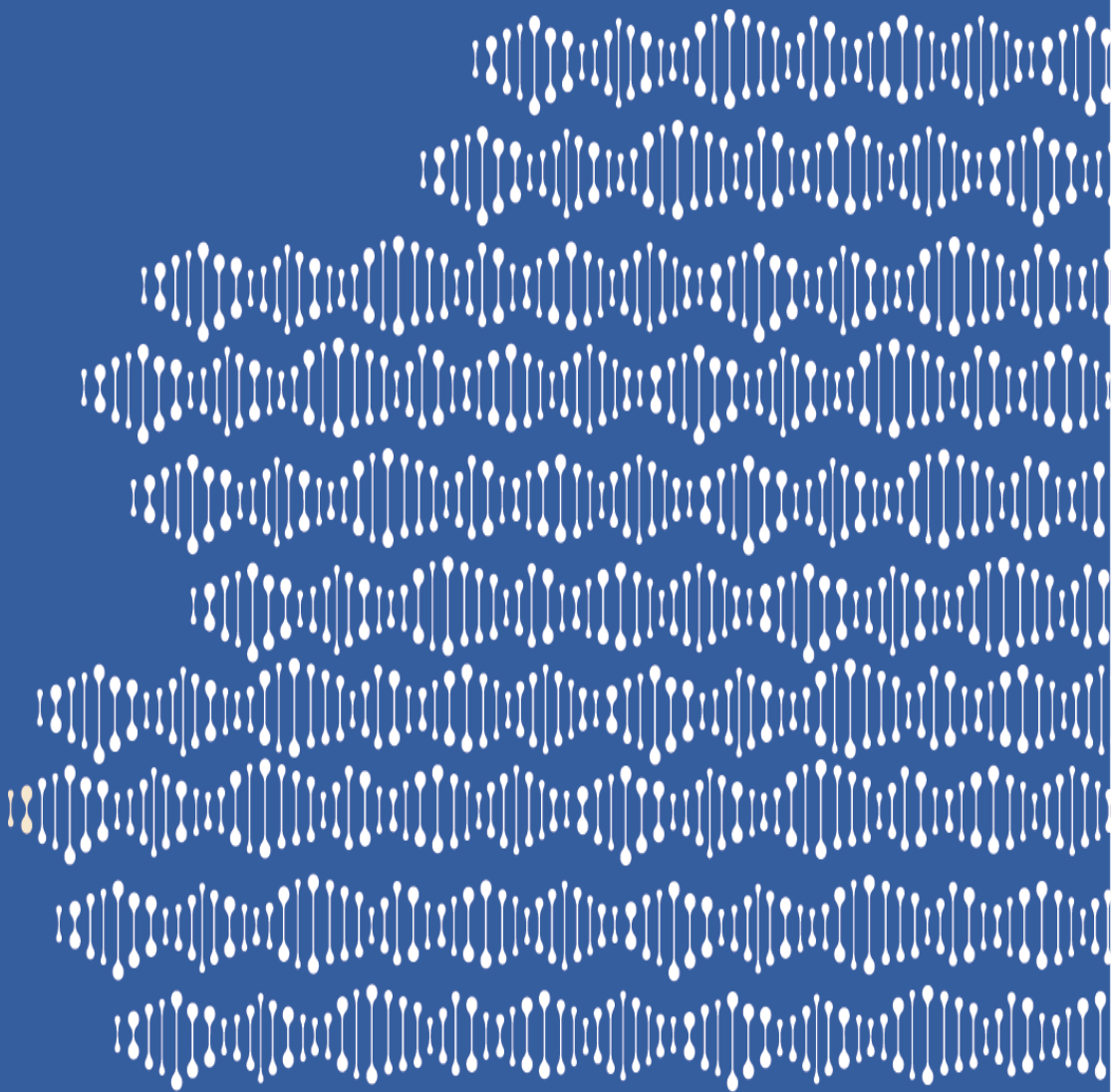
CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Meeting

May 17, 2023



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Summary Overview of the May 17, 2023, Oversight Committee Meeting

This summary provides an overview of major agenda items and background on key issues for Committee consideration at the May 17, 2023, Oversight Committee meeting.

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

Chief Compliance Officer Report
Vince Burgess will report on the status of required grantee reports, financial status report reviews, desk reviews, site visits, annual compliance attestation, audit tracking, and training. He will also certify that the proposed awards and review process for the academic research and product development 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) recruitment award recommendations. She will also present FY 2024 requests for applications for approval.

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

Chief Prevention Officer Report
Ramona Magid will update the Oversight Committee on the on the Prevention Program.

Chief Product Development Officer Report
Dr. Ken Smith will provide an update on the Product Development Research Program and will present the PIC's product development award recommendations.

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

Internal Auditor Report
Weaver and Tidwell, CPRIT's internal auditor, will provide an internal audit update and present the Contract Risk Assessment Model Advisory Audit Report, 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 - Scientific Research and Prevention Programs Committee, Clinical Trials Advisory Committee, and Prevention Advisory Committee
Mr. Roberts has provisionally appointed seven new members to CPRIT's Scientific Research and Prevention Programs Committees. Presiding Officer Dr. Patel has appointed a new member for the Oversight Committee's Clinical Trials Advisory Committee and a new appointment to the Prevention Advisory Committee. CPRIT's statute requires the Oversight Committee to finalize the appointments with votes of approval. CPRIT has provided the appointees' biographical sketches for the Oversight Committee's consideration.

Advisory Committee Annual Presentations
Two of the Oversight Committee's six advisory committees – the University Advisory Committee and the Product Development Advisory Committee - will present annual reports and answer Oversight Committee member's questions. (The final two advisory committees will present their annual reports at the August Oversight Committee meeting.)

Proposed Amendments to 25 TAC Chapters 701 and 703
Cameron Eckel will present proposed Chapters 701 and 703administrative rule changes for Oversight Committee consideration and approval to publish in the *Texas Register*.

Fiscal Year 2024 Bond Issuance Resolution

Ms. McConnell will lay out the FY 2024 Bond Issuance Resolution for approval by the Oversight Committee.

Contract Approvals

Ms. McConnell will explain CPRIT's staff recommendation to approve the FY 2024 grant management support services contract.

Chief Operating Officer Report
Heidi McConnell will discuss the operating budget, performance measures, and debt issuance history for the second quarter of FY 2023 as well as provide an update on the CPRIT conference.

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

CANCER PREVENTION & RESEARCH
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Oversight Committee Meeting Agenda

May 17, 2023
9:00 a.m.

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

The Oversight Committee may discuss or act on any item on this agenda, and as authorized by the Texas Open Meetings Act, Texas Government Code Section 551.001 et seq., may meet in closed session concerning any purpose permitted by the Act. If the Oversight Committee meets in closed session, it will do so in the Barbara Jordan Building, Room 2.027.

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

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

1. Call to Order
2. Roll Call/Excused Absences
3. Adoption of Minutes from the February 15, 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
   - FY 2024 Request for Applications
   - Grant Award Recommendations
8. Chief Prevention Officer Report — Tab 5
9. Chief Product Development Officer Report — Tab 6
   - Grant Award Recommendations
10. Internal Auditor Report — Tab 7
    - Contract Risk Assessment Model Advisory Audit Report
    - Internal Audit Report over Information Technology General Controls
11. Scientific Research and Prevention Program Committee Appointments — Tab 8
12. Advisory Committees — Tab 9
    - Appointments
    - University Advisory Committee Presentation
    - Product Development Advisory Committee Presentation

13. Amendments to 25 T.A.C. Chapters 701 and 703 — Tab 10
    - Proposed Amendments to Chapters 701 and 703
14. Chief Operating Officer Report — Tab 11
15. Fiscal Year 2024 Bond Issuance Resolution — Tab 12
16. Contract Approvals — Tab 13
    - Grant Management Support Services
17. Communications Report — Tab 14
18. Subcommittee Business
19. Compliance Investigation Pursuant to Health & Safety Code § 102.2631
20. Consultation with General Counsel
21. Future Meeting Dates and Agenda Items
22. Adjourn

CANCER PREVENTION & RESEARCH
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Oversight Committee Meeting Minutes
February 15, 2023

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

Call to Order – Agenda Item 1

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

Roll Call/Excused Absences – Agenda Item 2

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

Presiding Officer Dr. Patel noted for the record that Dr. Cummings and Dr. Rice are participating in the meeting via videoconference.

Adoption of Minutes from the November 16, 2022, Meeting – Agenda Item 3, Tab 1

MOTION:
On a motion by Mr. Margo and seconded by Mr. Montgomery, the Oversight Committee voted unanimously to approve the minutes of the November 16, 2022, Oversight Committee meeting as presented.

Public Comment – Agenda Item 4

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

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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 announced that CPRIT received a donation from Travis County ESD #12. He acknowledged Kassidy Buth, the department's Public Information Officer, who attended the meeting on behalf of Travis County ESD #12.

He reported the amount of grant funds available for the remainder of FY2023 and noted that each of the three programs is fully subscribed for this fiscal year. He also introduced new personnel and notified members that CPRIT has filled 42 FTEs and is in the process of hiring a technical writer and compliance specialist.

Mr. Roberts noted the release of the Fiscal Year 2022 CPRIT Annual Report on January 31. He thanked CPRIT staff for their contributions and recognized Mark Loeffler, Justin Rand, Kristen Doyle, Bridget Barstow, and the CPRIT IT team for their work to write and design the report.

Mr. Roberts informed members that he testified before Senate Finance on January 30 and will appear before the House Appropriations Subcommittee on Articles I, IV, & V on February 21.

He concluded his presentation with the CEO FY 2022 report on the progress and continued merit of each research program, as required by Texas Health and Safety Code § 102.260(c). He referred to his written report behind Tab 2, which provides an overview of the progress made in advancing CPRIT's mission to create and expedite innovation in cancer research and cancer prevention in FY 2022.

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 to present the Compliance Report and Compliance Certification of Grant Award Process.

Mr. Burgess directed the oversight committee members to tab three of the meeting book and presented the report for the past quarter's compliance activities.

An Oversight Committee member asked how CPRIT addresses repeat findings in the compliance review process. Mr. Burgess explained that the compliance team incorporates repeat findings into the compliance monitoring review process for appropriate follow up.

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

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

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

Dr. Le Beau directed Oversight Committee members to Table 1 on page 4 of the Proposed Grant Awards Book, which displayed the Scientific Review Council (SRC) and Program Integration Committee (PIC) recommendations for the FY2023 review cycle 1 and recruitment cycles 23.2 and 23.3. Dr. Le Beau noted that one recruitment application withdrew from consideration after the PIC meeting. She recommended that the Oversight Committee approve 39 awards and award funding of $75,134,078 and defer action on IIRA applications recommended by the SRC with overall scores of 2.8 and higher.

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

Recommended Individual Investigator Research Awards (IIRA) FY23.1

Rank	Grant ID	Award	Score	Application Title	PI	Organization	Budget
1	RP230026	IIRA-CCA	**1.0**	Identifying Clinical Methotrexate Toxicity Phenotypes Across Phases of Pediatric Leukemia Therapy	Bernhardt, Melanie	Baylor College of Medicine	$1,392,407
2	RP230036	IIRA-PED	**1.0**	Geospatial Approaches to Melanoma Early Detection: The GAMED Project	Nelson, Kelly	The University of Texas M. D. Anderson Cancer Center	$1,998,196
3	RP230222	IIRA	**1.1**	Personalized Auricular Point Acupressure to Self-Manage Cancer-Related Pain	Yeh, Chao Hsing	The University of Texas Health Science Center at Houston	$1,046,680
4	RP230140	IIRA	**1.1**	Changes in Tumor Microenvironment That Promote Cachexia	Infante, Rodney	The University of Texas Southwestern Medical Center	$1,050,000
5	RP230093	IIRA	**1.8**	Targeting the Mlc1-GlialCAM Protein Complex in Invasive Glioma Cells	McCarty, Joseph	The University of Texas M. D. Anderson Cancer Center	$1,050,000
6	RP230018	IIRA-CCA	**1.9**	Neuronal Alterations in the Midbrain Dopaminergic System Function: A Novel Mechanism of Radiation-Induced Cognitive Dysfunction	Zhang, Die	The University of Texas M. D. Anderson Cancer Center	$1,399,730
7	RP230117	IIRA-PED	**1.9**	Randomized Controlled Trial to Assess Innovative Smoking Cessation Services for Young Adults in Texas	Chalela, Patricia	The University of Texas Health Science Center at San Antonio	$1,992,330
8	RP230072	IIRA	**1.9**	Studying and Therapeutically Targeting Ferroptosis Liability in BRCA1-Deficient Cancer	Gan, Boyi	The University of Texas M. D. Anderson Cancer Center	$1,050,000

Rank	Grant ID	Award	Score	Application Title	PI	Organization	Budget
9	RP230360	IIRA	**1.9**	Rational Design, Synthesis, and Biological Evaluation of Simplified Taccalonolide Analogs for the Treatment of Cancer	Frantz, Douglas	The University of Texas at San Antonio	$1,049,128
10	RP230135	IIRA	**2.0**	Blocking DNA Damage Response Induction of "Don't Eat Me" Signals Converts Local Radiotherapy into Systemic Immunotherapy	Curran, Michael	The University of Texas M. D. Anderson Cancer Center	$1,049,905
11	RP230344	IIRA	**2.0**	Development and Evaluation of Lanosterol Synthase Inhibitors in Preclinical GBM Models	McBrayer, Samuel	The University of Texas Southwestern Medical Center	$1,048,465
12	RP230109	IIRA	**2.0**	Autophagy and Tumor Endothelium	Terada, Lance	The University of Texas Southwestern Medical Center	$1,049,994
13	RP230373	IIRA	**2.0**	Mapping the Geospatial Tumor Clonal Architecture to Restore Immune Recognition in Pancreatic Cancer	Viale, Andrea	The University of Texas M. D. Anderson Cancer Center	$1,049,985
14	RP230224	IIRA	**2.0**	Enhancing Immune Responses in Pancreatic Cancer by Stromal Inhibition of HIF2	Taniguchi, Cullen	The University of Texas M. D. Anderson Cancer Center	$1,049,997
15	RP230382	IIRA	**2.0**	Characterization of 3D Genome Organization and Transcriptional Regulation in Prostate Cancer	Mani, Ram	The University of Texas Southwestern Medical Center	$1,049,641
16	RP230247	IIRA	**2.0**	A Novel Combination Therapeutic Approach to Revitalizing Immunotherapy for Bone Metastatic Prostate Cancer	Lin, Sue-Hwa	The University of Texas M. D. Anderson Cancer Center	$1,050,000
17	RP230063	IIRA-PED	**2.1**	Whole-Genome DNA Methylation Markers for Tracking and Predicting Advanced Liver Fibrosis as a Precursor of Liver Cancer in NAFLD	Tsai, Robert	Texas A&M University System Health Science Center	$2,000,000
18	RP230285	IIRA-CT	**2.2**	Harnessing Endoplasmic Reticulum Stress to Overcome Resistance to Immunotherapy in Immune-Cold Breast Cancer	Chen , Xi	Baylor College of Medicine	$2,000,000
19	RP230160	IIRA-CSBC	**2.2**	Overcoming Therapy Resistance by Integrated Computational Modeling of the Bone Metastatic Niche in Prostate and Renal Cancers	Dondossola , Eleonora	The University of Texas M. D. Anderson Cancer Center	$1,025,623
20	RP230334	IIRA	**2.5**	Elucidating the Mutagenesis Mechanism of BRAF in Melanoma	Lee, Seongmin	The University of Texas at Austin	$1,050,000

Rank	Grant ID	Award	Score	Application Title	PI	Organization	Budget
21	RP230120	IIRA-CCA	**2.5**	Clonal Evolution and Chemoresistance of Hepatoblastomas with Hepatocellular Carcinoma Features	Sumazin, Pavel	Baylor College of Medicine	$1,371,733
22	RP230213	IIRA-PED	**2.6**	Multicomponent Interventions to Improve Uptake and Adherence to Lung Cancer Screening	Volk, Robert	The University of Texas M. D. Anderson Cancer Center	$1,988,211
23	RP230363	IIRA-CSBC	**2.6**	Developing Knowledge-Guided Deep Learning Models to Predict the Binding Between T-Cell Receptors and Neoantigens for Facilitating TCR-T Therapies	Wang, Tao	The University of Texas Southwestern Medical Center	$1,199,997
24	RP230391	IIRA	**2.6**	Understanding and Improving CAR T-Cell Therapy of T-ALL and LBL	Mamonkin, Maksim	Baylor College of Medicine	$1,050,000
25	RP230345	IIRA	**2.6**	The Development of Reversible Chemogenetic Switches for Chimeric Antigen Receptor T-Cell Therapy	Liu, Wenshe	Texas A&M University	$1,050,000
26	RP230166	IIRA-CSBC	**2.6**	Integrative Modeling of Spatially Resolved Multiomics Data to Identify Bladder Cancer Mucosal Field Effects	Wei, Peng	The University of Texas M. D. Anderson Cancer Center	$1,199,994
27	RP230154	IIRA-CCA	**2.6**	Normalizing Membrane Homeostasis in Microglia/Macrophages of Pediatric High-Grade Gliomas	Hu, Jian	The University of Texas M. D. Anderson Cancer Center	$1,400,000
28	RP230271	IIRA	**2.7**	Targeting Distinct Metabolic Vulnerabilities of Aggressive Renal Cell Carcinoma Variants	Zacharias Millward, Niki	The University of Texas M. D. Anderson Cancer Center	$1,019,997
29	RP230330	IIRA-CCA	**2.7**	Integrate Whole-Slide Imaging and Genomic Data to Study Pediatric Rhabdomyosarcoma	Xiao, Guanghua	The University of Texas Southwestern Medical Center	$1,303,815
30	RP230050	IIRA	**2.7**	A Novel Therapeutic Strategy Targeting Pancreatic Cancer	Yao, Wantong	The University of Texas M. D. Anderson Cancer Center	$1,049,854
31	RP230261	IIRA	**2.7**	Investigating the Mechanism of NLRP3 Inflammasome Hyperactivation During Hepatocellular Carcinoma Development	Zhong, Zhenyu	The University of Texas Southwestern Medical Center	$1,049,997

IIRA – Individual Investigator Research Award
IIRA-CCA – Individual Investigator Research Award for Cancer in Children and Adolescents
IIRA-CT – Individual Investigator Research Award for Clinical Translation
IIRA-CSBC – Individual Investigator Research Award for Computational Systems Biology of Cancer
IIRA-PED – Individual Investigator Research Award for Prevention and Early Detection

Recommended Texas Regional Excellence in Cancer (TREC) Awards FY23.1

Rank	Grant ID	Award	Score	Application Title	PI	PI Organization	Budget
1	RP230419	TREC	2.8	South Texas Center of Excellence in Cancer Research (ST-CECR)	Chauhan, Subhash	The University of Texas Rio Grande Valley	$6,000,000
2	RP230420	TREC	2.8	Impacting Cancer Outcomes in Hispanics (ICOHN)	Lakshmanaswamy, Rajkumar	Texas Tech University Health Sciences Center at El Paso	$6,000,000
3	RP230204	TREC	2.8	Gene-Environment: Lifestyle Interactions in Cancer	Ramos, Kenneth	Texas A&M University System Health Science Center	$5,998,422

Recommended Recruitment Awards FY 2023 Cycle 23.4

Rank	Grant ID	Award	Score	Application Title	Candidate	Organization	Budget
1	RR230012	RFTFM	1	First-Time, Tenure-Track: Dr. Kenneth Hu	Kenneth Hu	UT MD Anderson Cancer Center	$2,000,000
2	RR230019	RFTFM	1.6	First-Time, Tenure-Track: Dr. Lu Wang	Lu Wang	UT HSC at San Antonio	$2,000,000
3	RR230020	REI	2.0	Recruitment of Established Investigators, Dr. Hongfang Liu	Hongfang Liu	UT Health Science Center at Houston	$6,000,000
4	RR230018	REI	2.7	Recruitment of Established Investigators, Dr. Rudi Fasan	Rudi Fasan	University of Texas at Dallas	$6,000,000
5	RR230015	RFTFM	2.8	First-Time, Tenure-Track: Dr. Ewan McRae	Ewan McRae	The Methodist Hospital Research Institute	$1,999,977

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

In response to a question from an Oversight Committee member inquiring about the funding status of deferred grant applications, Dr. Le Beau explained that CPRIT could fund the deferred applications before September 1, 2023, if money is available.

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 Dr. Rosenfeld reported a conflict of interest with one academic research application recommended for an award, grant ID number RP230344.

Approval Process – Academic Research Awards

MOTION:
On a motion made by Mr. Margo and seconded by Dr. Hernandez, the Oversight Committee members present and able to vote unanimously approved the PIC's recommendation for an Individual Investigator Research Award for grant application number RP230344**.**

Presiding Officer Dr. Patel noted for the record that Dr. Rosenfeld did not vote.

MOTION:
On a motion made by Mr. Margo and seconded by Mr. Montgomery, the Oversight Committee members voted unanimously to approve the PIC's recommendations for the eight mechanisms: Recruitment of First-Time, Tenure-Track Faculty Members; Recruitment of Established Investigators; the Texas Regional Excellence in Cancer; and Individual Investigator Research Awards, including those specifically awarded for Childhood and Adolescent Cancers, Computational Systems Biology of Cancer, Clinical Translation, and Prevention and Early Detection.

MOTION:
On a motion made by Mr. Montgomery 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 Process – Academic Research Proposed FY 2024 Cycle 1 RFAs

Dr. Le Beau introduced and provided an overview of five proposed FY2024 Cycle 1 (FY24.1) RFAs for Academic Research:

- Individual Investigator Research Awards
- Individual Investigator Research Awards for Computational Systems Biology of Cancer
- Individual Investigator Research Awards for Cancer in Children and Adolescents
- Individual Investigator Research Awards for Prevention and Early Detection
- Individual Investigator Research Awards for Clinical Translation

An Oversight Committee member commended Dr. Le Beau and CPRIT for funding research and researchers at institutions across Texas.

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

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

Presiding Officer Dr. Patel recognized Chief Prevention Officer Ramona Magid to present the prevention program report and award recommendations.

Ms. Magid provided an overview of the eight Prevention awards totaling $13,577,257 recommended by the Program Integration Committee for FY 2023 review cycle 1. Ms. Magid reported that all applications address one or more of the Prevention Program priorities.

Recommended Prevention Program Awards FY 23.1

Grant ID	Mech	Application Title	PD	Organization	Score	Rank	Budget
PP230018	PPC	Implementation and Evaluation of an Evidence-Based Multilevel Lifestyle Intervention for Underserved/Rural Populations in South Texas: Tu Salud ¡Si Cuenta!	Reininger, Belinda	The University of Texas Health Science Center at Houston	2.5	1	$999,254
PP230013	CSD	Community Expansion and Re-engagement for Breast Cancer Screening and Patient Navigation	Argenbright, Keith E	The University of Texas Southwestern Medical Center	2.7	2	$2,500,000
PP230046	CSD	Screen, Treat, or Prevent (STOP) Hepatocellular Cancer-Hepatitis C (HCC-HCV): Expansion to All Adults	Jain, Mamta	The University of Texas Southwestern Medical Center	2.7	3	$2,499,616
PP230033	DI	All for Them Texas: A multifaceted dissemination and implementation approach to increase HPV vaccination	Cucarro, Paula	The University of Texas Health Science Center at Houston	3.0	4	$449,959
PP230002	DI	Taking Texas Tobacco Free: Dissemination to and Implementation within Lung Cancer Screening Programs	Reitzel, Lorraine	University of Houston	3.0	5	$448,726
PP230038	CSD	Salud en Mis Manos (SEMM): An Evidence-Based Breast & Cervical Cancer Early Detection and Prevention Program for Underserved Latinas	Savas, Lara	The University of Texas Health Science Center at Houston	3.1	6	$2,499,492
PP230041	CSD	PP190052 - Integrated lung cancer screening and tobacco cessation in an urban safety-net system	Gerber, David E	The University of Texas Southwestern Medical Center	3.1	7	$1,922,312
PP230043	PPC	School-based Human Papillomavirus Vaccination Program in the Rio Grande Valley: Continuation and Expansion in Hidalgo, Cameron, and Willacy Counties	Rodriguez, Ana	The University of Texas Medical Branch at Galveston	3.2	8	$2,257,898

Primary Prevention of Cancer - PPC
Cancer Screening and Early Detection - CSD
Dissemination of CPRIT-Funded Cancer Control Interventions - DI

In response to an Oversight Committee member's question, Ms. Magid confirmed that the HPV vaccination projects deliver services in public school systems.

An Oversight Committee member inquired about parental permission; Ms. Magid clarified that

HPV vaccinations require written parental consent.

Compliance Certification

Presiding Officer Dr. Patel reminded members that Mr. Burgess previously certified compliance of the prevention 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 of the proposed prevention awards.

Approval Process – Prevention Awards

MOTION:
On a motion made by Mr. Montgomery and seconded by Mr. Margo, the Oversight Committee members voted unanimously to approve the PIC's eight recommendations for the following mechanisms: Cancer Screening and Early Detection, Dissemination of CPRIT-Funded Cancer Control Interventions; and Primary Prevention of Cancer.

MOTION:
On a motion made by Mr. Montgomery 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 Process – Proposed Prevention RFAs for FY 2024 Cycle 1

Ms. Magid introduced and provided an overview of four proposed Prevention RFAs for FY 2024 Cycle 1:

- Dissemination of CPRIT- funded Cancer Prevention and Control Interventions
- Primary Prevention of Cancer
- Screening and Early Detection
- Colorectal Cancer Screening Coordinating Center

MOTION:
On a motion made by Mr. Montgomery and seconded by Mr. Margo, the Oversight Committee members voted unanimously to approve the Prevention FY 2024 Cycle 1 proposed RFAs.

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 reported that the PDRC submitted their final six award recommendations for FY 2023 to the PIC and the Oversight Committee. However, because the requested project budgets recommended for funding exceed the total available funding for FY 2023 product development awards, he requested that the PIC defer action until the May meeting. With the additional time, he will negotiate the proposed budgets with each company. The goal is to reduce the requested project budgets to a total amount sufficient to fund all companies recommended for an award.

In response to a question by an Oversight Committee member regarding the timing and process for budget negotiations, Dr. Smith explained that he has communicated initially with the six companies and directed them to scrub their budgets. If CPRIT staff and the companies cannot reduce the budgets by an amount that will allow CPRIT to fund all six recommendations, then CPRIT will explore other options – including funding companies in the rank order until CPRIT depletes grant funds.

In response to a question by an Oversight Committee member inquiring about how the new preliminary application process was working for the program, Dr. Smith reported that the process worked well and that CPRIT will use the preliminary application process for the FY 2024 awards.

An Oversight Committee member asked whether the companies knew the PDRC's ranked order of companies recommended for funding. Dr. Smith responded that companies do not know their rank order.

An Oversight Committee member inquired regarding award caps and whether caps should be reinstituted. Dr. Smith responded that he did not recommend reinstituting a budget cap at this time. He noted that only two preliminary applications requested a budget that exceeded the previous $20 million award cap, and neither application submitted a full application.

An Oversight Committee member asked about feedback from the companies on the FY 2023 review process. He also wanted to know the total time to approval if CPRIT acts on the proposed FY 2023 awards at the May meeting and how that compares to previous cycles. Dr. Smith explained that CPRIT is continually evaluating the review process for efficiency. The program has not yet received feedback from the companies.

An Oversight Committee member noted that he would like the program to reach out to county judges and economic development offices and request support from local municipalities. He feels that these offices should support CPRIT because CPRIT funds companies, and the local offices can assist with matching funds. Dr. Smith responded that this is an idea to investigate.

Dr. Smith briefly outlined his plans for the FY 2024 review cycle, including a more strenuous preliminary application review and expanding the pool of expert reviewers. He also explained that program staff will increase outreach regarding the Texas New Technologies Company and Texas Diagnostic and Devices Company RFAs.

Approval Process – Proposed Product Development RFAs for FY2024

Dr. Smith introduced the four proposed Product Development RFAs for FY 2024. He explained that the 2024 RFAs are the same as the FY 2023, with non-substantive changes:

- Texas Therapeutic Company
- Texas Device and Diagnostics Company
- Texas New Technologies Company
- Seed Company

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

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

Presiding Chair Dr. Patel took up agenda item 11 out of order and recognized Mr. Roberts to present his six appointments to the peer review panels.

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

- Andrew Chow, M.D., Ph.D.
- Edward H. Cho, Ph.D.
- Eric J. Gomez, Ph.D.
- Holly K. Koblish, Ph.D.
- Michael Hostetler, J.D., Ph.D.
- Sydney Xin-Li Lu, M.D., Ph.D.

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

Advisory Committees – Item 12, Tab 9

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

Mr. Roberts presented Dr. Atul Varadhachary's appointment to the Advisory Committee on Childhood Cancers and Harry Bushong's appointment to the Product Development Advisory Committee.

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

Academic Research Advisory Committee on Childhood Cancer presentation:

Presiding Officer Dr. Patel called on Dr. Le Beau to introduce Dr. Richard Gorlick, Chair of the Advisory Committee on Childhood Cancers (ACCC) to provide the ACCC annual report and recommendations.

Dr. Le Beau introduced Dr. Gorlick

Dr. Gorlick presented the ACCC annual report and recommendations.

Following Dr. Gorlick's report, an Oversight Committee member noted that the best care is usually close to home. Dr. Gorlick responded that large institutions in Texas are currently partnering with smaller rural institutions, and agreed that further expansion of these efforts was necessary.

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

Prevention Advisory Committee Presentation:

Presiding Officer Dr. Patel called on Ms. Magid to introduce Dr. Navkiran Shokar, Chair of the Prevention Advisory Committee (PAC) and Ms. Suncerria Tillis, Vice Chair of the PAC.

Dr. Shokar and Ms. Tillis presented the PAC annual report and recommendations.

Dr. Shokar explained that the data reflected current projects (vs. historic data) in response to an Oversight Committee member's question.

In response to a question by an Oversight Committee member asking whether prevention project grantees collaborate with the private sector, Dr. Shokar mentioned several CPRIT-funded prevention projects have worked with private entities such as for-profit hospitals.

An Oversight Committee member about working with health plans for population health issues. Dr. Shokar responded that working with both the insured and uninsured populations is important to make an impact.

In response to an Oversight Committee member's question about Texas Cancer Registry data, Dr. Shokar explained that the registry provides excellent data on cancer incidence and mortality but does not collect the additional data that the PAC recommends CPRIT receive.

In response to a question by the Oversight Committee chair inquiring how long it would take to operationalize the recommendations, Dr. Shokar clarified that this was a long-term plan and

needs to be one that the PAC maintains and documents.

