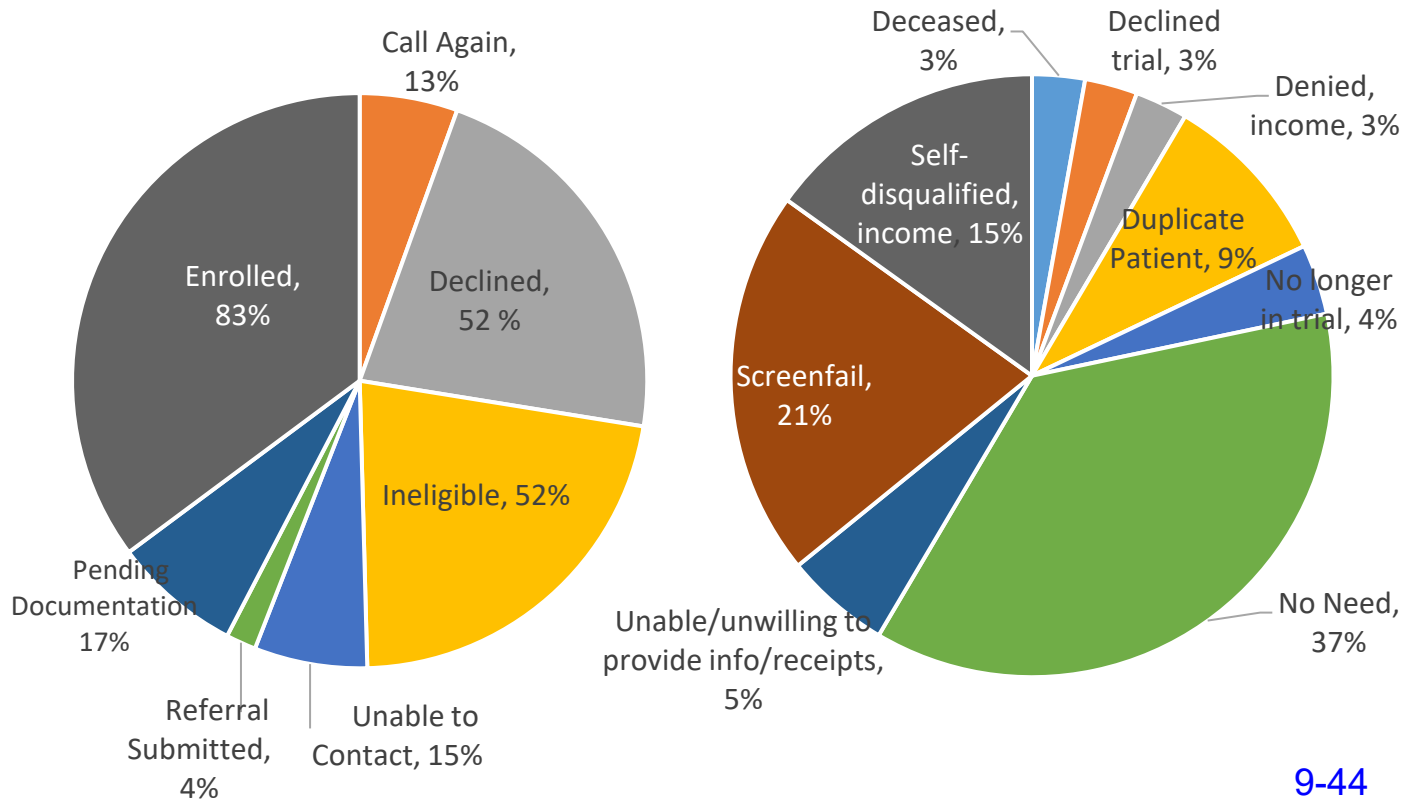
Referred



Enrolled



There are multiple reasons for referred patients not being enrolled in the financial reimbursement program



The CTNA and CTPA are designed to make clinical trials more accessible, equitable, and generalizable

- The Texas Clinical Trials Network will make cancer clinical trials more accessible to the 30 million diverse residents of Texas
- Future growth planned toward the Panhandle and West Texas
- Understanding the needs of patients, clinical sites, and study sponsors is critical to trial selection and program success
- Assisting patients with out-of-pocket expenses may overcome barriers to clinical trial enrollment and retention
- Evaluation of both programs ongoing

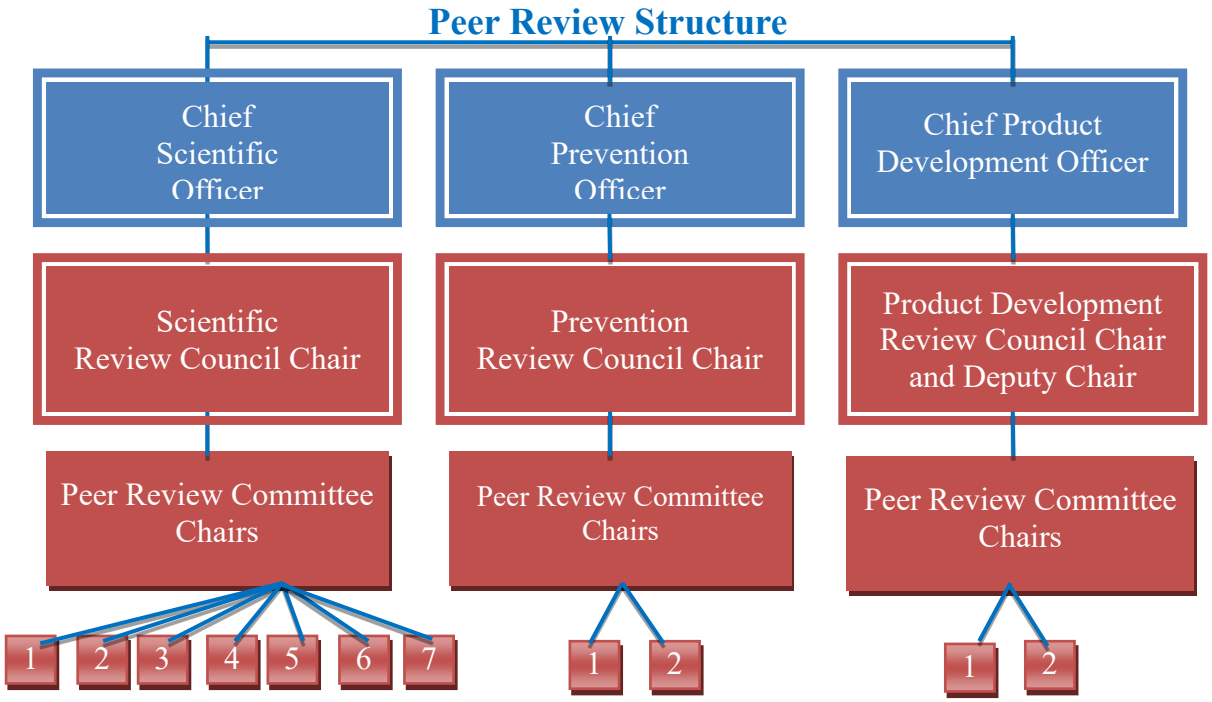
Thank you!

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.

Clinical Trial Advisory Committee Report

CPRIT PEER REVIEW FY 2024 HONORARIA POLICY[1]

Peer review of prevention and research applications is the evaluation process conducted by qualified experts for feasibility, significance, and potential for impact. Like many funding agencies, CPRIT has implemented a tiered peer review process designed to identify the best projects based on excellence, program-specific objectives, and organizational priorities.[2] Maximizing the success of CPRIT's academic research, product development, and prevention programs is dependent upon the quality of the peer reviewers CPRIT recruits. Therefore, the peer reviewers must be exceptionally qualified, highly respected, well-established members of the cancer research, product development, and prevention communities.



CPRIT relies upon a pool of more than 200 expert peer reviewers to evaluate, score and rank grant applications based upon significance and merit. As reflected above, the general peer review structure is the same for CPRIT's three grant programs. CPRIT assigns reviewers to peer review committees based upon their expertise and background. The evaluations conducted by the peer review committees inform the list of grant applications recommended for CPRIT grant awards.[3]

CPRIT's expert peer reviewers live and work outside Texas, which is an uncommon requirement among grant-making organizations. CPRIT implemented this peer reviewer qualification to

[1] Adopted pursuant to TEX. HEALTH & SAFETY CODE Section 102.151(e).
[2] The National Academies of Sciences recommends a tiered approach to peer review.
[3] For more information about the grant review process undertaken by the peer review committees, please see CPRIT's administrative rules, 25 T.A.C. Part 11, Sections 703.6 and 703.7.

ensure an impartial review, minimize conflicts of interest, and provide the opportunity to select the best projects without regard for self-interest.

Honoraria

In recognition of the work undertaken by CPRIT peer reviewers, state law authorizes CPRIT to pay honoraria to its peer reviewers.[4] CPRIT's ability to pay honoraria is essential to retaining individuals with the expertise and experience to carry out the complex review process required by statute and CPRIT's administrative rules.

CPRIT recruits world-renowned experts who live and work outside of the state to be peer reviewers. CPRIT's residency policy is important to maintaining a review process that minimizes the potential for political and other outside influences, but it means that the CPRIT review process, by design, lacks non-monetary incentives common to other grant review processes that may otherwise justify the time commitment required of CPRIT peer reviewers in addition to their full-time jobs.

Specifically, CPRIT reviewers are not eligible to compete for CPRIT grants. This is different from other cancer grant-making organizations such as National Institutes of Health (NIH), Centers for Disease Control and Prevention, Department of Defense, American Cancer Society, and Susan G. Komen for the Cure. For example, NIH reviewers may review grant applications as well as compete for NIH grants. Familiarity with the NIH review process gained by serving as an NIH peer reviewer provides the individual a significant non-monetary benefit since that understanding better positions the reviewer to compete for and secure NIH grant funds as an applicant. This benefit is not available to CPRIT's reviewers.

A second nonmonetary benefit from serving on a review panel is that such service is an indication of external recognition in one's field, which is essential for academic and industry promotions. Using individuals already well established in their careers means that this is not an incentive for CPRIT peer reviewers to participate.

The Chairs of CPRIT review committees are all highly distinguished in their respective fields and bring enormous stature to the peer review process. Unlike chairs of other review processes, CPRIT's chairs are responsible for recruiting peer reviewers for their panel. In addition, they serve as strategic advisors for CPRIT's grant programs. These responsibilities are unique to CPRIT review committee chairs and require more effort and expertise than simply chairing a committee. Having committee chairs of this caliber distinguishes CPRIT's peer review process from all others.

Honoraria Payment Process and Documentation

Review Council and Committee Chairs receive quarterly honoraria payments directly from CPRIT. The honoraria payment process for Review Council chairs and Committee chairs is as follows:

[4] TEX. HEALTH & SAFETY CODE Section 102.151(d)

1. At the end of the fiscal quarter, the Review Council chairs and the Committee chairs submit to CPRIT a written confirmation of the work performed and an estimate of hours[5] spent related to CPRIT's peer review activities for the quarter.

2. The CPRIT Program Officer reviews the confirmations and approves payment of quarterly honoraria to the Review Council chair and Committee chairs.

3. CPRIT's financial staff authorizes payment of the honoraria and retains the documentation supporting the honoraria payment.

4. The Chief Compliance Officer and Internal Auditor may also review the confirmations submitted.

CPRIT's third party grant administrator pays peer reviewers for each review cycle in which they participate. To document the work performed by a peer review committee member for the review cycle, CPRIT's third party grant administrator confirms that the reviewer attended the peer review meeting and submitted written comments and scores for the grants assigned to the reviewer for evaluation.

CPRIT also reimburses travel expenses and pays the Texas state per diem when peer reviewers, Review Council chairs, and Committee chairs travel to attend peer review meetings. CPRIT relies upon standard travel documentation for travel reimbursements.

In the event a Review Council chair, Committee chair, or peer reviewer is not able to complete a full review cycle due to unforeseen circumstances, the CPRIT Program Officer may approve, in his or her discretion, a partial payment of the honorarium. The Program Officer should explain in writing the basis for approving a change to the reviewer's honorarium; CPRIT will retain such explanation as part of the grant review records. Nothing herein prevents the Program Officer from approving full payment even if the reviewer is unable to participate in every aspect of the review cycle so long as the reason is well justified.

Peer Review Responsibilities

All CPRIT programs plan standard multi-cycle grant review activities to fully award all available grant funds allocated for FY 2024. CPRIT will continue to convene peer review meetings via videoconference for FY 2024. CPRIT first used videoconference meetings for all peer review activities held after March 2020 and the process has worked well.

[5] CPRIT pays honorarium for the annual service of the Review Council chair or Committee chair. The payment does not use an hourly wage structure; the estimated number of hours devoted to CPRIT activities by a Review Council or Committee chair may vary by quarter depending upon the timing of review cycle activities. CPRIT uses the hourly estimate at the end of the year to set honoraria payment structures for the next fiscal year.

Review Council Chairs

The Council Chair works directly with the CPRIT Program Officer to coordinate the peer review activities for each CPRIT program. The CPRIT model for peer review is unique. Other grant-making programs typically use committee chairs only to preside at committee meetings; however, CPRIT engages preeminent experts in their field for the Council Chair and Committee Chair positions to advise CPRIT on program aspects, including the short-term and long-term direction of the program, the review process itself, and the award portfolio composition. The chair's does this work in addition to the administrative tasks associated with chairing Review Council meetings. Many of the Council Chair responsibilities are similar across the three CPRIT programs, including:

- advising on the selection of committee chairs
- recruiting specialized peer reviewers and assisting with peer reviewer selection
- reviewing all abstracts of projects discussed at Prevention, Scientific, and Product Development Review Council meetings
- chairing Review Council meetings
- chairing a peer review panel meeting if a chair has an unexpected conflict[6]
- finalizing grant award recommendations submitted to the Chief Executive Officer
- providing ongoing advice to CPRIT staff on programs, review processes, and future funding opportunities

Estimated Annual Time Commitment: CPRIT expects Council Chairs to commit approximately 300 hours to CPRIT-related activities in FY 2024. This equates to 14.4% of a standard 2080-hour work year. **Table 1** provides a detailed analysis of the activities, hours, and units used to project the Council Chair workload. The information in Table 1 reflects 2018 – 2023 review cycle information and the projected workload for FY 2024.

NOTE: Due to changes in the Product Development Program review process that CPRIT instituted in FY 2023, CPRIT will continue to use a bifurcated honoraria policy for the Product Development Review Council (PDRC) Chair and Deputy Chair:

- As reflected on Table 1, the PDRC Chair and Deputy Chair[7] will receive a base honoraria that reflects their work advising CPRIT on the review process and RFAs, monitoring the preliminary application review implementation, advising CPRIT on review panel assignments as well as activities coordinating the review of annual progress reports and milestone funding decisions and providing expert advice and assistance related to CPRIT's product development portfolio and substantive grant contract amendment requests.

- In addition to the base honoraria, if the PDRC Chair or Deputy Chair participate in the review of preliminary applications and/or the review of full applications, they will receive honoraria for participation in those review activities as set forth on Table 4.

[6] The Product Development Committee Chair regularly chairs review committee meetings.
[7] In FY 2016, CPRIT created the PDRC Deputy Chair position. This position is equivalent to the PDRC Chair position except that the Deputy Chair will not prepare slate recommendation for the Chief Executive Officer.

Hourly Rate Proxy: CPRIT pays honorarium for the annual service of the Review Council chair and is not based on an hourly wage structure. However, for comparison, the honoraria paid to Review Council chairs equate to a $250/hour rate. This is in line with hourly rates paid for skilled professional services in other industries and less than the $500+/hour rate paid for medical experts in malpractice cases.[8] The hourly rate used by CPRIT is also likely to be less than rates used to calculate consultant fees for physicians and scientists who advise pharmaceutical companies. Although there is no standard rate for consulting fees, one Texas institution of higher education limits the amount of consulting fees a professor may accept to 25% of their base salary. The capped amount is greater than the $72,000 - $83,400 honoraria paid to CPRIT Review Council Chairs.

Review Committee Chairs

A Committee Chair leads each peer review committee. The CPRIT model for peer review is unique. Other grant-making programs typically use committee chairs only to preside at committee meetings; CPRIT engages preeminent experts in their field for the Committee Chair positions to advise CPRIT on program aspects, including the short-term and long-term direction of the program, the review process itself, and the award portfolio composition. The Committee Chair does this work in addition to the administrative tasks associated with chairing peer review committee meetings. Committee Chairs are also members of the Review Council for the program. Duties of the committee chair include:

- recruiting reviewers for their review panels
- assigning applications to their panel members
- becoming familiar with the abstracts and applications assigned to their panel
- determining order of review for applications for panel discussion
- chairing panel discussions; capturing key discussion points
- reviewing full applications to participate in programmatic review meetings
- evaluating CPRIT Scholar recruitment grants (Scientific Review Committee chairs)
- assessing due diligence and intellectual property reports for product development applications (Product Development Review Committee chairs)
- ranking grant applications and developing a list of recommended grant awards and supporting information for consideration by the CPRIT Program Integration Committee
- reviewing annual progress reports and milestone funding decisions (Product Development Program)
- participating in meetings with CPRIT staff to provide advice on future program directions, processes, evaluation criteria, and other related issues

Estimated Annual Time Commitment: The amount of time spent on committee chair activities varies depending on the program. CPRIT expects Review Committee chairs to commit between 190 and 250 hours to CPRIT-related activities in FY 2024. **Table 2** provides a detailed analysis

[8] Data from *National Medical Consultants, P.C.*, a physician owned and operated company representing a panel of over 2700 medical experts who are distinguished specialists in all areas of medicine.

of the activities, hours, and units used to project the committee chair workload. The information in Table 2 reflects 2009 – 2023 review cycle information and the projected workload for FY 2024. For the purposes of the honoraria policy, CPRIT refers to Product Development Review Council members as "committee chairs" and they perform all activities listed in Table 2.

NOTE: Due to changes in the Product Development Program review process that CPRIT instituted in FY 2023, CPRIT will continue to use a bifurcated honoraria policy a bifurcated honoraria policy for the PDRC Committee Chairs:

- As reflected on Table 2, the PDRC Committee Chairs will receive a base honorarium that reflects their work advising CPRIT on the review process and RFAs, as well as activities coordinating the review of annual progress reports and milestone funding decisions and providing expert advice and assistance related to CPRIT's product development portfolio and substantive grant contract amendment requests.

- In addition to the base honoraria, the PDRC Committee Chairs participating in the review of preliminary applications and/or the review of full applications will receive honoraria for their participation in those review activities as set forth on Table 4.

Hourly Rate Proxy: CPRIT pays honorarium for the annual service of the Review Committee chair and is not based on an hourly wage structure. However, for comparison, the honoraria paid to Committee chairs equates to a $200/hour fee. This is in line with hourly rates paid for skilled professional services in other industries and less than the $500+/hour rate paid for medical experts in malpractice cases.[9] The hourly rate used by CPRIT is also likely to be less than rates used to calculate consultant fees for physicians and scientists who advise pharmaceutical companies. Although there is no standard rate for consulting fees, one Texas institution of higher education limits the amount of consulting fees a professor may accept to 25% of their base salary. The capped amount is more than the $37,000 - $50,000 honoraria paid to CPRIT Review Committee Chairs.

Review Committee Members

The number of peer review committees varies by program based on the volume of grant applications submitted. Peer reviewers are responsible for individually reviewing, scoring and critiquing 6-10 applications per cycle, as well as participating in panel discussions about grant applications assigned to the peer review committee. A reviewer spends 6 – 8 hours for a full review of a single application, but the reviewer may require much more time for complex, highly technical applications. A typical CPRIT grant application averages about 40 pages in length with additional supporting documentation. Applications for multimillion-dollar collaborative research projects and product development projects may be far more extensive.

Estimated Time Commitment per Review Cycle: Peer reviewer activity varies by program and number of applications assigned. CPRIT expects academic research peer reviewers to commit approximately 85 hours per review cycle. Prevention peer reviewers will commit 55-70 hours per cycle. **Table 3** provides a detailed analysis of the activities, hours, and units used to project the

[9] Data from *National Medical Consultants, P.C.*, a physician owned and operated company representing a panel of over 2700 medical experts who are distinguished specialists in all areas of medicine.

peer review workload. The information in Table 3 reflects 2009–2023 review cycle information and the projected workload for FY 2024.

For product development peer reviewers, CPRIT instituted a change in FY 2023 that will continue for FY 2024 in which the agency pays honoraria on an application vs. review cycle basis. This change provides CPRIT more flexibility to use ad hoc reviewers whose expertise aligns with the application's underlying science, product, and development/ regulatory stage. Before FY 2023, the Product Development Program relied upon two review panels populated by 20-24 experts that met two times per year to evaluate all product development applications submitted by a set deadline. For scheduling purposes, the process required CPRIT to create the panels in advance of receiving applications, which decreased CPRIT's ability to add reviewers with specific expertise based upon the applications received. In addition, some potential expert reviewers were unable to participate due to the significant time commitment (at least four full business days of meetings per cycle and 80 – 100 hours for reviewing and scoring applications.) A manageable time commitment for the reviewers is a significant incentive for potential review candidates and is crucial to CPRIT's ability to expand its bench of expert reviewers.

Hourly Rate Proxy: CPRIT pays honorarium to Academic Research and Prevention peer reviewers for a given review cycle, which is not based on an hourly wage structure. However, for comparison, honoraria paid to Academic Research and Prevention peer reviewers equates to a rate of $50/hour. Honoraria paid to Product Development peer reviewers is $65/hour. These reviewers must have both academic research and product development backgrounds and are more difficult to recruit. While the hourly rates are significantly less than those paid to professionals of this caliber, the rate is appropriate given the workload and responsibilities compared to Review Council and Committee chairs.

Comparison to other Grant Making Organizations

Grant-making organizations use various models and methods for compensating peer review committee members. A survey of 21 cancer granting organizations reported wide variation among programs such that an average compensation scheme for panel members was not possible. The disparity among organizations makes it difficult to devise a benchmark compensation method or amount. Reported compensation practices may fail to include intangible benefits available to reviewers in addition to monetary compensation, which further complicates the ability to make a meaningful comparison between CPRIT and other grant-making organizations. As discussed earlier, these non-monetary incentives are unavailable to CPRIT reviewers because of CPRIT's policy to use highly qualified, experienced, out-of-state reviewers.

- International Cancer Research Partners (ICRP) surveyed 31 of its partner organizations and 21 responded. The report found that organizations paid different honoraria depending on the role of the reviewer. Chairs often received more than committee members did, and teleconference or online reviewers typically received less

compensation than those members who participated in-person. The report did not compute an average based on the supplied data.[10]

- CPRIT's third party grant administrator reports that two other clients pay reviewers $1,250 and $2,000 per review meeting.

- NCI's website reports that NCI pays $200 per day of review in addition to travel expenses.

[10] The report did not include a range, but the survey sponsors indicated the range for compensation for panel members was $150-$3,000 per day.

Table 1. Council Chair Activities (See Table 5 for an explanation of the correlation between units and hours.)