Presiding Officer Dr. Patel and the Oversight Committee members thanked Dr. Shokar and Ms. Tillis for the presentation.

Chief Operating Officer Report – Agenda Item 13, Tab 10

Presiding Chair Dr. Patel recognized Chief Operating Officer Heidi McConnell.

Ms. McConnell presented her report on the operating budget, performance measures, and debt issuance history located behind Tab 10. She updated members on the amount of revenue sharing payments from grantees, including a milestone payment of more than $1 million and a quarterly royalty payment from Merck. She also notified members that CPRIT completed a "soft release" of the 2023 CPRIT Innovations VI Conference website earlier in February.

In response to a question by an Oversight Committee member, Ms. McConnell explained CPRIT expects 700-800 attendees will register for the conference.

Communication Report – Agenda Item 14, Tab 11

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

Internal Auditor Report – Agenda Item 10, Tab 7

Returning to Agenda Item 10, Presiding Chair Dr. Patel recognized Mr. Graves to present the internal auditor report. He noted that at the conclusion of Mr. Graves report, the Oversight Committee would convene in closed session to receive an update on the Internal Audit Report over Information Technology General Controls.

Mr. Graves provided a status update on the fiscal year 2023 Internal Audit Plan and Schedule. He directed members to the Table of Summary Findings by year on pages 7-3 and 7-4.

There were no questions for Mr. Graves.

Presiding Chair Dr. Patel announced the committee would go into closed session at 11:49 a.m. pursuant to Texas Government Code § 551.076. He asked for Mr. Roberts, Ms. Doyle, Ms. McConnell, Mr. Burgess, Cameron Eckel, Shannon Cusick, Soma Emenike and Mr. Graves to join the members in closed session.

Presiding Officer Dr. Patel noted that upon return from closed session, the Oversight Committee would take up agenda items 18-19.

The Board reconvened in open session at 12:45 p.m.

Presiding Officer Dr. Patel announced that the Oversight Committee would not take up standing agenda items 15, 16 and 17.

Future Meeting Dates and Agenda Items – Agenda Item 18

Presiding Officer Dr. Patel reminded members that the CPRIT Oversight Committee will meet on May 17, 2023.

Adjournment – Agenda Item 19

Before adjournment, Mr. Roberts thanked Melanie Richardson and the CPRIT IT team for preparing the room for the first Oversight Committee meeting held in the Barbara Jordan building.

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

Meeting adjourned at 12:46 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:	MAY 10, 2023

The Chief Executive Officer Report presented at the May 17 Oversight Committee meeting will include the following items. In addition, attached behind this memo are copies of the February/March 2023 and April 2023 CPRIT Activity Updates for your reference.

Intellectual Property Data Base Update

Chief Strategic Initiatives and Intellectual Property Officer Tracey Davies will provide a brief status report on the intellectual property database.

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 and Product Development Research awards at the Program Integration Committee recommended level of nearly $73.1 million, we will have $52.0 million remaining for Academic Research and Prevention awards at the August meeting. At this time Heidi McConnell, Chief Operating Officer, and I estimate that we will close out the 2023 award year with a balance of a little under $1.2 million for the agency.

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

Personnel

CPRIT has filled 43 of our 44 full-time equivalent positions and has four positions in progress: Program Manager for Academic Research, Program Specialist for Product Development, and two Grant Compliance Specialist positions.

Legislative Update

An update on the few outstanding legislative issues as of the morning of May 17 will occur.

Additional items will be added as warranted.

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CPRIT has awarded **1,865** grants totaling **$3.261 billion**

- 282 prevention awards totaling $341.5 million
- 1,583 academic research and product development research awards totaling $2.92 billion

Of the $2.92 billion in academic research and product development research awards,

- 30.9% of the funding ($901.3 million) supports clinical research projects
- 24.1% of the funding ($705.0 million) supports translational research projects
- 29.2% of funding ($853.6 million) supports recruitment awards
- 12.7% of the funding ($369.5 million) supports discovery stage research projects
- 3.1% of funding ($90.4 million) supports training programs.

CPRIT has 13 open Requests for Applications (RFAs)

- 2 Academic Research Recruitment
- 5 Academic Research
- 2 Prevention
- 4 Product Development Research

FY 2023 GRANT AWARD FUNDS AVAILABLE

General Obligation Bond Proceeds

	Prevention	Academic / Product Development Research	1% Grant Funding Buffer	Operating Budget	Total Appropriations
Available Appropriated 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	$ -		
Announced Grant Award Subtotal	**$ 13,577,257**	**$ 119,901,790**	**$ 16,154,562**	$ -	**$ 149,633,609**
Available Grant Funds as of May 17, 2023	**$ 14,083,523**	**$ 51,942,805**	**$ 59,081,927**		**$ 125,108,255**
Pending Grants-PIC Recommendations					
Recruitment Awards (3)	$ -	$ 14,000,000	$ -		
Company Grant Awards (6)	$ -	$ -	$ 59,081,927		
Pending Award Subtotal	**$ -**	**$ 14,000,000**	**$ 59,081,927**		**$ 73,081,927**
Total Potential Grant Funding Committed	**$ 13,577,257**	**$ 133,901,790**	**$ 75,236,489**		**$ 222,715,536**
Uncommitted Grant Funds as of May 17, 2023	**$ 14,083,523**	**$ 37,942,805**	**$ -**		**$ 52,026,328**
Grant Funding Buffer	**$ -**	**$ 1,170,316**	**$ -**		**$ 1,170,316**
Total Remaining Funds	**$ 14,083,523**	**$ 39,113,121**	**$ -**		**$ 53,196,644**

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							75	
New Grant Contracts Signed	10	11	15	13	4	3	5	17					78	
New Grant Contracts In Negotiation			8			30							38	
Grant Reimbursements Processed (#)	172	150	124	193	148	149	195	185					1316	
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					$ 150,814,041	
Revenue Sharing Payments Received	$ 20,611	$ 10,783	$ 70,854	$ 3,100	$ 41,334	$ 1,020,317	$ 115,886	$ -					$ 1,282,885	$ 9,008,424
Grants Awarded (#)/ Applications Rec'd (#)	18%	18%	18%	18%	18%	19%	19%	19%						
Grantee Compliance Trainings	2	4	3	4	1	3	4	1					22	
Grantee Compliance Monitoring Visits	0	0	2	4	1	4	2	1					14	
Awards with Delinquent Reimbursement Submission (FSR)			0			1								
Awards with Delinquent Matching Funds Verification			3			13								
Awards with Delinquent Progress Report Submission			4			0								
MISSION														
Open RFAs	7	6	6	10	14	10	11	11						
Prevention Applications Received	0	0	0	0	0	25	0	0					25	988
Product Development Preliminary Applications Received	26	11	9	9	2	0	0	0					57	701
Product Development Full Applications Received	0	0	14	0	1	0	0	0						
Academic Research Applications	4	3	0	4	0	7	0	36					54	8,727
Help Desk Calls/Emails	175	221	132	136	123	91	71	131					1,080	
Number of Research Grants Announced (Annual)	24		2			40							66	
Recruited Scientists Contracted														287
Number of Product Development Grants Announced (Annual)	1		0			0							1	
Life Science Companies Recruited (in TX)													0	14
Number of Product Development Jobs Created & Maintained														1,228
Number of Prevention Grants Announced (Annual)			0			8							8	
Total Number of Education, Navigation and Training Services			162,223			127,978							290,201	
Total Number of Clinical Services			46,301			40,140							86,441	
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						
Total Unique Visitors to Website (Users)	8,280	7,276	7,070	5,081	8,142	29,224	8,115	6,508						

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	CPRIT ACTIVITIES UPDATE FOR APRIL 2023
DATE:	MAY 4, 2023

Topics in this memo address CPRIT activities in April, including preparation for the upcoming May 17 Oversight Committee meeting, recent milestones in our fight against cancer, a staffing summary, outreach efforts, the 2023 Texas legislative session, and updates from Compliance, Programs, and Operations.

The Oversight Committee will meet in person on Wednesday, May 17, in the new Barbara Jordan State Office Building. We will have a full agenda with grant award recommendations as well as annual reports presented by two advisory committees. Please notify me as soon as possible if you are unable to attend the May 17 meeting or have schedule constraints that require you to arrive at the meeting after 9:00 a.m. or leave prior to 12:30 p.m.

You will receive an email from CPRIT by May 5 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. The academic research and product development programs will present award recommendations at the meeting. 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 May 9. Oversight Committee members will receive an electronic copy of the agenda packet by May 10. Hard copies of the agenda and proposed award packets will be available at the meeting.

Recent Milestones in the Fight Against Cancer

CPRIT Grantees in the News

- Factors such as the patient's socioeconomic status or their location may limit access to early-phase cancer clinical trials, creating a barrier of entry for diverse and medically underserved populations who are frequently not enrolled onto early-phase studies. To expand access to cancer care and research, Stand Up To Cancer® (SU2C) launched a four-team initiative across the United States

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to address cancer disparities and facilitate development of new treatments with the potential to benefit patients and may be replicable across other institutions.

On February 8, CPRIT grantee David Gerber, M.D., and Chika Nwachukwu, M.D., Ph.D., received one of the four SU2C grants to translate their efforts in "transferring care" to enhance access to early-phase cancer clinical trials at The University of Texas Southwestern Medical Center and Simmons Comprehensive Cancer Center in Dallas. Using their existing platform of "sharing care" for patients with cancer between Parkland Health, a safety-net system serving underrepresented minorities, and the UT Southwestern Medical Center, the investigators will tackle trial availability, one of three main areas affecting access to clinical trials.

The investigators will leverage existing support systems already in place at Parkland, including bilingual clinical research navigators that help patients through the Parkland system and patient navigators to assist with care coordination, to provide psychosocial support, and to address logistical barriers to ensure the broadest benefit to diverse populations.

Dr. Gerber is a professor of internal medicine, co-director of the Experimental Therapeutics Program at UT Southwestern Medical Center, Simmons Cancer Center, and principal investigator of a CPRIT Clinical Trials Network Award to expand access to clinical trials (RP220542), and several CPRIT-funded clinical trials (RP160030, RP210115) totaling $6 million.

- The University of Texas Southwestern Medical Center and The University of Texas Health Science Center at San Antonio announced a partnership on March 29 with TripleBlind, a leader in data de-identification, to collaborate on cancer prevention research. The collaboration will use TripleBlind's automated de-identification and privacy enhancing software to enable the researchers to study the impact of collaborative research on the quality of patient care. The team will investigate the advantages of TripleBlind's technology on monitoring quality-of-care delivery across multiple federally qualified health centers in South Texas. The research will demonstrate the effect of using TripleBlind's software to improve quality of care via more direct data interactions between collaborating entities. The partnership will use the CPRIT-funded "Screen, Treat, or Prevent Hepatocellular Cancer-Hepatitis C (STOP-HCC)" project, led by UT Southwestern's Dr. Mamta Jain, which focuses on Hepatitis B vaccination and Hepatitis C screening and navigation to treatment.

  CPRIT awarded three grants to UT Southwestern and Dr. Jain totaling $6.3 million since 2018 (PP170121, PP180091, PP230046) to create and expand the STOP-HCC program.

- The University of North Texas Health Science Center at Fort Worth's March 30 newsletter featured the CPRIT-funded "All For Them" HPV vaccination program led by Dr. Paula Cuccaro, assistant professor of Health Promotion and Behavioral Sciences and a researcher at The University of Texas Health Science Center at Houston's Center for Health Promotion and Prevention Research. The program has partnered with Dr. Erika Thompson in Fort Worth to bring HPV vaccinations to students in North Texas.

The All For Them initiative, run by UTHealth Houston's School of Public Health, provides free vaccination clinics at middle and high schools in six public school districts: Aldine ISD, Crowley ISD, Fort Worth ISD, Goose Creek CISD, Houston ISD and Spring ISD. The clinics in medically underserved schools offer all childhood and adolescent vaccines — including the HPV vaccine, which protects against six types of cancer.

CPRIT awarded UTHealth Houston three prevention awards totaling nearly $4 million since 2017 (PP170046, PP20017, PP230033) to establish and expand the All For Them comprehensive school-based approach to increase HPV vaccination through public schools.

- KXXV TV, Waco's ABC affiliate, interviewed Jason McKnight, M.D., M.S., FAAFP, on April 3 about the importance of colorectal screening and prevention during Colorectal Cancer Awareness Month, encouraging those without health insurance to contact the CPRIT-funded Texas C-STEP project about receiving free screenings.

  Dr. McKnight, clinical associate professor at the Texas A&M University School of Medicine and director of residency recruitment for the Texas A&M Family Medicine Residency program, is also the director of the CPRIT project, "Leveraging Texas C-STEP's Robust Rural Partnerships for Successful Expansion of its Proven Colorectal Cancer Screening Program to Include HCV Screening." CPRIT awarded Texas A&M University Health Science Center nearly $4 million since 2018 (PP220013, PP180037) to support this prevention project.

- The American Association for Cancer Research (AACR) announced April 12 that CPRIT Scholar Valentina Hoyos Velez, M.D., assistant professor, Center for Cell and Gene Therapy at Baylor College of Medicine received the 2022 Victoria's Secret Global Fund for Women's Cancers Career Development Award, in Partnership with Pelotonia & AACR, for her research "Chimeric Antigen-Receptor T Cell Therapy Against a Novel Target for the Treatment of Triple Negative Breast Cancer." Baylor College of Medicine recruited Dr. Velez in 2017 from Johns Hopkins University with the support of a $2 million CPRIT Recruitment of First-Time, Tenure-Track Faculty Members grant (RR170024).

- On April 13, the American Cancer Society (ACS) awarded an American Cancer Society Clinical Research Professor Award to CPRIT-grantee Dr. Michael Pignone of the Dell Medical School at The University of Texas at Austin. The ACS Clinical Research Professor Award is a major honor for investigators who have made seminal contributions that transform cancer research. It recognizes an exceptional track record in cancer control research that changed the direction of clinical, psychosocial, behavioral, health policy, or epidemiologic cancer research, as well as leadership and mentoring in cancer research.

  With this award, ACS recognizes Dr. Pignone's national impact in improving cancer screening and prevention, including success in partnering with community organizations to reduce disparities among underserved communities in Central Texas. The $400,000 five-year grant will help fund Dr. Pignone's project to reach underserved populations in Texas and nationally through widespread implementation of mailed interventions to increase colon cancer screening. This research will investigate cost-effectiveness to inform resource

allocation for cancer screening programs to reduce disparities. Dr. Pignone will also develop a cancer control fellowship training and career mentorship program to grow a diverse workforce of cancer screening and prevention-focused researchers.

CPRIT awarded The University of Texas at Austin $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.

- The American Association for Cancer Research (AACR) Academy elected two researchers from The University of Texas MD Anderson Cancer Center to the 2023 class of Fellows at the AACR Annual Meeting on April 14 -19. AACR honored CPRIT Scholar Andy Futreal, Ph.D., chair of Genomic Medicine, and CPRIT grantee Helen Piwnica-Worms, Ph.D., professor of Experimental Radiation Oncology, for their respective contributions to advancing understanding of cancer genomics and cell cycle regulation. The mission of the AACR Academy is to recognize distinguished scientists whose contributions have propelled significant progress and breakthroughs against cancer.

  Dr. Futreal's election as an AACR Fellow acknowledges his pioneering use of large-scale genomics to understand cancer pathogenesis and to identify novel human cancer genes. His breakthrough discovery of BRAF mutations in human melanoma led to developing the first effective targeted therapy for advanced melanoma, thus inspiring a global effort in cancer genomics. MD Anderson recruited Dr. Futreal to Texas from the Wellcome Trust Sanger Institute with a $7 million CPRIT Established Investigator Recruitment grant (R1205) in 2011.

  AACR recognized Dr. Piwnica-Worms for her breakthrough contributions to understanding the biochemical mechanisms of cell cycle regulation and for determining how perturbations in cell cycle control mechanisms contribute to cancer onset. She elucidated the biochemical mechanism by which the key mitotic regulator CDK1 turns on and off during a normal cell cycle, and how cell cycle checkpoints prevent its activation. CPRIT has awarded MD Anderson and Dr. Piwnica-Worms multiple CPRIT awards since 2015 (RP150148, RP200120, RP220567) totaling $2.05 million.

  Drs. Futreal and Piwnica-Worms join several previously elected fellows from MD Anderson, including CPRIT Scholars James Allison, Ph.D., Neal Copeland, Ph.D., Nancy Jenkins, Ph.D.; CPRIT grantees Guillermina (Gigi) Lozano, Ph.D., and Ronald DePinho, M.D.; and former CPRIT Chief Scientific Officer Margaret Kripke, Ph.D.

- On April 20, the *San Antonio Express-News* published an editorial by CPRIT grantees Keith Argenbright, M.D., professor at The University of Texas Southwestern Medical Center and director of the UT Southwestern Moncrief Cancer Institute, and David Lakey, M.D., vice chancellor for Health Affairs and chief medical officer at The University of Texas System, about the need for colorectal cancer treatment funding for underinsured/uninsured Texans.

- The American Society for Investigative Pathology (ASIP) announced May 1 that CPRIT Scholar Dr. Qing Zhang, Associate Professor in the Department of Pathology and Co-Director of the

Kidney Cancer Career Enhancement Program at The University of Texas Southwestern Medical Center is the 2024 recipient of the ASIP Outstanding Investigator Award. The ASIP Outstanding Investigator Award recognizes mid-career investigators with demonstrated excellence in experimental pathology research, including impactful achievements related to research, teaching, mentorship, leadership in the field of pathology, and contributions to the Society.

Dr. Zhang and his group at UT Southwestern are studying a fundamental question in the cancer field – how do cancer cells sense low oxygen tension, adapt to this stressful environment, and proliferate out of control? To address these broad but critical questions, Dr. Zhang has pioneered unbiased genome and proteome-wide approaches to identify new signaling molecules in oxygen sensing signaling pathways, which have yielded new therapeutic targets in cancer. UT Southwestern recruited Dr. Zhang to Texas in 2019 with a $4 million (RR190058) CPRIT Recruitment of Rising Stars grant award.

- On May 1, The University of Texas System announced that it earned a top-five global ranking for most patents granted from the National Academy of Inventors (NAI). Having received 225 U.S. utility patents, UT institutions rank No. 4 in the latest NAI listing, increasing the total number of patents granted in 2022 from 203 the previous year. In addition to its success in securing patents, the UT System set an all-time high in fiscal year 2022 with $3.8 billion in research expenditures across UT's 13 academic and health institutions. With more than $1.7 billion in federally-sponsored research expenditures – a widely-recognized benchmark for research success – the UT System ranks No. 1 in Texas and No. 2 in the nation.

- The prestigious National Academy of Sciences (NAS) announced on May 3 its election of two CPRIT grantees from The University of Texas MD Anderson Cancer Center to its membership. The NAS election recognizes Helen Piwnica-Worms, Ph.D., professor of Experimental Radiation Oncology, and Richard Wood, Ph.D., professor of Epigenetics and Molecular Carcinogenesis, for their respective contributions to advancing our understanding of cancer genetics, biochemistry and cell biology.

  Dr. Piwnica-Worms has made significant contributions to the understanding of the biochemical mechanisms of cell cycle regulation and to determining how perturbations in cell cycle control mechanisms contribute to cancer onset. She discovered the biochemical mechanism that activates or deactivates CDK1, a key regulator of mitosis during the cell cycle and how cell cycle checkpoints prevent CDK1 activation. This was the first direct link demonstrated between cell cycle checkpoints and mitotic control. Her work has been essential to the understanding of breast cancer development and progression, and her discoveries have prompted clinical studies for agents targeting the cell cycle and checkpoint proteins in multiple cancer types. She currently identifying alterations driving triple-negative breast cancer (TNBC) and therapeutic resistance mechanisms. This research has already demonstrated that chemotherapy resistance in TNBC can occur through adaptable and reversible pathways, and it pointed to new vulnerabilities in drug-tolerant cancer cells. CPRIT has awarded MD Anderson and Dr. Piwnica-Worms multiple CPRIT awards since 2015 (RP150148, RP200120, RP220567) totaling $2.05 million.

Dr. Wood has made foundational contributions to the biochemistry and genetics of DNA repair and cancer development, explaining how eukaryotic cells are protected from ultraviolet (UV) radiation damage. He established the first cell-free system for nucleotide excision repair (NER) in eukaryotes, allowing him to precisely define the NER mechanism and identify key enzymes in UV-induced damage repair. By reconstituting the entire NER pathway using 30 purified proteins, he made it possible for the first time to determine the role of each protein at each step. These experiments included the discovery of the roles of replication proteins during NER and defining sequential NER steps at the molecular level, including opening the double helix by a multi-protein complex. The work revealed the specific biochemical defects in xeroderma pigmentosum, an inherited disease conferring a greatly increased risk of skin cancer. Dr. Wood was also the first to isolate the XPG and ERCC1-XPF nucleases and discovered their action via structure-specific incision. This work helped found the field of DNA structure-selective enzymology, now studied in multiple areas of DNA biology. His recent work has yielded numerous discoveries that define the roles of various DNA polymerases in genome stability and cancer. CPRIT awarded MD Anderson and Dr. Wood a $450,000 Individual Investigator grant (RP130297) in 2012.

Notable CPRIT-Supported Research and Prevention Accomplishments

- Acute myeloid leukemia (AML) is an aggressive malignancy that causes uncontrolled accumulation of white blood cells with poor life outcomes. Researchers at Baylor College of Medicine led by CPRIT Scholar H. Courtney Hodges, Ph.D., and collaborating institutions reported in *Cancer Research* on April 1 a new vulnerability of this cancer that researchers can target with a class of experimental drugs. These drugs target a protein complex called SWI/SNF, which many cells use to make DNA more open and accessible. The robust regression of leukemic burden seen over a short two-week treatment period suggests a considerable therapeutic window in immunocompetent settings for some patients and provides a compelling justification for continued study of SWI/SNF inhibitors in the treatment of AML.

  Baylor College of Medicine recruited Dr. Hodges, now assistant professor, Department of Molecular and Cellular Biology, from the Stanford University College of Medicine in 2017 with the support of a $2 million CPRIT Recruitment of First-Time, Tenure-Track Faculty Members grant (RR170036). Two CPRIT-funded core facilities at Baylor College of Medicine (RP180672, $5.17 million) and The University of Texas MD Anderson Cancer Center (RP120348, $5.9 million) also supported this research.

- **“EXTEND”ing Therapeutic Options in Metastatic Prostate Cancer.** Oligometastatic prostate cancer is a cancer in which cancer cells from the original tumor spread to one or two other parts of the body and form small tumors. Oligometastatic is curable with treatment that typically includes hormone therapy and radiation, but scientists have not extensively studied the addition of metastasis-directed therapy (MDT) to hormone therapy.

  Dr. Chad Tang, an Associate Professor at The University of Texas MD Anderson Cancer Center, led a CPRIT-funded phase 2 clinical trial (ClinicalTrials.gov Identifier:

NCT03599765) to investigate whether adding MDT to intermittent hormone therapy improves outcomes and preserves time with eugonadal testosterone in men with oligometastatic prostate cancer. The External Beam Radiation to Eliminate Nominal Metastatic Disease (EXTEND) trial enrolled 87 men (median age, 67 years) with oligometastatic prostate cancer previously treated with hormone therapy for at least two months. The trial randomly assigned patients to receive MDT and intermittent hormone therapy or hormone therapy alone. A planned break in hormone therapy occurred six months after enrollment, after which clinicians withheld hormone therapy until progression. The primary end point was disease progression, defined as death or radiographic, clinical, or biochemical progression.

As reported in *JAMA Oncology*, published online April 6, the trial found that the combined therapy arm had significantly improved progression-free survival and eugonadal progression-free survival compared to the hormone therapy only arm. The results suggest that adding MDT to hormone therapy can improve outcomes in patients with oligometastatic prostate cancer. This treatment approach may be particularly beneficial for men who wish to prolong hormone therapy cessation. The findings could also pave the way for future clinical trials testing various combination therapies to improve outcomes in this patient population.

CPRIT awarded MD Anderson and Dr. Tang a $2.4 million CPRIT Individual Investigator Research Award for Clinical Translation (RP180140). Dr. Tang is also the recipient of a $1.5 million CPRIT Early Clinical Investigator Award (RP200669) to advance his career development as a clinical researcher.

- **"Survival of the Fittest" Cell Clones.** As we age, genetic mutations can accumulate in our non-malignant tissues. Some of these mutations can potentially increase the risk of developing cancer or other diseases. However, new research led by Dr. Hao Zhu, Associate Professor of the Children's Research Institute, Department of Pediatrics, and the Simmons Comprehensive Cancer Center at The University of Texas Southwestern Medical Center, suggests that some mutations may lead to a reversal of disease or adaptation to disease.

  Dr. Zhu's team of investigators at UT Southwestern studied mouse models with a high density of mutations in the context of common liver diseases. They found that certain mutations mitigate the toxic effects of lipotoxicity and increase the survival of liver cell clones in the presence of non-alcoholic steatohepatitis (NASH), a leading risk factor for liver cancer. By identifying mutant cells with greater fitness than healthy cells within a diseased environment, the team was able to identify potential targets for therapy. The team also identified genes such as Tbx3, Bcl6, and Smyd2 that can promote liver fitness and suppress lipotoxicity, providing potential targets for therapy.
  These findings, published online in the journal *Cell* on April 10, shed light on key pathways that regulate metabolic disease and provide insight into the evolutionary selection of somatically mosaic tissues as a high-throughput approach for identifying adaptive metabolic disease pathways. By identifying mutant cells with greater fitness than healthy cells within a diseased environment and understanding how some mutations may reverse or adapt to

disease, researchers can identify potential targets for therapy for liver diseases like NASH and potentially other metabolic diseases.

UT Southwestern recruited Dr. Zhu to Texas from the Dana-Farber Cancer Institute & Children's Hospital in 2012 with a $2 million First-Time, Tenure-Track CPRIT award. CPRIT has awarded UT Southwestern and Dr. Zhu three additional grants totaling $3.96 million (RP170267, RP180268, RP220614) since 2017. CPRIT Scholar Dr. Yujin Hoshida, (RR180016, $4 million) also contributed to this work.

- CPRIT Scholar Thomas Yankeelov, Ph.D., professor, Department of Biomedical Engineering, Diagnostic Medicine, and Oncology, and David Hormuth, Ph.D., Center for Computational Oncology, both from The University of Texas at Austin, and colleagues are developing a web-based tool called MIRACCL (molecular and imaging response analysis of co-clinical trials) to help manage and analyze data generated from patient-derived xenograft (PDX) models of cancer.

  PDX models have shown promise in replicating much of the biology and treatment responses of the matched tumors-of-origin. However, a major challenge in co-clinical trials is how to manage, integrate, and analyze the abundance of data generated across both spatial and temporal scales, as well as across species. MIRACCL leverages the wealth of PDX-related and clinical data, the robust informatics capabilities of LinkedOmics, and the high-quality displays enabled in ePAD to provide an intuitive, easy-to-use, and analytically robust tool, thus removing the need to involve multiple specialists.

  As reported in *MDPI Tomography* on April 10, the researchers simulated data for a co-clinical trial in triple-negative breast cancer for prototyping and cross-referenced image features derived from datasets to "omic" data to evaluate MIRACCL's functionality. Once completed, the MIRACCL platform will provide users with integrative analyses of pre-clinical PDX-based trials, clinical trials, and co-clinical trials. The platform will allow integration of imaging features with molecular "omic" data to address treatment response assessment and prediction, as well as possible mechanisms of treatment resistance.

  UT Austin recruited Dr. Yankeelov in 2015 from Vanderbilt University with the support of a $6 million CPRIT Recruitment of Established Investigators grant (RR160005). Other CPRIT grants supported this research, including a $1.2 million Academic Research grant (RP220225) awarded to UT Austin and two CPRIT Core Facility grants awarded to Baylor College of Medicine (RP170691, RP220646) in 2017 and 2022 totaling $8.76 million.

- Studies have shown that the available HPV vaccines reduced cervical cancer incidence by 90% in fully vaccinated girls and young adults. However, approximately 80% of eligible individuals (male and female) are not up to date on this vaccination series. To develop predictors for incomplete HPV vaccination, Abbey Berenson, M.D., Ph.D., professor, Departments of Obstetrics & Gynecology and Pediatrics and fellow researchers from The University of Texas Medical Branch at Galveston analyzed data regarding HPV vaccination among thousands of individuals aged 27–45 in the U.S.

This retrospective cohort study used multilevel multivariable logistic regression models for data on 7,662 individuals either fully or partially vaccinated against HPV, nested within 3,839 neighborhoods across the U.S. The results, published in *MDPI: Vaccines* on April 10, revealed that approximately half of the patients in this study did not complete the HPV vaccine series. After adjusting for all other covariates, the odds of not completing the HPV vaccinations included participants older than 30 years of age and participants living in South-region neighborhoods of the U.S. compared with those residing in Northeast-region neighborhoods. This study revealed that interventions to improve HPV vaccination series completion rates for this age group should take into consideration both individual and contextual factors.

The University of Texas Medical Branch at Galveston received a $2 million CPRIT Prevention grant (PP200005) in February 2020 to provide up-to-date, accurate, and credible data to inform the design of programs and interventions to address the high rate of incomplete HPV vaccine series.

- Researchers, including CPRIT Scholar Andre Catic, M.D., Ph.D., assistant professor, Baylor College of Medicine, have discovered that a mutation in a protein called SKD3, which is important for maintaining protein quality control in animal cells, can cause a genetic disease known as 3-methylglutaconic aciduria (MGCA7). The protein SKD3 belongs to unfoldases, a family of proteins found in many organisms, including humans. As reported in the journal *Nature Communications* on April 11, the team focused on the unfoldase present in humans, which can cause MGCA7 when mutated. The researchers found that a mutation in the non-catalytic part of the enzyme leads to the formation of a bond that inactivates the enzyme, resulting in the accumulation of misfolded proteins in cells. This work provides evidence that SKD3 is a central player in maintaining protein quality control in mitochondria and proposes the first mechanism by which non-catalytic domain mutations in SKD3 can lead to MGCA7 and highlights the importance of SKD3 in maintaining protein quality control in mitochondria.

  Experimentally, the team confirmed that this mutant enzyme causes massive protein aggregation in cells where the enzyme function is crucial for maintaining the structure of mitochondria. Without this specific mutation in the non-catalytic domain, the enzyme retains its normal function. Baylor College of Medicine recruited Dr. Catic in 2014 from Harvard University with a $2 million CPRIT Recruitment of First-Time, Tenure-Track Faculty Members grant (RR140038).