Table 1 - Review Council Chair Activities, Hours, Units						
Academic Research Program		**Prevention Program**		**Product Development Program – Base***		
Units	Activity	Units	Activity	Units Chair	Units Deputy	Activity
5	Consult with staff on vision and direction for the program; bi-weekly calls with staff	5	Consult with staff on vision and direction for the program; bi-weekly calls with staff	20	20	Review grantee progress reports, advise staff on grantee activities, overall program direction; semi-monthly conference calls w/ staff
3.5	Help select and recruit Committee Chairs	2	Help select and recruit Committee Chairs	3	3	Select and recruit review council members and expert reviewers
6	Advise on peer review, CPRIT 2.0, Program Priorities, and other processes as needed	2	Advise on peer review and other processes as needed	5	5	Advise on peer review process and RFAs, participate in grant application/review webinars and other programmatic processes as needed
5	Review draft RFAs, propose new ones, etc	4	Review draft RFAs, propose new ones, etc	4.5	4.5	Advise/monitor preliminary review.
3	Communicate with Committee Chairs prior to peer review & programmatic mtg	1	Communicate with Committee Chairs prior to peer review & programmatic mtg	4.5	4.5	Assign full applications to panels, monitor full application review process
2	Prepare for Programmatic meetings; review materials	4	Prepare for Programmatic meetings; review materials	2	2	Advise/monitor due diligence review
2	Lead programmatic review	4	Lead programmatic review	3	2	Lead /participate in slate discussion
2	Prepare slate recommendations for CEO and Oversight Committee Chair	1	Prepare slate recommendations for CEO and Oversight Committee Chair			
24	Review recruitment applications, become familiar with applications for discussion	15	Review abstracts, attend portions of panel meetings, back up for panel Chair			
6	Lead monthly discussion on recruitment awards	4	Collaborate on articles for publication			
4	Analyze data for Research program	4	Analyze data for Prevention program			
		3	Participate in quarterly teleconference			
		6	Review dissemination applications			
		5	Review Annual and Final progress reports			
62.5		60		42	41	
$ 1,200	Unit cost	$1,200	Unit cost		$1,200	Unit cost
$ 250	Hourly rate	$250	Hourly rate		$250	Hourly rate
$75,000	Annual honoraria	**$72,000**	Annual honoraria		**$50,400**	Annual base honoraria Chair
					$49,200	Annual base honoraria Deputy Chair

*The PDRC Chair and Vice Chair may receive honoraria in addition to the base honoraria if they participate in reviewing preliminary or full applications. See Table 4.

Table 2. Committee Chair* Activities (See Table 5 for an explanation of the correlation between units and hours.)

Table 2 - Committee Chair Activities, Hours, Units					
Academic Research Review		**Prevention Review**		**Product Development Review – Base***	
Units	Activity	Units	Activity	Units	Activity
2	Select/recruit committee members	2	Select/recruit committee members	2	Select/recruit committee members
3	Review draft RFAs and provide input (as needed)	2	Review draft RFAs and provide input (as needed)	18	Review grantee progress reports; advise staff on grantee activities; participate in semi-monthly conference calls with staff.
10	Read abstracts; assign grants to reviewers	12	Read abstracts assigned to their committee; review panel assignments	3	Advise on review process, RFAs; participate in grant application/review webinars and other programmatic processes as needed
1	Assist with follow up of delinquent reviewers	1	Assist with follow up of delinquent reviewers	2	Participate in award slate meetings.
4	Chair the assigned committee review process via conference call or in person meeting	6	Chair the assigned committee review process via conference call or in person meeting		
1	Prepare for Programmatic meetings; review materials	2	Prepare for Programmatic meetings; review materials		
1	Participate in Chair's programmatic review meetings	6	Participate in Chair's programmatic review & debriefing meetings		
6	Participate in debriefing sessions, discussion of future direction of program, development of new RFAs, CPRIT 2.0 and Program Priorities	2	Participate in debriefing sessions, discussion of future direction of program, development of new RFAs		
		3	Prepare and participate in quarterly Review Council teleconferences		
24	Review recruitment applications	4	Review dissemination applications		
5	Participate in monthly review of recruitment applications	2	Participate in review of dissemination applications		
57		42		25	
$875	Unit cost	$875	Unit cost	$875	Unit cost
$200	Hourly	$200	Hourly	$200	Hourly
$50,000	**$50,000** Annual honoraria	$36,750	**$37,000** Annual honoraria	$21,875	**$22,000** Annual base honoraria

See Table 5 for an explanation of the correlation between units and hours.

* For the Product Development Program, the members of the Product Development Review Council (PDRC) fulfill the "Committee Chair" activities.

** The PDRC may receive honoraria in addition to the base honoraria if they participate in reviewing preliminary or full applications. See Table 4.

Table 3. Peer Reviewer Activities per Cycle (See Table 5 for an explanation of the correlation between units and hours.)

Prevention Review: ~20 reviewers		Academic Research Review: ~ 130 reviewers	
Units	**Activity**	**Units**	**Activity**
1	Declaration of expertise and conflicts	1	Declaration of expertise and conflicts
8	Preparation of full critiques	10	Preparation of critiques*
1	Premeeting preparation of video conferencing capabilities	1	Premeeting preparation of video conferencing capabilities
4	Participation at meeting	3	Participation at meeting
1	Post-meeting discussion**	1	Post-meeting discussion**
1	Post-meeting survey to provide CPRIT feedback on CPRIT 2.0	1	Post-meeting survey to provide CPRIT feedback on CPRIT 2.0
16	$250 Unit cost $50 avg. hourly rate $4,000 per cycle	17	$250 Unit cost $50 avg. hourly rate $4,250 per cycle

* This may be less for reviewers that participate only in the preliminary application review. The grant mechanism specifies when CPRIT uses preliminary reviews.
** Post-meeting discussion activities may include finalizing funding recommendations, finalizing critiques, clarifying recommendations related to funding or goals/objective changes, de-briefing about the review cycle, and/or other activities specified by the CPRIT Program Officer.

NOTE: CPRIT pays peer reviewers only for activities in which they participate. For example, participation at a research peer review meeting is 3 units (11-15 hours) and CPRIT values each unit at $250; thus, the amount paid to an academic research peer reviewer for attendance at a peer review meeting is $750. If the reviewer was unable to attend the meeting, then CPRIT subtracts $750 from the honorarium paid to the reviewer. In the event a Review Council chair, Committee chair, or peer reviewer is not able to complete a full review cycle due to unforeseen circumstances, the CPRIT Program Officer may approve, in his or her discretion, a partial payment of the honorarium.

Table 4. Product Development Peer Reviewer Activities per Application (See Table 5 for the correlation between units and hours.)

Preliminary Application Review (PDRC members only) ~ 8 – 12 members	
Units	**Activity**
2	Declaration of conflicts
14	Review, score and critique preliminary applications
4	Participation in preliminary application panel teleconference
20	**Total Units for Preliminary Application Review**
$875	**Unit Cost**
$17,500	**Total**
Full Application Review (per application) ~ 60 reviewers	
Units	**Activity**
.5	Declaration of conflicts and expertise
3.5	Review full application, score and prepare critique
1	Participate in company presentation meeting and peer review panel discussion
2.5*	Participate in due diligence review and meetings, funding recommendation
2**	Lead panel member who manages panel discussion, coordinates critiques and scoring
5 – 9.5	**Total Review Units per Full Application**
$325	**Unit cost**
$1,625 – $3,075	**Total per Full Application**
* Only those applications scoring sufficiently well will proceed to due diligence review; reviewer will only receive this additional honorarium if the application undergoes due diligence review.	
** Each review panel will have one lead member; only the reviewer designated as the lead member receives this additional honorarium.	

Table 5. Hours and Units Calculation

PARTICIPATION (HOURS)	UNITS		Council Chairs (and Vice Chair)	Committee Chairs	Peer reviewers
1-5	1		Unit Cost		
6-10	2		$1200	$875	$250-$325
11-15	3		Average Hourly Rate		
16-20	4		$250	$200	$50-$65
21-25	5		Honoraria		
26-30	6		$65,400 - $83,400 annually	$36,750 - $50,000 annually	$4,250 - $6,500 per cycle
31-35	7				
36-40	8				
41-45	9				
46-50	10				
51-55	11				
56-60	12				
61-65	13				
66-70	14				
71-75	15				

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE CHAIR MAHENDRA PATEL
FROM:	WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	SECTION 102.1062 WAIVER—BRANDY FY 2024
DATE:	AUGUST 8, 2023

Waiver Request and Recommendation

I request that the Oversight Committee approve a conflict of interest waiver for FY 2024 for Mr. Donald Brandy, CPRIT's Contract Specialist and HUB Coordinator, pursuant to Health & Safety Code Section 102.1062 "Exceptional Circumstances Requiring Participation." The Oversight Committee approved the same waiver for Mr. Brandy since FY 2015.

Mr. Brandy is not involved in the grant application or reporting process in his official capacity in the procurement of goods and services for the agency. However, the waiver ensures transparency regarding Mr. Brandy's relationship with some universities that receive CPRIT grants. Furthermore, CPRIT's Code of Conduct makes it clear that the agency's conflict of interest provisions apply to any expenditure of CPRIT funds. Although it is unlikely that CPRIT will procure goods and services from a university receiving grant funds from CPRIT, having the conflict of interest waiver in place ensures that Mr. Brandy can perform his duties. Together with the waiver's proposed limitations, adequate protections are in place to mitigate the opportunity for a conflict of interest to unduly influence agency purchases.

Background

Mr. Brandy serves as the agency procurement contract specialist, responsible for planning, organizing, coordinating, and preparing bid specifications and procurement documents to acquire goods and services from vendors and outside contractors used by the agency. The agency procurement contract specialist role requires little, if any, involvement with CPRIT's grant award process because CPRIT's grant award contracts are not vendor or outside service contracts.

At the time CPRIT hired Mr. Brandy, he requested approval to continue his outside employment as a referee for tennis tournaments held in and around Austin. In addition to refereeing for adult and junior-level tournaments, he serves as a referee for NCAA tennis matches held at area universities, including The University of Texas at Austin. The university athletic department pays Mr. Brandy for his services as an independent contractor when he referees collegiate matches.

CPRIT employees may engage in outside employment so long as the employment does not detract from the employee's ability to fulfill his or her responsibilities to CPRIT. Employees

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

must receive written approval from the CEO to engage in outside employment and I notify the Audit Subcommittee regarding any approvals. I also annually report to the Oversight Committee all approved outside employment. I notified the Audit Subcommittee regarding my approval for Mr. Brandy's outside employment and the subcommittee first discussed it at the December18, 2014, subcommittee meeting.

Exceptional Circumstances Requiring Mr. Brandy's 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 or other expenditure of CPRIT funds.[1]

This conflict of interest waiver is different than other waivers I have requested in that it is not seeking a waiver for actions related to CPRIT's grant review or grant monitoring process. As CPRIT's procurement contract specialist, I do not anticipate that Mr. Brandy will play any role in the review process for grant applications or grant reports. The procurement contract specialist deals only with agency procurement matters and has no influence over the grant award processes of the agency. To the extent that his outside employment necessitates involvement with university personnel, it is with collegiate athletic department staff that have no interaction with researchers working on or applying for grants. Nevertheless, if Mr. Brandy must be part of the review process or grant monitoring activities, he will comply with CPRIT's conflict of interest notification and recusal requirements.

However, as part of his official duties there may be circumstances requiring Mr. Brandy to procure goods or services on CPRIT's behalf from a university that has also employed him as a tennis referee. This is unlikely to occur; to date, CPRIT has had only two service contracts (both now closed) with an academic institution, Texas Tech University and The University of Texas at Austin LBJ School of Public Affairs. As CPRIT's lead contact for agency purchases, Mr. Brandy should be able to perform his official duties as fully as possible. Any involvement with university athletic department personnel resulting from his outside employment is unlikely to be the same individuals at the university responsible for contracting with CPRIT.

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. Brandy to perform all duties assigned as procurement contract specialist, subject to the limitations stated below:

1. Provide the Chief Operating Officer a list of universities that have used his services as referee during the past twelve months;

[1] CPRIT's Code of Conduct Section III.B(2) states that, "The conflict of interest statutory and administrative rule provisions **apply to any decision to commit CPRIT funds**, whether or not the commitment is part of the grant award process or to a Grant Applicant." (emphasis added)

2. Notify the Chief Operating Officer prior to taking any action on a contract or other procurement document that would result in payment of CPRIT funds to a university on the list referenced above; and
3. The Chief Operating Officer, in conjunction with the CEO, Chief Compliance Officer and General Counsel, can review the circumstances and determine whether Mr. Brandy should be recused from involvement in the procurement.