- Lung adenocarcinomas (LUADs) are a type of lung cancer that can display different structures and characteristics. Scientists do not fully understand how these differences reflect tumor evolution and disease progression. To better understand this, a team of researchers led by CPRIT Scholar Peter Van Loo, Ph.D., professor, Departments of Genetics and Genomic Medicine at The University of Texas MD Anderson Cancer Center integrated whole-exome sequencing and RNA-sequencing data from hundreds of primary tumor and metastatic samples across 248 LUADs. They also conducted detailed histopathological analysis of the tumors.

  Their findings, published April 12 in *Nature Medicine*, provide new insights into the relationship between LUAD morphology, the underlying genomic landscape, and the risk of clinical relapse. By analyzing the genetic mutations and changes in gene expression associated with different

tumor structures, the researchers were able to identify distinct evolutionary pathways that lead to different types of LUADs.

The study also revealed that certain types of LUADs are associated with a higher risk of relapse and metastasis, which could have important implications for treatment decisions and patient outcomes. By better understanding the relationship between tumor morphology, genomic changes, and clinical outcomes, researchers hope to develop more effective treatments for LUADs and improve patient survival rates.

The University of Texas MD Anderson Cancer Center recruited Dr. Van Loo in 2020 with the support of a $6 million CPRIT Recruitment of Established Investigators grant (RR210006).

- Esophageal adenocarcinoma (EAC) is a highly lethal cancer that can develop from a pre-cancerous condition called Barrett's esophagus. Extrachromosomal DNA (ecDNA), a type of DNA found outside the chromosomes in the cell, drives the growth of tumors and their resistance to treatment. It is not clear whether ecDNA is a later result of genetic instability or whether it is an early event in the transition from pre-cancerous conditions to cancer.

  To better understand the development of ecDNA, CPRIT Scholar Sihan Wu, Ph.D., assistant professor, Children's Medical Center Research Institute at The University of Texas Southwestern Medical Center, and fellow researchers, analyzed whole-genome sequencing (WGS) data from patients with EAC or Barrett's esophagus, which included 206 biopsies in Barrett's esophagus surveillance and EAC cohorts from Cambridge University. The findings, published in *Nature* on April 12, 2023, show that ecDNA can develop early in the transition from pre-cancerous conditions to cancer and that ecDNA forms and evolves over time.

  The University of Texas Southwestern Medical Center recruited Dr. Wu in 2021 with the support of a $2 million CPRIT Recruitment of First-Time, Tenure-Track Faculty Members grant (RR210034).

- OncoNano Medicine, Inc. presented positive nonclinical data for their lead therapeutic development candidate ONM-501 at the American Association for Cancer Research (AACR) Annual Meeting held April 14 - 18. ONM-501 is a dual-activating STING agonist formulated with the company's OMNI polymer technology. The posters presented at the conference detailed the positive nonclinical results for ONM-501, as well as positive data for encapsulated bispecific antibody and cytokine using the company's ON-BOARD tumor specific delivery technology.

  The ON-BOARD pH-sensitive micelle delivery platform has demonstrated improvement of therapeutic indices with a variety of therapeutic protein payloads, including the highly potent interleukin-12 and T-cell engagers. The company's research and development vice president, Tian Zhao, Ph.D., explained that other IL-12 and T-cell engager programs have faced challenges due to suboptimal therapeutic index associated with toxicities related to systemic exposure. In contrast, the tumor-specific delivery of ON-BOARD encapsulated molecules demonstrates a much broader therapeutic window.

The promising data suggest that OncoNano's technology may provide a solution to overcome the clinical application limitations of these highly potent protein therapeutics. By using tumor-specific delivery technology, the company hopes to improve therapeutic outcomes while minimizing the risk of toxicities associated with systemic exposure.

Since 2014 CPRIT has awarded Southlake-based OncoNano three Product Development Research grants (DP140072, DP190066, DP200081) totaling $31 million to develop pegsitacianine and ONM-501.

- **Tumors Metastasizing to the Brain Develop Unique "Communication Highways."** Researchers at The University of Texas MD Anderson Cancer Center have discovered that tumors that metastasize to the brain develop unique "communication highways." While immune checkpoint inhibitors have revolutionized the treatment of metastatic renal cell carcinoma, recent studies have found that brain metastases can occur in over 25% of patients treated with immunotherapy. This is because the brain can tolerate foreign antigens without triggering an inflammatory response, allowing tumor cells to escape the effects of immunotherapy. Patients with renal cell cancers that have metastasized to the brain have lower response rates to treatment and worse outcomes.

  To understand the differences in the tumor microenvironment between primary kidney tumors, extracranial metastases, and brain metastases, a team of investigators, led by Eric Jonatsch, M.D., Professor, Department of Genitourinary Medical Oncology, Division of Cancer Medicine, and Elshad Hasanov, M.D., Ph.D., medical oncology fellow at MD Anderson developed a detailed single-cell atlas of renal cell carcinoma brain metastases, along with their matched extracranial and primary tumors, using frozen or formalin-fixed paraffin-embedded tissue samples from patients with renal cell carcinoma.

  Compared to primary tumors or extracranial metastases, brain metastases had greater infiltration of neuronal and glial cells into the tumor microenvironment, which enhances cancer growth and metastasis. The investigators also found that neuronal and glial cell interactions with immune cells potentially suppress antitumor immune activity. The tumor microenvironment of brain metastases had fewer proliferating T cells, memory B cells, dendritic cells, and monocytes than primary tumors and extracranial metastases. Furthermore, T cells in brain metastases expressed higher levels of immune checkpoint proteins than T cells in other sites, and macrophages in the brain were more likely to express an immune-suppressing M2 gene signature.

  Tumor cells in the brain had greater expression of serum amyloid A1, which promotes immune-suppressive effects in macrophages, and higher activity of the VEGFR and FGFR4 growth-promoting proteins. They also had greater expression of genes that allowed them to adapt to the brain environment, including target genes regulated by the MYC oncoprotein and genes involved in mTORC1 signaling, epithelial-mesenchymal transition, fatty acid metabolism, oxidative phosphorylation, and the response to reactive oxygen species. The researchers noted communication "highways" between neuronal cells and other cell populations that do not exist in other metastatic sites but are dominant in the brain.

This research, reported at the American Association for Cancer Research Annual Meeting on April 18, helps scientists to identify potential therapeutic targets and design therapies that can improve patient outcomes. Based on these results, the researchers plan to pursue further preclinical studies and clinical trials to test various combination therapies against VEGFR and FGFR4 and other identified targets in combination with immune checkpoint inhibitors for patients with renal cell carcinoma brain metastases.

The CPRIT-funded Integrated Single Cell Genomics Core Facility at MD Anderson (RP180684, $4.9 million), led by co-author Nicholas Navin, Ph.D., made this research possible.

- PLUS Therapeutics announced on April 18 the completion of Cohort 3 of the ReSPECT-LM Phase 1/2a dose-escalation clinical trial of rhenium (186Re) obisbemeda to treat leptomeningeal metastases (LM) from solid tumors less than one month since its initiation. Rhenium (186Re) obisbemeda is a novel injectable radiotherapy specifically formulated to deliver highly targeted high dose radiation in central nervous system (CNS) tumors in a safe, effective and convenient manner to optimize patient outcomes. This novel radiotherapy has the potential to reduce risks and improve outcomes for CNS cancer patients, versus currently approved therapies, with a more targeted and potent radiation dose. Additionally, the company has expanded the number of clinical trial sites to include Northwestern Memorial Hospital in Chicago, marking the first expansion of the ReSPECT-LM trial beyond Texas. Thus far, clinicians have treated 10 patients across three cohorts in the ReSPECT-LM Phase 1/Part A dose escalation clinical trial.

  CPRIT awarded Austin-based Plus Therapeutics a $17.6 million CPRIT Product Development Research grant (DP220039) in August 2022 to support the ReSPECT-LM program.

- The blood-brain barrier (BBB) is a protective barrier that controls the entry of endogenous and foreign substances in the central nervous system from the bloodstream. Anesthetics like isoflurane alter the structure of cell membranes in the brain, making it easier for certain substances to pass through the blood-brain barrier and potentially cause harm. Clinical implications may arise when potentially neurotoxic drugs gain enhanced access to the central nervous system under inhalational anesthetics. Ulrich Bickel, M.D., professor and associate dean, Department of Pharmaceutical Sciences, and colleagues at the Texas Tech University Health Sciences Center, studied the effects of isoflurane and sevoflurane, two commonly used anesthetics, on the fluidity of lipid membranes and the permeability of the BBB. The data, published in *The Journal of Pharmacology and Experimental Therapeutics* on May 1, 2023, found that these anesthetics caused an increase in the permeability of the BBB in mice, which suggests that they may make it easier for harmful substances to enter the brain. Texas Tech University Health Sciences Center received a $2.83 million Core Facility Support Awards grant (RP200572) in August 2020 to enhance the quality of obtainable data in ongoing and future cancer research projects with the addition of three cutting edge instruments.

Personnel

CPRIT has filled 43 of our 44 full-time equivalent positions and has four positions in progress: Program Manager for Academic Research, Program Specialist for Product Development, and two Grant Compliance Specialist positions.

CPRIT Symposium on Computational Oncology

CPRIT co-sponsored the symposium "Expanding Texas Leadership in Computational Oncology Throughout the Cancer Continuum," held April 20 at The University of Texas Austin Dell Medical School. Other co-sponsors included the Livestrong Cancer Institutes and the Oden Institute for Computational Engineering and Sciences at UT Austin, and The University of Texas MD Anderson Cancer Center.

Cancer is a complex multi-scale disease involving the interaction of dynamic processes at the molecular, cellular, and multicellular levels. Cancer computational oncology has emerged as a powerful field that employs multidimensional data, as well as mathematical and computational modeling, to address these complexities in cancer biology and to predict integrated mechanisms underlying cancer initiation, progression, metastasis, prognosis, and treatment response.

The all-day symposium, attended by more than 160 scientists and trainees in-person and online, featured research presentations from leading investigators at multiple Texas institutions, including many CPRIT-funded scientists using computational approaches to understand the complexities of cancer, as well as post-doctoral fellows and doctoral students training in this field. Through breakout working groups, symposium participants identified leading-edge research opportunities with a focus on opportunities that are unique to Texas, as well as resources, research expertise, and infrastructure needed to further elevate Texas' preeminence in this field. The event also provided an opportunity for networking and developing collaborations.

Several CPRIT staff attended the symposium (Chief Scientific Officer Dr. Michelle Le Beau, Director of Research Dr. Patty Moore, Deputy Executive Officer and General Counsel Kristen Doyle, Chief Strategic Initiatives Officer and Intellectual Property Officer Tracey Davies, Chief Prevention Officer Ramona Magid, Director of Communications Mark Loeffler, Digital Communications Specialist Justin Rand, and me), as well as CPRIT Oversight Committee member Dr. William Rice.

88th Texas Legislature Update and Activities

The 88th Texas Legislature convened in Austin at noon on January 10 and will adjourn *sine die* at midnight on May 29. As of March 10 (the 60th day of the session), legislators filed 8,276 bills by the deadline, a record number. The information reported below on CPRIT's budget, CPRIT-related legislation, and other notable legislation is current as of 8:00 a.m. May 4.

Senate Confirms Dr. David Cummings' Reappointment to the Oversight Committee

On April 24, the Senate Committee on Nominations considered Governor Abbott's reappointment of Dr. David Cummings to the Oversight Committee. The committee did not ask Dr. Cummings to appear before approving his nomination and forwarding the nomination to the full Senate for confirmation. The Senate confirmed Dr. Cummings' appointment on April 26 for a term that will expire January 31, 2029.

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

The House and Senate released the draft appropriations bills January 18. Both provide 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.

Both draft bills include 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 does not provide additional general revenue to fund the COLA; instead, the budget writers transfer the money from (and thereby reduce) the money available for CPRIT's research and prevention programs. The draft bills also include an increase to the CEO position of $402 purportedly to match a market compensation report issued by the State Auditor's Office.

The 5% COLA increase does not apply to our two exempt positions (the Chief Scientific Officer and CEO), even though CPRIT's Legislative Appropriations Request specifically asked that any COLA granted to non-exempt employees also apply to exempt positions. I repeated this request in my presentation to the Senate and House budget committees on January 30 and February 21, respectively, emphasizing only the one for the scientific officer.

The House Appropriations Subcommittee on Articles I, IV and V, chaired by Representative Mary González, recommended including the COLA increase for the CSO in Article XI (wish list). The full House Appropriations Committee adopted the subcommittee's recommendation, as did the full House on April 6.

On March 27, the Senate Finance Committee adopted the recommendations of the Senate Finance Workgroup on Article I, IV and V chaired by Senator Juan "Chuy" Hinojosa. The workgroup recommended CPRIT's request for the COLA increase for the CSO exempt salary position. The full Senate adopted the Senate Finance Committee Substitute for House Bill 1 on April 17.

The House and Senate named their appointments to the Conference Committee on House Bill 1 on April 20 and 21. The House conferees are Representatives Greg Bonnen, Mary González, Jacey Jetton, Gary VanDeaver and Armando Walle. Senate conferees are Senators Joan Huffman, Robert Nichols, Lois Kolkhorst, Brandon Creighton and Charles Schwertner.

The CSO COLA will be our only issue for the state budget conference committee to resolve. I am optimistic the conference committee will recommend adoption. The only item CPRIT requested not included in either bill is the same COLA for the CEO position. Without Oversight Committee intervention, it is unlikely that the legislature will adopt this request.

CPRIT-Related Legislation

- Senate Bill 1838/House Bill 4160 (companions)
  Senator Juan "Chuy" Hinojosa and Representative Ryan Guillen filed companion legislation that makes significant changes to CPRIT's enabling legislation.

  The proposed legislation would imbed within CPRIT an Oversight Committee for Neurodegenerative Diseases as the governing body of the Alzheimer's Research Collaborative of Texas. The bill would alter the use of CPRIT bond proceeds from cancer prevention and research grants to Alzheimer's disease research.

  We believe the bills are unconstitutional and would violate the terms of the bond covenants related to CPRIT debt issuance by the Texas Public Finance Authority. I reached out to both authors' offices, and I had a brief initial discussion with Senator Hinojosa about the bill. I await a response to my request to speak with 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.

  Senator Hinojosa added $200 million in general revenue for CPRIT in the Senate proposed budget's Article XI (wish list). Without legislative or appropriations guidance, implementation of this funding and Senate Bill 1838 will be difficult.

  As of May 4, neither the House Committee on Public Health nor the Senate Committee on Health and Human Services have set the bills for committee hearings.

- House Bill 3914
  Representative Oliverson filed legislation that would 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 requires 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 have some 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 is set for a hearing.

As of May 4, the House Public Health Committee has not set the bill for a hearing.

Other Notable Legislation

- House Bill 15/House Joint Resolution 135
  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 are among Speaker Phelan's priorities for the session.

  The legislation proposes to fund the new agency through a constitutional dedication of $3 billion of general revenue. We have 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.

  The House passed both bills on April 11 with a vote of 116 yeas and 29 nays (2 present, not voting, and 3 absent.) The Senate received both bills on April 11. I do not know if the supporters of the legislation have identified a senate sponsor. As of May 4, the Senate has not assigned the bills to a committee for hearing.

- Senate Bill 989/House Bill 3188
  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" is 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.

  The Senate adopted SB 989 on April 12 by a vote of 26 yeas and 4 nays, with one member absent. The House received SB 989 and referred it to the House Insurance Committee, which approved the bill. The House Local and Consent Calendar Committee reported favorably SB 989 on April 27.

- Senate Bill 704 (Paxton), Senate Bill 1014 (Hughes), Senate Bill 2086 (Kolkhorst), Senate Bill 1544 (Johnson)/House Bill 2545 (Capriglione) (companions)
  Several legislators have filed bills this session relating to the use of an individual's genetic data. The House and Senate have referred the bills to various committees, including Senate State Affairs, Senate Business & Commerce, Senate Health & Human Services, and House Business & Industry.

  These bills appear to address genetic testing companies that use the data for commercial purposes, such as 23&Me, and incorporate restrictions on retention of the genetic data and

require heightened procedures for informed consent. However, some CPRIT grantees have expressed concern that the legislation may affect genetic data used for research purposes, including de-identified data maintained in research databases. We are monitoring the status of these bills.

Of the legislation filed on this issue, only HB 2545 and SB 2086 have garnered legislative action:

HB2545: The House Committee on Business & Industry held a hearing on the proposed legislation on March 27 where Rep. Capriglione filed a committee substitute to address some of the concerns raised about the legislation inadvertently infringing upon the use of genetic data for research purposes. The committee recommended the committee substitute to the Local and Consent Calendar Committee. The House passed the legislation by record vote on April 28. The Senate received the bill on May 1 and assigned it to the Senate Business & Commerce Committee for a hearing on May 4.

SB 2086: On April 26, the Senate Health & Human Services Committee held a public hearing on the bill and left it pending. The committee took a vote on the bill on May 3.

CPRIT Outreach

Advanced Research Projects Agency for Health (ARPA-H) and Federal Outreach

On March 15, ARPA-H announced its intent to create sites in three geographic locations across America through a "hub-and-spoke" strategy, forming a health network to advance the agency's mission. Each hub will sustain a network of "spokes" (partners) to support ARPA-H's needs. The sites will form a center for key ARPA-H functions, but with a "light" footprint, housing a small number of ARPA-H team members and meeting facilities, alongside key personnel to support agency objectives. Individual projects would then leverage program-relevant assets - the spokes - throughout the country from the hubs.

- ARPA-H will locate Hub One in the Washington, DC, area; it will focus on stakeholder engagement and operations (read "administration").

- Hub Two, a customer experience hub, will drive user testing, adoption, access, and trust of ARPA-H's projects, taking a "human-centered" approach to design products and services that people need and want. It will take a proactive approach to enhance clinical trials, reach representative patient populations, and capture outcomes data for future research.

- Hub Three, an investor catalyst, will provide resources to help performers bring their ideas to market.

Hub Sites Two and Three will be determined by open solicitation through a Request for Consortium Agreement (RCA). The consortium will be comprised of a central "hub" facility which will contract directly with ARPA-H. The various spokes and other necessary capabilities to complete ARPA-H projects will subcontract with the hub consortium.

ARPA-H held an informational proposer's day on March 24 to review the draft RCA, get feedback, and respond to questions. Responses to the solicitation were due April 21. Dallas and Houston each submitted proposals for Hub Two, the customer experience hub. We have not seen the proposals, but understand that the Dallas proposal teams with Austin, San Antonio, Tyler, Lubbock and El Paso with some 600 additional spokes around the country. We believe that Houston's collaborators are largely Texas Medical Center institutions.

ARPA-H will announce the preliminary selections on May 12, with in-person pitch days running from May 29 through June 26. Full proposal submission deadline is July 7 with the final award notification on September 22.

CPRIT Engagement with the ARPA-H

Last November I wrote to ARPA-H Director Dr. Renee Wegrzyn offering to discuss opportunities to integrate CPRIT's efforts with ARPA-H initiatives. On May 10 Chief Scientific Officer Dr. Michell Le Beau, Deputy Executive Officer and General Counsel Kristen Doyle, Chief Strategic Initiatives and Intellectual Property Officer Tracey Davies and I will meet with a senior official of ARPA-H to begin discussing these opportunities. As with the similar outreach to the National Cancer Institute, the discussion will be introductory. CPRIT will discuss ideas with appropriate CPRIT advisory committees and interested Oversight Committee members.

Other Staff Outreach

Staff outreach activities during April include:

- On April 4, Senior Program Manager for Product Development Research Dr. Abria Magee, participated on a panel titled, "Houston as a Biomedical Innovation Hub Connecting Texas to Asia and Beyond." The discussion focused on the importance of maintaining and building connections between Houston's biomedical community and Asia, as well as the need to build a critical mass to ensure Houston becomes a long-term global hub of biomedical innovation. The discussion featured Ann Tanabe, CEO of BioHouston; Dr. Ferran Prat, Senior Vice President of Research Administration and Industry Ventures at The University of Texas MD Anderson Cancer Center; Eric Johnson, Executive Managing Director for Transwestern's Life Science Advisory Services Group; Dr. Paul Cherukuri, Vice President for Innovation at Rice University; and Convergence Venture's partner John Nghiem.

- Dr. Le Beau and I met with representatives of the Leukemia and Lymphoma Society on April 5 to discuss various legislative and advocacy interests.

- On April 18, Dr. Magee met with Dr. Joe McDonough, Vice President of Research at the Southwest Research Institute in San Antonio. Dr. McDonough presented a cancer immunotherapeutic core idea to Dr. Magee. They discussed the opportunity to leverage San Antonio collaboratives for this new idea and how CPRIT could potentially be involved.

- On April 19, Dr. Magee and Jean Gilbert, Business Development Manager in the Office of Strategic Industry Ventures at The University of Texas MD Anderson Cancer Center, met in-person to discuss cancer-focused companies that have partnered with MD Anderson who are interested in applying for CPRIT awards.

- On April 25 representatives of CPRIT grantee OncoNano provided an update on the company's progress to Chief Product Development Officer Dr. Ken Smith, Senior Program Manager for Product Development Dr. Abria Magee, Program Manager for Product Development Dr. Waye Leeuwon, Dr. Le Beau, Ms. Doyle, Ms. Davies and me.

- On April 26 I attended Governor Abbott's celebration of the 75th Anniversary of the Independence of the State of Israel and the Friends of Israel Legislative Caucus at the Governor's Mansion. I plan to attend a similar celebration on May 18 in Houston at the invitation of the Consular General of Israel.

- Product Development Program Manager Dr. Waye Leeuwon and Dr. Magee met with several companies, including Slipstream RX and Alethiah, in April to discuss the CPRIT product development application process and timeline.

- The industry group BIO invited Ms. Doyle to participate on a panel discussion with a representative of the California Institute of Regenerative Medicine (CIRM) at the big BIO International conference held in Boston in early June. The panel will discuss the impact these two large state research funds are having on the health and economies of their states. This is a presentation we have envisioned for several years. Dr. Smith, Dr. Magee, and Dr. Leeuwon also plan to attend the BIO International conference as part of the Texas delegation coordinated by the Texas Healthcare and Bioscience Institute (THBI.)

Compliance Program Update

Submission Status of Required Grant Recipient Reports

As of April 26, seven entities had not filed six academic research reports, and one product development report. CPRIT's grant accountants and compliance specialists review and process incoming reports and reach out to grantees to resolve filing issues. In most cases, CPRIT does not disburse grant funds until the grantee files the required reports. In some instances, grantee institutions may be ineligible to receive a future award if the grantee does not submit required reports.

Financial Status Report Reviews

CPRIT's compliance specialists performed 162 second-level reviews of grantee Financial Status Reports (FSRs) in April. Nineteen FSRs (12%) 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 five enhanced desk-based financial monitoring reviews in April. 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 one onsite review in April. 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.

Match Expenditures Review

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

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

staff performed two annual match expenditure reviews for two grantees in April. The total amount of match expenses reviewed by compliance staff for FY 2023 is $16,339,607.50. The unallowable match expenses for FY 2023 total $22,368.06.

Training and Support

CPRIT staff conducted one new Authorized Signing Official (ASO) training webinar in April for University of Houston - Downtown. 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 a compliance training within 60 days of the change.

Academic Research Program Update

Recruitment FY 2023 Review Cycle 3

CPRIT's Scientific Review Council (SRC) reviewed recruitment applications for the third quarter of FY 2023 on March 16. Dr. Le Beau will present the SRC's award recommendations for recruitment awards to the Program Integration Committee (PIC) and the Oversight Committee in May.

FY 23 Mechanism	Received	Funds Requested	Recommended	Recommended Funds
Recruitment of Established Investigators	4	$23,999,986	2	$12,000,000
Recruitment of First-Time, Tenure Track Faculty Members	3	$6,000,000	2	$4,000,000
TOTAL	**7**	**$29,999,986**	**4**	**$16,000,000**

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. 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. CPRIT received 26 applications by the deadline. Peer review panels will meet virtually in June to consider the applications. Dr. Le Beau will present the SRC's recommendations to the PIC and the Oversight Committee in August.

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 and opened the online application portal on March 15. CPRIT will accept applications through June 14. Peer review will take place in the Fall. 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.

Product Development Research Program Update

Product Development FY 2023 Review Cycle

CPRIT released four FY 2023 Product Development Research RFAs and opened the portal to receive preliminary applications on a rolling basis beginning August 24, 2022. CPRIT received 59 preliminary applications before CPRIT stopped accepting applications in late January.

Of the 29 companies CPRIT invited to submit full applications, 14 companies filed full applications by the November 1, 2022, deadline for the 10 review slots available in the first review cycle. The first ten companies, requesting $149 million, presented their full applications to review panels the week of December 12 – 16, 2022. The review panels recommended six companies, requesting $82.5 million, to proceed to due diligence review. The panels met January 13 – January 20 to consider due diligence reports.

Based on the work done by the peer review panels, the Product Development Review Council (PDRC) recommended six companies for product development awards in a January letter to the PIC and the Oversight Committee. The table below provides information about the full application review.

FY 2023 RFA	Submitted by Nov 1	Budget Request	Review Cycle 1	Review Cycle 1 Request	Due Diligence	Due diligence Request
TTC	9	$150,026,040	7	$118,109,015	4	$67,456,802
TDDC	1	$3,644,032	0	N/A	N/A	N/A
TNTC	2	$27,982,099	2	$27,982,099	1	$12,000,000
Seed	2	$5,983,763	1	$2,999,858	1	$2,999,858
TOTAL	**14**	**$183,991,902**	**10**	**$149,091,114**	**6**	**$82,456,660**

The total budget request for the six companies recommended by the PDRC was $82.5 million, which exceeds the $57 million available for FY 2023 product development awards. With the goal of funding as many companies recommended by the PDRC with the available FY 2023 budget, Chief Product Development Officer Dr. Ken Smith requested, and the PIC agreed at its February meeting, to defer PIC action on the PDRC's recommendations until the May Oversight Committee meeting.

Dr. Smith negotiated the proposed budgets requested by the companies. Each of the recommended companies worked in good faith with Dr. Smith to identify ways to decrease CPRIT-funded project expenses while maintaining the goals and objectives of the recommended project. As a result of this work, Dr. Smith has decreased the total award amount requested by the six recommended companies to an amount that CPRIT may fund with the available FY 2023 product development budget. He will present the companies recommended for product development awards to the Oversight Committee at the May 17 meeting.

Product Development FY 2024 Review Cycle 1 (24.1)

On May 1 CPRIT posted the four FY 2024 Product Development Research Program RFAs approved by the Oversight Committee at its February meeting. CPRIT also began accepting preliminary applications the same day and will do so on a rolling basis for the next several weeks. As of 8:00 a.m. on May 4, 14 companies have already submitted preliminary applications and eight other companies have started preliminary applications in the system.

Like the FY 2023 review cycle, CPRIT will issue invitations to submit full applications only to companies that have submitted meritorious preliminary applications as determined by the preliminary application peer review panel. CPRIT will accept full applications through August 1. Although CPRIT will limit the number of full applications reviewed in the first FY 2024 review cycle, we plan to provide five more slots for full application presentations than we offered in FY 2023, for a total of 15 company slots.

Full application panel review and company presentations will take place in September. Due diligence review will occur in October for those companies that the panels intend to recommend for CPRIT funding, with a final vote of the PDRC expected in mid-October. Dr. Smith will present the 24.1 cycle product development awards to the PIC and the Oversight Committee in November.

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. CPRIT peer reviewers will evaluate the applications in April - June.

Chief Prevention Officer Ramona Magid will present the Prevention Review Counsel's (PRC) 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 will release two prevention RFAs (*Primary Prevention of Cancer* and *Cancer Screening and Early Detection*) in May for the first cycle of FY 2024. CPRIT has scheduled peer review 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 is in the process of identifying a database and software as a service (SaaS) provider that will store the IP information and underlying documentation reported by grantees. The proposed database will enable searching, tracking, and data analysis, and will issue reports across a variety of parameters. We anticipate identifying and engaging a database/SaaS provider by late June.

The third phase of the project (data migration) will begin once CPRIT contracts with a database 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 Geographic Diversity Advisory Committee met April 14.
- The Prevention Advisory Committee met April 27.

Operations, Finance, and Conference Update

CPRIT finalized the conference schedule and speakers this month. The abstract submission system and the conference registration portal, available through the dedicated website for the conference, www.texascancerconference.org, are both live. As of May 2, CPRIT has received 65 paid registrations for the Innovations VI Conference. CPRIT sent a listserv notice May 2 reminding potential attendees that the early bird registration rates end May 15, with the regular registration rate increases in effect on May 16.

CPRIT's internal auditor, Weaver and Tidwell, completed the contract risk assessment advisory engagement. Weaver assisted CPRIT in creating a contract risk assessment tool to measure the risk rating of CPRIT's service contracts (by contrast, CPRIT risk-rates the grant contracts using the grant compliance risk assessment tool) and ensure that appropriate contract monitoring is in place for each of those contracts. CPRIT will use the new risk assessment tool for the first time in the agency procurement process later this fiscal year to rate the FY 2024 service contracts.

Upcoming Subcommittee Meetings

Listed below are the subcommittee meetings in advance of the May 17 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	May 4 at 10:00 a.m.
Audit	May 8 at 10:00 a.m.
Prevention	May 9 at 12:00 p.m.
Academic Research	May 10 at 12:00 p.m.
Product Development	May 11 at 10:00 a.m.

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CPRIT has awarded **1,865** grants totaling **$3.261 billion**

- 282 prevention awards totaling $341.5 million
- 1,583 academic research and product development research awards totaling $2.92 billion

Of the $2.92 billion in academic research and product development research awards,

- 30.9% of the funding ($901.3 million) supports clinical research projects
- 24.1% of the funding ($705.0 million) supports translational research projects
- 29.2% of funding ($853.6 million) supports recruitment awards
- 12.7% of the funding ($369.5 million) supports discovery stage research projects
- 3.1% of funding ($90.4 million) supports training programs.

CPRIT has 11 open Requests for Applications (RFAs)

- 2 Recruitment
- 5 Academic Research
- 4 Product Development Research

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	CPRIT ACTIVITIES UPDATE FOR FEBRUARY AND MARCH 2023
DATE:	APRIL 4, 2023

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

Recent Milestones in the Fight Against Cancer

CPRIT Grantees in the News

- The Texas Academy of Medicine, Engineering, Science and Technology (TAMEST) announced January 17 that it will honor two preeminent researchers at The University of Texas MD Anderson Cancer Center with awards at its annual conference on May 24.

  Jennifer A. Wargo, M.D., professor in the departments of surgical oncology and genomic medicine at The University of Texas MD Anderson Cancer Center, will receive the 2023 Edith and Peter O'Donnell Award in Medicine for her contributions to the understanding of how the gut microbiome influences responses to immunotherapy and other cancer treatments. TAMEST bestows the O'Donnell Awards annually in five categories – medicine, engineering, biological sciences, physical sciences, and technology innovation – to recognize and support Texas researchers who are addressing the essential roles that science and technology play in society, and whose work meets the highest standards of exemplary professional performance, creativity, and resourcefulness.