Important Information Regarding this Waiver and the Waiver Process

- The Oversight Committee may amend, revoke, or review this waiver, including but not limited to the list of approved activities and duties and the limitations on duties and activities. Approval of any change to the waiver granted shall be by a vote of the Oversight Committee in an open meeting.
- CPRIT limits this waiver to the conflict of interest specified in this request. To the extent that Mr. Brandy has a conflict of interest not addressed in this waiver, then Mr. Brandy will follow the required notification and recusal process.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	SECTION 102.1062 WAIVER—REVIEW COUNCILS FY 2024
DATE:	AUGUST 8, 2023

Waiver Request and Recommendation

I request that the Oversight Committee approve a fiscal year 2024 conflict of interest waiver for review council members pursuant to Health & Safety Code § 102.1062 "Exceptional Circumstances Requiring Participation." Unlike other conflict of interest waivers that the Oversight Committee has approved previously, CPRIT does not grant this waiver for a specific conflict of interest or person. Instead, CPRIT intends to invoke this waiver as necessary to address the unusual scenario when a review council member has a conflict with a grant application that is part of the larger group of proposals that the review panel or review council must act upon (usually to recommend for awards). The waiver is necessary for a review council member to participate in the overall discussion and vote on the slate of award recommendations. This waiver is the same waiver the Oversight Committee approved for FY 2023.

Although it would be ideal to consider each instance individually before granting the conflict of interest waiver, a prospective waiver is necessary in this scenario given the timing of the review process and scheduled Oversight Committee meetings. It is unlikely that review panel schedules will align with Oversight Committee meeting dates such that CPRIT will be able to secure a conflict of interest waiver in time for the review council member to participate in the review process. However, adequate protections are in place that, together with the waiver's proposed limitations, mitigate the opportunity for factors other than merit and established criteria to influence review council members' decisions regarding the award of grant funds.

Background

Health & Safety Code § 102.1062 directs the Oversight Committee to adopt administrative rules governing the waiver of the conflict of interest requirements of the statute in exceptional circumstances. CPRIT's administrative rule § 702.17(3) authorizes the Oversight Committee to approve a waiver that applies for all activities affected by the conflict during the fiscal year. The rules require that a majority of the Oversight Committee members must vote to approve the waiver. CPRIT must report any approved waiver to the lieutenant governor, speaker of the house of representatives, the governor, and the standing committees of each house of the legislature with primary jurisdiction over CPRIT matters.

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The issue addressed by this waiver results from the role review council members play in the review process. At the review panel level, the review council member chairs the review panel meeting. Occasionally, a review council member will identify a conflict of interest with an application assigned to the member's panel. If CPRIT is unable to reassign the application to a different panel, then the review council member follows the process set forth in CPRIT's conflict of interest rules and recuses himself or herself from any discussion, scoring, deliberation, or vote on the application. The proposed waiver will not change the review council member's responsibility to disclose the conflict or to recuse from the review of the application.

The difficulty arises when the review council member must lead the discussion, in his or her role as chair of the review panel, about the group of applications the panel recommends moving forward to the review council. If the application with which the review council member is in conflict advances as part of the group that scored well enough to move forward, the review council member's participation in the discussion of the group violates the member's agreement to not participate in "any discussion" of the conflicted application.

A similar challenge arises at the review council level. If the application that the member is in conflict is part of the group considered by the review council, the conflict of interest rules prohibit the member from participating in the review council's discussion or vote on the group of awards. The review council member is unable to address questions about other applications heard by his or her panel due to his or her recusal from the process, potentially disadvantaging the other applications.

Exceptional Circumstances Requiring the Review Council Member's 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. In this case, exceptional circumstances exist due to the necessity of the review council member's participation in the process to develop the overall award recommendation slates and the Oversight Committee should grant the proposed waiver. The limitations mitigate the potential for bias.

CPRIT's administrative rules require the Chief Compliance Officer to attend or designate an independent third party to attend peer review meetings and review council meetings when the panel discusses grant applications. The third-party observer must document that the reviewers follow CPRIT's grant review process consistently, including observing CPRIT's conflict of interest rules. The third-party observer will document any violation of this waiver in his or her written report, which CPRIT provides to the Oversight Committee prior to the vote on the award recommendations.

Proposed Waiver and Limitations

In granting the conflict of interest waiver, I recommend that CPRIT permit the review council member to continue to perform the following activities and duties associated with CPRIT's review process subject to the stated limitations:

1. The review council member must disclose any conflict in writing pursuant to the electronic grant management process CPRIT has in place.
2. The review council member must recuse himself or herself from participation in the review, discussion, scoring, deliberation, and vote on the specific grant(s) identified as the conflict.
3. When the review panel or review council takes up the grant applications as a group, the review council member may participate in the discussion and vote on the proposed awards, so long as the review council member does not advocate for or against the application that the member has identified as a conflict.
4. Whenever CPRIT invokes this waiver, the Chief Compliance Officer will provide information about the use of the waiver, including the name of the review council member and the identified conflict, in the Chief Compliance Officer's Certification report. I will also include this information in the CEO affidavit I submit for the grant award mechanism.

Due to the nature of the conflict or the type of review process, this conflict of interest waiver will not apply to following:

- When the review council member's conflict of interest is a conflict described by T.A.C. § 702.13(c); or
- When the review council is acting as the only review panel in the review process (e.g., CPRIT recruitment awards and prevention dissemination awards.)

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 review council members operating under the circumstances specified in this request.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

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

SUBJECT: CHAPTERS 701 AND 703 RULE CHANGES PROPOSED FOR FINAL ADOPTION

DATE: AUGUST 4, 2023

Summary and Recommendation

The Board Governance Subcommittee convened on August 3 to review the final order adopting rule amendments to Chapters 701 and 703. Once the Oversight Committee approves the final order adopting the changes to T.A.C. §§ 701.3, 703.6, 703.7, 703.10, 703.21, and 703.25, CPRIT will submit the amendment to the Secretary of State and the change will be effective 20 days later.

Discussion

State law requires an agency to set policy using a rulemaking process, which includes an opportunity for public comment on proposed rules and rule changes before the agency formally adopts the policy. CPRIT published the proposed amendments in the June 2, 2023, edition of the *Texas Register*. CPRIT received no public comments regarding the proposed rule changes that affect Chapters 701 and 703.

The change to § 701.3(63) amends the defined term, "Scope of Work," to include "specific aims and subaims, if appropriate." The remaining amendments in Chapter 701 and throughout Chapter 703 ensure that CPRIT consistently refers to the term "Scope of Work" in the administrative rules.

The Board Governance Subcommittee met on August 3 to discuss adoption of the proposed rule changes to Chapters 701 and 703 with CPRIT staff. The subcommittee voted to recommend that the Oversight Committee approve adoption of the rule change.

Next Steps

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

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The Cancer Prevention and Research Institute of Texas ("CPRIT" or "the Institute") adopts the amendments to 25 Tex. Admin. Code §§ 701.3(29), (63) without changes to the proposed amendments as published in the June 2, 2023, issue of the Texas Register (48 TexReg 2818); therefore, the rules will not be republished. The amendments relate to the definition and use of "Scope of Work."

Reasoned Justification

CPRIT amends the term "Scope of Work" to include "specific aims and subaims, if appropriate." Grant applicants submit a Scope of Work with their grant application and, if approved, the Scope of Work becomes part of the grant contract.

Summary of Public Comments and Staff Recommendation

CPRIT received no public comments regarding the proposed amendments to § 701.3; CPRIT staff recommends moving forward with adoption of the amendments.

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

Certification

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

To be filed with the Office of Secretary of State on August 18, 2023.

<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) 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.

(5) 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.

(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 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.

(51) 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.

(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.

The Cancer Prevention and Research Institute of Texas ("CPRIT" or "the Institute") adopts the amendments to 25 Tex. Admin. Code §§ 703.6, 703.7, 703.10, 703.21, and 703.25 without changes to the proposed amendments as published in the June 2, 2023, issue of the Texas Register (48 TexReg 2818); therefore, the rules will not be republished. The amendments ensure that CPRIT consistently uses the term "Scope of Work" throughout the Institute's administrative rules.

Reasoned Justification

The amendments replace inconsistent use of scope of work (e.g, project goals, goals and objectives, timeline) with "Scope of Work," which is a defined term in Texas Administrative Code Chapter 701.

Summary of Public Comments and Staff Recommendation

CPRIT received no public comments regarding the proposed amendments to § 701.3; CPRIT staff recommends moving forward with adoption of the amendments.

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

Certification

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

To be filed with the Office of Secretary of State on August 18, 2023.

<rule>

§703.6.Grant Review Process.

(a) For all Grant Applications that are not administratively withdrawn by the Institute for noncompliance or otherwise withdrawn by the Grant Applicant, the Institute shall use a two-stage Peer Review process.

(1) The Peer Review process, as described herein, is used to identify and recommend meritorious Cancer Research projects, including those projects with Cancer Research Product Development prospects, and evidence-based Cancer Prevention and Control projects for Grant Award consideration by the Program Integration Committee and the Oversight Committee.

(2) Peer Review will be conducted pursuant to the requirements set forth in Chapter 702 of this title (relating to Institute Standards on Ethics and Conflicts, Including the Acceptance of Gifts and Donations to the Institute) and Chapter 102, Texas Health and Safety Code.

(b) The two stages of the Peer Review Process used by the Institute are:

(1) Evaluation of Grant Applications by Peer Review Panels; and

(2) Prioritization of Grant Applications by the Prevention Review Council, the Product Development Review Council, or the Scientific Review Council, as may be appropriate for the Grant Program.

(c) Except as described in subsection (e) of this section, the Peer Review Panel evaluation process encompasses the following actions, which will be consistently applied:

(1) The Institute distributes all Grant Applications submitted for a particular Grant Mechanism to one or more Peer Review Panels.

(2) The Peer Review Panel chairperson assigns each Grant Application to no less than two panel members that serve as the Primary Reviewers for the Grant Application. Assignments are made based upon the expertise and background of the Primary Reviewer in relation to the Grant Application.

(3) The Primary Reviewer is responsible for individually evaluating all components of the Grant Application, critiquing the merits according to explicit criteria published in the Request for Applications, and providing an individual Overall Evaluation Score that conveys the Primary Reviewer's general impression of the Grant Application's merit. The Primary Reviewers' individual Overall Evaluation Scores are averaged together to produce a single initial Overall Evaluation Score for the Grant Application.

(4) The Peer Review Panel meets to discuss the Grant Applications assigned to the Peer Review Panel. If there is insufficient time to discuss all Grant Applications, the Peer Review Panel chairperson determines the Grant Applications to be discussed by the panel. The chairperson's decision is based largely on the Grant Application's initial Overall Evaluation Score; however, a Peer Review Panel member may request that a Grant Application be discussed by the Peer Review Panel.

(A) If a Grant Application is not discussed by the Peer Review Panel, then the initial Overall Evaluation Score serves as the final Overall Evaluation Score for the Grant Application. The Grant Application is not considered further during the Grant Review Cycle.

(B) If a Grant Application is discussed by the Peer Review Panel, each Peer Review Panel member submits a score for the Grant Application based on the panel member's general impression of the Grant Application's merit and accounting for the explicit criteria published in the Request for Applications. The submitted scores are averaged together to produce the final Overall Evaluation Score for the Grant Application.

(i) The panel chairperson participates in the discussion but does not score Grant Applications.

(ii) A Primary Reviewer has the option to revise his or her score for the Grant Application after panel discussion or to keep the same score submitted during the initial review.

(C) If the Peer Review Panel recommends changes to the Grant Award funds amount requested by the Grant Applicant or to the Scope of Work for the proposed project, then the recommended changes and explanation shall be recorded at the time the final Overall Evaluation Score is set.

(5) At the conclusion of the Peer Review Panel evaluation, the Peer Review Panel chairperson submits to the appropriate Review Council a list of Grant Applications discussed by the panel ranked in order by the final Overall Evaluation Score. Any changes to the Grant Award funding amount or to the Scope of Work recommended by the Peer Review Panel shall be provided to the Review Council at that time.

(d) The Review Council's prioritization process for Grant Award recommendations encompasses the following actions, which will be consistently applied:

(1) The Review Council prioritizes the Grant Application recommendations across all the Peer Review Panels by assigning a Numerical Ranking Score to each Grant Application that was discussed by a Peer Review Panel. The Numerical Ranking Score is substantially based on the final Overall Evaluation Score submitted by the Peer Review Panel, but also takes into consideration how well the Grant Application achieves program priorities set by the Oversight Committee, the overall Program portfolio balance, and any other criteria described in the Request for Applications.

(2) The Review Council's recommendations are submitted simultaneously to the presiding officers of the Program Integration Committee and Oversight Committee. The recommendations, listed in order by Numerical Ranking Score, shall include:

(A) An explanation describing how the Grant Application meets the Review Council's standards for Grant Award funding;

(B) The final Overall Evaluation Score assigned to the Grant Application by the Peer Review Panel, including an explanation for ranking one or more Grant Applications ahead of another Grant Application with a more favorable final Overall Evaluation Score; and

(C) The specified amount of the Grant Award funding for each Grant Application, including an explanation for recommended changes to the Grant Award funding amount or to the Scope of Work.

(3) A Grant Award recommendation is not final until the Review Council formally submits the recommendation to the presiding officers of the Program Integration Committee and the Oversight Committee. The Program Integration Committee, and, if appropriate, the Oversight Committee must make a final decision on the Grant Award recommendation in the same state fiscal year that the Review Council submits its final recommendation.

(e) Circumstances relevant to a particular Grant Mechanism or to a Grant Review Cycle may justify changes to the dual-stage Peer Review process described in subsections (c) and (d) of this section. Peer Review process changes the Institute may implement are described in this subsection. The list is not intended to be exhaustive. Any material changes to the Peer Review

process, including those listed in this subsection, shall be described in the Request for Applications or communicated to all Grant Applicants.

(1) The Institute may use a preliminary evaluation process if the volume of Grant Applications submitted pursuant to a specific Request for Applications is such that timely review may be impeded. The preliminary evaluation will be conducted after Grant Applications are assigned to Peer Review Panels but prior to the initial review described in subsection (c) of this section. The preliminary evaluation encompasses the following actions:

(A) The criteria and the specific Grant Application components used for the preliminary evaluation shall be stated in the Request for Applications;

(B) No less than two Peer Review Panel members are assigned to conduct the preliminary evaluation for a Grant Application and provide a preliminary score that conveys the general impression of the Grant Application's merit pursuant to the specified criteria; and

(C) The Peer Review Panel chairperson is responsible for determining the Grant Applications that move forward to initial review as described in subsection (c) of this section. The decision will be based upon preliminary evaluation scores. A Grant Application that does not move forward to initial review will not be considered further, and the average of the preliminary evaluation scores received becomes the final Overall Evaluation Score for the Grant Application.

(2) The Institute shall assign all Grant Applications submitted for recruitment of researchers and clinicians to the Scientific Review Council.

(A) The Scientific Review Council members review all components of the Grant Application, evaluate the merits according to explicit criteria published in the Request for Applications, and, after discussion by the Review Council members, provide an individual Overall Evaluation Score that conveys the Review Council member's recommendation related to the proposed recruitment.

(B) The individual Overall Evaluation Scores are averaged together for a final Overall Evaluation Score for the Application.

(C) If more than one recruitment Grant Application is reviewed by the Scientific Review Council during the Grant Review Cycle, then the Scientific Review Council shall assign a Numerical Ranking Score to each Grant Application to convey its prioritization ranking.

(D) If the Scientific Review Council recommends a change to the Grant Award funds requested by the Grant Application, then the recommended change and explanation shall be recorded at the time the final Overall Evaluation Score is set.

(E) The Scientific Review Council's recommendations shall be provided to the presiding officer of the Program Integration Committee and to the Oversight Committee pursuant to the process described in subsection (d) of this section.

(3) The Institute may assign continuation Grant Applications to the appropriate Review Council.

(A) The Review Council members review all components of the Grant Application, evaluate the merits according to explicit criteria published in the Request for Applications, and, after discussion by the Review Council members, provide an individual Overall Evaluation Score that conveys the Review Council member's recommendation related to the progress and continued funding.

(B) The individual Overall Evaluation Scores are averaged together for a final Overall Evaluation Score for the Application.

(C) If more than one continuation Grant Application is reviewed by the Review Council during the Grant Review Cycle, then the Review Council shall assign a Numerical Ranking Score to each continuation Grant Application to convey its prioritization ranking.

(D) If the Review Council recommends a change to the Grant Award funds or to the Scope of Work requested by the continuation Grant Application, then the recommended change and explanation shall be recorded at the time the final Overall Evaluation Score is set.

(E) The Review Council's recommendations shall be provided to the presiding officer of the Program Integration Committee and to the Oversight Committee pursuant to the process described in subsection (d) of this section.

(4) The Institute's Peer Review process described in subsections (c) and (d) of this section may include the following additional process steps for Product Development of Cancer Research Grant Applications:

(A) A Grant Applicant may be invited to deliver an in-person presentation to the Peer Review Panel. The Product Development Review Council chairperson is responsible for deciding which Grant Applicants will make in-person presentations. The decision is based upon the initial Overall Evaluation Scores of the primary reviewers following a discussion with Peer Review Panel members, as well as explicit criteria published in the Request for Applications.

(i) Peer Review Panel members may submit questions to be addressed by the Grant Applicant at the in-person presentation.

(ii) A Grant Application that is not presented in-person will not be considered further. The average of the primary reviewers' initial Overall Evaluation Scores will be the final Overall Evaluation Score for the Grant Application.

(iii) Following the in-person presentation, each Peer Review Panel member submits a score for the Grant Application based on the panel member's general impression of the Grant Application's merit and accounting for the explicit criteria published in the Request for Applications. The submitted scores are averaged together to produce the final Overall Evaluation Score for the Grant Application.

(B) A Grant Application may undergo business operations and management due diligence review and an intellectual property review. The Peer Review Panel submits a list of applications recommended for due diligence review to the Product Development Review Council. The Product Development Review Council decides which Grant Applications submitted by the Peer Review Panel will undergo business operations and management due diligence and intellectual property review. The decision is based upon the Grant Application's final Overall Evaluation Score, but also takes into consideration how well the Grant Application achieves program priorities set by the Oversight Committee, the overall Program portfolio balance, and any other criteria described in the Request for Applications. A Grant Application that is not recommended for due diligence and intellectual property review will not be considered further.

(i) Business operations and management due diligence may be conducted by an outside vendor, contracted by the Institute or by members of the Product Development Review Council.

(ii) It will be at the Institute's discretion as to who to use to perform business operations and management due diligence; factors may include volume of work and expertise required.

(C) After receipt of the business operations and management due diligence and intellectual property reviews for a Grant Application, the Product Development Review Council and the Primary Reviewers meet to determine whether to recommend the Grant Application for a Grant Award based upon the information set forth in the due diligence and intellectual property reviews. The Product Development Review Council may recommend changes to the Grant Award budget and Scope of Work.

(D) The Product Development Review Council assigns a Numerical Ranking Score to each Grant Application recommended for a Grant Award.

(f) Institute Employees and Oversight Committee members may attend Peer Review Panel and Review Council meetings. If an Institute Employee or an Oversight Committee member attends a Peer Review Panel meeting or a Review Council meeting, the attendance shall be recorded and the Institute Employee or Oversight Committee member shall certify in writing compliance with the Institute's Conflict of Interest rules. The Institute Employee's and Oversight Committee member's attendance at the Peer Review Panel meeting or Review Council meeting is subject to the following restrictions:

(1) Unless waived pursuant to the process described in Chapter 702, §702.17 of this title (relating to Exceptional Circumstances Requiring Participation), Institute Employees and Oversight Committee members shall not be present for any discussion, vote, or other action taken related to a Grant Applicant if the Institute Employee or Oversight Committee member has a Conflict of Interest with that Grant Applicant; and

(2) The Institute Employee or Oversight Committee member shall not participate in a discussion of the merits, vote, or other action taken related to a Grant Application, except to answer technical or administrative questions unrelated to the merits of the Grant Application and to provide input on the Institute's Grant Review Process.

(g) The Institute's Chief Compliance Officer shall observe meetings of the Peer Review Panel and Review Council where Grant Applications are discussed.

(1) The Chief Compliance Officer shall document that the Institute's Grant Review Process is consistently followed, including observance of the Institute's established Conflict of Interest rules, and that participation by Institute employees, if any, is limited to providing input on the Institute's Grant Review Process and responding to committee questions unrelated to the merits of the Grant Application. Institute Program staff shall not participate in a discussion of the merits, vote, or any other action taken related to a Grant Application.

(2) The Chief Compliance Officer shall report to the Oversight Committee prior to a vote on the award recommendations specifying issues, if any, that are inconsistent with the Institute's established Grant Review Process.

(3) Nothing herein shall prevent the Institute from contracting with an independent third party to serve as a neutral observer of meetings of the Peer Review Panel and/or the Review Council where Grant Applications are discussed and to assume the reporting responsibilities of the Chief Compliance Officer described in this subsection. In the event that the independent third party observes the meeting of the Peer Review Panel and/or the Review Council, then the independent third party reviewer shall issue a report to the Chief Compliance Officer specifying issues, if any, that are inconsistent with the Institute's established Grant Review Process.

(h) Excepting a finding of an undisclosed Conflict of Interest as set forth in §703.9 of this chapter (relating to Limitation on Review of Grant Process), the Review Council's decision to not include a Grant Application on the prioritized list of Grant Applications submitted to the Program Integration Committee and the Oversight Committee is final. A Grant Application not included on the prioritized list created by the Review Council shall not be considered further during the Grant Review Cycle.

(i) At the time that the Peer Review Panel or the Review Council concludes its tasks for the Grant Review Cycle, each member shall certify in writing that the member complied with the Institute's Conflict of Interest rules. An Institute Employee or an Oversight Committee member attending one or more Peer Review Panel meetings during the Grant Review Cycle shall certify compliance with the Institute's Conflict of Interest rules.

(j) The Institute shall retain a review record for a Grant Application submitted to the Institute, even if the Grant Application did not receive a Grant Award. Such records will be retained by the Institute's electronic Grant Management System. The records retained by the Institute must include the following information:

(1) The final Overall Evaluation Score and Numerical Ranking Score, if applicable, assigned to the Grant Application;

(2) The specified amount of the Grant Award funding for the Grant Application, including an explanation for recommended changes to the Grant Award funding amount or to the Scope of Work;

(3) The Scientific Research and Prevention Programs Committee that reviewed the Grant Application;

(4) Conflicts of Interest, if any, with the Grant Application identified by a member of the Scientific Research and Prevention Programs Committee, the Review Council, the Program Integration Committee, or the Oversight Committee; and

(5) Documentation of steps taken to recuse any member or members from the Grant Review Process because of disclosed Conflicts of Interest.

(k) For purposes of this rule, a Peer Review Panel chairperson or a Review Council chairperson that is unable to carry out his or her assigned duties due to a Conflict of Interest with regard to one or more Grant Applications or for any other reason may designate a co-chairperson from among the appointed Scientific Research and Prevention Programs committee members to fulfill the chairperson role. Such designation shall be recorded in writing and include the specific time and extent of the designation.

§703.7.Program Integration Committee Funding Recommendation.

(a) The Institute uses a Program Review process undertaken by the Institute's Program Integration Committee to identify and recommend for funding a final list of meritorious Cancer Research projects, including those projects with Cancer Research Product Development prospects, and evidence-based Cancer Prevention and Control Program projects that are in the best overall interest of the State.