  Dr. Wargo led a team of researchers that cataloged the intestinal microbiomes in patients with melanoma, demonstrating that patients with metastatic melanoma had improved responses to immunotherapy if they had a more diverse population of microbes or an abundance of certain types of bacteria in their gut. The December 24, 2021, issue of *Science*, published the findings, which contributed to launching a new line of inquiry in cancer research – evaluating whether scientists can improve therapeutic efficacy and outcomes by modulating the microbiome. The work also led to an ongoing MD Anderson clinical trial, led by Jennifer McQuade, M.D., to evaluate the impact of a high-fiber diet on the microbiome and immunotherapy responses in patients with melanoma and other cancers.

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An internationally renowned physician scientist, Dr. Wargo runs a translational research laboratory studying the genetics of melanoma and other cancers with the goal of understanding what allows them to proliferate, metastasize, and evade the immune system. CPRIT awarded grants totaling $1.15 million (RP150030, RP200574) to support Dr. Wargo's research.

Florencia McAllister, M.D., associate professor in the clinical cancer prevention department, will receive the 2023 Mary Beth Maddox Award and Lectureship in Cancer Research. Named for TAMEST's former executive director, the award recognizes women scientists in Texas bringing new ideas and innovations to the fight against cancer.

The award recognizes Dr. McAllister's pioneering research on the intra-tumoral bacteria detected in long-term pancreatic cancer survivors and the discovery of a gut-tumor axis that inspired the use of fecal microbial transplants to improve therapy outcomes. Dr. McAllister will promote her work and discoveries across the state through a series of lectures at the four NCI Designated Cancer Centers in Texas.

CPRIT awarded MD Anderson and Dr. McAllister a $2 million Individual Investigator Research Awards for Clinical Translation grant (RP200173) in 2020 to support this work.

- On February 9, the Research Corporation for Science Advancement (RCSA) named CPRIT Scholar Julian West, Ph.D., as a 2023 Cottrell Scholar. RCSA annually honors 25 scientists with the prestigious early-career awards. The highly selective program accepts proposals from chemists, physicists and astronomers from U.S. and Canadian research universities. Awardees receive $100,000 and are eligible to compete for future funding through the Cottrell Plus Awards program. Rice University recruited Dr. West to Texas from the California Institute of Technology with a $2 million CPRIT Recruitment of First-Time, Tenure-Track Faculty Members grant (RR190025) in 2019.

- The University of Texas MD Anderson Cancer Center announced February 22 that CPRIT-grantee Dr. Jennifer Wargo received the 2023 Sergio Lombroso Award in Cancer Research. The award, bestowed by the Weizmann Institute of Science, recognizes an internationally distinguished scientist, medical researcher, or physician, who has made highly significant contributions to the understanding of the causes and mechanisms of cancer, or to its diagnostics and therapy. CPRIT awarded MD Anderson grants totaling $1.15 million (RP150030, RP200574) to support Dr. Wargo's research.

- On February 27, *UTMB News* featured Dr. Ana Rodriguez's CPRIT project, "School-Based Human Papillomavirus Vaccination Program in the Lower Rio Grande Valley." CPRIT awarded The University of Texas Medical Branch at Galveston nearly $7 million since 2016 (PP160097, PP190023, PP200057, PP230043) to support this prevention project.

- Aravive, Inc., a late clinical-stage oncology company developing targeted therapeutics to treat metastatic disease, announced on February 28 that the FDA granted Orphan Drug Designation (ODD) to batiraxcept for the treatment of pancreatic ductal adenocarcinoma cancer. The FDA's Office of Orphan Products Development grants ODD status to a drug or

biological product to prevent, diagnose or treat a rare disease or condition affecting fewer than 200,000 people in the U.S.

Aravive's CEO Gail McIntyre, Ph.D., DABT, explained, "Receiving Orphan Drug Designation is another important milestone for batiraxcept, and it underscores the significant unmet medical need in patients with pancreatic cancer, typically diagnosed at an incurable advanced stage with a 5-year survival rate of 11%." The Phase 1b portion of the trial is ongoing, with the dose escalation phase initiated in February. The company expects preliminary results from the 20mg/kg batiraxcept plus gemcitabine and nab-paclitaxel cohort in the second half of 2023.

Houston-based Aravive received a $20 million CPRIT New Company Product Development Award (DP150127) in November 2015.

- Recent CPRIT-grantee Prana Thoracic announced March 3 the closing of its $3 million founding Series A financing led by New World Angels and joined by Johnson & Johnson Innovation, Inc., Texas Medical Center Venture Fund and the University City Science Center's Phase 1 Ventures. William McKeon, President & CEO of the Texas Medical Center (TMC) congratulated the company, noting, "Prana's cutting-edge technology was developed on the TMC campus, and we are excited to continue to support Prana in meeting its next milestone through funding from the TMC Venture Fund. The technology they are spearheading could be a game changer in how physicians detect and treat lung cancer."

  CPRIT awarded the Houston-based medical device company $3 million in August 2022 (DP220054) to develop the first minimally invasive lung tissue excision tool for early intervention in lung cancer. With the Series A funds and the CPRIT grant, Prana will continue product development and conduct the first-in-human clinical studies.

- The San Antonio Women's Hall of Fame inducted CPRIT grantee Dr. Amelie Ramirez at an event on March 4. Since 1984, the San Antonio Women's Hall of Fame has annually inducted women from Bexar and surrounding counties who have shaped the future of San Antonio and paved the way for women in Texas business, service, education, health and more.

  Dr. Ramirez is a professor and chair of the Department of Population Health Sciences, director of the Institute for Health Promotion Research at The University of Texas Health Science Center at San Antonio, and the associate director of cancer outreach and engagement at the Mays Cancer Center. She directs the *Salud America*! national multimedia program, conducts breast cancer disparities research on quality of life and survivorship issues, and directs *Quitxt*, a bilingual tobacco-cessation service for young Latino adults using mobile-phone text messages, funded by CPRIT. In 2022, TV personality Oprah Winfrey selected Ramirez as a "Cycle Breaker" for her groundbreaking work to build health equity in the Latino community.

CPRIT awarded UT Health San Antonio and Dr. Ramirez more than $4 million in three prevention project grants since 2014 (PP140176, PP170099, PP180092) to increase accessibility and use of evidence-based smoking cessation services among underserved young adults in South Texas.

- On March 7, the National Colorectal Cancer Roundtable, co-founded by the American Cancer Society and the Centers for Disease Control and Prevention, honored five organizations for their exceptional work to increase colorectal cancer screening rates across the U.S. The 2023 "80% In Every Community National Achievement Award" recognizes individuals and organizations for dedicating their time, talent, and expertise to advance colorectal cancer screening rates to 80% or higher across the United States in an equitable manner.

  The Grand Prize Winner was the CPRIT-funded project "Expanding Mailed Stool Test-Based Colorectal Cancer Screening in Vulnerable Populations in Central Texas," directed by Dr. Michael Pignone at The University of Texas Austin's Dell Medical School in partnership with CommUnityCare Health Centers.

  The project team mailed Fecal Immunochemical Test (FIT) kits coupled with bilingual, bi-cultural screening navigation to ensure patients with abnormal FIT results received timely colonoscopies. Since 2017, the project sent out more 58,000 FITs. Nearly 13,500 patients completed the testing, with 726 positive tests. The program successfully navigates more than 75% of FIT-positive patients to colonoscopy. In less than five years, CommUnityCare has doubled the proportion of patients up to date with CRC screening (from 19% to 44%) with no disparities based on insurance status, race, or ethnicity. These results are even more significant because the project team achieved them amidst the challenges of COVID-19. To date, the program has detected 16 colorectal cancers (70% early stage) and removed over 195 adenomas.

  CPRIT awarded UT's Dell Medical School and Dr. Pignone $4.4 million since 2017 (PP170082, PP200066, PP220006) to support and expand this prevention project.

- On March 8 KFDA News in Amarillo featured Dr. Izi Obokhare of Texas Tech University Health Sciences Center at Amarillo as part of its "Health Watch" segment during Colorectal Cancer Awareness Month. Dr. Obokhare highlighted the increasing rate of colorectal cancer cases in young adults in the region and nationwide. He is the director of CPRIT project, "Get F.I.T. to Stay Fit - Stepping up to Fight Colorectal Cancer in the Panhandle." CPRIT awarded Texas Tech University Health Sciences Center more than $5 million since 2014 (PP150031, PP180031, PP210017) to support this prevention project.

- The March 14 edition of *Vital Record, News from Texas A&M Health* featured a discussion with Jason McKnight, M.D., M.S., FAAFP, about the basics of colorectal screening and prevention. Dr. McKnight, clinical associate professor at the Texas A&M University School of Medicine and director of residency recruitment for the Texas A&M Family Medicine Residency program, is also the director of the CPRIT project, "Leveraging Texas C-STEP's

Robust Rural Partnerships for Successful Expansion of its Proven Colorectal Cancer Screening Program to Include HCV Screening." CPRIT has awarded Texas A&M University Health Science Center nearly $4 million since 2018 (PP220013, PP180037) to support this prevention project.

- On March 14, the Third Annual Healthcare Digital Marketing Awards recognized The Rose for their outstanding digital marketing efforts to empower women to take control of their breast health. The Rose, a recipient of multiple CPRIT prevention awards and the leading nonprofit breast health care organization in southeast Texas, received a Gold Award for the character "Mona the Mammo Queen" and a Silver Award for The Rose's educational video "Let's Talk about Your Breasts".

  Their "Mona the Mammo Queen" campaign is a creative and engaging way to encourage women to get their mammograms. The Rose developed the character of Mona to speak to younger women, especially those turning 40 and help them feel comfortable about the screening process. The campaign was highly successful in increasing mammogram appointments and encouraging women to take control of their breast health. The Rose's video, "Let's Talk about Your Breasts," is a powerful and uplifting resource that focuses on partnering with the community to raise awareness about breast health in a positive and inclusive way, across cultures where conversations about the body and health are often silenced.

  CPRIT has awarded The Rose eight CPRIT breast cancer screening and early detection grants since 2010 (PP100096, PP110154, PP120040, PP140171, PP150080, PP170091, PP190043, PP220015) totaling nearly $12 million.

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

- **Amplifying the Impact of Personalized Medicine with Artificial Intelligence.** The recent decrease in cancer death rates for patients with non-small cell lung cancer (NSCLC) treated with tyrosine kinase inhibitors (TKIs), such as Erlotinib, demonstrates the power of personalized oncology. TKIs targeting the epidermal growth factor receptor (EGFR) are effective for many patients with lung cancer with EGFR mutations (60-80%). But not all patients harboring such mutations respond to these drugs, making it clinically important to identify predictors of response and resistance to EGFR TKIs.

  Routine clinical diagnostic procedures for NSCLC – one of the deadliest cancers – center around the analysis of hematoxylin and eosin-stained slides of tumor tissue by pathologists that provide detailed tumor morphological characterization at high resolution. With the development of whole-slide image scanning techniques and deep-learning based image analysis methods, the application of artificial intelligence to guide computational analysis of pathology images holds tremendous potential to assist pathologists with cancer diagnosis and prognosis.

As reported in the January 17 issue of the *Journal of Clinical Investigation*, a team of investigators led by Yang Xie, Ph.D., professor and Raymond D. and Patsy R. Nasher Distinguished Chair in Cancer Research in the Lyda Hill Department of Bioinformatics at The University of Texas Southwestern Medical Center, harnessed the power of artificial intelligence for sophisticated pathology image analysis culminating in the development of an algorithm to predict response to EGFR TKIs.

Using a multi-step approach, the investigators initially quantified the cells and cellular interaction features of the tumor microenvironment (TME) using routine stained tumor biopsy sections. Researchers use these TME features to develop a prediction model for survival benefit from EGFR TKI therapy in patients with lung adenocarcinoma and EGFR mutations in the Lung Cancer Mutation Consortium 1 (LCMC1) database and validated in an independent LCMC2 cohort. The EGFR TKI survival benefit positively correlated with tumor-tumor interaction image features and negatively correlated with tumor-stroma interaction.

Next, researchers used gene expression analysis in a third independent cohort to examine potential molecular mechanisms of resistance suggested by the risk prediction model. This analysis revealed that the tumor-stroma interaction was associated with higher activation of cell signaling pathways, such as the PI3K/AKT pathway and the epithelial-mesenchymal transition process -indicative of the metastatic process - supporting the hypothesis of tumor microenvironment cell-involved resistance to EGFR TKI treatment. Developing digital image-based predictive models in lung cancer may be universally applicable and adaptable to other cancers; thus, these models may inform other treatment decisions, e.g., combination therapy and immunotherapies, as well as drug development.

CPRIT awarded UT Southwestern three research grants totaling $4.5 million to support the work of Dr. Xie (RP120732, RP180805) and her co-senior author Guanghua Xiao (RP190107).

- **Finding Order in Chaos.** A research team at The University of Texas Southwestern Medical Center, led by CPRIT Scholar Benjamin Sabari, Ph.D., discovered a previously unrecognized mechanism that cells use to turn genes on and off to regulate the timing, location, and amount of a given gene product (usually a protein) present in a cell. Surprisingly, this level of control involves “disordered” regions of proteins whose function has long been a mystery. The findings, reported in the January 19 issue of *Cell*, could lead to new ways of controlling gene regulation, and may one day lead to new treatments for a broad array of diseases. This study is the Sabari laboratory’s first independent published research.

  Dr. Sabari, an assistant professor in the Cecil H. and Ida Green Center for Reproductive Biology Sciences at the Harold C. Simmons Comprehensive Cancer Center, together with his laboratory colleagues, focused on MED1, a protein that forms part of a complex involved in transcribing mRNA from DNA, a critical step in the process through which genes produce proteins. MED1, which has a large “intrinsically disordered region” (IDR), is present in some

biomolecular condensates and linked to the pathogenesis of estrogen receptor-positive breast cancer.

Understanding how interactions among different IDRs within condensates are dysregulated in diseases, such as cancer, and finding ways to alter their interactions may lead to a new class of treatments for these conditions. Dr. Sabari's plans to leverage the CPRIT-funded core facilities at UT Southwestern to perform high-throughput screening to identify small molecule inhibitors or peptides that that can disrupt these IDR-mediated interactions occurring within condensates.

UT Southwestern recruited Dr. Sabari to Texas with a $2 million CPRIT First-time, Tenure-Track Award (RR190090) in 2019.

- **The "Chicken or the Egg" Mystery of Human Papilloma Virus.** Human papillomavirus (HPV) causes more than 630,000 cancers worldwide each year, including anogenital and oropharyngeal squamous cell carcinomas. Early in the infection, the viral genome exists as a small extrachromosomal circular DNA molecule. In most subsequent cancers, HPV DNA integrates into the host genome. However, researchers have not yet determined the consequences of viral integration on the integrity of the host DNA, how the host DNA affects the virus, and how this process contributes to cancer development.

  Seminal research reported by CPRIT Scholar Maura Gillison, M.D., Ph.D., in the January 30 issue of *Cancer Discovery*, may have cracked this scientific "Chicken or the Egg" mystery of how HPV affects, or is affected by, host DNA and how it drives cancer development. Using long-read DNA sequencing, the research team from The University of Texas MD Anderson Cancer Center led by Dr. Gillison credits heterocateny, a previously unreported form of genomic structural variation. With this new heterocateny model, the authors demonstrated for the first time how HPV contributes to intratumoral heterogeneity and clonal evolution, driving the creation and development of tumors. Heterocateny is characterized by diverse, interrelated and repetitive patterns of virus and host DNA segments within a cancer. It is the result of genetic instability caused by HPV insertion into and excision from host chromosomes, a process by which the virus hijacks, amplifies and recombines host DNA. These findings may have broader implications for cancers caused by other DNA tumor viruses that integrate into host DNA, including the hepatitis B virus.

  MD Anderson recruited Dr. Gillison, a renowned investigator in HPV-related cancers, to Texas from Ohio State University with a $6 million CPRIT Established Investigator Recruitment Award (RR170005) in 2017.

- Despite recent improvements in targeted and immune therapy, pancreatic ductal adenocarcinoma (PDAC) is incurable. One of the major obstacles to treating PDAC is the tumor microenvironment that is highly resistant to immunotherapy. Researchers including CPRIT Scholar Leng Han, Ph.D., Department of Biochemistry and Molecular Biology, The University of Texas Health Science Center at Houston, and CPRIT Scholar Zhi Tan, M.D., Ph.D., Department of Pathology, Baylor College of Medicine, set out to understand the role

of these cells by characterizing the gene signature of tumor-associated nonmyelinating Schwann cells (TASc). The researchers found that the abundance of TASc was correlated with poor patient outcomes. Specifically, TASc express a long noncoding RNA (lncRNA) named PVT1, which triggers a signal pathway that promotes tumor growth. As reported in the February 1 edition of *Science Advances*, treatment response to immune checkpoint inhibitors improved using a TASc inhibitor in vivo, highlighting TASc and lncRNAs as potential therapeutic targets for pancreatic cancer.

Several CPRIT grants supported this research, including an academic research grant to Texas A&M University System Health Science Center (RP190570) in 2019, and two grants to The University of Texas MD Anderson Cancer Center (RP180259, RP200423). Baylor College of Medicine recruited Dr. Tan to Texas in 2022 through a CPRIT Recruitment of First-Time, Tenure-Track Faculty Members grant (RR220039). The University of Texas Health Science Center at Houston recruited Dr. Han in 2015 through a CPRIT Recruitment of First-Time, Tenure-Track Faculty Members grant (RR150085).

- Colorectal cancer (CRC) screening is effective in reducing CRC incidence and death, but it is underutilized, particularly in under-resourced communities and populations. Federally qualified health centers (FQHCs) serve populations at high risk for being unscreened, including uninsured and rural populations. However, these efforts are challenging, particularly in states like Texas, where 40% of patients seen in FQHCs are uninsured. Only 36% of patients seen by the 72 FQHCs in Texas are up to date with CRC screenings.

  A team led by Michael Pignone, Ph.D., professor, Department of Internal Medicine at The University of Texas at Austin, conducted geospatial analysis of data obtained from the CDC, the Texas Department of State Health Services, and other sources. This analysis identified and mapped a list of priority FQHCs in Texas that 1) had a high number of patients without up-to-date CRC screening and 2) that were not participating in CPRIT-funded CRC screening projects. The results of the geospatial analysis and map, published in the March 2 edition of *Preventing Chronic Disease*, produced a list of 11 FQHCs without current CPRIT funding where improvements in CRC screening among eligible patients could have the largest impact. In the next phase of the research, the team will use the mapped information to contact and consult with the FQHCs and help them apply for CPRIT funding to enhance CRC screening in their systems. The University of Texas at Austin received a $300,000 CPRIT Prevention grant (PP210045) in August 2021 to develop an evidence-informed blueprint, implementation guide, and consultation service for expanding mailed FIT programs to underserved areas of Texas.

- OncoNano Medicine, Inc., presented data from a Phase 2 study of pegsitacianine, a pH-sensitive fluorescent nanoprobe for image-guided cancer surgery, at the Society of Surgical Oncology 2023 International Congress on Surgical Cancer Care held in Boston March 22-25.

  The primary objective of the company's Phase 2 study was for researchers to determine if the administration of pegsitacianine (1 mg/kg) prior to surgery results in the detection of additional disease following standard of care surgical resection of peritoneal metastases. The

results reveal that, under pegsitacianine guidance, 20 of 40 evaluable patients had pathology-confirmed disease resected after fluorescent visualization that surgeons did not resect in the planned standard of care surgery.

"These results show that pegsitacianine can safely be administered up to three days in advance of surgery, without any impact on the planned surgical approach. Importantly, the results of this Phase 2 trial demonstrate pegsitacianine's potential as a new advance for real-time surgical imaging for peritoneal metastasis surgery," explained OncoNano's Chief Medical Officer Kartik Krishnan M.D., Ph.D.

Southlake-based OncoNano received three CPRIT Product Development Research grants between 2014 – 2020 totaling $31.4 million (DP140072, DP190066, DP200081) to develop this proprietary technology.

- **"Enlightened" CAR-T cell therapies.** For patients with certain forms of blood cancers, such as acute lymphoblastic leukemia or B-cell non-Hodgkin Lymphoma, chimeric antigen receptor or CAR T-cell therapy can be a "miracle cure." Despite the extraordinary efficacy, some patients receiving CAR-T cell therapy, a form of immunotherapy, will experience serious, life-threatening side effects due to the lack of precise control over the dose, location, and timing of activity of the engineered T cells - "on-target, off-tumor" cytotoxicity.

  Researchers designed FDA-approved CAR T-cell therapies primarily to recognize the CD19 protein, which is abundantly expressed on the surface of cancer cells. However, the CD 19 protein is also present on normal B lymphocyte. CAR T-cell therapies lack the ability to discriminate between normal CD19-positive cells and CD19-positive tumor cells, which could lead to a common side effect known as B-cell aplasia, depletion of B-cells in the blood and a poor immune response to infections.

  Patients urgently need intelligent CAR T-cell-based therapies with precise spatial and temporal control over therapeutic activities. To address this issue, CPRIT Scholar Yun "Nancy" Huang, Ph.D., associate professor at the Center for Epigenetics and Disease Prevention, and Yubin Zhou, M.D., Ph.D., professor and Presidential Impact Fellow, both at Texas A&M University School of Medicine's Institute of Biosciences and Technology, engineered light-switchable, anti-CD19 CAR T-cells (LiCAR-T) that precisely mount anti-tumor immune responses in the dual presence of tumor antigen and light.

  As reported in the March 23 edition of *Nature Reviews Bioengineering*, the researchers built the LiCAR-T system upon engineered CAR T-cells that remain inactive without photo stimulation, but quickly restore their tumor-killing function when illuminated with blue light. To move this technology one step closer to real-world applications, the investigators overcame the limited depth of tissue penetration (less than 1 mm) of visible light by reengineering "upconversion" nanoparticles capable of capturing near infrared light that is invisible to human eyes and converting it into blue light. Clinicians can introduce the nanoparticles surgically or by injection. This near infrared light-tunable nano-optogenetic platform enables spatiotemporal control of CAR T-cell mediated cytotoxicity against both

hematological malignancies and solid tumors with tailored doses and duration, thereby greatly mitigating side effects associated with the current immunotherapy. Moreover, this research exemplifies the power of integrating multi-disciplinary approaches in biomedical research.

CPRIT research grants (RR140053, RP180131) totaling $3.2 million to Dr. Huang supported this work. Nhung Nguyen, Ph.D., a CPRIT-funded Cancer Therapeutics Training Program (RP210043) postdoctoral fellow in Dr. Zhou's laboratory, spearheaded the laboratory work.

Personnel

CPRIT has filled 42 of our 44 full-time equivalent positions.

- Dr. Waye Leeuwon accepted the position of Program Manager for Product Development effective March 1. She previously worked at Texas A&M University managing programs and intellectual property management.

- Bridget Barstow, who has worked at CPRIT as a contract employee since July 2022, accepted the permanent position of Technical Writer effective March 27.

- CPRIT has two positions in progress: Program Manager for Academic Research and Grant Compliance Specialist.

88th Texas Legislature Update and Activities

The 88th Texas Legislature convened in Austin at noon on January 10 and will adjourn *sine die* at midnight on May 29. As of March 10 (the 60th day of the session), legislators filed 8,276 bills by the deadline, a record number. The information reported below on CPRIT's budget, CPRIT-related legislation, other notable legislation is current as of 5:00 a.m. April 3.

<u>General Appropriations Bills (Senate Bill 1 and House Bill 1)</u>

The House and Senate released the draft appropriations bills January 18. Both provide 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.

Both draft bills include a five percent (5%) per year cost-of-living-adjustment (COLA) for non-exempt employees specifically shown in our bill pattern. Since CPRIT is a special fund agency, the legislature does not provide additional general revenue to fund the COLA; instead, the budget writers transfer the money from (and thereby reduce) the money available for CPRIT's research and prevention programs. The draft bills also include an increase to the CEO position of $402 to match a market compensation report issued by the State Auditor's Office this past fall.

Because the 5% COLA change for non-exempt employees does not apply to our two exempt positions (the Chief Scientific Officer and CEO), CPRIT's Legislative Appropriations Request, which the Oversight Committee approved last summer, includes a request to apply the COLA adjustment to CPRIT's two exempt positions.

The Senate Committee on Finance held CPRIT's budget hearing January 30. Chief Operating Officer Heidi McConnell and I presented our budget request. I addressed the need for a COLA adjustment for the CSO in my testimony. On March 27, the full committee adopted the recommendations of the Senate Finance Workgroup on Article I, IV and V chaired by Senator Hinojosa. The workgroup recommended CPRIT's request for the 5% per year COLA for the CSO exempt salary position.

I presented our budget request, including the need to apply the 5% COLA for the CSO position, to the House Appropriations Subcommittee on Articles I, IV and V on February 21. Subcommittee members had no questions and after my brief presentation, Chair Mary González was complimentary of CPRIT's progress. The subcommittee's markup is complete with no changes to CPRIT. Regarding CPRIT's requested CSO COLA adjustment, the subcommittee recommended including this request in Article XI (wish list). The full House Appropriations Committee adopted the subcommittee's recommendation.

The CSO COLA will be our only issue for the state budget conference committee to resolve. I am optimistic the conference committee will recommend adoption. The only item CPRIT requested not included in either bill is the same COLA for the CEO position. Without Oversight Committee intervention, it is unlikely that the legislature will adopt this request.

CPRIT-Related Legislation

- Senate Bill 1838/House Bill 4160 (companions)
  Senator Juan "Chuy" Hinojosa and Representative Ryan Guillen filed companion legislation that makes significant changes to CPRIT's enabling legislation.

  The proposed legislation would imbed within CPRIT an Oversight Committee for Neurodegenerative Diseases as the governing body of the Alzheimer's Research Collaborative of Texas. The bill would alter the use of CPRIT bond proceeds from cancer prevention and research grants to Alzheimer's disease research.

  We believe the bills are unconstitutional and would violate the terms of the bond covenants related to CPRIT debt issuance by the Texas Public Finance Authority. I reached out to both authors' offices, and I had a brief initial discussion with Senator Hinojosa about the bill. I await a response to my request to speak with 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.

Senator Hinojosa added $200 million in general revenue for CPRIT in the Senate proposed budget's Article XI (wish list). Without legislative or appropriations guidance, implementation of this funding and Senate Bill 1838 will be difficult.

- House Bill 3914
  Representative Oliverson filed legislation that would 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 requires 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 have some 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 have reached out to his office and will discuss making the same changes.

Other Notable Legislation

- House Bill 15/House Joint Resolution 135
  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 are among Speaker Phelan's priorities for the session indicating that they have a high probability of passing the House and going over to the Senate for consideration. I do not know if the supporters of the legislation have identified a senate sponsor at this time.

  The legislation proposes to fund the new agency through a constitutional dedication of $3 billion of general revenue. We have 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.

  The Higher Education Committee voted out both bills on March 21. The House Calendars Committee has not yet scheduled the bills for a House vote. We will keep you updated.

- Senate Bill 989/House Bill 3188
  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"

is 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.

The Senate Health & Human Services Committee considered SB 989 on March 29 and voted approval on April 3. The House referred HB 3188 to the House Insurance Committee, where it awaits a hearing.

- Senate Bill 704 (Paxton), Senate Bill 1014 (Hughes), Senate Bill 2086 (Kolkhorst), Senate Bill 1544 (Johnson)/House Bill 2545 (Capriglione) (companions)
  Several legislators have filed bills this session relating the use of an individual's genetic data. The House and Senate have referred the bills to various committees, included Senate State Affairs, Senate Business & Commerce, Senate Health & Human Services, and House Business & Industry. Except for the House Business & Industry committee, no committees have scheduled hearings as of this report.

  These bills appear to address genetic testing companies that use the data for commercial purposes, such as 23&Me, and incorporate restrictions on retention of the genetic data and require heightened procedures for informed consent. However, some CPRIT grantees have expressed concern that the legislation may affect genetic data used for research purposes, including de-identified data maintained in research databases. We are monitoring the status of these bills.

  The House Committee on Business & Industry held a hearing on March 27 regarding HB2545. Rep. Capriglione filed a committee substitute. The committee took testimony on the bill, but has left the bill pending further action as of April 3.

Testimony and Legislative Briefings

- On March 13, Ms. Doyle, Ms. McConnell, and I briefed Representative Emilio "Mano" DeAyala on CPRIT activities and our budget request. Rep. DeAyala is a new member of the House Appropriations Subcommittee on Articles I, IV and V.

- As noted earlier, Ms. Doyle testified as an invited resource witness on March 20 before the House Committee on Higher Education regarding HB15.

- Ms. Doyle and I met with Andria Franco on March 22 to discuss CPRIT-related legislation. Ms. Franco is the Health and Human Services Advisor to Lt. Governor Dan Patrick.

CPRIT Outreach

Advanced Research Projects Agency for Health (ARPA-H) and Federal Outreach

I went to Washington, D.C., on February 6 as part of the Coalition for Health Advancement and Research in Texas (CHART) to brief the seven new members of the Texas congressional delegation on our efforts to establish an ARPA-H presence in Texas. These briefings were like the ones I participated in last July. As a result of the visit, Rep. Jasmine Crockett is coordinating a letter from the Texas freshman to Director Wegrzyn emphasizing their support to locate at least part of ARPA-H in Texas.

On March 10, a second letter from all members of the Texas delegation except Reps. Cloud and Roy went to Secretary Xavier Becerra at the Department of Health and Human Services. This letter further emphasizes the delegation's desire to make sure ARPA-H has a Texas presence. Representatives of CHART, including Chief Strategic Initiatives and Intellectual Property Officer Tracey Davies and me, continue working with ARPA-H staff for a Texas site tour by Director Rene Wegrzyn. We expect the visit will occur sometime in late Spring (April – June).

On March 15, ARPA-H announced its intent to create sites in three geographic locations across America through a "hub-and-spoke" strategy, forming a health network to advance the agency's mission. Each hub will sustain a network of "spokes" (partners) to support ARPA-H's needs. The sites will form a center for key ARPA-H functions, but with a "light" footprint, housing a small number of ARPA-H team members and meeting facilities, alongside key personnel to support agency objectives. Individual projects would then leverage program-relevant assets - the spokes - throughout the country from the hubs.

- Hub One will be somewhere in the Washington, DC, area and will focus on stakeholder engagement and operations (read "administration").

- Hub Two, a customer experience hub, will drive user testing, adoption, access, and trust of ARPA-H's projects, taking a "human-centered" approach to design products and services that people need and want. It will take a proactive approach to enhance clinical trials, reach representative patient populations, and capture outcomes data for future research.

- Hub Three, an investor catalyst, will provide resources to help performers bring their ideas to market.

Hub Sites Two and Three will be determined by open solicitation through a Request for Consortium Agreement (RCA). The consortium will be comprised of a central "hub" facility which will contract directly with ARPA-H. The various spokes and other necessary capabilities to complete ARPA-H projects will subcontract with the hub consortium.

ARPA-H held an informational proposer's day on March 24 to review the draft RCA, get feedback, and respond to questions. ARPA-H expects to finalize the RCA in the coming weeks and to announce the awards by early Fall 2023.

ARPA-H is encouraging "teaming" by assets throughout the country to respond to the RCA. In Texas, the cities of Austin, San Antonio, Dallas and Houston are in discussion with each other and with other relevant institutions throughout the nation. We expect each of the four cities to submit responses to the RCA, either independently or in coordination with one another.

Engagement with the National Cancer Institute

On February 10 Chief Scientific Officer Dr. Michelle Le Beau and I teleconferenced with Dr. Douglas Lowy, Principal Deputy Director of the National Cancer Institute, to discuss planning for aligning the efforts of NCI and CPRIT. The discussion was positive, and he offered suggestions that we will discuss with appropriate CPRIT advisory committees and interested Oversight Committee members.

Other Staff Outreach

Staff outreach activities during February and March include:

- On February 24, Oversight Committee member Dr. Ambrosio Hernandez, Chief Scientific Officer Dr. Michelle Le Beau, Director of Academic Research Dr. Patty Moore, Communications Director Mark Loeffler and I participated in a media event on the campus of The University of Texas Rio Grande Valley celebrating the institution's recent CPRIT Texas Regional Excellence in Cancer Award. Senator Juan Hinojosa and Representative Bobby Guerra attended and spoke at the event. UTRGV President Guy Bailey, UTRGV Dean of the School of Medicine Dr. Michael B. Hocker, Dr. Hernandez, Dr. Le Beau and I also spoke about the important cancer research at UTRGV. Following the press conference Dr. Subhash Chauhan and Dr. Sarah Williams-Blangero hosted CPRIT staff on a tour of the UTRGV research facilities that included brief research overviews from early-stage investigators and staff members.

- Senior Product Development Program Manager Dr. Abria Magee presented an overview of CPRIT and discussed the product development program at the monthly meeting of the "Israelis in Biotech" group. Dr. Irit Milman Krentisis, the Israelis in Biotech social media community manager and a computational scientist at The University of Texas M.D. Anderson Cancer Center, invited Dr. Magee to make the virtual live presentation.

- On March 3, Dr. Le Beau, Dr. Moore, Chief Product Development Officer Dr. Ken Smith, Deputy Executive Officer and General Counsel Kristen Doyle, and I hosted representatives from WA CARE (the Andy Hill CARE Fund), Washington's Cancer Research Endowment, in our Austin office. Washington created The Andy Hill CARE Fund in 2015 to advance research in the prevention and treatment of cancer. The WA CARE team traveled to Texas

to learn from CPRIT and share promising practices in managing a state-funded cancer research fund.

- On March 6, Dr. Magee met with students at the University of Houston's School of Business who are working on a project analyzing CPRIT-funded companies. She spoke to the students about CPRIT and the product development program and new funding mechanisms.

- Ms. Doyle spoke on the "Women Driving Innovation" panel held March 8 and hosted by the BioNorthTX at Pegasus Park in Dallas. The program celebrated International Women's Day.

- On March 8, Dr. Magee met with Jean Gilbert, business development manager in the Industry Ventures group at The University of Texas MD Anderson Cancer Center. They discussed company relocation issues and the new product development RFAs.

- Dr. Le Beau, Dr. Moore and Chief Prevention Officer Ramona Magid attended the "Cancer Prevention & Control Research Consortium," held March 22 and hosted by The University of Texas Dell Medical School's Livestrong Cancer Institute. Dr. Le Beau and Ms. Magid also addressed the attendees about opportunities available through the CPRIT Academic Research and Prevention Programs.

- On March 29, Dr. Magee and Product Development Program Manager Dr. Waye Leeuwon met with Skipper Biomed. Texas-based Skipper Biomed is the only research consultancy that provides pro bono business and technology development services to startups and academic investigators with promising lung or pancreatic cancer technologies. A private U.S. family foundation solely supports Skipper's patient-focused mission, which allows Skipper to work with clients and partners without charging any compensation. The CPRIT team and Skipper staff discussed partnership opportunities and their interest in attending CPRIT's conference in October.

- In February and March, the product development team met with several companies interested in applying for product development research awards, including Koya Medical (California medical device company developing treatments for venous diseases and lymphedema), Slingshot Biosciences (California company that produces cell line mimics for acute myeloid leukemia)

- The industry group BIO invited Ms. Doyle to participate on a panel discussion with a representative of the California Institute of Regenerative Medicine (CIRM) at the big BIO International conference held in Boston in early June. The panel will discuss the impact these two large state research funds are having on the health and economies of their states. This is a presentation we have envisioned for several years. Dr. Smith, Dr. Magee, and Dr. Leeuwon also plan to attend the BIO International conference as part of the Texas delegation coordinated by Texas Healthcare and Bioscience Institute (THBI.)

Compliance Program Update

Submission Status of Required Grant Recipient Reports

As of March 21, 10 entities had not filed 12 academic research reports, two prevention reports, and two product development reports. CPRIT's grant accountants and compliance specialists review and process incoming reports and reach out to grantees to resolve filing issues. In most cases, CPRIT does not disburse grant funds until the grantee files the required reports. In some instances, grantee institutions may be ineligible to receive a future award if the grantee does not submit required reports.

Financial Status Report Reviews

CPRIT's compliance specialists performed 305 second-level reviews of grantee Financial Status Reports (FSRs) in February and March. Twenty-five FSRs (13%) 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.

Onsite Reviews

CPRIT completed four onsite reviews in February and March. 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.

Annual Compliance Attestation

CPRIT requires grantees to submit an annual attestation form, demonstrating compliance with statutory and administrative grant requirements, CPRIT's policies and procedures, grant contract terms, and the Texas Grant Management Standards. This opportunity to self-report, in the form of a checklist, provides a baseline of grantee compliance and allows compliance specialists to proactively work with grantees towards full compliance prior to a desk review or onsite review. Grantees have until December 31 to submit the completed attestation. As of March 21, all grantees have submitted their annual compliance attestation. As part of the annual attestation process, product development grantees must submit documentation demonstrating compliance with the Texas Location Criteria, pursuant to Texas Administrative Code §701.19. All product development grantees have submitted their Texas Location Criteria documentation.

Training and Support

CPRIT staff conducted a series of annual compliance training webinars on March 7-8 for 164 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 first training series offered this year for the annual compliance training requirement, which requires the Authorized Signing Official (ASO) and at least one other employee from each grantee organization to attend an annual compliance training by December 31 of each year.

CPRIT staff conducted two new ASO training webinars in February for Stellanova Therapeutics and University of North Texas Health Science Center at Fort Worth. The trainings covered grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. Pursuant to Texas Administrative Code §703.22, CPRIT requires new ASOs to complete a compliance training within 60 days of the change.

CPRIT staff conducted one new grantee training webinar in March for ImmuneSensor 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 grantees to complete the initial compliance training program prior to receiving disbursement of grant award funds.

Academic Research Program Update

Recruitment FY 2023 Review Cycle 3

CPRIT's Scientific Review Council (SRC) reviewed recruitment applications for the third quarter of FY 2023 on March 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 May.

FY 23 Mechanism	Received	Funds Requested	Recommended	Recommended Funds
Recruitment of Established Investigators	4	$23,999,986	2	$12,000,000
Recruitment of First-Time, Tenure Track Faculty Members	3	$6,000,000	2	$4,000,000
TOTAL	**7**	**$29,999,986**	**4**	**$16,000,000**

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 will accept applications January 25 – April 18. 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. Peer review panels will meet virtually in June to consider the applications. Dr. Le Beau will present the SRC's recommendations to the PIC and the Oversight Committee in August. I have listed a brief synopsis of each grant below.

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 and opened the online application portal on March 15. I have provided a brief description of each RFA below. CPRIT will accept applications through June 14. Peer review will take place in the Fall. 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.

- *Individual Investigator Research Awards*

  Solicits 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 for a maximum of three years. Exceptions permitted if extremely well justified.

- *Individual Investigator Research Awards for Computational Systems Biology of Cancer*

  Solicits 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 per year for a maximum of three years. Exceptions permitted if extremely well justified.

- *Individual Investigator Research Awards for Cancer in Children and Adolescents*

  Solicits 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 for a maximum of four years. 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.

- *Individual Investigator Research Awards for Prevention and Early Detection*

  Solicits applications that propose clinical and population-based projects designed to develop effective prevention and early detection interventions to reduce cancer risk, mortality, and morbidity among Texans. CPRIT strongly encourages projects that propose 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).
  Award: Up to $400,000 per year for a maximum of five years. Exceptions permitted if extremely well justified.

- *Individual Investigator Research Awards for Clinical Translation*

  Solicits 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. Applicant must plan clinical trial to begin when CPRIT awards grant contract.
  Award: Up to $500,000 per year for a maximum of four years. Exceptions permitted if extremely well justified.

Product Development Research Program Update

Product Development FY 2023 Review Cycle

CPRIT released four FY 2023 Product Development Research RFAs and opened the portal to receive preliminary applications on a rolling basis beginning August 24, 2022. CPRIT received 59 preliminary applications before CPRIT stopped accepting applications in late January.

Of the 29 companies CPRIT invited to submit full applications, 14 companies filed full applications by the November 1, 2022, deadline for the 10 review slots available in the first review cycle. The first ten companies, requesting $149 million, presented their full applications to review panels the week of December 12 – 16, 2022. The review panels recommended six companies, requesting $82.1 million, to proceed to due diligence review. The panels met January 13 – January 20 to consider due diligence reports.

Based on the work done by the peer review panels, the Product Development Review Council (PDRC) recommended six companies for product development awards in a January letter to the PIC and the Oversight Committee. The table below provides information about the full application review.

FY 2023 RFA	Submitted by Nov 1	Budget Request	Apps Review Cycle 1	Review Cycle 1 Request	Due Diligence Apps	Due diligence Request
TTC	9	$150,026,040	7	$118,109,015	4	$67,456,802
TDDC	1	$3,644,032	0	N/A	N/A	N/A
TNTC	2	$27,982,099	2	$27,982,099	1	$12,000,000
Seed	2	$5,983,763	1	$2,999,858	1	$2,999,858
TOTAL	**14**	**$183,991,902**	**10**	**$149,091,114**	**6**	**$82,456,660**

The total budget request for the six companies recommended by the PDRC was $82.5 million, which exceeds the $57 million available for FY 2023 product development awards. With the goal of funding as many companies recommended by the PDRC with the available FY 2023 budget, Chief Product Development Officer Dr. Ken Smith requested, and the PIC agreed at its February meeting, to defer PIC action on the PDRC's recommendations until the May Oversight Committee meeting.

Dr. Smith negotiated the proposed budgets requested by the companies. Each of the recommended companies worked in good faith with Dr. Smith to identify ways to decrease CPRIT-funded project expenses while maintaining the goals and objectives of the recommended project. Several of the companies increased the company's financial commitment to the recommended project to directly offset the CPRIT grant budget reductions. As a result of this work, Dr. Smith has decreased the total award amount requested by the six recommended companies to an amount that CPRIT may fund with the available FY 2023 product development budget. He will present the companies recommended for product development awards to the Oversight Committee at its May meeting.

Product Development FY 2024 Review Cycle 1 (24.1)

The Oversight Committee approved proposed FY 2024 product development RFAs at its February 15 meeting. CPRIT will accept preliminary applications for several weeks beginning May 1 and invited full applications through August 1. Although CPRIT will limit the number of full applications reviewed in the first FY 2024 review cycle, we plan to provide five more slots for full application presentations than we offered in FY 2023, for a total of 15 slots. Full application panel review and company presentations will take place in September. Due diligence review will occur in October for those companies that the panels intend to recommend for CPRIT funding, with a final vote of the PDRC expected in mid-October. Dr. Smith will present the 24.1 cycle product development awards to the PIC and the Oversight Committee in November.

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. CPRIT peer reviewers will evaluate the applications in April - June. Chief Prevention Officer Ramona Magid will present the Prevention Review Counsel's (PRC) 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 plans to release two prevention RFAs in May for the first cycle of FY 2024. CPRIT has scheduled peer review for October – December. Ms. Magid will present the PRC's recommendations to the PIC and the Oversight Committee in February 2024.

Advisory Committee Meetings

- The Clinical Trials Advisory Committee met February 28
- The Product Development Advisory Committee met March 7.
- The University Advisory Committee met March 31.
- The Geographic Diversity Advisory Committee will meet April 14.

Operations, Finance, and Conference Update

Ms. McConnell, Communications Director Mark Loeffler, Digital Communications Specialist Justin Rand, and Information Resources Manager Shannon Cusick as well as the conference meeting planner, Deb Swift, traveled to Galveston on March 7-8 and conducted a site visit of the meeting and exhibit space at the Moody Gardens Hotel, Spa and Conference Center for the 2023 CPRIT Innovations Conference VI. They also met with the property's onsite audiovisual company Encore.

On March 27, CPRIT officially opened registration through the dedicated website for the conference, www.texascancerconference.org,. As of March 30, we have 12 paid registrations. CPRIT also released information about conference sponsorship packages via the conference website. We have received several inquiries on sponsorship.

Upcoming Subcommittee Meetings

Listed below are the subcommittee meetings in advance of the May 17 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	May 4 at 10:00 a.m.
Audit	May 8 at 10:00 a.m.
Prevention	May 9 at 12:00 p.m.
Academic Research	May 10 at 12:00 a.m.
Product Development	May 11 at 10:00 a.m.

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CPRIT has awarded **1,865** grants totaling **$3.261 billion**

- 282 prevention awards totaling $341.5 million
- 1,583 academic research and product development research awards totaling $2.92 billion

Of the $2.92 billion in academic research and product development research awards,

- 30.9% of the funding ($901.3 million) supports clinical research projects
- 24.1% of the funding ($705.0 million) supports translational research projects
- 29.2% of funding ($853.6 million) supports recruitment awards
- 12.7% of the funding ($369.5 million) supports discovery stage research projects
- 3.1% of funding ($90.4 million) supports training programs.

CPRIT has 11 open Requests for Applications (RFAs)

- 2 Recruitment
- 9 Academic Research

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: VINCE BURGESS, CHIEF COMPLIANCE OFFICER

SUBJECT: COMPLIANCE PROGRAM UPDATE

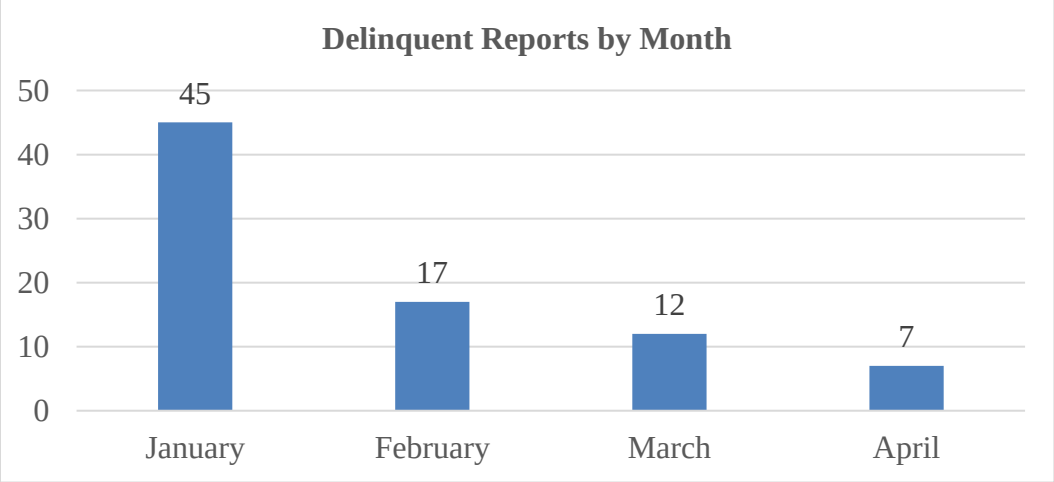
DATE: MAY 8, 2023

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 April 28, seven entities had not filed six academic research reports and one product development report. CPRIT's grant accountants and compliance specialists review and process incoming reports and reach out to grantees to resolve filing issues. In most cases, CPRIT does not disburse grant funds until the grantee files the required reports. In some instances, grantee institutions may be ineligible to receive a future award if the grantee does not submit the required reports.

Delinquent reports continue to trend downward and are currently well under the 5% threshold.



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Financial Status Report Reviews

CPRIT's compliance specialists performed 573 second-level reviews of grantee Financial Status Reports (FSRs) in February, March, and April. Seventy-nine FSRs (14%) needed resubmission due to insufficient or inaccurate documentation sent by the grantee. CPRIT's grant accounting staff completes the first review of the FSRs and supporting documentation before routing them to the compliance specialists for final review and disposition.

Single Audit Tracking

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

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

Desk Reviews

CPRIT staff performed 14 enhanced desk-based financial monitoring reviews in February, March, and April. 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 three grantees to address desk review findings.

Onsite Reviews

CPRIT completed five onsite reviews in February, March, and April. 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 four grantees to address onsite review findings.

Annual Compliance Attestation

CPRIT requires grantees to submit an annual attestation form, demonstrating compliance with statutory and administrative grant requirements, CPRIT's policies and procedures, grant contract terms, and the Texas Grant Management Standards. This opportunity to self-report, in the form of a checklist, provides a baseline of grantee compliance and allows compliance specialists to proactively work with grantees towards full compliance prior to a desk review or onsite review.

All grantees have submitted their annual compliance attestation. As part of the annual attestation process, product development grantees must submit documentation demonstrating compliance with the Texas Location Criteria, pursuant to Texas Administrative Code §701.19. All grantees have submitted the appropriate Texas Location Criteria documentation.

Match Expenditures Review

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

Product development grantees 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 six annual match expenditure reviews for three grantees in February, March, and April. The total amount of match expenses reviewed by compliance staff for FY 2023 is $16,339,607.50. The unallowable match expenses for FY 2023 total $22,368.06.

Training and Support

CPRIT staff conducted three new Authorized Signing Official (ASO) training webinars in February, March, and April for The University of North Texas Health Science Center – Fort Worth, Stellanova Therapeutics, and University of Houston – Downtown. The trainings covered grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. Pursuant to Texas Administrative Code §703.22, CPRIT requires new ASOs to complete a compliance training within 60 days of the change.

CPRIT staff conducted a series of annual compliance training webinars on March 7-8 for 164 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 first training series offered this calendar 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 one new grantee training webinar in March for ImmuneSensor 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 grantees to complete the initial compliance training program prior to receiving disbursement of grant award funds.

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:	MAY 17, 2023

Proposed Academic Research Recruitment RFAs for Fiscal Year 2024 Cycle 1 (FY24.1)

Recruitment of Established Investigators (RFA R-24-1 REI):
Recruits outstanding senior research faculty with distinguished professional careers and established cancer research programs to academic institutions in Texas.
Award: Up to $6 million over a period of five years.

Recruitment of Rising Stars (RFA R-24-1 RRS):
Recruits outstanding early-stage investigators to Texas, who have demonstrated the promise for continued and enhanced contributions to the field of cancer research.
Award: Up to $4 million over a period of five years.

Recruitment of First-Time Tenure Track Faculty Members (RFA R-24-1. RFT):
Supports very promising emerging investigators, pursuing their first faculty appointment in Texas, who have the ability to make outstanding contributions to the field of cancer research.
Award: Up to $2 million over a period up to five years.

FY2023 Recruitment Update
Table 1 displays an overview of the status of CPRIT recruitment applications received for the third cycle of FY2023. The Scientific Review Council reviewed applications for Cycle 23.4 on March 16, 2023. Dr. Le Beau will present the Scientific Review Council's award recommendations for the third quarter of FY23 to the Program Integration Committee and the Oversight Committee in May 2023.

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Table 1: FY2023 Recruitment data for Cycle 23.4

Mechanism	Number Received	Funds Requested	# SRC Recommended	SRC Recommended Funds
Recruitment of Established Investigators	4	$23,999,986	2	$12,000,000
Recruitment of First-Time, Tenure Track Faculty Members	3	$6,000,000	2	$4,000,000
TOTAL	**7**	**$29,999,986**	**4**	**$16,000,000**

FY2023 Cycle 2 RFAs

The following FY23.2 RFAs were posted on January 17, 2023. CPRITs Application Receipt System (CARS) opened for applications on January 25, 2023 and will close on April 18, 2023. Virtual Peer Review will be conducted in June 2023. Dr. Le Beau will present the Scientific Review Council's recommendations to PIC and the Oversight Committee in August 2023.

- **Texas Connect for Cancer Prevention Study Awards (RFA R-23.2 TCCPA):**
  Solicits applications from institutions to establish a Texas Connect for Cancer Prevention Study of 25,000-35,000 adults in collaboration with the NCI CONNECT Study. This prospective study will address priorities in cancer prevention, early detection, and etiology research, which include emerging exposures, novel biomarkers, genomics, cutting-edge methodology and diverse and special populations. The CONNECT Study has the long-term potential to identify social, environmental, and behavioral, and genetic factors that underlie cancer risk among Texans.
  Award: Up to $7.5 million over a period of 5 years.

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

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

recognized by their institutions for their high potential and strong interest in pursuing careers as independent cancer researchers.
Award: Total of $850,000 over a period of 3 years.

- **TREC Major Instrumentation Award (RFA R-23.2 TREC MIA):**
  Solicits applications from TREC-eligible institutions to enhance research capacity by supporting the purchase of major instrumentation for one or more Core Facilities that will support multiple cancer researchers.
  Award: Total of $1 million over a period of 2 years

Table 2: Application Submission data for FY2023 Cycle 2

Mechanism	Submitted	Total Funding Requested
TREC: Pilot Study Award	14	$2,800,000
TREC: Major Instrument Award	5	$4,700,000
TREC: Institutional Postdoctoral Training Award	3	$2,5000,000
Texas Connect for Cancer Prevention Study Awards	4	$29,500,000

FY2024 Cycle 2 RFAs

The following FY24.2 RFAs were posted on February 17, 2023. CPRITs Application Receipt System (CARS) opened for applications on March 15, 2023 and will close on June 14, 2023. Virtual Peer Review will be conducted in June 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.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: RAMONA MAGID, CHIEF PREVENTION OFFICER

SUBJECT: PREVENTION PROGRAM UPDATE

DATE: MAY 17, 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. The remaining twenty applications requesting a total of $31,166,458 will undergo peer review on May 22 by teleconference. The two applications responding to the Colorectal Cancer Screening Coordinating Center mechanism will be reviewed by the Prevention Review Council (PRC) on June 9, 2023, and programmatic review by the PRC will be conducted July 10. The Program Integration Committee (PIC) meets in August 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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Other Activities

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.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

To: OVERSIGHT COMMITTEE MEMBERS
From: KEN SMITH, PHD, CHIEF PRODUCT DEVELOPMENT OFFICER
Subject: PRODUCT DEVELOPMENT RESEARCH PROGRAM UPDATE
Date: MAY 10, 2023

Product Development FY 2023 Review Cycle

CPRIT released four FY 2023 Product Development Research RFAs and opened the portal to receive preliminary applications on a rolling basis beginning August 24, 2022. CPRIT received 59 preliminary applications before CPRIT stopped accepting applications in late January.

Of the 29 companies CPRIT invited to submit full applications, 14 companies filed full applications by the November 1, 2022, deadline for the 10 review slots available in the first review cycle. The first ten companies, requesting $149 million, presented their full applications to review panels the week of December 12 – 16, 2022. The review panels recommended six companies, requesting $82.5 million, to proceed to due diligence review. The panels met January 13 – January 20 to consider due diligence reports.

Based on the work done by the peer review panels, the Product Development Review Council (PDRC) recommended six companies for product development awards in a January letter to the PIC and the Oversight Committee. The table below provides information about the full application review.

FY 2023 RFA	Submitted by Nov 1	Budget Request	Review Cycle 1	Review Cycle 1 Request	Due Diligence	Due diligence Request
TTC	9	$150,026,040	7	$118,109,015	4	$67,456,802
TDDC	1	$3,644,032	0	N/A	N/A	N/A
TNTC	2	$27,982,099	2	$27,982,099	1	$12,000,000
Seed	2	$5,983,763	1	$2,999,858	1	$2,999,858
TOTAL	**14**	**$183,991,902**	**10**	**$149,091,114**	**6**	**$82,456,660**

The total budget request for the six companies recommended by the PDRC was $82.5 million, which exceeds the $57 million available for FY 2023 product development awards. With the goal of funding as many companies recommended by the PDRC with the available FY 2023 budget, I requested, and the PIC agreed at its February meeting, to defer PIC action on the PDRC's recommendations until the May Oversight Committee meeting.

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I negotiated the proposed budgets requested by the companies. Each of the recommended companies worked in good faith with me to identify ways to decrease CPRIT-funded project expenses while maintaining the goals and objectives of the recommended project. As a result of this work, we decreased the total award amount requested by the six recommended companies to an amount that CPRIT may fund with the available FY 2023 product development budget. I will present the companies recommended for product development awards to the Oversight Committee at the May 17 meeting.

Product Development FY 2024 Review Cycle 1 (24.1)

On May 1 CPRIT posted the four FY 2024 Product Development Research Program RFAs approved by the Oversight Committee at its February meeting. CPRIT also began accepting preliminary applications the same day and will do so on a rolling basis for the next several weeks. As of 10:00 a.m. on May 10, 27 companies have submitted preliminary applications and 10 other companies have started preliminary applications in the system.

Like the FY 2023 review cycle, CPRIT will issue invitations to submit full applications only to companies that have submitted meritorious preliminary applications as determined by the preliminary application peer review panel. CPRIT will accept full applications through August 1. Although CPRIT will limit the number of full applications reviewed in the first FY 2024 review cycle, we plan to provide five more slots for full application presentations than we offered in FY 2023, for a total of 15 company slots.

FY 2024 RFA	Prelim Apps Started/ Submitted	Prelim App Budget Request
Texas Therapeutics Company	20/16	$218,576,255
Texas Device & Diagnostics Company	1/1	$5,141,000
Texas New Technology Company	3/2	$17,680,000
SEED Company	13/8	$22,710,303
Total	37/27	$264,107,558

Full application panel review and company presentations will take place in September. Due diligence review will occur in October for those companies that the panels intend to recommend for CPRIT funding, with a final vote of the PDRC expected in mid-October. I will present the 24.1 cycle product development awards to the PIC and the Oversight Committee in November.

Product Development Program Outreach

- Senior Product Development Program Manager Dr. Abria Magee presented an overview of CPRIT and discussed the product development program at the monthly meeting of the "Israelis in Biotech" group. Dr. Irit Milman Krentisis, the Israelis in Biotech social media community manager and a computational scientist at The University of Texas M.D. Anderson Cancer Center, invited Dr. Magee to make the virtual live presentation.

- On March 6, Dr. Magee met with students at the University of Houston's School of Business who are working on a project analyzing CPRIT-funded companies. She spoke to the students about CPRIT and the product development program and new funding mechanisms.

- On March 8, Dr. Magee met with Jean Gilbert, business development manager in the Industry Ventures group at The University of Texas MD Anderson Cancer Center. They discussed company relocation issues and the new product development RFAs.

- On March 29, Dr. Magee and Product Development Program Manager Dr. Waye Leeuwon met with Skipper Biomed. Texas-based Skipper Biomed is the only research consultancy that provides pro bono business and technology development services to startups and academic investigators with promising lung or pancreatic cancer technologies. A private U.S. family foundation solely supports Skipper's patient-focused mission, which allows Skipper to work with clients and partners without charging any compensation. The CPRIT team and Skipper staff discussed partnership opportunities and their interest in attending CPRIT's conference in October.

- On April 4, Dr. Magee, participated on a panel titled, "Houston as a Biomedical Innovation Hub Connecting Texas to Asia and Beyond." The discussion focused on the importance of maintaining and building connections between Houston's biomedical community and Asia, as well as the need to build a critical mass to ensure Houston becomes a long-term global hub of biomedical innovation. The discussion featured Ann Tanabe, CEO of BioHouston; Dr. Ferran Prat, Senior Vice President of Research Administration and Industry Ventures at The University of Texas MD Anderson Cancer Center; Eric Johnson, Executive Managing Director for Transwestern's Life Science Advisory Services Group; Dr. Paul Cherukuri, Vice President for Innovation at Rice University; and Convergence Venture's partner John Nghiem.

- On April 18, Dr. Magee met with Dr. Joe McDonough, Vice President of Research at the Southwest Research Institute in San Antonio. Dr. McDonough presented a cancer immunotherapeutic core idea to Dr. Magee. They discussed the opportunity to leverage San Antonio collaboratives for this new idea and how CPRIT could potentially be involved.

- On April 19, Dr. Magee and Jean Gilbert, Business Development Manager in the Office of Strategic Industry Ventures at The University of Texas MD Anderson Cancer Center, met in-person to discuss cancer-focused companies that have partnered with MD Anderson who are interested in applying for CPRIT awards.

- On April 25 representatives of CPRIT grantee OncoNano provided an update on the company's progress to Mr. Roberts, Dr. Magee, Dr. Leeuwon, Dr. Le Beau, Ms. Doyle, Ms. Davies and me.

- In February, March, and April the product development team met with several companies interested in applying for product development research awards, including Koya Medical (California medical device company developing treatments for venous diseases and

lymphedema), Slingshot Biosciences (California company that produces cell line mimics for acute myeloid leukemia), Slipstream RX, and Alethiah to discuss the CPRIT product development application process and timeline.

- On May 4, Dr. Magee and Dr. Leeuwon attended the JLABS@TMC Investor Day in Houston. The CPRIT team spoke with several companies about the CPRIT application process, including Astero Erado, Sporos Biodiscovery, Stingray Therapeutics, March Bio, Resonant Therapeutics, RiverWalk Therapeutics, Immunophotonics, and Immunogenesis.

- Dr. Magee, Dr. Leeuwon and I will attend the BIO International conference held in Boston in early June as part of the Texas delegation coordinated by the Texas Healthcare and Bioscience Institute (THBI.) CPRIT Deputy Executive Officer and General Counsel Kristen Doyle will also attend and speak on one of panel discussions at the BIO International conference. She and a representative of the California Institute of Regenerative Medicine (CIRM) will discuss the impact these two large state research funds are having on the health and economies of their states.