(b) Program Review shall be conducted pursuant to the requirements set forth in Chapter 702 of this title (relating to Institute Standards on Ethics and Conflicts, Including the Acceptance of Gifts and Donations to the Institute) and Chapter 102, Texas Health and Safety Code.

(c) The Program Integration Committee shall meet pursuant to a schedule established by the Chief Executive Officer, who serves as the Committee's presiding officer, to consider the prioritized list of Grant Applications submitted by the Prevention Review Council, the Product Development Review Council, or the Scientific Review Council.

(d) The Program Integration Committee shall approve by a majority vote a final list of Grant Applications recommended for Grant Awards to be provided to the Oversight Committee, including a list of Grant Applications, if any, that have been deferred until a future meeting of the Program Integration Committee. In composing the final list of Grant Applications recommended for Grant Award funding, the Program Integration Committee shall:

(1) Substantially base the list upon the Grant Award recommendations submitted by the Review Council.

(2) To the extent possible, give priority for funding to Grant Applications that:

(A) Could lead to immediate or long-term medical and scientific breakthroughs in the area of Cancer Prevention or cures for cancer;

(B) Strengthen and enhance fundamental science in Cancer Research;

(C) Ensure a comprehensive coordinated approach to Cancer Research and Cancer Prevention;

(D) Are interdisciplinary or interinstitutional;

(E) Address federal or other major research sponsors' priorities in emerging scientific or Technology fields in the area of Cancer Prevention, or cures for cancer;

(F) Are matched with funds available by a private or nonprofit entity and institution or institutions of higher education;

(G) Are collaborative between any combination of private and nonprofit entities, public or private agencies or institutions in this state, and public or private institutions outside this state;

(H) Have a demonstrable economic development benefit to this state;

(I) Enhance research superiority at institutions of higher education in this state by creating new research superiority, attracting existing research superiority from institutions not located in this state and other research entities, or enhancing existing research superiority by attracting from outside this state additional researchers and resources;

(J) Expedite innovation and commercialization, attract, create, or expand private sector entities that will drive a substantial increase in high-quality jobs, and increase higher education applied science or Technology research capabilities; and

(K) Address the goals of the Texas Cancer Plan.

(3) Document the factors considered in making the Grant Award recommendations, including any factors not listed in paragraph (2) of this subsection;

(4) Explain in writing the reasons for not recommending a Grant Application that was recommended for a Grant Award by the Review Council or for deferring a Grant Application recommendation until a future meeting date;

(5) Specify the amount of Grant Award funding for each Grant Application.

(A) Unless otherwise specifically stated, the Program Integration Committee adopts the changes to the Grant Award amount recommended by the Review Council.

(B) If the Program Integration Committee approves a change in the Grant Award amount that was not recommended by the Review Council, then the Grant Award amount and a written explanation for the change shall be provided.

(6) Specify changes, if any, to the Grant Application's Scope of Work recommended for a Grant Award and provide an explanation for the changes made;

(7) Address how the funding recommendations meet the annual priorities for Cancer Prevention, Cancer Research and Product Development programs and affect the Institute's overall Grant Award portfolio established by the Oversight Committee; and

(8) Provide a list of deferred Grant Applications, if any.

(e) In the event that the Program Integration Committee's vote on the final list of Grant Award recommendations or deferrals is not unanimous, then the Program Integration Committee Member or Members not voting with the majority may submit a written explanation to the Oversight Committee for the vote against the final list of Grant Award recommendations or deferrals. The explanation may include the Program Integration Committee Member or Members' recommended prioritized list of Grant Award recommendations or deferrals.

(f) The Program Integration Committee's decision to not include a Grant Application on the prioritized list of Grant Applications submitted to the Oversight Committee is final. A Grant Application not included on the prioritized list created by the Program Integration Committee shall not be considered further during the Grant Review Cycle, except for the following:

(1) In the event that the Program Integration Committee's vote on the final list of Grant Award recommendations is not unanimous, then, upon a motion of an Oversight Committee Member, the Oversight Committee may also consider the Grant Award recommendations submitted by the non-majority Program Integration Committee Member or Members;

(2) A finding of an undisclosed Conflict of Interest as set forth in §703.9 of this chapter (relating to Limitation on Review of Grant Process); or

(3) A decision by the Program Integration Committee to defer a decision to include a Grant Application on the prioritized list of Grant Applications submitted to the Oversight Committee until a future meeting of the Program Integration Committee, subject to subsection (k).

(g) The Chief Compliance Officer shall attend and observe Program Integration Committee meetings to document compliance with Chapter 102, Texas Health and Safety Code and the Institute's administrative rules.

(h) At the time that the Program Integration Committee's final Grant Award recommendations are formally submitted to the Oversight Committee, the Chief Executive Officer shall prepare a written affidavit for each Grant Application recommended by the Program Integration Committee containing relevant information related to the Grant Application recommendation.

(1) Information to be provided in the Chief Executive Officer's affidavit may include:

(A) The Peer Review process for the recommended Grant Application, including:

(i) The Request for Applications applicable to the Grant Application;

(ii) The number of Grant Applications submitted in response to the Request for Applications;

(iii) The name of the Peer Review Panel reviewing the Grant Application;

(iv) Whether a preliminary review process was used by the Peer Review Panel for the Grant Mechanism in the Grant Review Cycle;

(v) An overview of the Conflict of Interest process applicable to the Grant Review Cycle noting any waivers granted; and

(vi) A list of all final Overall Evaluation Scores for all Grant Applications submitted pursuant to the same Grant Mechanism, de-identified by Grant Applicant;

(B) The final Overall Evaluation Score and Numerical Ranking Score assigned for the Grant Applications recommended during the Peer Review process; and

(C) A high-level summary of the business operations and management due diligence and intellectual property reviews, if applicable, conducted for a Cancer Research Product Development Grant Application.

(2) In the event that the Program Integration Committee's final Grant Award recommendations are not unanimous and the Program Integration Committee Member or Members in the non-majority recommend Grant Applications not included on the final list of Grant Award recommendations, then the Chief Executive Officer shall also prepare a written affidavit for each Grant Application recommended by the non-majority Program Integration Committee Member or Members.

(i) To the extent that the information or documentation for one Grant Application is the same for all Grant Applications recommended for Grant Award funding pursuant to the same Grant Mechanism, it shall be sufficient for the Chief Executive Officer to provide the information or documentation once and incorporate by reference in each subsequent affidavit.

(j) At least three business days prior to the Oversight Committee meeting held to consider the Grant Applications for Grant Award funding, the Chief Executive Officer shall provide a list of Grant Applications, if any, recommended for an advance of Grant Award funds upon execution of the Grant Contract. The list shall include the reasons supporting the recommendation to advance funds.

(k) The Program Integration Committee's decision to defer the final Grant Award recommendation for a Grant Application is only effective for the state fiscal year in which the Program Integration Committee's deferral decision is made.

(1) A Grant Application that is deferred by the Program Integration Committee and is pending a final Grant Award recommendation at the end of the state fiscal year shall be considered not

recommended for a Grant Award without further action from the Program Integration Committee.

(2) A Grant Application that is deferred and pending a final Grant Award recommendation at the end of the state fiscal year may be resubmitted by the Grant Applicant in a subsequent review cycle. Such resubmission will not count against the resubmission limit, if any, stated in the Request for Applications.

§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 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 of funding specified in the Award Contract. For the purpose of this subsection, a Grant Progress Report submitted at the completion of a 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 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.

§703.25.Grant Award Budget.

(a) The Grant Contract shall include an Approved Budget that reflects the amount of the Grant Award funds to be spent for each Project Year.

(b) All expenses charged to a Grant Award must be budgeted and reported in the appropriate budget category.

(c) Actual expenditures under each category should not exceed budgeted amounts authorized by the Grant Contract as reflected on the Approved Budget for each Grant Award.

(d) Recipients may make transfers between or among lines within budget categories listed on the Approved Budget so long as the transfer fits within the Scope of Work and the total Approved Budget; is beneficial to the achievement of the Scope of Work; and is an efficient, effective use of Grant Award funds.

(e) Except as provided herein, all budget changes or transfers require Institute approval.

(1) The Grant Recipient may make budget changes or transfers without prior approval from the Institute for expenses not specified in the equipment category if:

(A) The total dollar amount of all changes of any single line item (individually and in the aggregate) within budget categories other than equipment is 10% or less of the total budget for the applicant grant year;

(B) The transfer will not increase or decrease the total grant budget; and

(C) The transfer will not materially change the nature, performance level, or Scope of Work.

(2) The Institute may reverse one or more budget changes or transfers under paragraph (1) of this subsection if the Institute determines that the Grant Recipient made multiple individual budget changes or transfers within the same category that, if considered together, would require Institute approval.

(f) A Grant Recipient awarded a Grant Award for a multiyear project that fails to expend the total Project Year budget may carry forward the unexpended budget balance to the next Project Year.

(1) If the amount of the unexpended balance for a budget line item in a Project Year exceeds twenty-five percent (25%) or more of the total budget line item amount for that year, Institute approval is required before the Grant Recipient may carry forward the unexpended balance to the next Project Year.

(2) For a budget carry forward requiring Institute approval, the Grant Recipient must provide justification for why the total Grant Award amount should not be reduced by the unexpended balance.

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:	CHAPTER 701 - PROPOSED RULE CHANGES
DATE:	AUGUST 4, 2023

Summary and Recommendation

The Board Governance Subcommittee convened August 3 to discuss the suggested rule changes to Texas Administrative Code § 701.25. 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 November 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 August 3 to discuss the proposed rule changes to Texas Administrative Code § 701.25 related to CPRIT's electronic signature policy that is available currently to grant recipients. The amendment proposes that the convenience and responsibilities associated with electronic signatures be available to grant applicants as well. The subcommittee voted to recommend that the Oversight Committee approve publication of the following 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.

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

CPRIT legal staff will summarize any comments received from the public for the Oversight Committee's consideration when approving the final rule changes in November.

The Cancer Prevention and Research Institute of Texas ("CPRIT" or "the Institute") proposes amending 25 Tex. Admin. Code § 701.25 relating to the applicability of CPRIT's electronic signature policy.

Background and Justification

CPRIT's electronic policy explicitly applies to Grant Recipients that use the Institute's electronic Grant Managements System (CGMS). The policy allows CPRIT to rely on information submitted by a Grant Recipient's Authorized Signing Official (ASO) as legally binding. An ASO is the designated representative of the applicant and/or grant organization with the authority to act on the organization's behalf in matters related to the application for and administration of a CPRIT grant award.

The proposed amendment expands the electronic signature policy to explicitly include Grant Applicants and ASOs who submit applications through CPRIT's electronic Application Receipt System (CARS). A Grant Applicant must create a user account in CARS before an application may be submitted to the Institute. As part of the registration process, a Grant Applicant is required to designate an ASO individual at the institution or organization with the authority to approve the submission of the grant application.

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 clarifying grantee reporting obligations and consequences.

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 October 2, 2023. 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>

§701.25.Electronic Signature Policy.

A Grant Recipient's use of the Institute's electronic Grant Management System or a Grant Applicant's use of the Institute's electronic Application Receipt System to create, exchange, execute, submit, and verify legally binding Grant Contract documents and Grant Award reports or a Grant Application shall be pursuant to an agreement between the Institute and the Grant Recipient or Grant Applicant regarding the use of binding electronic signatures. Such agreement shall include at least the following minimum standards:

(1) The Grant Recipient or Grant Applicant agrees that by entering the Authorized Signing Official's password in the electronic Grant Management System or Application Receipt System at certain specified points, the Grant Recipient or Grant Applicant electronically signs the Grant Contract document or related form or Grant Application. The Grant Recipient or Grant Applicant further agrees that the electronic signature is the legal equivalent of the Authorized Signing Official's manual signature.

(2) The Institute may rely upon the electronic signature rendered by entering the Authorized Signing Official's password as evidence that the Grant Recipient or Grant Applicant consents to be legally bound by the terms and conditions of the Grant Contract or related form or Grant Application as if the document was manually signed.

(3) The Grant Recipient or Grant Applicant shall provide prompt written notification to the Institute of any changes regarding the status or authority of the individual(s) designated by the Grant Recipient or Grant Applicant to be the Grant Recipient's or Grant Applicant's Authorized Signing Official. The notice must be provided to an individual designated by the Institute.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	HEIDI MCCONNELL, CHIEF OPERATING OFFICER
SUBJECT:	CHIEF OPERATING OFFICER REPORT
DATE:	AUGUST 1, 2023

CPRIT Financial Overview for FY 2023, Quarter 3

FY 2023, Quarter 3 Operating Budget

In the third quarter of FY 2023, CPRIT has encumbered or expended 63% of the $5.2 million Indirect Administration budget and 95% of the $16.2 million Grant Review and Award Operations budget. The Grant Review and Award Operations budget includes the majority of the agency's vendor contracts which support grant award and administration, including the $9.9 million contract for grant management support services with GDIT.

CPRIT received $20,731 in revenue sharing payments during the third quarter. Total revenue sharing payment deposits from CPRIT's inception equaled almost $9.3 million through the end of May 2023.

FY 2023, Quarter 3 Performance Measure Report

In the third quarter, CPRIT reported to the Legislative Budget Board a total of 251,237 people served through CPRIT prevention and control grants, with a total of 627,887 served through the year to date.

There was no company relocation. However, CPRIT already met the performance target of one completed relocation in the second quarter.

Debt Issuance History

The Texas Public Finance Authority (TPFA) issued $79 million in commercial paper notes on CPRIT's behalf in April 2023 bringing the total commercial paper notes issued through the end of the third quarter to $224.5 million. By the end of FY 2023, $298.3 million of bond proceeds will be issued.

2023 CPRIT Innovations VI Conference Update

There are more than 400 conference registrations including 287 paid general, 13 paid advocate, and 107 paid student registrants. Approximately 55% of the registrants are CPRIT grantees. The regular registration rates ended July 31, and late registration rates are in effect. Two reminders about this pricing change were sent to the CPRIT listserv on July 5, 2023, and July 24, 2023, along with reminders about abstract submission and conference sponsor and exhibit opportunities.

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To date, the sponsor and exhibitor commitments include:

- Scorpius BioManufacturing—Day 1 conference lunch sponsor
- Levitas Bio—Exhibitor
- Collaborative Drug Discovery—Exhibitor
- Agilent Technologies, Inc.—Exhibitor
- The Greater Houston Partnership—Exhibitor
- Metabolon—Exhibitor
- Shimadzu Scientific Instruments—Exhibitor
- H2Ocean—Exhibitor

Cancer Prevention and Research Institute of Texas
Quarterly Financial Report
As of May 31, 2023

Indirect Administration (B.1.1.)

		2023 Appropriated	2023 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	$ 1,842,388		$ 1,275,430	566,958	69%	$ 1,275,430	$ 566,958
1002	Other Personnel Costs	38,785	41,036		41,036	0	100%	41,036	0
2001	Professional Fees and Services	1,038,960	1,206,500		1,199,845	6,655	99%	1,199,845	6,655
2003	Consumable Supplies	24,000	24,000		3,373	20,627	14%	3,373	20,627
2004	Utilities	58,600	58,600		24,600	34,000	42%	24,600	34,000
2005	Travel	45,000	45,000		36,625	8,375	81%	36,625	8,375
2006	Rent-Building	11,000	11,000		3,099	7,901	0%	3,099	7,901
2007	Rent-Machine and Other	39,172	39,172		19,743	19,429	50%	19,743	19,429
2009	Other Operating Expenses	1,807,951	1,906,951		658,736	1,248,215	35%	658,736	1,248,215
	Subtotal - Indirect Administration (B.1.1.)	**$ 4,910,893**	**$ 5,174,647**	**1.74%**	**$ 3,262,487**	**$ 1,912,160**	**63%**	**$ 3,262,487**	**$ 1,912,160**

Grant Review and Award Operations (A.1.3.)

		2023 Appropriated	2023 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	3,291,812		$ 2,957,140	$ 334,672	90%	$ 2,957,140	$ 334,672
1002	Other Personnel Costs	45,000	97,555		97,555	(0)	0%	97,555	(0)
2001	Professional Fees and Services	12,420,663	12,582,169		12,278,317	303,852	98%	12,278,317	303,852
2003	Consumable Supplies	-	-		-	-	0%	-	-
2004	Utilities	12,000	14,665		14,665	0	100%	14,665	0
2005	Travel	45,000	45,000		19,877	25,123	44%	19,877	25,123
2009	Other Operating Expenses	70,359	166,921		21,387	145,534	13%	21,387	145,534
	Subtotal - Grant Operations (A.1.3.)	**$ 16,098,895**	**$ 16,198,122**	**5.45%**	**$ 15,388,941**	**$ 809,181**	**95%**	**$ 15,388,941**	**$ 809,181**

Grants

		2023 Appropriated	2023 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	$ 27,718,402		$ 13,577,257	$ 14,141,145	49%	$ 13,577,257	$ 14,141,145
4000	Grants - Research (A.1.1.)	248,251,400	$ 248,251,400		136,056,352	$ 112,195,048	55%	136,056,352	112,195,048
	Subtotal - Grants	**$ 275,923,180**	**$ 275,969,802**	**92.81%**	**$ 149,633,609**	**$ 126,336,193**	**54%**	**$ 149,633,609**	**$ 126,336,193**
	Grand Totals	**$ 296,932,968**	**$ 297,342,571**	**100.00%**	**$ 168,285,037**	**$ 129,057,534**	**57%**	**$ 168,285,037**	**$ 129,057,534**

Cancer Prevention and Research Institute of Texas

Cancer Prevention and Research Institute Fund Account - 5136

As of May 31, 2023

	05/01/2023-05/31/2023	AY 21 Year to Date as of 05/31/2023
Beginning Balance : 9/01/2022		**$ 600,506**
Increases:		
(1)	$ -	$ -
(2)	-	
Total Increases	**$ -**	**$ 600,506.00**
Reductions:		
Expenditures - Appropriated	$ -	$ -
	$ -	$ -
	$ -	$ -
Total Reductions	**$ -**	**$ -**
Ending Balance: 05/31/2023		**$ 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 May 31, 2023

		05/01/2023-05/31/2023	AY 21 Year to Date as of 05/31/2023
Beginning Balance : 9/01/2022			**$ 46,621.77**
Increases:			
(1)	License Plate Revenue Received	$ 504.16	$ 4,773.93
	Interest	$ 171.91	$ 1,191.85
Total Increases		**$ 676.07**	**$ 52,587.55**
Reductions:			
	Expenditures - Appropriated	$ -	$ -
		-	-
Total Reductions		**$ -**	**$ -**
Ending Balance: 05/31/2023			**$ 52,587.55**

Note:

Balance forward from 2022 License Plate $46,621.77

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Cancer Prevention and Research Institute of Texas

Appropriated Receipts - 666

As of May 31, 2023

		05/01/2023-05/31/2023	AY 21 Year to Date as of 05/31/2023
Beginning Balance : 9/01/2022			**$ 34,246.90**
Increases:			
(1)	Product Development Application Fees Received	$ -	$ 6,500.00
(2)	Conference Registration Fees	$ 46,300.00	$ 63,500.00
(3)	Conference Registration Fees-Credit Card	$ 1,069.67	$ 1,480.01
Total Increases		**$ 47,369.67**	**$ 71,480.01**
Reductions:			
	Conference Expenditures - Appropriated	$ -	$ -
	Credit Card Fees Expended	$ -	$ -
	Refund-Application Fees	$ -	$ -
	Legal Services Expenses (Application Fees)	$ -	$ -
Total Reductions		**$ -**	**$ -**
Ending Balance: 05/31/2023			**$ 105,726.91**

Forward balance for FY 2022 is $34,246.90
Application Fees

Cancer Prevention and Research Institute of Texas
Interest & Sinking Fund Account - 5168
As of May 31, 2023

		05/01/2023-05/31/2023	AY 21 Year to Date as of 05/31/2023
Beginning Balance : 9/01/2022			**$ 4,467,549.58**
Increases:			
(1)	Revenue Sharing / Royalties	$ 260,510.91	$ 1,533,612.94
		$ -	
Total Increases		**$ 260,510.91**	**$ 6,001,162.52**
Reductions:			
	Expenditures - Appropriated	$ -	$ -
		$ -	
		$ -	$ -
Total Reductions		**$ -**	**$ -**
Ending Balance: 05/31/2023			**$ 6,001,162.52**

Balance forward from FY 2022 is $4,467,549.58

Cancer Prevention and Research Institute of Texas
FY 2023, Quarter 3 Performance Measure Report

Measure	Targeted Performance	QTR 1	QTR 2	QTR 3	QTR 4	Sum of QTRs	% of Mandate Attained
Number of People Served by Institute Funded Prevention and Control Activities	700,000	208,532	168,118	251,237	-	627,887	89.70%
Number of Entities Relocating to TX for Cancer Research Related Projects	1	0	1	0	-	1	100.00%
Annual Age-adjusted Cancer Mortality Rate	141.0	N/A	N/A	N/A	N/A	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 People Served by Institute Funded Prevention and Control Activities
CPRIT prevention grantees have continued to be successful at delivering cancer prevention education and clinical services to more people than they anticipated, stretching their CPRIT-grant funds further to serve Texans. They have resumed providing cancer prevention clinical services, such as mammograms and colonoscopies, following COVID-19 precautions which include the use of COVID-19 tests and extra safety precautions.

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%
		March 2, 2023	$ 66,000,000		Commercial Paper Notes	Series A, Taxable		Interest rate of 4.80%
		April 6, 2023	$ 79,000,000		Commercial Paper Notes	Series A, Taxable		Interest rate of 5.10%
				$ 224,500,000				
TOTAL ISSUED TO DATE				**$ 2,737,900,000**				

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	HEIDI MCCONNELL, CHIEF OPERATING OFFICER
SUBJECT:	FY 2024 SERVICE CONTRACT AND CONTRACT RENEWAL APPROVAL
DATE:	AUGUST 1, 2023

Recommendation

CPRIT staff recommends the Oversight Committee approve an FY 2024 with The Perryman Group for $195,000 to perform an economic assessment of the cost of cancer in Texas.

In addition, CPRIT staff recommends the Oversight Committee approve the following contract renewals for FY 2024 with:

- Alan Boyds Consultants Inc. for $330,000 to perform diligence reviews of product development research grant applications, and
- Business and Financial Management Solutions (BFS) for $121,409 to monitor all peer review meetings.

The contract costs for consideration are not-to-exceed amounts, and payment is based on the delivery of actual services through time and materials expended by the vendor or as a fee for service based on the delivery of a report.

Background

Economic Assessment of the Cost of Cancer in Texas Contract

CPRIT conducted a competitive solicitation request for proposal (RFP) for economic assessment services during summer 2023. CPRIT received one proposal by the solicitation period close on July 21, 2023. In the evaluation of the proposal, CPRIT staff determined that The Perryman Group (TPG) meets the requirements outlined in the RFP and will be able to deliver a final report with the necessary metrics by mid-December when CPRIT requires the information for inclusion in the agency's statutorily required annual report. TPG is the incumbent vendor.

The report produced by TPG provides CPRIT with the:

- statutorily required measurement of the cost of cancer in Texas;
- measurement of key economic performance indicators based on CPRIT funding and program impact; and

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- estimates of the economic impact to Texas if CPRIT were not to exist and no additional funding is provided beyond the $3 billion in general obligation debt authorized by the Texas Constitution.

Due Diligence Review Services Contract Renewal

Alan Boyds Consultants Inc. (Boyds) provides due diligence review reports which are an evaluation of a product development research grant applicant's business operations and management that covers discovery science capability, preclinical and clinical research capabilities, manufacturing facilities, regulatory approval pathway, management capability, financial viability, and commercial viability. Boyds performs the diligence evaluation on product development grant applications following the completion of peer review evaluation.