May 2023 Oversight Committee
Internal Audit Status Report
As of May 1, 2023

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

2023 Internal Audit Plan and Schedule

Based on the approval of the 2023 Internal Audit Plan by the Oversight Committee in the November meeting, we have coordinated and planned the timing of the internal audits and follow-up procedures for the 2023 Internal Audit Plan.

2023 NEW INTERNAL AUDITS		
Internal Audit	**Description**	**Status**
Contract Risk Assessment	Internal Audit Advisory Project will include a review of risks and internal controls in place related to CPRIT's Contract Risk Assessment practices. Activities include developing a contract risk assessment process and contract risk assessment matrix in compliance with state requirements.	Completed
Post-Award Compliance Program	Internal Audit Advisory Project will include a review of risks and internal controls in place related to CPRIT's Post-Award Compliance Program practices. Post-Award Compliance Program activities to be evaluated will include grantee monitoring, compliance monitoring, sub-recipient monitoring, and grantee reporting.	In Progress
Purchasing	Internal Audit will include a review of risks and internal controls in place related to CPRIT's Purchasing practices. Purchasing activities to be evaluated will include purchase orders, bidding process and award, contract negotiation and approval, vendor selection, vendor acceptance and set-up, P-card, central travel card, and employee travel cards.	In Progress
IT General Controls	Internal Audit will include a review of risks and internal controls in place related to CPRIT's IT General Controls practices. IT General Control activities to be evaluated will include network operations, help desk, change management, website maintenance, and back-up an d recovery.	In Progress

2023 NEW INTERNAL AUDIT FOLLOW-UPS		
Communications Follow-Up • 1 High Finding	Internal Audit will perform follow-up procedures on the one open finding from the 2018 Internal Audit to ensure corrective action has been taken.	July 2023
Information Security Follow-Up	Internal Audit will perform follow-up procedures on the open findings from the 2016 Internal Audit to ensure corrective action has been taken.	In Progress
Disaster Recovery and Business Continuity Follow-up • 5 Findings	Internal Audit will performed follow-up procedures on the five open findings from the 2020 Internal Audit to ensure corrective action has been taken.	July 2023
Vendor Contract Compliance Follow-Up • 1 Low Finding	Internal Audit will performed follow-up procedures on the two open findings from the 2022 Internal Audit to ensure corrective action has been taken.	July 2023

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

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

Cancer Prevention and Research Institute of Texas
Schedule of Audits, Status, and Findings Summary
As of May 1, 2023

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

Note 1

Cancer Prevention and Research Institute of Texas
Schedule of Audits, Status, and Findings Summary
As of May 1, 2023

Audit	Fiscal Year	Status/Timing	Report Date	Report Rating	Open Findings				Closed Findings				Total Findings			
					High	Mod	Low	Total	High	Mod	Low	Total	High	Mod	Low	Total
Fiscal Year 2023																
Contract Risk Assessment	2023	Completed	May 1, 2023	N/A	-	-	-	-	-	-	-	-	-	-	-	-
Post-Award Compliance Program	2023	In Process	N/A	N/A	-	-	-	-	-	-	-	-	-	-	-	-
Purchasing	2023	Scheduled	N/A	N/A	-	-	-	-	-	-	-	-	-	-	-	-
IT General Controls	2023	Scheduled	N/A													
2016 Information Security Follow-Up	2023	Scheduled	N/A													
2018 Communications Follow-Up	2023	Scheduled	N/A	N/A	1	4	-	5	-	4	-	4	1	-	-	1
2020 Disaster Recovery and Business Continuity Follow-up	2023	Scheduled	N/A	N/A	-	-	-	30	-	-	-	25	-	-	-	5
2022 Vendor Contract Compliance	2023	Scheduled	N/A	N/A	-	-	2	2	-	-	1	1	-		1	1
Fiscal Year 2023 Subtotal					**1**	**4**	**2**	**37**	**-**	**4**	**1**	**30**	**1**	**-**	**1**	**8**

Open Items Summary																	
Audit	**Fiscal Year**	**Status/Timing**	**Report Date**	**Report Rating**	**Findings**				**Closed Findings**				**Total Open Findings**				**IA Follow-Up Procedure Timing**
					High	Mod	Low	Total	High	Mod	Low	Total	High	Mod	Low	Total	
2016 Information Security Follow-Up	2020	August 2020	October 28, 2022														**FY 2023**
2018 Communications Follow-Up	2020	November 2020	October 28, 2022	Satisfactory	1	4	-	5	-	4	-	4	1	-	-	1	**FY 2023**
2020 Disaster Recovery and Business Continuity Follow-up	2020	September 2021	September 28, 2021	Satisfactory	-	-	-	30	-	-	-	25	-	-	-	5	**FY 2023**
Information Technology General Computer Controls	2021	September 2021	September 24, 2022														**FY 2023**
2022 Vendor Contract Compliance	2022	September 2021	September 28, 2021	Satisfactory	-	-	2	2	-	-	1	1	-	-	1	1	**FY 2023**
2023 Contract Risk Assessment	2023	May 2023	May 1, 2023	N/A	-	-	-	-	-	-	-	-	-	-	-	1	**FY 2024**
Total Findings For Internal Audit Follow-Up					**1**	**4**	**2**	**37**	**-**	**4**	**1**	**30**	**1**	**-**	**1**	**8**	

NOTE 1: The 2020 Disaster Recovery and Business Continuity findings are recommendations for improvement of the DR/BCP documentation. Therefore, they do not have a risk rating associated with them.

Cancer Prevention and Research Institute of Texas

Contract Risk Assessment Model Advisory Audit Report
Report Date: April 11, 2023
Issued: May 1, 2023

weaver
Assurance • Tax • Advisory

CONTENTS

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

This report presents the results of the audit advisory procedures performed for the Cancer Prevention and Research Institute of Texas (CPRIT or 'the Institute') during the period November 28, 2022, through April 11, 2023, relating to the development of a contract risk assessment model.

The objective of the audit advisory procedures was to assist CPRIT management in the design of an effective contract risk assessment model to comply with the contract management requirements of the Texas Comptroller of Public Accounts (CPA).

To accomplish this objective, we conducted interviews with CPRIT personnel, examined existing contracts of the agency and utilized the State of Texas Procurement and Contract Management Guide published by the CPA to ensure compliance with regulatory requirements and appropriate risk coverage. Our procedures were completed on April 11, 2023.

The following report summarizes the results of our procedures.

Weaver and Tidwell, L.L.P.

WEAVER AND TIDWELL, L.L.P.

Austin, Texas
May 1, 2023

Cancer Prevention and Research Institute of Texas

Contract Risk Assessment Model Advisory Audit Report

April 11, 2023

Issued: May 1, 2023

Background

The Texas Comptroller of Public Accounts'(CPA) Statewide Procurement Division (SPD) updated the State of Texas Procurement and Contract Management Guide in May of 2022. As the central authority for state agency procurement guidance, education, and contract development, the SPD includes in the State of Texas Procurement Contract Management Guide information and direction for state agencies on contact management.

This contract management guidance includes the requirement for agencies to establish a process to perform a risk assessment of their contracts in order to determine the appropriate level of management and oversight of those contracts. This risk assessment includes an evaluation of the likelihood that an event will occur that could adversely affect the agency, as well as the magnitude of consequence the agency would experience if that event were to occur.

The results of this risk assessment are used by an agency to determine the nature, timing and extent of monitoring procedures an agency will perform for each vendor and vendor contract. The design and preparation of a risk assessment model for the ongoing use by CPRIT management was included as part of the fiscal year 2023 Internal Audit Plan.

Audit Scope & Objectives

This audit advisory project focused on collaborating with CPRIT's management team to develop a contract risk assessment model. We utilized the guidance in State of Texas Procurement and Contract Management Guide published by the Comptroller of Public Accounts to assist CPRIT in designing a risk assessment model that complies with the requirements in the state's Contract Management Guide.

Our procedures included interviews with CPRIT personnel and examining existing contracts that are managed by CPRIT.

Executive Summary

The outcome of our internal audit advisory procedures resulted in the development of a contract risk assessment model, risk definitions and procedures for CPRIT personnel to update, maintain and utilize the risk assessment in compliance with the CPA's contract management guidance.

The model was completed, updated with current vendor contract information and provided to CPRIT management along with guidance and procedures for the ongoing maintenance and update of the risk assessment model.

Conclusion:

CPRIT now has a contract risk assessment model that is based on the State of Texas Procurement and Contract Management Guide (version 2.1). This model can be updated and maintained by CPRIT personnel for current and future use of monitoring vendor contracts utilizing a risk-based strategy.

Detailed Procedures Performed

Cancer Prevention and Research Institute of Texas

Contract Risk Assessment Model Advisory Audit Report

April 11, 2023

Issued: May 1, 2023

Objective: Develop Contract Risk Assessment Model

The objective of the audit advisory procedures was to assist CPRIT management in the design of an effective contract risk assessment model to comply with the contract management requirements of the Texas Comptroller of Public Accounts.

Procedures Performed:

Our procedures included interviews with CPRIT personnel to gain an understanding of the active contracts in place and managed by CPRIT personnel. We evaluated the different characteristics of the contracts and compared those attributes to the risk factors presented in the State of Texas Procurement and Contract Management Guide. Through this comparison, we identified the relevant risk factors for CPRIT contracts and, with the assistance of CPRIT management, determined which risk factors would be included in CPRIT's contract risk assessment model.

We also assisted CPRIT in establishing risk definitions and risk ratings for each one of the risk factors that are included in the risk assessment model. Through this process we divided the risk categories into two main classifications: Financial Exposure and Entity Experience.

The Financial Exposure risk factors evaluate the financial risks to CPRIT based on the contract value, the length of CPRIT's contract with the vendor, the billing method of the vendor, and the status of the vendor with state vendor rating systems.

Entity Experience risk factors evaluate the relationship of the vendor with CPRIT, including CPRIT's dependence on the vendor/contract for operations, any prior experience CPRIT has with the vendor, and turnover of key employees at the vendor who provide service to CPRIT.

The risk ratings for each one of these considerations was also provided and evaluated with CPRIT management. We made recommendations on providing quantitative parameters for each of the risks to determine if CPRIT's risk in each risk factor was Low, Moderate or High.

Based on these risk ratings and risk factor definitions, we designed a method to weight each of the risk factors and to perform a mathematical calculation of each risk factor and the assessed risk. This final quantification of risk in the model provides a final risk-based rating that CPRIT management will use to determine the appropriate level of monitoring of each vendor.

As part of the design of the risk assessment model, we updated the model with the information of current CPRIT contracts. We populated the risk assessment model with this information and reviewed it with CPRIT management. Throughout the process of designing the model and ultimately populating it with current information, we met with CPRIT management to receive feedback and fine-tune the various risk factors, risk ratings and the instructions for maintaining the model with current information.

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: MAY 8, 2023

Summary and Recommendation

The Chief Executive Officer has appointed seven experts to CPRIT's Scientific Research and Prevention Programs Committee. CPRIT's statute requires Oversight Committee approval for the appointments. At their May 4 meeting, the Board Governance subcommittee reviewed the appointees and recommends approval by the Oversight Committee.

Discussion

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

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

The Board Governance Subcommittee reviewed the appointees at its May 4 meeting and recommends their approval by the Oversight Committee.

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CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Scientific Research and Prevention Programs Committees ("Peer Reviewer") Appointments
May 2023

Academic Research		
Nominees	**Panel Assignment**	**Expertise**
Nathanael S. Gray, Ph.D. Professor of Chemical and Systems Biology Stanford University Standford, CA	Scientific Review Council – ad hoc member	A recognized leader in the field of chemical biology and small molecule protein kinase inhibitors. An expert in the disciplines of combinatorial, medicinal chemistry and small molecule mechanism of action studies.
Lourdes Baezconde-Garbanati, Ph.D., M.P.H. Professor of Preventative Medicine University of Southern California/Norris Comprehensive Cancer Center Los Angeles, CA	Texas Connect for Cancer Prevention	Cancer Prevention and Screening; Population-based Cohort Studies; Tobacco Use and Control; Human Papillomavirus; cervical cancer; Racial/Health Disparities especially Hispanic Populations; Community outreach and engagement; community based participatory research
Erin Kobetz, Ph.D. Professor and Vice Provost for Research Departments of Medicine, Public Health, Obstetrics and Gynecology, Marine Biology and Ecology University of Miami School of Medicine Miami, FL	Texas Connect for Cancer Prevention	Clinical/Translational Science; Community Engagement; Cancer Disparities; Health Equity; Multilevel Interventions
Isabel Scarinci, Ph.D. Professor and Senior Scientist Division of Preventive Medicine University of Alabama at Birmingham Birmingham, AL	Texas Connect for Cancer Prevention	Cancer Prevention and Screening; Community Based Participatory Research; Cervical Cancer (screening and HPV vaccination); Tobacco Control; Racial/Health Disparities.
Melissa Troester, Ph.D. Professor Department of Epidemiology University of North Carolina at Chapel Hill School of Public Health Chapel Hill, NC	Texas Connect for Cancer Prevention	Breast Cancer; Molecular Pathology; Gene Expression; microRNA; Cancer Epidemiology and Risk Factors; Tumor Microenvironment; DNA Repair; Racial Disparities

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Product Development Research			
Name	**Organization**	**Title**	**Expertise**
Tristan Sissung, Ph.D.	National Cancer Center	Staff Scientist	Pharmacogenetics, clinical pharmacology, medical oncology
Felicitas L. Lacbawan, M.D.	Becton Dickinson	Vice President, Medical Affairs, Integrated Diagnostics Solutions	Molecular Genetic Pathology, clinical genetics, anatomic pathology, clinical pathology, advanced diagnostics

Academic Research nominations for Peer Reviewers

Nominees	Panel Assignment	Expertise
Nathanael S. Gray, Ph.D. Professor of Chemical and Systems Biology Stanford University Standford, CA	Scientific Review Council – ad hoc member	A recognized leader in the field of chemical biology and small molecule protein kinase inhibitors. An expert in the disciplines of combinatorial, medicinal chemistry and small molecule mechanism of action studies.
Lourdes Baezconde-Garbanati, Ph.D., M.P.H. Professor of Preventative Medicine University of Southern California/Norris Comprehensive Cancer Center Los Angeles, CA	Texas Connect for Cancer Prevention	Cancer Prevention and Screening; Population-based Cohort Studies; Tobacco Use and Control; Human Papillomavirus; cervical cancer; Racial/Health Disparities especially Hispanic Populations; Community outreach and engagement; community based participatory research.
Erin Kobetz, Ph.D. Professor and Vice Provost for Research Departments of Medicine, Public Health, Obstetrics and Gynecology, Marine Biology and Ecology University of Miami School of Medicine Miami, FL	Texas Connect for Cancer Prevention	Clinical/Translational Science; Community Engagement; Cancer Disparities; Health Equity; Multilevel Interventions
Isabel Scarinci, Ph.D. Professor and Senior Scientist Division of Preventive Medicine University of Alabama at Birmingham Birmingham, AL	Texas Connect for Cancer Prevention	Cancer Prevention and Screening; Community Based Participatory Research; Cervical Cancer (screening and HPV vaccination); Tobacco Control; Racial/Health Disparities.
Melissa Troester, Ph.D. Professor Department of Epidemiology University of North Carolina at Chapel Hill School of Public Health Chapel Hill, NC	Texas Connect for Cancer Prevention	Breast Cancer; Molecular Pathology; Gene Expression; microRNA; Cancer Epidemiology and Risk Factors; Tumor Microenvironment; DNA Repair; Racial Disparities

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

Product Development Peer Review Appointments

May 2023

Name	Organization	Title	Expertise
Tristan Sissung, PhD	National Cancer Center	Staff Scientist	Pharmacogenetics, clinical pharmacology, medical oncology
Felicitas L. Lacbawan, MD	Becton Dickinson	Vice President, Medical Affairs, Integrated Diagnostics Solutions	Molecular Genetic Pathology, clinical genetics, anatomic pathology, clinical pathology, advanced diagnostics

**2 Appointees*

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:	MAY 8, 2023

Summary

At its May 4 meeting, the Board Governance subcommittee reviewed Presiding Officer Dr. Mahendra Patel's proposed appointments to the Clinical Trials Advisory Committee (CTAC) and Prevention Advisory Committee (PAC). The subcommittee recommends that the Oversight Committee approve the two 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 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 PAC advises the Oversight Committee on important issues surrounding cancer prevention and control. The members of the PAC share their advice on opportunities to increase CPRIT's impact on cancer prevention and control in Texas.

The presiding officer of the Oversight Committee is responsible for appointing experts to serve on CPRIT's advisory committees, including the CTAC and PAC. Appointments to each advisory committee other than the University Advisory Committee must be approved by the Oversight Committee.

The Board Governance subcommittee reviewed the appointments to the CTAC and PAC at its May 4 meeting and voted to recommend approval to the Oversight Committee.

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CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Advisory Committee Appointments
May 2023

Advisory Committee	Nominee	Institution/Organization
Clinical Trials Advisory Committee	Pavan Reddy, M.D., Director of the Dan L. Duncan Comprehensive Cancer Center	Baylor College of Medicine
Prevention Advisory Committee	Laura Wood, CHES State Partnerships – Texas	American Cancer Society
University Advisory Committee	Pavan Reddy, M.D., Director of the Dan L. Duncan Comprehensive Cancer Center	Baylor College of Medicine
University Advisory Committee	Dr. Shreek Mandayam, Vice President for Research	Texas State University
University Advisory Committee	Ramamoorthy Ramesh, Ph.D. Vice President for Research	Rice University

No Oversight Committee action is required for University Advisory Committee (UAC) appointments. CPRIT's statute creates the UAC and mandates that chancellors from various institutions of higher education are responsible for fulfilling appointments to the UAC.

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Baylor College of Medicine

DAN L DUNCAN COMPREHENSIVE CANCER CENTER

Pavan Reddy, M.D., is the **Director of the Dan L Duncan Comprehensive Cancer at Baylor College of Medicine**. In addition to this role, he is Senior Associate Dean of Cancer Programs and holds an executive physician leadership role/leads all Oncology Services, research, and strategic growth at **Baylor St. Luke's Medical Center.**

A physician-scientist who does both bench and translational research, his work is focused on understanding the role of immune cells in blood diseases, cancer and transplantation. His groundbreaking research is supported by funding from the National Institutes of Health, the Leukemia and Lymphoma Society, and other foundations.

Dr. Reddy was born and raised in India. He earned his medical degree from Osmania University in Hyderabad in 1994 then came to the United States where he completed a residency in internal medicine at the University of Missouri in 1998. Following the completion of fellowships in hematology/oncology and bone and marrow transplantation at the University of Michigan, he joined the U-M faculty in 2002 and began to co-direct the Bone Marrow Transplant Program and the Hematologic Malignancies Program since 2011. He served as the Chief of the Division of Hematology/Oncology and Deputy Director of the Rogel Cancer Center at University of Michigan until September 2022, when he joined Baylor College of Medicine as the Director of the Dan L Duncan Comprehensive Cancer Center in Houston, Texas. He is the author or co-author of over 250 peer-reviewed journal articles and book chapters. Dr. Reddy has received many honors, including the Jerome Conn Award from department of medicine, awards from national societies including the election to honorary societies such as American Society of Clinical Investigation (ASCI), Association of American Physicians (AAP), and American Clinical and Climatological Association (ACCA). He holds leadership roles in multiple scientific committees and served as the immediate past-President of the American Society of Transplantation and Cellular Therapy (ASTCT), scientific committees of the American Society of Hematology (ASH), NIH panels. He is the Deputy Editor of *JCI Insight*, and Associate Editor for the journals *Hematologica, Transplantation and Cellular Therapy*.

In the laboratory, Dr. Reddy focuses on the immunobiology of graft-versus-host disease (GVHD), a devastating immune response that can occur after a stem cell or bone marrow transplant in which the newly transplanted donor cells attack the transplant recipient's body. Dr. Reddy hopes to translate the knowledge he gains through his research into powerful, lifesaving treatments for patients everywhere. His research has been continuously funded by the NIH with multiple grants for over 20 years.

Dr. Reddy and his wife Dr. Madhulata Reddy have two sons: Sidharth and Saahith.

Laura Wood, CHES
Associate Director, State Partnerships – Texas, American Cancer Society

Laura is a strategic leader with 20+ years of progressive experience in the healthcare industry developing, implementing, and evaluating strategic solutions to advance organizational impact. She has led teams and cultivated partnerships with state associations, Federally Qualified Health Centers (FQHC), hospitals and cancer treatment facilities resulting in improved cancer control practice to increase cancer screenings HPV vaccination coverage levels, the utilization of tobacco cessation options, and enhanced American Cancer Society resources for caregivers and patients. In her current role, she strategically aligns and collaborates with state level partners to bring equitable solutions impacting cancer control outcomes. She currently serves on the Texas Cancer Registry Advisory Committee. Laura has her BS in Health and is a Certified Health Education Specialist. She currently resides in North Texas.

Dr. Shreek Mandayam
Vice President for Research
Texas State University
601 University Drive
JC Kellam Suite 489
San Marcos, TX 78666
shreek@txstate.edu
(512) 245-2314
www.txst.edu/research/

Dr. Shreekanth (Shreek) Mandayam is the Vice President for Research at Texas State University. Dr. Mandayam leads the Division of Research (which includes the offices of Research Operations, Sponsored Programs, Research Development, and Innovation & Commercialization) university-level research centers, the Science, Technology, and Advanced Research (STAR) Park, and serves as the university's liaison to The Texas State University System's Office of Governmental Relations.

Dr. Mandayam holds a Bachelor of Engineering degree from Bangalore University in India and an M.S. and Ph.D. Degree in Electrical Engineering from Iowa State University in Ames, Iowa. Dr. Mandayam is joining Texas State from Rowan University in New Jersey, where he has served in various leadership roles, including Vice President for Research, Executive Director of the South Jersey Technology Park, and Chair of the Department of Electrical and Computer Engineering.

Dr. Mandayam is tenured Professor of Electrical Engineering and an active scholar whose research expertise is in the area of advanced visualization and virtual reality. He is the founder and lead investigator in Rowan University's Virtual Reality (VR) Center, where he has secured over $15 million in funding for research projects sponsored by the National Science Foundation, NASA, U.S. Army, U.S. Navy, U.S. Department of Commerce, U.S. Department of Energy, Elekta Corporation, Medtronic, and others. In executing projects in the VR Center, he has partnered with faculty from a variety of disciplines, including those in engineering, the humanities, social sciences, communications, medicine, fine arts, performing arts, science, and mathematics. Dr. Mandayam has authored over 90 publications in peer-reviewed journals and conference proceedings and has advised 30 master's and doctoral students.

Professor Ramamoorthy Ramesh

Vice President for Research

Rice University

Ramesh pursues key materials physics and technological problems in complex multifunctional oxides. Using conducting oxides, he solved the 30-year enigma of polarization fatigue in ferroelectrics. He pioneered research into manganites coining the term, Colossal Magnetoresistive (CMR) Oxides. His work on multiferroics demonstrated electric field control of ferromagnetism, a critical step towards ultralow power memory and logic elements.

His extensive publications on the synthesis and materials physics of complex oxides are highly cited (over 100,000 citations, H-factor =150). He is a fellow of APS, AAAS & MRS and an elected member of the U.S. National Academy of Engineering, a Foreign member of the Royal Society of London, the Indian National Science Academy, the Indian National Academy of Engineering and a Fellow of the American Academy for Arts and Sciences. His awards include the Humboldt Senior Scientist Prize, the APS Adler Lectureship and McGroddy New Materials Prize, the TMS Bardeen Prize and the IUPAP Magnetism Prize and Neel Medal and the Europhysics Prize in 2022. He was recognized as a Thomson-Reuters Citation Laureate in Physics for his work on multiferroics.

He served as the Founding Director of the successful Department of Energy SunShot Initiative in the Obama administration, envisioning and coordinating the R&D funding of the U.S. Solar Program, spearheading the reduction in the cost of Solar Energy. He also served as the Deputy Director of Oak Ridge National Laboratory and the Associate Lab Director at LBNL. Most recently, he served on the Biden-Harris Transition Team for Energy. He is also a co-founder of Kepler Computing, which is focused on low-power computing using ferroelectrics.

Starting 15 August, he is serving as the Vice President for Research at Rice University

Laura Wood, CHES
Associate Director, State Partnerships – Texas, American Cancer Society

Laura is a strategic leader with 20+ years of progressive experience in the healthcare industry developing, implementing, and evaluating strategic solutions to advance organizational impact. She has led teams and cultivated partnerships with state associations, Federally Qualified Health Centers (FQHC), hospitals and cancer treatment facilities resulting in improved cancer control practice to increase cancer screenings HPV vaccination coverage levels, the utilization of tobacco cessation options, and enhanced American Cancer Society resources for caregivers and patients. In her current role, she strategically aligns and collaborates with state level partners to bring equitable solutions impacting cancer control outcomes. She currently serves on the Texas Cancer Registry Advisory Committee. Laura has her BS in Health and is a Certified Health Education Specialist. She currently resides in North Texas.

Dr. Peter Davies, MD, PhD is Professor and Director of the Center for Translational Cancer Research at the Texas A&M University Institute of Biosciences and Technology in Houston. He also serves as Head of the Department of Translational Medical Sciences, Texas A&M College of Medicine. Dr. Davies has had a long-standing interest cancer therapeutics and academic drug discovery. Following physician-scientist training at the University of Miami, he completed 4 years of post-doctoral training at the National Cancer Institute before joining the faculty of the University of Texas Medical School in Houston. He spent more than 30 years at UT-Houston rising to the rank of Professor of Pharmacology and Medicine, Executive Vice-President for Research and Provost of the Health Science Center. In 2011 he moved to Texas A&M University to lead a program in cancer-related drug discovery research at the A&M Institute of Biosciences and Technology. Dr. Davies is grateful for the generous research grant support that he and his colleagues have received from CPRIT and is committed to supporting CPRIT in its goal of the developing advances in the prevention and treatment of cancer that will benefit the citizens of Texas, the nation and the world.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

CPRIT University Advisory Committee: 2023 Annual Report

CPRIT Oversight Committee Meeting
May 17, 2023

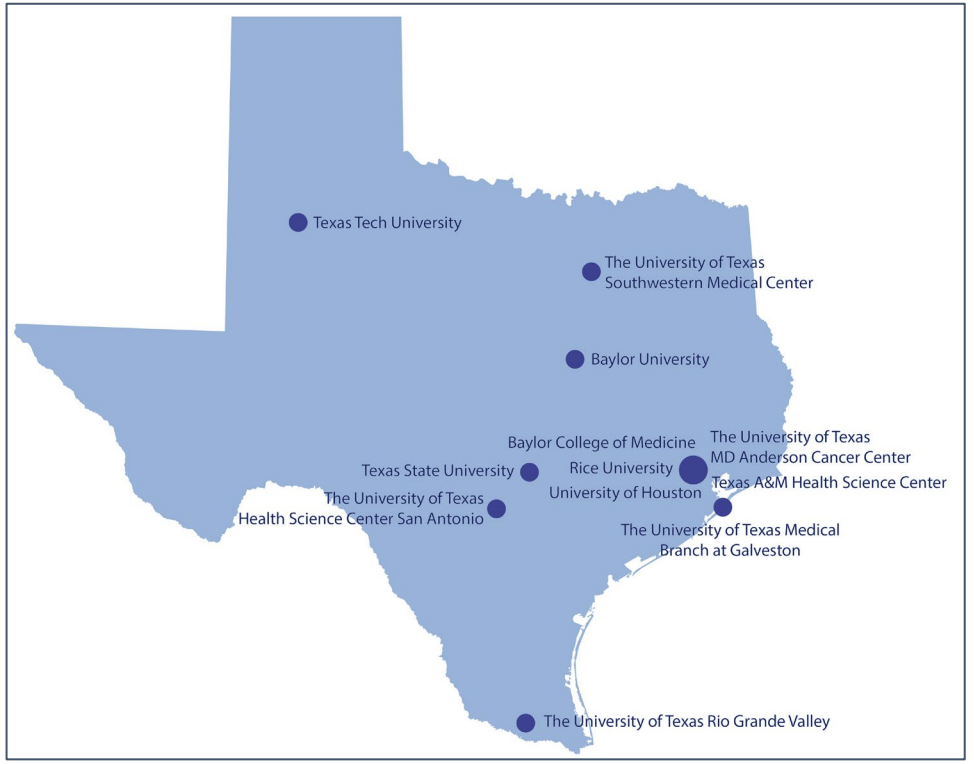
Peter Davies MD, PhD, Chair

University Advisory Committee (UAC) – Membership
FY2022 - 2023

Peter Davies, M.D., Ph.D. Chair, Head. Dept of Translational Medical Sciences Director, Center for Translational Cancer Research Texas A&M Health Science Center ***Translational cancer research – CPRIT – funded investigator***	**Carlos L. Arteaga, M.D. (Vice Chair)** Director of the Harold C. Simmons Comprehensive Cancer Center Associate Dean of Oncology Programs The University of Texas Southwestern Medical Center ***Clinical oncologist – CPRIT Scholar***
Pavan Reddy, MD Director. Dan L Duncan Comprehensive Cancer Center Baylor College of Medicine ***Clinical Oncology – CPRIT Scholar***	**Shreek Mandayam, Ph.D.** Vice President for Research Texas State University ***Engineering***
Abbey B. Berenson, M.D., MMS, Ph.D. Professor of Obstetrics/Gynecology and Pediatrics Director, Center for Interdisciplinary Research in Women's Health The University of Texas Medical Branch at Galveston ***Clinical researcher, CPRIT – funded investigator***	**Claudia Neuhauser, Ph.D.** Associate Vice President for Research and Technology Transfer HHMI Professor, Mathematics, Division of Research University of Houston/University of Houston System ***Mathematics and Quantitative biology***
Subhash C. Chauhan, Ph.D. Professor and Chairman, Department of Immunology and Microbiology Director, South Texas Centre of Excellence in Cancer Research The University of Texas Rio Grande Valley ***CPRIT funded investigator and TREC PI***	**Ramamoorthy Ramesh, Ph.D.** Vice President for Research Professor of Materials Science, Physics and Astronomy Rice University ***Materials science and physics***
Giulio F. Draetta, M.D., Ph.D. Chief Scientific Officer Chair, Department of Genomic Medicine, The University of Texas MD Anderson Cancer Center ***Translational Cancer research – CPRIT Funded investigator***	**John Louis Wood, Ph.D.** Robert A. Welch Distinguished Professor Professor of Chemistry & Biochemistry Baylor University ***Chemistry – CPRIT Scholar***
Pending *The University of Texas Health Science Center San Antonio*	**Joseph "Joe" Heppert, Ph.D.** Vice President for Research Texas Tech University, ***Chemistry***