Peer Review Monitoring Service Contract Renewal

Business and Financial Management Solutions (BFS) personnel attend every meeting of the three program's review councils and peer review panels. Following the conclusion of each meeting BFS provides a written summary to the Chief Compliance Officer of their observations of:

- the meetings following CPRIT's established procedure for panelists who have declared a conflict of interest (e.g., reviewers leave a videoconference);
- CPRIT program staff participation at meetings being limited to offering general points of information when asked by peer review panel members;
- CPRIT program staff not engaging in the panel's discussion on the merits of applications; and
- the peer review panel discussion being focused on the established scoring criteria and/or making grant award recommendations.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: MARK DALLAS LOEFFLER
SUBJECT: COMMUNICATIONS UPDATE
DATE: AUGUST 7, 2022

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

CPRIT Annual Report Kickoff

The communications team initiated the FY 2023 Annual Report process. CPRIT will publish the report online in January 2024.

Texas Tech University Health Sciences Center El Paso visit

We partnered with Texas Tech University Health Sciences Center El Paso (TTUHSC) to highlight the recent CPRIT TREC award during a visit on July 28. TTUHSC held a media event at its administration building, which several local media outlets attended. Prior to the press conference, Dr. Rajkumar Lakshmanaswamy led the CPRIT team on a tour of the TTUHSC laboratory facility and the Texas Tech Dental Oral Health Clinic Dental Clinic Building.

Peer Review Training Video

We worked with the product development team to create a new training video for the product development peer reviewers. Peer reviewers may view the webinar online through the agency YouTube platform.

CPRIT Conference

The communications team continued work on the upcoming CPRIT Innovations VI conference, including expanding the sponsorship and exhibitor options, acquiring speaker bios and photos, revising the abstract submission information, and updating the website. We also assisted with naming and award selection of upcoming conference awards.

PDR Work

We are assisting the product development team on a *Texas Life Science Resource Guide* for use by bioscience companies, including CPRIT grant applicants and grantees. The guide will feature information related to investors, service providers, and other resources.

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We also updated the product development company portfolio on CPRIT website to include recent grantees and to provide additional information regarding company name changes and acquisitions.

BIO Boston Materials

The communications team created educational materials for CPRIT's presence at the BIO International Convention in Boston (June 3 - 6). Materials included flyers and a standee soliciting peer reviewers for the product development program.

Direct Communication

The communications team distributed listserv notifications regarding CPRIT's academic research cycle 24.1 Recruitment RFAs, CPRIT conference reminders (registration and abstract submission), proposed changes to agency rules, and the updated *CPRIT Grant Policies and Procedures Guide*.

Media Relations

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

- Media advisory (May 15, 2023): CPRIT to meet Wednesday on $73 million of new cancer research grants
- Press release (May 17, 2023): CPRIT awards more than $73 million to Texas in the fight against cancer
- Media advisory (July 21, 2023): CPRIT to visit TTUHSC in El Paso to spotlight major new state cancer research grant
- Press release (July 28, 2023): CPRIT visits Texas Tech El Paso to spotlight major new state cancer research grant

In addition, we coordinated a television news interview for the May 17 Oversight Committee meeting that aired twice in the Austin market and interviews with El Paso television and print media regarding the TTUHSC press conference.

Newsclips
We shared 567 articles and social media posts through CPRIT ENews from May 8 - August 4.

Social Media Statistics
Social Media from May 8, 2023 – August 4, 2023

Facebook	Twitter	LinkedIn
5.25% post engagement rate	**2.58%** engagement rate	**5.03%** engagement rate
1,248 Fans (**+15**)	**3,491** followers (**+18**)	**2,900** followers (**+167**)

Top Post: **17.31%** engagement (7/28)	Top Tweet: **2,751** impressions (5/17)	Top Post: **2,907** impressions (5/17)

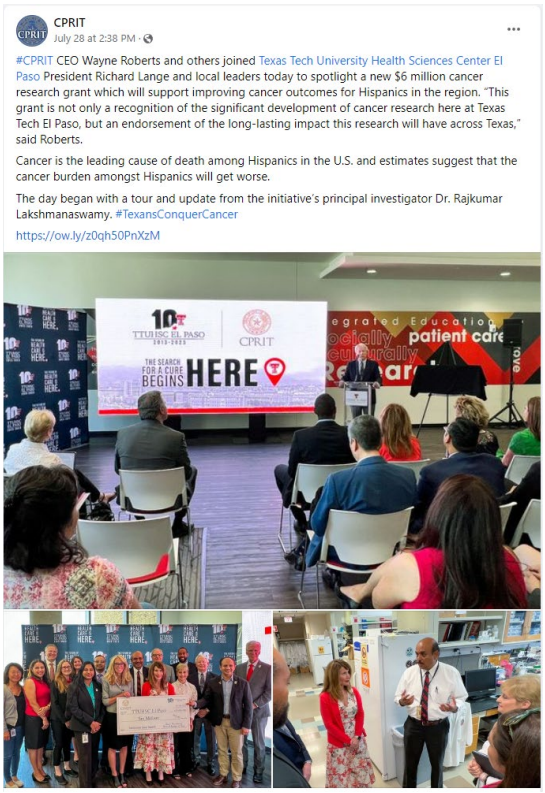
Website Hits and Visitors May 8 to August 4, 2023

Users	New Users	Sessions (Visits)	Pageviews	Pages / Session
18,810	**17,905**	**33,109**	**62,962**	**0.92**

Top Performing Posts

FACEBOOK: 7/28

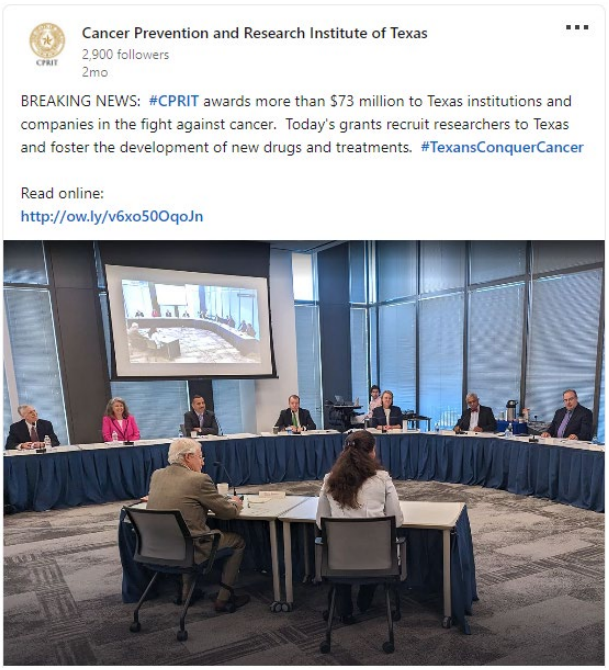
#CPRIT CEO Wayne Roberts and others joined Texas Tech University Health Sciences Center El Paso President Richard Lange and local leaders today to spotlight a new $6 million cancer research grant which will support improving cancer outcomes for Hispanics in the region. “This grant is not only a recognition of the significant development of cancer research here at Texas Tech El Paso, but an endorsement of the long-lasting impact this research will have across Texas,” said Roberts. Cancer is the leading cause of death among Hispanics in the U.S. and estimates suggest that the cancer burden amongst Hispanics will get worse. The day began with a tour and update from the initiative’s principal investigator Dr. Rajkumar Lakshmanaswamy. #TexansConquerCancer https://ow.ly/z0qh50PnXzM



TWITTER: 2/15

BREAKING NEWS: #CPRIT awards more than $73 million to Texas institutions and companies in the fight against cancer. Today's grants recruit researchers to Texas and foster the development of new drugs and treatments. #TexansConquerCancer

LINKEDIN:



BREAKING NEWS: #CPRIT awards more than $73 million to Texas institutions and companies in the fight against cancer. Today's grants recruit researchers to Texas and foster the development of new drugs and treatments. #TexansConquerCancer Read online: http://ow.ly/v6xo50OqoJn

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE

FROM: MAHENDRA PATEL, M.D., PRESIDING OFFICER

SUBJECT: FY 2024 – 2025 PROPOSED SUBCOMMITTEE ASSIGNMENTS

DATE: AUGUST 8, 2023

The Oversight Committee votes to revise subcommittee assignments at its last meeting of the fiscal year in every odd-number year. CPRIT staff solicited members' preference last month. The new assignments reflect expressed preferences and balance the workload among members. The Board Governance subcommittee met August 3 to review the proposed appointments and recommends that the Oversight Committee approve the new assignments.

2024-2025 Assignments	Audit	Board Gov	Prevention	Academic Research	Product Dev	Contract	Special Issues
Cummings	X		X			X	X
Hernandez		X	X				
Margo		X	X				X
Montgomery		X		X		X	X
Patel	X			X			
Payne	X				X	X	
Rice	X			X	X		X
Rosenfeld		X			X		

X denotes proposed subcommittee chairs; the Contract and Special Issues subcommittees will meet as needed

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CANCER PREVENTION & RESEARCH
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MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	MAHENDRA PATEL, M.D., PRESIDING OFFICER
SUBJECT:	FY 2024 – 2025 CPRIT OVERSIGHT COMMITTEE OFFICERS
DATE:	AUGUST 9, 2023

Oversight Committee bylaws require that the members elect a new presiding officer, vice presiding officer and secretary for two-year terms. The election takes place at the last Oversight Committee meeting of the fiscal year in every odd-numbered year. As the outgoing presiding officer, I work with the Board Governance subcommittee to assemble and propose a slate of candidates for Oversight Committee consideration.

The Board Governance subcommittee and I have reviewed the proposed slate of officer candidates, listed below, to lead the Oversight Committee for fiscal years 2024 and 2025. The three potential officer candidates are interested and willing to serve. I recommend that the Oversight Committee vote to approve this highly qualified slate of officers.

Proposed Officers for FY 2024 – 2025

- David Cummings, M.D., Presiding Officer
- Cindy Barberio Payne, Vice Presiding Officer
- Ambrosio Hernandez, M.D., Secretary

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Cancer Prevention & Research Institute of Texas

Oversight Committee Meetings and Standing Subcommittees Meetings FY 2024

November 2023

Sun	Monday	Tuesday	Wednesday	Thursday	Friday	Sat
			1 PIC Meeting CPRIT Staff Only	2 Board Governance	3 Portal Opens Geographic Diversity Advisory	4
5	6 Audit	7 Prevention	8 Academic Research	9 Product Development	10	11
12	13	14	**15 Oversight Committee Meeting**	16	17	18

February 2024

Sun	Monday	Tuesday	Wednesday	Thursday	Friday	Sat
4	5	6	7 PIC Meeting CPRIT Staff Only	8 Board Governance	9 Portal Opens Geographic Diversity Advisory	10
11	12 Audit	13 Prevention	14 Academic Research	15 Product Development	16	17
18	19	20	**21 Oversight Committee Meeting**	22	23	24

May 2024

Sun	Monday	Tuesday	Wednesday	Thursday	Friday	Sat
			1 PIC Meeting CPRIT Staff Only	2 Board Governance	3 Portal Opens Geographic Diversity Advisory	4
5	6 Audit	7 Prevention	8 Academic Research	9 Product Development	10	11
12	13	14	**15 Oversight Committee Meeting**	16	17	18

August 2024

Sun	Monday	Tuesday	Wednesday	Thursday	Friday	Sat
4	5	6	7 PIC Meeting CPRIT Staff Only	8 Board Governance	9 Portal Opens Geographic Diversity Advisory	10
11	12 Audit	13 Prevention	14 Academic Research	15 Product Development	16	17
18	19	20	**21 Oversight Committee Meeting**	22	23	24

Note: Unless the subcommittee members agree to a different time, all subcommittee meetings will begin at 10:00 a.m. Members of the Audit and Program subcommittees should allocate 1.5 hours for a meeting. All others subcommittee meetings require one hour.