UAC - broad representation

- **Institutional Representatives- senior administrative leaders**
- **Health-related Institutions and Academic Campuses**
- **Active researchers – CPRIT Scholars and funded investigators**
- **Regional representation**



9-10

UAC Meetings – Challenges of Post-Covid Era
2022 / 2023

June 13, 2022 - Special Meeting to Discuss FY22/ FY23 Budget Adjustments

a. FY22 Programmatic Update

b. FY23 Budget Constraints

March 31, 2023 – UAC Meeting to Discuss Recommendations for FY24 Adjustments to Academic Research and Recruitment Programs

- FY24.2 Academic Research RFAs
- Discuss current and proposed IIRA funding levels
- Discuss parameters for recruitment awards

Focus of Discussion

- **Recruitment Program**
- **Individual Investigator Research Awards (IIRA) Program**

9-11

June 13, 2022 UAC Meeting

FY22 Academic Research Program Data Funding Information

Cycle	Mechanism	# Applications Submitted	Total Funding Requested	Applications Recommended by SRC	Total Funding Recommended by SRC	Success Rate
22.1	Individual Investigator Research Awards (IIRA)	282	$285,494,299	41	$41,390,000	15%
22.1	IIRA for Children and Adolescents	50	$67,884,165	7	$9,730,000	14%
22.1	IIRA for Clinical Translation	27	$52,079,326	1	$1,990,000	4%
22.1	IIRA for System Computational Biology	21	$23,825,931	3	$3,570,000	14%
22.1	IIRA for Prevention and Early Detection	23	$44,112,406	6	$11,480,000	26%
[1] **22.1**	**IIRA Totals**	**403**	**$473,396,127**	**58**	**$68,160,000**	
22.1	Recruitment of Established Investigators	17	$92,670,539	8	$47,999,721	47%
22.1	Recruitment of Rising Stars	15	$55,999,661	9	$31,999,661	60%
22.1	Recruitment of First-Time, Tenure Track FM	43	$94,000,000	28	$56,000,000	65%
22.1	**Recruitment Totals**	**75**	**$242,670,200**	**45**	**$135,999,382**	
FY22.1 Totals		**478**	**$716,066,327**	**103**	**$204,159,382**	

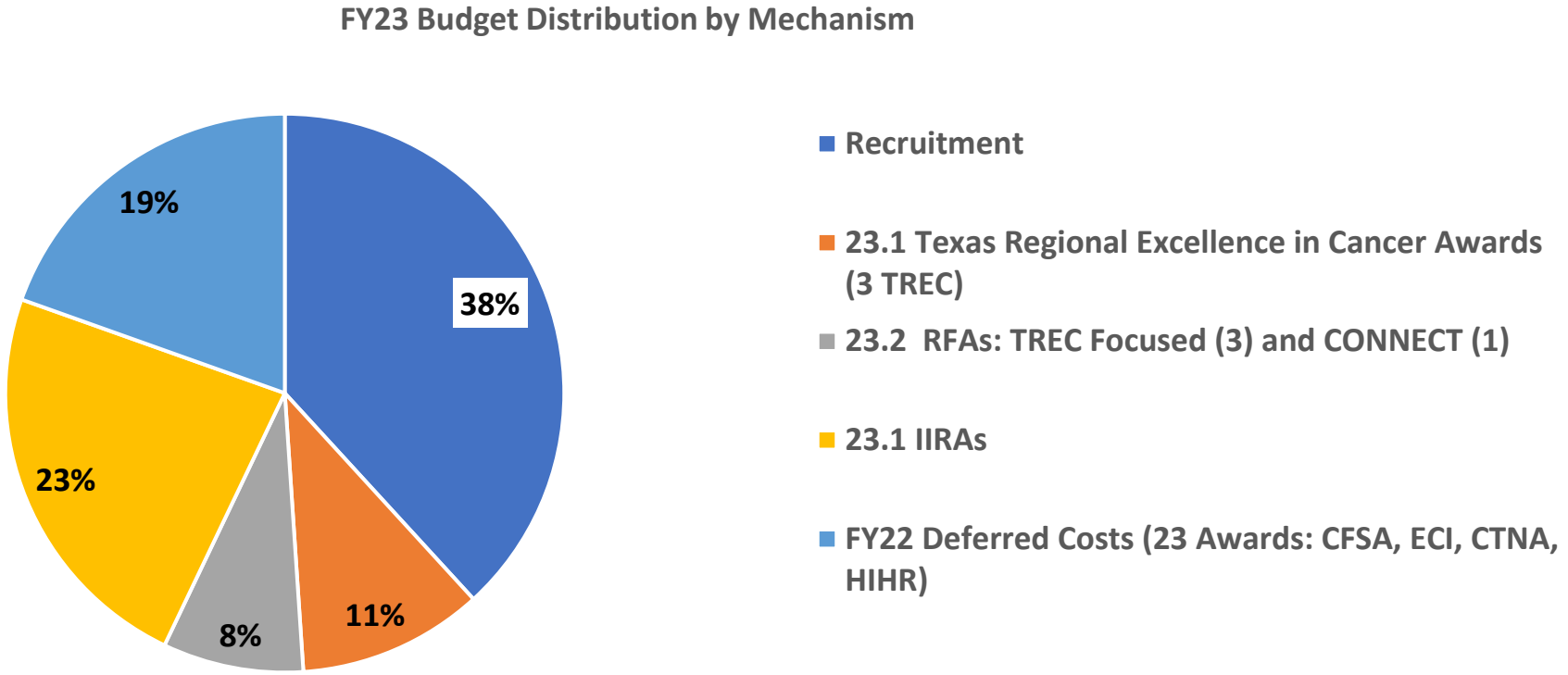
[1] FY 22.2: The SRC recommended 29 applications totaling $41,759,145 in requested funding. The Oversight Committee will review PIC recommendations in September with funding deferred to FY23 budget.

Summary of FY23 measures implemented to align budget

1. Reduced recruitment cycles from 12 to 6 – recommend fewer nominees (50-60% of previous years)
2. Reduced number of research awards funded - 23.1 IIRAs, 329 grants received– reduced the payline from ~15 percentile to ~10 percentile
3. Did not post 23.2 RFAs (CFSA; High-Impact/High-Risk Awards). Considered bridge funding for Core renewals, as needed and with available funds
4. Preserved TREC program budget.

9-12

March 31, 2023 – UAC Meeting



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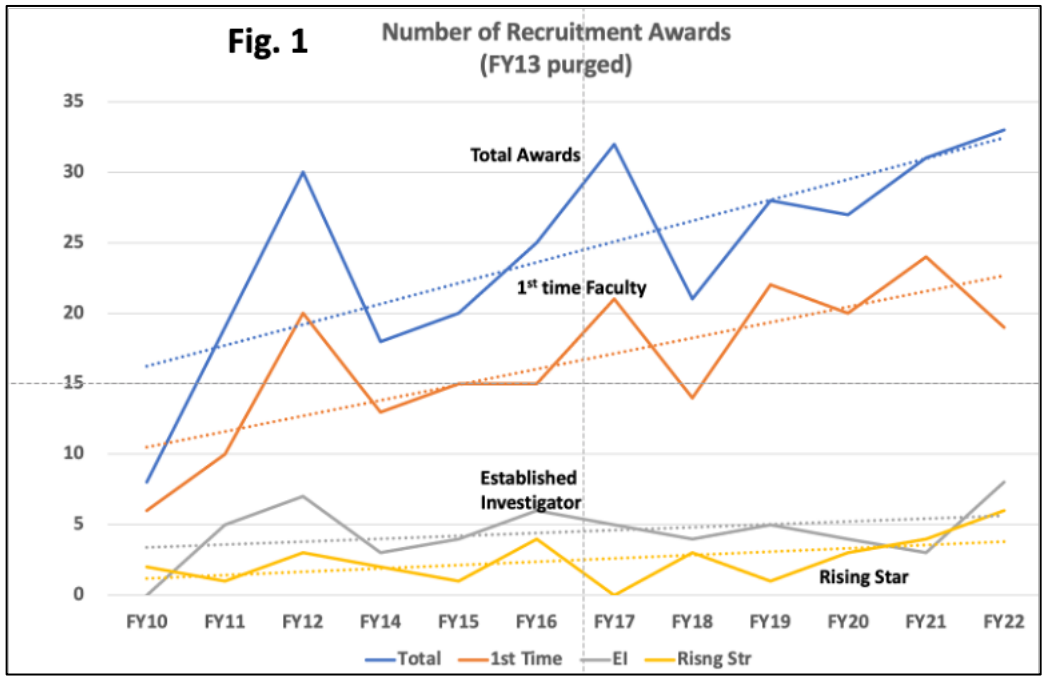
9-13

CPRIT Scholars Program – A Jewel in the Crown of the Academic research Program

Scholars Program

- Unique Program building human capacity for cancer research across the State of Texas
- Targeting both outstanding new researchers and recognized leaders in cancer research Table I
- Major impact on cancer research programs in both health-related and academic institutions statewide
- Over last 13 years, steady increase in number of scholar awards, primarily in 1st Time recruiting awards Figure 1
- Increase expenditures in recruiting awards matched by a reciprocal decrease in research (non-recruiting) funding. Figure 2



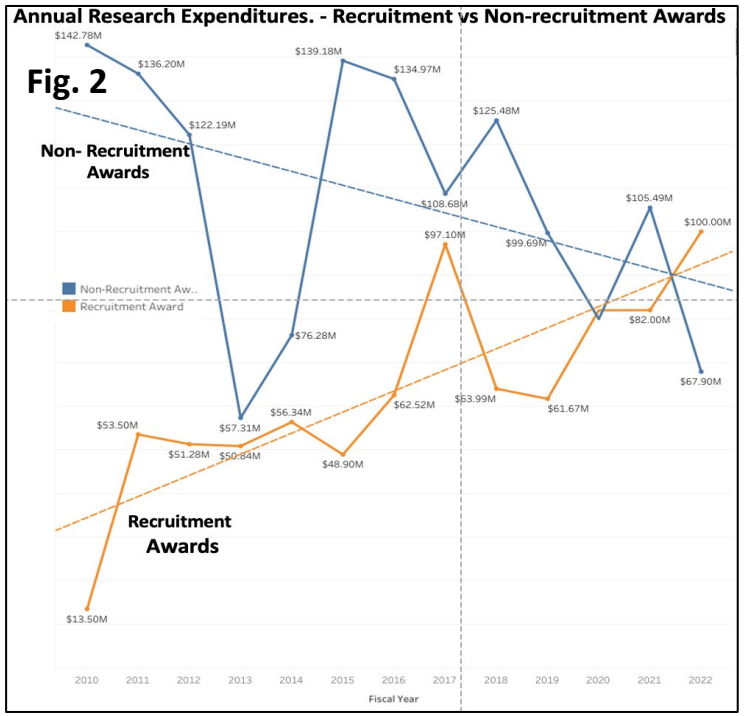


TABLE I

Mechanism	Mechanism Totals		
	# App Sub.	# Funded	Success Rate
Recruitment Award Totals:	**763**	**299**	**39%**
Recruitment of First-Time, Tenure-Track Faculty Members	452	202	45%
Recruitment of Established Investigators	158	58	37%
Recruitment of Rising Stars	129	30	23%
Recruitment of Missing Links	24	3	13%

9-14

Options for Managing the Scholars Program

Proposed

1. **Reinstate monthly cycles for FY24.**
2. **Allow an unlimited number of nominations to be submitted by each institution per cycle; smaller percentage of nominees (~30%) will be funded.**
3. **Reinstate the Rising Stars category**

Discussion and Recommendations

1. **Goal needs to be a balanced investment in recruitment versus research (non-recruitment) research program**
2. **Recognition that some form of cost containment is likely to be required to establish a balanced portfolio**
3. **Reinstate monthly application cycles**
4. **Reinstate the Rising Star category**
5. **2-month review cycle would be manageable**
6. **Discussion of the impact of potential reductions in funding levels of REI and RRS awards. Recommended for further discussion (Table I)**

TABLE I

Mechanism	Current	Proposed
REI	$6 million	**$5 million**
RRS	$4 million	**$3 million**
FTTT	$2 million	$2 million

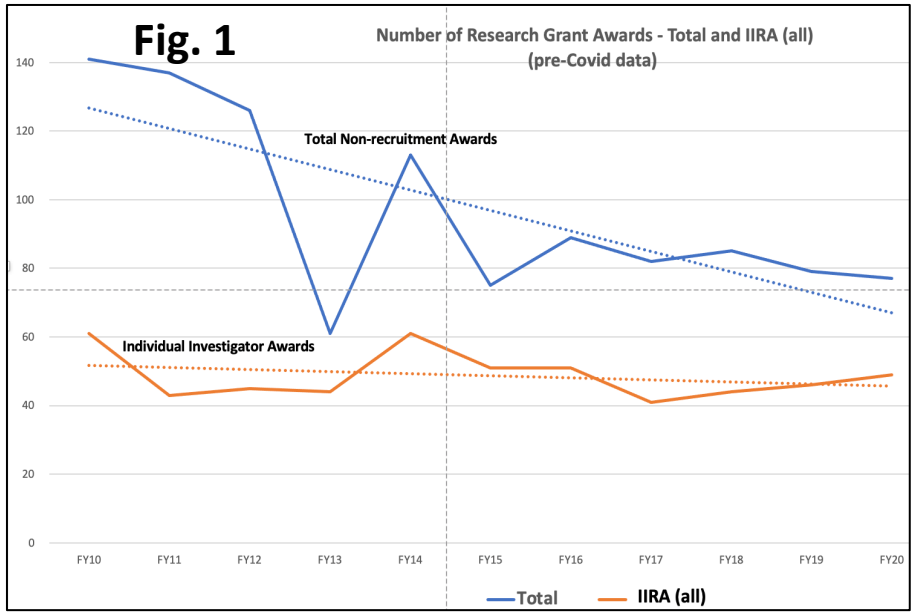
1. **Discussion of initiating Institutional Caps based on either number of applications or total awards (based on size)**
    1. **Issue is prioritization of Excellence versus Distribution of Benefits**
    2. **Further discussion before considering implementation**

9-15

Individual Investigator Research Award (IIRA) Program
A Second Jewel in the Crown of the Academic Research Program

Individual Investigator Research Award Program

- The heart of the Academic Research Program. The engine that drives innovation and discovery
- Over the last 13 years, Texas' cancer researchers have submitted >5,500 research projects as applications for research funding. CPRIT has funded 650 individual projects. On average 300 – 400 investigators annually submit research project proposals.
- Over the last 10 years, while total number of research grant awards has declined, number of IIRA awards has remained constant. Figure 1
- IIRA projects are rigorously reviewed, <12%, only the most outstanding, are selected for funding. Figure 2
- The IIRA supports both projects targeted to research areas selected as CPRIT strategic priorities as well as investigator-initiated projects across all areas of basic, translational and clinical cancer research. Table 1



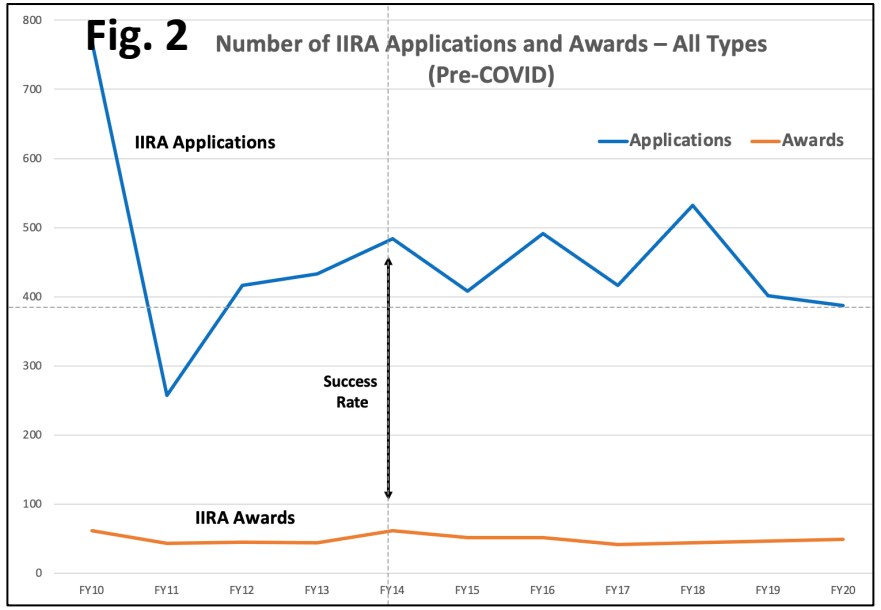


TABLE I

	FY2022			
	IIRA - Type	# App. Sub.	# Funded	Success Rate
	All Types	398	58	15%
Untargeted	Individual Investigator Research Awards	281	41	15%
Targeted	Individual Investigator Research Awards for Cancer in Children and Adolescents	49	7	14%
Targeted	Individual Investigator Research Awards for Clinical Translation	24	1	4%
Targeted	Individual Investigator Research Awards for Computational Biology	21	3	14%
Targeted	Individual Investigator Research Awards for Prevention and Early Detection	23	6	26%

Options for Managing the IIRA Program Funding

Discussion and Recommendations - IIRA Funding

- Historically the IIRA has achieved a stable level of funding approx. 11%. Table I
- Cycle 23.1 was anomalous with funding level <10%, and a gap of 25 projects (>$28M) recommended for funding based on scientific merit, but not funded.
- It is a priority to maintain the Success Rate for IIRA proposals at least at historic levels , 11%-12% (Note: NCI currently at 12% with goal 15%).
- If necessary, modest reductions in amount and/or duration of awards may be necessary to maintain maintain success rates at acceptable levels. Table II
- Initiation of new research programs should be be viewed in the context of their potential impact on the Investigator Initiated Research Program.
- Explore opportunities for collaborative programs with other funding agencies with a shared interest in supporting Investigator-initiated cancer research (AACR, ASCO, SU2C etc.)

TABLE I

IIRA Success Rate (all mechanisms)			
	# App Sub.	# Funded	Success Rate
New Submissions	5717	650	11.40%
Resubmissions	593	100	16.90%

TABLE II

Mechanism	Current Total/yr (No. years)	Proposed Total/yr (No. years)
Individual Investigator Research Awards (IIRA)	$350,000/yr (3 yrs)	$300,000/yr (3 yrs)
IIRA for Children and Adolescents	$350,000/yr (4 yrs) $500,000 w. trial	$300,000/yr (4 yrs) $400,000 w. trial
IIRA for Clinical Translation	$500,000/yr (4 yrs)	$400,000/yr (4 yrs)
IIRA for Computational Systems Biology	$400,000/yr (3 yrs)	$300,000/yr (3 yrs)
IIRA for Prevention and Early Detection	$400,000/yr (5 yrs)	$300,000/yr (4 yrs)

* Total cost reduction for the 31 IIRAs in FY23 would be $7.9 to $8.9 million

9-17

Communication in the Post-Covid Era

- **Disruptions in CPRIT's Academic research grants awards program due to the unprecedent impact of the COVID have caused hardships in the academic community**
- **UAC recommends a vigorous program of outreach and communication to reassure the user community to CPRIT's ongoing commitment to the support of cancer-related research in Texas**
  - **Conferences and Information exchanges**
  - **Regional workshops and townhall meetings**
  - **Social media**

The Value Proposition

An Economic Assessment of the Cost of Cancer in Texas
and the Benefits of the
Cancer Prevention and Research Institute of Texas (CPRIT)
and its Programs:

2022 Update

THE PERRYMAN GROUP

Scientific research, as is facilitated by CPRIT, is valuable to society in large part due to the benefits that it facilitates downstream.

Basic medical research is part of society's essential infrastructure, and CPRIT has demonstrated capacity to enhance the health of Texans and the economy at a pace that far exceeds the direct investment. 9-19

Summary and Conclusions

- **The Covid catastrophe has provided an important opportunity to take stock of priorities and recalibrate existing programs as well as new programs to leverage the accomplishments of the last 14 years in charting a new course for the future.**
- **From UAC perspective, the Academic Research Program is a remarkable accomplishment – a stable, valuable program supporting all aspects of cancer research in Texas.**
- **Academic Research Community, through the UAC, expresses its gratitude to the leadership of CPRIT for their support and the very inclusive approach they have taken to engage the opinion of key stakeholders in the research enterprise.**

9-20

Thank You

Hogan Lovells

Andrew Strong

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Andrew is an experienced and trusted advisor and counsel to public and private life sciences, pharmaceutical, and emerging technology global clients on matters involving corporate formation, public and private financing, M&A, cross-border licensing and joint ventures, employment and executive compensation and intellectual property.

He has experience starting up and selling a successful Texas biotech company that has grown to 800+ employees, has served and presently serves as the general counsel for several private and publicly traded drug development biotech clients and has served as a board member and in leadership positions for NYSE, Nasdaq and private corporations and for the Texas A&M University System.

He is the co-founder and Chairman of the Board of K2 Biolabs, a drug development accelerator providing CRO and CDMO services in Texas

Education

J.D., South Texas College of Law, 1994

B.S., Civil Engineering, Texas A&M University, 1989

Michele Park, PhD

Partner
Menlo Park

- Healthcare
- Life Sciences

Michele Park joined NEA Ventures in 2021 as Partner on the healthcare team focused on the biopharma space. Prior to NEA, Michele was an investor at life sciences-focused venture capital firm, Clarus Ventures (now Blackstone Life Sciences), where she led the initiative to launch the Clarus Cancer Fund—a novel investment model designed to generate returns and fuel cancer research through donation. Before Clarus, she spent time in biotechnology research analyst roles at Credit Suisse and Piper Jaffray.

Michele received her Ph.D. in Molecular Biology from Weill Cornell Graduate School of Medical Sciences and completed her dissertation at Memorial Sloan-Kettering Cancer Center. She also holds a B.A. in Molecular Biology from Princeton University. Park serves as Co-Chair of the Cancer Prevention and Research Institute of Texas (CPRIT) Product Development Advisory Committee; Board Trustee for the American Friends of the Royal Philharmonic Orchestra (AFRPO); and is a member of the Council of Korean Americans (CKA) and Private Equity Women Investor Network.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

2023 Report from the Product Development Advisory Committee

Andrew Strong and
Michele Park

9-24

PDAC Presenters

Andrew Strong

Partner, Houston
Hogan Lovells US, LLP
+1 713 899 3930
andrew.strong@hoganlovells.com

Andrew is an experienced and trusted advisor and counsel to public and private life sciences, pharmaceutical, and emerging technology global clients on matters involving corporate formation, public and private financing, M&A, cross-border licensing and joint ventures, employment and executive compensation and intellectual property.

Education

J.D., South Texas College of Law, 1994

B.S., Civil Engineering, Texas A&M University, 1989

Andrew previously served as the general counsel and compliance officer for the Texas A&M University System where he was responsible for, among other things, technology commercialization, business contracting, litigation and Board governance for the system's universities and state agencies.

He has experience starting up and selling a successful biotech company that has grown to 900+ employees, has served and presently serves as the general counsel for several private and publicly traded drug development biotech clients and has served as a board member and in leadership positions for NYSE, Nasdaq, and private corporations.

Michele Park

Partner, Menlo Park
New Enterprise Associates (NEA)
mpark@nea.com

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Product Development Advisory Committee (PDAC)

Co-Chair Michele Park, PhD, Partner, NEA
Co-Chair Andrew Strong, JD, Partner, Hogan Lovells, LLP*

David Arthur, CEO, Salarius Pharmaceuticals*
Bruce Butler, PhD, VP, Research and Technology, Director, OTM, UTHSC at Houston
Julie Goonewardene, AVP for Innovation and Strategic Investment, UT System
Gabby Everett, PhD, Site Director, BioLabs Pegasus Park
Victoria Ford, President and CEO, Texas Healthcare & Bioscience Institute
Greg Hartman, COO and SVP for Strategic Partnerships, Texas A&M University, Vice Chancellor at TAMU System
Heather Hanson, President, BioMedSA
Dan Hargrove, JD, Co-founder and President, Trauma Insight, LLC and Cancer Insight, LLC
Paul Lammers, MD, CEO, Triumvira Immunologics, Inc.*
David Lowe, PhD, Co-Founder, Aeglea Biotherapeutics; MDir, AllosteRx Capital*
Tom Luby, PhD, Director, Texas Medical Center (TMC) Innovation
Jonathan MacQuitty, PhD, Venture Partner, Lightspeed Venture Partners
Dennis McWilliams, Venture Partner, Sante Ventures*
Jon Mogford, PhD, COO and SVP, Texas A&M University Health Science Center
Tracy Saxton, PhD, CEO, Lengo Therapeutics; Adviser, Frazier Healthcare Partners
Emma Schwartz, President, Medical Center of the Americas Foundation
Greg Stein, MD, CEO, Curtana Pharmaceuticals*
Ann Tanabe, CEO, BioHouston, Inc.
Claire Aldridge, PhD, Chief of Staff and SVP, Business Operations, Taysha Gene Therapies
Harry Bushong, Convergence Ventures

9-26

Market Conditions

Michele Park

9-27

9-28

Review - EVERY YEAR Recommendations

Recommendation #1:

Increase the # of Product Development awards made annually, with goal to allocate ~30% of annual CPRIT budget to Product Development Research ($70+ million/year)

- MISSION ACCOMPLISHED

Recommendation #2:

Implement New Funding Opportunities/RFAs, with a focus on starting up/spinning out NewCos and regional or cross platform acceleration programs

- MISSION ACCOMPLISHED

9-29

How was the Mission Accomplished?

Increase # of Awards and deploy full PD Budget

FY	# of Cycles	# of Apps	# of Awards Approved	FY Funding Rate	Running Funding Rate	Total Award Amount Approved
2010	1	25	4	16%	16%	$21,523,951
2011	2	18	1	5.6%	11.6%	$5,680,310
2012	3	78	6	7.7%	9.1%	$65,444,537
2013	3	49	5	10.2%	9.4%	$49,157,565
2014	1	41	4	9.8%	9.5%	$59,579,105
2015	4	43	7	16.3%	10.6%	$77,072,632
2016	2	57	4	7.0%	10.0%	$58,896,837
2017	2	39	1	2.6%	9.1%	$8,998,067
2018	2	38	3	7.9%	9.0%	$50,587,540
2019	2	65	8	12.5%	9.5%	$51,183,034
2020	2	68	7	10.4%	9.6%	$47,649,610
2021	1	35	2	5.7%	9.4%	$27,565,207
2022		47	12	25.5%	10.6%	$87,021,483
Total	**27**	**603**	**62**		**10.6%**	**$610,359,878**

9-30

How was the Mission Accomplished?

Texas Therapeutic Company (TTC) Award

- Early-stage companies focused on research and development of innovative therapeutic products, services, and infrastructure
- Award: uncapped $ amount; 3 years

Texas Device/Diagnostic Company (TDDC) Award

- Early-stage companies focused on research and development of diagnostic tests and devices to treat, detect, diagnose, monitor, and assist in the treatment of cancer.
- Award: uncapped $ amount; 3 years

Texas New Technologies Company (TNTC) Award

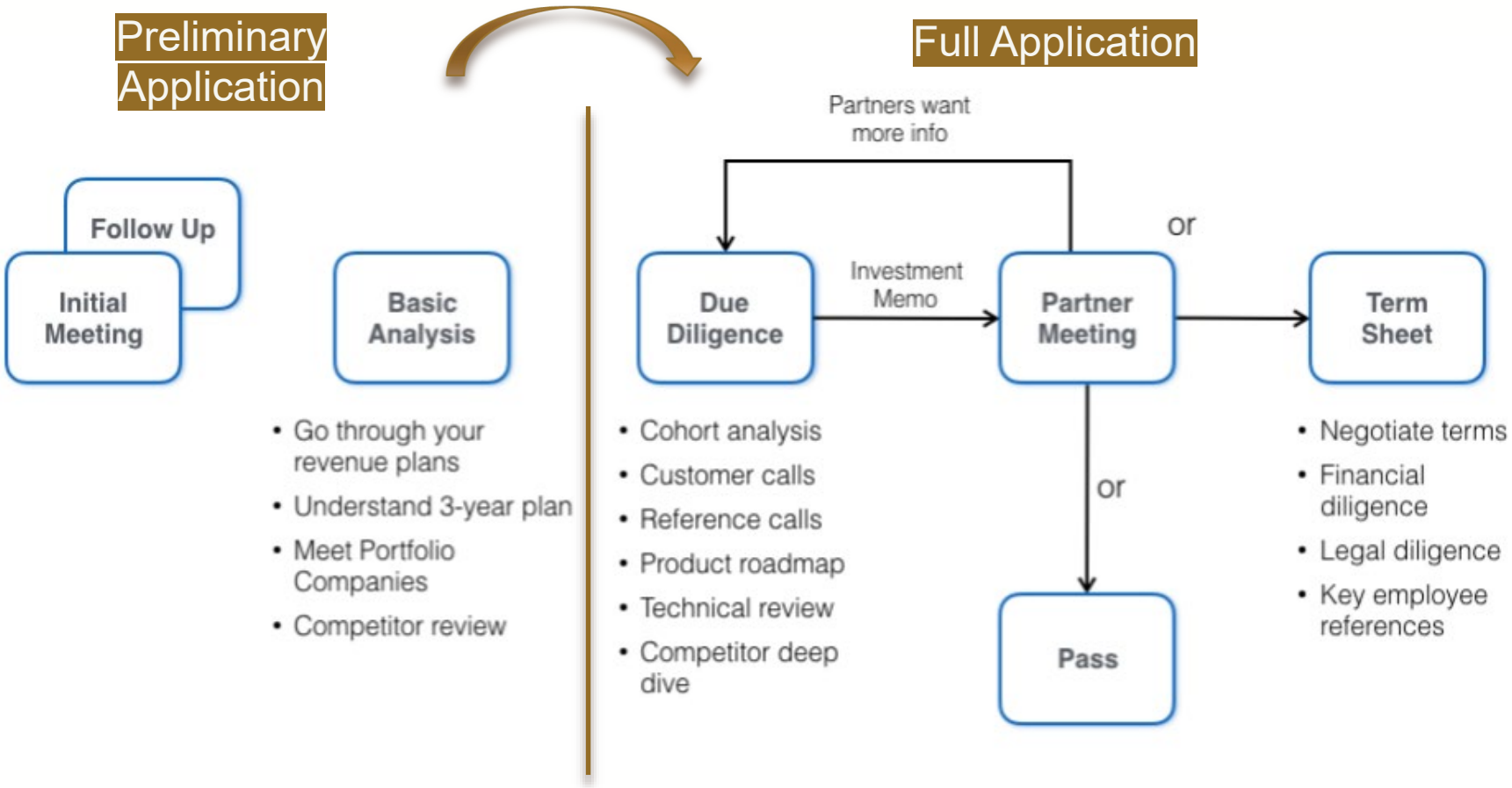
- Early-stage companies focused on research and development of research and development of new and emerging technologies for the detection, diagnosis, prognosis, monitoring, or treatment of cancer.
- Award: uncapped $ amount; 3 years

Seed (SEED) Award

- Startup companies; already based in Texas or willing to relocate to Texas focused on research and development of innovative products, services, and infrastructure with significant potential impact on cancer patient care.
- Award: Up to $3 million; 3 years

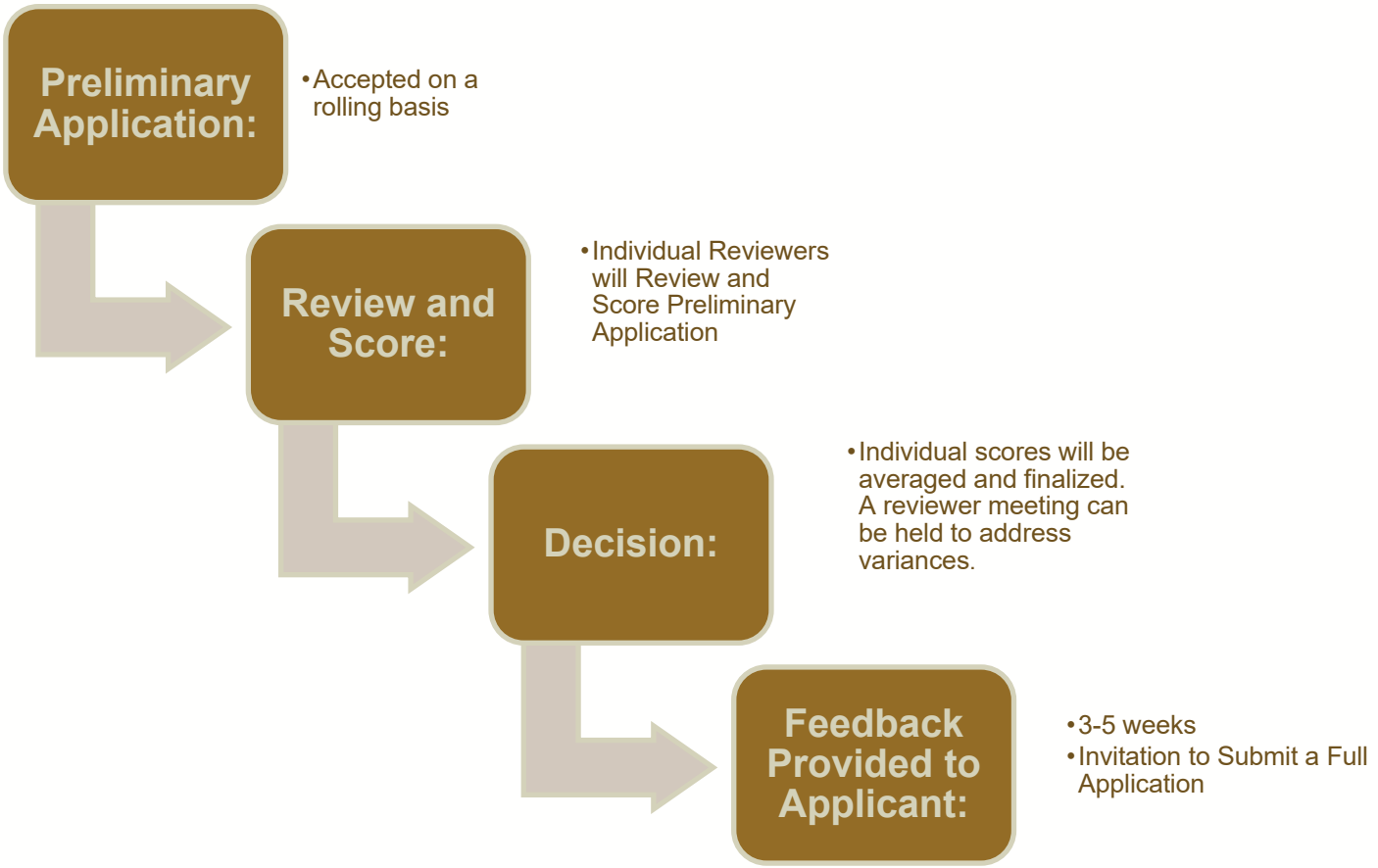
9-31

Typical Venture Investment Process



9-32

Preliminary Application Process



9-33

Full Application Process

- Submission of Full Application
  - By November 1, 2022, 14 submitted, accepted 10 (4 in time but not considered)
- In-Person Presentation
  - November cohort – 10 presented with more time and each applicant given extra time to present
- Focused Due Diligence Review
  - November cohort – 6 advanced to diligence, process was streamlined
- PDRC Recommendation
  - November cohort – 6 recommended for funding but amount asked exceeded amount available; notified that decision would be carried to May 2023 OC Meeting
- PIC Review/Approval
- Oversight Committee Review/Approval

9-34

Looking Forward

CPRIT has delivered on its promise to streamline the application process and, so far, is fully awarding the monies allocated for Product Development. But, with anything new, challenges are emerging

- Available 2023 award monies was reduced by the carry over of a $16 million award from 2022
- The cap of full applications accepted for the November 2022 cycle was unexpected and left 4 applicants who timely submitted unable to advance (first thinking February and then told next fiscal year)
- Now, there is a “race to submit” mentality with 27 preliminary applications submitted in the first 10 days of May and the PD program is setting a cap of 15 full applications being accepted for the August cycle

9-35

Looking Forward – PDAC Thoughts

Questions to Consider / Thoughts

1. *With the rush to submit mentality, have we come full circle back to where we started but now with one cycle in the fiscal year?*
2. *Should there be a limit on the number of full applications in each cycle?*
3. *Considering the current market conditions, should CPRIT review and award grants more like a venture investor (e.g., a more wholistic review of the company's ability to raise funds to advance)?*
4. *Should CPRIT keep "dry powder" to support companies it has previously funded?*
5. *What post award support can CPRIT provide the companies that it is funding?*

9-36

Thank you!

9-37

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	KRISTEN PAULING DOYLE, DEPUTY EXECUTIVE OFFICER & GENERAL COUNSEL CAMERON ECKEL, ASSISTANT GENERAL COUNSEL
SUBJECT:	CHAPTERS 701 AND 703 - PROPOSED RULE CHANGES
DATE:	MAY 8, 2023

Summary and Recommendation

The Board Governance Subcommittee convened May 4 to discuss the suggested rule changes to Texas Administrative Code Chapters 701 and 703. 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 August 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 May 4 to discuss the proposed rule changes to Texas Administrative Code (TAC) Chapters 701 and 703. The subcommittee voted to recommend that the Oversight Committee approve publication of the following suggested changes in the *Texas Register*.

- § 701.3: Amend the definition of "Scope of Work" to add "specific aims and subaims." Currently "Scope of Work" includes goals and objectives and timelines and milestones of a grant project. A grant applicant submits a Scope of Work to CPRIT as part of the grant application and, if approved, the Scope of Work becomes part of the grant contract. A Request for Applications may refer to a Scope of Work using the terms goals and objectives or aims and subaims. The definition of "Grant Progress Report" is also amended to consistently refer to "Scope of Work."

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- §§ 703.6, 703.7, 703.10, 703.21, and 703.25: Replace different terms found throughout Chapter 703 with "Scope of Work." Currently, Chapter 703 refers to Scope of Work in a variety of ways (e.g., scope of project, project goals, project objectives). The proposed changes to Chapter 703 replace the different iterations of scope with the term "Scope of Work" so that the rules consistently refer to the defined term. The proposed changes do not affect the substantive requirements in Chapter 703.

Next Steps

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

The Cancer Prevention and Research Institute of Texas ("CPRIT" or "the Institute") proposes amending 25 Tex. Admin. Code § 701.3(29) relating to the definition of "Grant Progress Report" and § 701.3(63) relating to the definition of "Scope of Work."

Background and Justification

CPRIT proposes a change to § 701.3(63) to amend the defined 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. Currently, the term includes project goals, objectives, timelines and milestones; the proposed amendment would add "aims and subaims." A Request for Applications will specify exactly what a grant applicant must submit to CPRIT, including goals and objectives or aims and subaims.

The proposed amendment to § 701.3(29) that defines "Grant Progress Report" removes a reference to "goals and objectives" and replaces it with "Scope of Work" so that the term is used consistently throughout CPRIT's administrative rules. The amendment does not substantively change the meaning of "Grant Progress Report."

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 July 3, 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>

§701.3. 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 [~~goals and objectives~~] 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") proposes amending 25 Tex. Admin. Code §§ 703.6, 703.7, 703.10, 703.21, and 703.25 to consistently use the term "Scope of Work" throughout the Chapter.

Background and Justification

Section 701.3 defines "Scope of Work" and currently includes the goals, objectives, timelines and milestones of a grant project. The proposed amendments to Chapter 703 replace inconsistent iterations of goals and objectives with the consistent use of Scope of Work. The proposed amendments do not change any substantive requirements in Chapter 703.

Fiscal Note

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

Public Benefit and Costs

Ms. Doyle has determined that for each year of the first five years the rule change is in effect the public benefit anticipated due to enforcing the rule will be 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 July 3, 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>

§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 ~~[goals and objectives or timeline]~~ for the proposed project, then the recommended changes and explanation shall be recorded at the time the final Overall Evaluation Score is set.

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

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

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

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

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

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

(C) The specified amount of the Grant Award funding for each Grant Application, including an explanation for recommended changes to the Grant Award funding amount or to the Scope of Work ~~[goals and objectives or timeline]~~.

(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 [~~scope of work or timeline~~] requested by the continuation Grant Application, then the recommended change and explanation shall be recorded at the time the final Overall Evaluation Score is set.

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

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

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

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

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

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

(B) A Grant Application may undergo business operations and management due diligence review and an intellectual property review. 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 [~~goals and objectives or timeline~~].

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

(f) Institute Employees 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 ~~[goals and objectives or timeline]~~;

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

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

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

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

§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 [~~goals and objectives or timeline~~] 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 [~~milestones and objectives included~~] in the Grant Contract;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

§703.21. 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 [~~scope of work and timeline~~] 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 [~~scope of work~~] specified by the Grant Contract, including information, data, and program metrics regarding the achievement of the Scope of Work [~~project goals and timelines~~];

(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 [~~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 [~~scope of the Grant Contract~~] and the total Approved Budget; is beneficial to the achievement of the Scope of Work [~~project objectives~~]; 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 [~~scope of the project~~].

(2) The Institute may reverse one or more budget changes or transfers under subsection (1) 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:	HEIDI MCCONNELL, CHIEF OPERATING OFFICER
SUBJECT:	CHIEF OPERATING OFFICER REPORT
DATE:	MAY 1, 2023

CPRIT Financial Overview for FY 2023, Quarter 2

FY 2023, Quarter 2 Operating Budget

In the second quarter of FY 2023, CPRIT has encumbered or expended 48% of the $5.2 million Indirect Administration budget and 88% of the $16.1 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 $1,162,326 in revenue sharing payments during the second quarter. This amount includes the receipt of a milestone and quarterly royalty payment for $1,002,414 from Merck & Co., Inc. from the sales revenue of WELIREG™ (belzutifan).

Revenue sharing payment deposits from CPRIT's inception total approximately $9 million through the end of February 2023.

FY 2023, Quarter 2 Performance Measure Report

In the second quarter, CPRIT reported to the Legislative Budget Board a total of 208,582 people served through CPRIT prevention and control grants. There was one company relocation, so CPRIT has met target for this performance measure for the year.

Debt Issuance History

The Texas Public Finance Authority (TPFA) issued $66 million in commercial paper notes on CPRIT's behalf at the beginning of March 2023. This was the second quarter tranche of bond proceeds. By the end of FY 2023, $298.3 million of bond proceeds will be issued.

2023 CPRIT Innovations VI Conference Update

As of May 8, 2023, there were 81 conference registrations including 63 general admission and 18 student registrations. Approximately three-quarters of the registrants are CPRIT grantees. The discounted early bird registration rates end May 15, and regular registration rates go into effect on May 16. A notification about this upcoming change was sent to the CPRIT listserv on May 2, 2023.

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All of the conference speakers and sessions have been finalized. There will be sessions focused on cancer prevention strategies on cervical cancer and HPV, liver cancer and hepatitis, breast cancer, colorectal cancer, lung cancer and tobacco cessation, and patient navigation as well as effective cancer prevention outreach to rural communities.

On the research side, there will be discussions about the:

- development of multi-cancer early detection (MCED) technologies to screen for cancers for which there are no available screening approaches;
- the development and application of genomic technologies and bioinformatics analysis to identify cancer risk; advances in computer-aided drug design and structure-based drug design to develop new cancer therapeutics;
- use of advanced imaging techniques and machine learning methods in enabling the discovery of diagnostic and predictive biomarkers to optimize cancer therapies;
- cancer vaccine development;
- expansion of capabilities in Texas to accelerate the development and manufacturing of cancer therapeutics; and
- use of advanced imaging techniques and machine learning methods to aid in the early detection of cancer.

The first conference sponsor commitment has been secured with Scorpius Biomanufacturing, a contract development and manufacturing organization, located in San Antonio, Texas.

Cancer Prevention and Research Institute of Texas
Quarterly Financial Report
As of February 28, 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	$ 1,847,425		$ 833,053	1,014,372	45%	$ 833,053	$ 1,014,372
1002	Other Personnel Costs	38,785	38,785		35,033	3,752	90%	35,033	3,752
2001	Professional Fees and Services	1,038,960	1,203,714		1,171,594	32,120	97%	1,171,594	32,120
2003	Consumable Supplies	24,000	24,000		1,975	22,025	8%	1,975	22,025
2004	Utilities	58,600	58,600		24,600	34,000	42%	24,600	34,000
2005	Travel	45,000	45,000		26,013	18,987	58%	26,013	18,987
2006	Rent-Building	11,000	11,000		2,658	8,342	0%	2,658	8,342
2007	Rent-Machine and Other	39,172	39,172		16,000	23,172	41%	16,000	23,172
2009	Other Operating Expenses	1,807,951	1,906,951		351,556	1,555,395	18%	351,556	1,555,395
	Subtotal - Indirect Administration (B.1.1.)	**$ 4,910,893**	**$ 5,174,647**	**1.74%**	**$ 2,462,482**	**$ 2,712,165**	**48%**	**$ 2,462,482**	**$ 2,712,165**

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	3,312,758		$ 1,935,642	$ 1,377,116	58%	$ 1,935,642	$ 1,377,116
1002	Other Personnel Costs	45,000	88,115		88,115	0	0%	88,115	0
2001	Professional Fees and Services	12,420,663	12,570,663		12,146,626	424,037	97%	12,146,626	424,037
2003	Consumable Supplies	-	-		-	-	0%	-	-
2004	Utilities	12,000	12,000		6,289	5,711	52%	6,289	5,711
2005	Travel	45,000	45,000		8,390	36,610	19%	8,390	36,610
2009	Other Operating Expenses	70,359	104,606		13,934	90,672	13%	13,934	90,672
	Subtotal - Grant Operations (A.1.3.)	**$ 16,098,895**	**$ 16,133,142**	**5.43%**	**$ 14,198,997**	**$ 1,934,145**	**88%**	**$ 14,198,997**	**$ 1,934,145**

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**	**92.83%**	**$ 149,633,609**	**$ 126,336,193**	**54%**	**$ 149,633,609**	**$ 126,336,193**
	Grand Totals	**$ 296,932,968**	**$ 297,277,591**	**100.00%**	**$ 166,295,088**	**$ 130,982,503**	**56%**	**$ 166,295,088**	**$ 130,982,503**

Cancer Prevention and Research Institute of Texas

Cancer Prevention and Research Institute Fund Account - 5136

As of February 28, 2023

	02/01/2023-02/28/2023	AY 21 Year to Date as of 02/28/2023
Beginning Balance : 9/01/2022		**$ 600,506**
Increases:		
(1)	$ -	$ -
(2)	-	
Total Increases	**$ -**	**$ 600,506.00**
Reductions:		
Expenditures - Appropriated	$ -	$ -
	$ -	$ -
	$ -	$ -
Total Reductions	**$ -**	**$ -**
Ending Balance: 02/28/2023		**$ 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 February 28, 2023

		02/01/2023-02/28/2023	AY 21 Year to Date as of 02/28/2023
Beginning Balance : 9/01/2022			**$ 46,621.77**
Increases:			
(1)	License Plate Revenue Received	$ 553.65	$ 3,272.44
	Interest	$ 155.93	$ 697.10
Total Increases		**$ 709.58**	**$ 50,591.31**
Reductions:			
	Expenditures - Appropriated	$ -	$ -
		-	-
Total Reductions		**$ -**	**$ -**
Ending Balance: 02/28/2023			**$ 50,591.31**

Note:

Balance forward from 2022 License Plate $46,621.77

Cancer Prevention and Research Institute of Texas

Appropriated Receipts - 666

As of February 28, 2023

		02/01/2023-02/28/2023	AY 21 Year to Date as of 02/28/2023
Beginning Balance : 9/01/2022			**$ 34,246.90**
Increases:			
(1)	Product Development Application Fees Received	$ -	$ 6,500.00
(2)	Conference Registration Fees	$ -	$ -
(3)	Conference Registration Fees-Credit Card	$ -	$ -
Total Increases		**$ -**	**$ 6,500.00**
Reductions:			
	Conference Expenditures - Appropriated	$ -	$ -
	Credit Card Fees Expended	$ -	$ -
	Refund-Application Fees	$ -	$ -
	Legal Services Expenses (Application Fees)	$ -	$ -
Total Reductions		**$ -**	**$ -**
Ending Balance: 02/28/2023			**$ 40,746.90**

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 February 28, 2023

		02/01/2023-02/28/2023	AY 21 Year to Date as of 02/28/2023
Beginning Balance : 9/01/2022			**$ 4,467,549.58**
Increases:			
(1)	Revenue Sharing / Royalties	$ 1,020,317.17	$ 1,157,216.06
		$ -	
Total Increases		**$ 1,020,317.17**	**$ 5,624,765.64**
Reductions:			
	Expenditures - Appropriated	$ -	$ -
		$ -	
		$ -	$ -
Total Reductions		**$ -**	**$ -**
Ending Balance: 02/28/2023			**$ 5,624,765.64**

Balance forward from FY 2022 is $4,467,549.58

Cancer Prevention and Research Institute of Texas

FY 2023, Quarter 2 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	-	-	376,650	53.81%
Number of Entities Relocating to TX for Cancer Research Related Projects	1	0	1	-	-	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	1,500	N/A	N/A	N/A	N/A	0	0.00%

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%
				$ 145,500,000				
TOTAL ISSUED TO DATE				**$ 2,658,900,000**				

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	HEIDI MCCONNELL, CHIEF OPERATING OFFICER
SUBJECT:	FY 2024 REQUEST FOR FINANCING OF CPRIT BONDS
DATE:	MAY 1, 2023

Recommendation

CPRIT staff recommends that the Oversight Committee approve the attached resolution for a request for financing for the Texas Public Finance Authority (TPFA) to issue debt on behalf of CPRIT in fiscal year 2024. The amount to be financed will not exceed $300 million in bond proceeds appropriated to CPRIT for its operations and prevention and research grant awards. I estimate that CPRIT will request TPFA to issue a total of $298.4 million in commercial paper notes four times during fiscal year 2024 to pay for CPRIT administrative operations and grant reimbursements or authorized advances related to awards made in fiscal years 2016, 2017, 2018, 2019, 2020, 2021, 2022, 2023, and 2024.

Background

By the end of fiscal year 2023, TPFA will have issued $298.3 million in general obligation debt on CPRIT's behalf for current agency operations and multiple year grant award expenses. TPFA has issued approximately $2.7 billion in general obligation debt for CPRIT from fiscal years 2010 through 2023. CPRIT has active grant awards from fiscal year 2016 through the current fiscal year.

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CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

A RESOLUTION
AUTHORIZING A REQUEST FOR FINANCING
AND THE EXECUTION AND DELIVERY OF DOCUMENTS
REQUIRED TO EFFECT SUCH FINANCING

Whereas, the Texas Public Finance Authority (the "Authority") is authorized to issue general obligation bonds to finance the grant program for cancer research and prevention and control for the use and benefit of the Cancer Prevention & Research Institute of Texas (the "Agency") pursuant to Article III, Section 67, Texas Constitution; Texas Health & Safety Code, Chapter 102, as amended; and Texas Government Code, Chapter 1232, as amended, (collectively, the "Authorizing Law");

Whereas, the Agency desires and intends to request the Authority to finance the costs of the program as permitted by the Authorizing Law; and

Whereas, the Agency recognizes that in order to finance the cost of the program, the Authority may issue short term obligations, general obligation bonds, either or both ("Obligations") in an aggregate principal amount sufficient to finance program costs in the estimated amount of $300,000,000, plus the costs of issuance and related administrative costs, if any, which will be determined at the time of issuance; and

Whereas, the form of a Request for Financing, dated as of May 17, 2023, (the "Request for Financing") from the Agency to the Authority, which includes a detailed description of the program to be financed for the Agency ("program" herein) and a proposed expenditure schedule is presently before the CPRIT Oversight Committee.

NOW THEREFORE BE IT RESOLVED by the CPRIT Oversight Committee that:

Section 1. The purpose of the financing is to provide funds sufficient to make grant awards for cancer research and prevention and control and for the operations of the Agency, and the financing thereof is appropriate at this time. Accordingly, the execution and delivery of the Request for Financing to the Authority pursuant to the Authorizing Law is hereby ratified, approved and confirmed.

Section 2. The Chief Executive Officer of the Agency is hereby empowered, authorized and directed to:

a. sign and deliver any and all documents necessary or desirable to effect the financing and provide the projects, which may include but not be limited to a Memorandum of Understanding and a Financing Agreement between the Agency and the Authority;

b. cooperate with the Authority and its consultants to prepare an Official Statement in connection with the sale of the Obligations;
c. and to take any other action necessary to assist in such sale.

Section 3. All actions not inconsistent with provisions of this Resolution heretofore taken by the Institute and the Chief Executive Officer or designee thereof and the other officers of, or consultants to the Institute, directed toward the financing of the Program, and the issuance of the Obligations are hereby ratified, approved and confirmed.

Section 4. The officers and employees of the Agency shall take all action in conformity with the Authorizing Law and the provisions of the General Appropriations Act, 88th Legislature, R.S. (2023) to effect the issuance of the Obligations and complete the Program as provided in the Agreement and take all action necessary or desirable or in conformity with the Authorizing Law for carrying out, giving effect to, and consummating the transactions contemplated by the Memorandum of Understanding, the Agreement, the Obligations, and this Request for Financing, including without limitation, the execution and delivery of any closing documents in connection with the closing of the Obligations.

Section 5. This Resolution was adopted at a meeting open to the public, and public notice of the time, place and purpose of said meeting was given, all as required by Ch. 551, Texas Government Code.

Adopted by the affirmative vote of a majority of the Cancer Prevention and Research Institute of Texas Oversight Committee present and voting on this 17th day of May, 2023.

Cancer Prevention and Research Institute
of Texas Oversight Committee

Attested:

Mahendra C. Patel, M.D.
Presiding Officer

Cindy Barberio Payne
Secretary

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Fiscal Year 2024 Request for Financing Program Description

Purpose

The Cancer Prevention and Research Institute of Texas (CPRIT) is the state agency mandated to:

1) create and expedite innovation in the area of cancer research and in enhancing the potential for a medical or scientific breakthrough in the prevention of cancer and cures for cancer;
2) attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in this state; and
3) develop and implement the Texas Cancer Plan.

Powers and Duties

CPRIT will make grants to provide funds to public or private persons to implement the Texas Cancer Plan, and make grants to institutions of learning and to advanced medical research facilities and collaborations in this state for:

1) research into the causes of and cures for all types of cancer in humans;
2) facilities for use in research into the causes of and cures for cancer;
3) research, including translational research, to develop therapies, protocols, medical pharmaceuticals, or procedures for the cure or substantial mitigation of all types of cancer in humans; and
4) cancer prevention and control programs in this state to mitigate the incidence of all types of cancer in humans.

Implementation Plan

CPRIT estimates that $298.4 million in bonds proceeds must be issued on an as-needed basis consistent with Texas Government Code, Chapter 1232 to cover grant award obligations from fiscal years 2016, 2017, 2018, 2019, 2020, 2021, 2022, 2023, and 2024 and operating costs for general agency administration and pre- and post-award grants management processes.

During fiscal year 2024, CPRIT will use the bond proceeds to disburse grant funds for grants awarded by CPRIT during fiscal years 2017, 2018, 2019, 2020, 2021, 2022, 2023, and 2024. CPRIT is authorized to obligate approximately $275.7 million for cancer prevention and research grant awards in fiscal year 2024.

CPRIT announces grant awards for cancer prevention education and service programs and academic and product development cancer research programs four times per year. CPRIT

anticipates that it will obligate the available $275.7 million for cancer prevention, product development research, and academic research grants.

Grant funds are generally disbursed quarterly on a reimbursement basis to grant recipients. For product development research grant awards, CPRIT may advance funds to provide recipients of those types of awards with working capital to meet their research milestones or objectives.

CPRIT is authorized to use bond proceeds to fund its grant review and award operations and indirect administration costs. At this time, the approximate budgeted amount of these two categories is $21.2 million in bond proceeds for fiscal year 2024 based on the appropriations provided in the General Appropriations Act (House Bill 1), 88th Legislature. CPRIT must transfer $3.1 million in bond proceeds to the Texas Department of State Health Services (DSHS) for the operating costs associated with the Texas Cancer Registry. From the total of all the agency's operating costs, CPRIT requires half of the proceeds to be available at the beginning of the state fiscal year to be able to cover the operating expenses for six months. CPRIT also requires proceeds at the beginning of each state fiscal quarter to pay for award costs reimbursed to grant recipients for the previous state fiscal quarter.

The academic research program provides awards in the following areas: cancer biology, cancer genetics, immunology, imaging, therapeutics, prevention/epidemiology, and informatics/ computation. The product development research program focuses awards on the development of cancer drugs, diagnostics, and devices based on discoveries made in one of the seven areas described above. Prevention program grants are awarded for cancer prevention information and services, early detection and treatment, professional education and practice, cancer data acquisition and utilization, or survivorship (the areas of the Texas Cancer Plan). Awards for all programs are issued for multiple years, ranging from two to five years.

CPRIT has established a grant process that allows grant proposals for cancer prevention, academic research, and product development research to be submitted through requests for applications (RFA) issued throughout each fiscal year. All proposals are reviewed by multiple experts in the appropriate area. CPRIT has approximately 200 national experts in cancer prevention, academic research, and product development research to review proposals and provide funding recommendations to CPRIT.

The award recommendations developed by the peer review committees are forwarded to the Program Integration Committee (PIC) for consideration. The five-member PIC is statutorily composed of the Chief Executive Officer (CEO), Chief Scientific Officer, Chief Prevention Officer, Chief Product Development Officer, and DSHS Commissioner. The PIC finalizes award recommendations across all programs prior to every Oversight Committee meeting. When those proposed awards are forwarded to the Oversight Committee, each recommended award is accompanied by an affidavit signed by the CEO to affirm that the award followed all required pre-award grant procedures. The Oversight Committee considers these recommendations and votes to approve the awards.

Fiscal Year	2010	2011	2012	2013^	2014	2015	2016	2017	SUBTOTAL
GAA Appropriations	**$ 225,000,000**	**$ 225,000,000**	**$ 300,000,000**	**$ 300,000,000**	**$ 300,000,000**	**$ 300,000,000**	**$ 300,000,000**	**$ 300,000,000**	**$ 2,250,000,000**
BRB-Approved Debt	**$ 225,000,000**	**$ 225,000,000**	**$ 300,000,000**	**$ 300,000,000**	**$ 300,000,000**	**$ 300,000,000**	**$ 300,000,000**	**$ 300,000,000**	**$ 2,250,000,000**
Total Value of Grant Awards Contracted	**$ 216,122,105**	**$ 210,651,285**	**$ 269,354,368**	**$ 105,493,808**	**$ 255,834,556**	**$ 269,707,850**	**$ 275,627,458**	**$ 272,030,746**	$ 1,874,822,176
Agency Operations and Transfer to DSHS (Texas Cancer Registry)	$ 8,866,523	$ 11,773,670	$ 18,591,666	$ 16,750,815	$ 20,492,668	$ 22,525,206	$ 20,341,154	$ 19,770,432	$ 139,112,134
Total Agency Expenses Obligated	$ 224,988,628	$ 222,424,955	$ 287,946,034	$ 122,244,623	$ 276,327,224	$ 292,233,056	$ 295,968,612	$ 291,801,178	$ 2,013,934,310
Issued Debt to Date	**$ 225,000,000**	**$ 221,851,288**	**$ 288,581,794**	**$ 122,244,623**	**$ 276,327,225**	**$ 288,915,409**	**$ 289,542,524**	**$ 262,296,455**	**$ 1,974,759,318**
Unobligated Bond Authority Appropriations	**$ -**	**$ 2,575,045**	**$ 12,053,966**	**$ 177,755,377**	**$ 23,672,776**	**$ 7,766,944**	**$ 4,031,388**	**$ 8,198,822**	**$ 236,054,318**
Remaining Balances in Closed Grant Contracts (Available for Deobligation)	**$ 38,525,292**	**$ 9,032,975**	**$ 13,321,630**	**$ 3,397,268**	**$ 23,978,388**	**$ 13,115,236**	**$ 7,818,406**	**$ 23,945,809**	**$ 133,135,004**
Unbudgeted ERS Cash Transfer for DSHS Retired Employee Insurance Payments	$ (10,779)	$ (11,953)	$ (103,591)	$ (91,534)	$ (134,151)	$ (129,694)	$ (139,609)	$ (156,337)	$ (777,648)

*Current state fiscal year

**Upcoming state fiscal year under consideration by the 88th Texas Legislature.

^State leadership moratorium on CPRIT grant awards.

Fiscal Year	2018	2019	2020	2021	2022	2023*	2024**	*2025***	TOTAL
GAA Appropriations	**$ 300,000,000**	**$ 300,000,000**	**$ 300,000,000**	**$ 300,000,000**	**$ 300,000,000**	**$ 300,000,000**	***$ 300,000,000***	***$ 300,000,000***	**$ 4,650,000,000**
BRB-Approved Debt	**$ 300,000,000**	**$ 300,000,000**	**$ 300,000,000**	**$ 300,000,000**	**$ 300,000,000**	**$ 300,000,000**			**$ 4,050,000,000**
Total Value of Grant Awards Contracted	**$ 257,225,313**	**$ 238,511,809**	**$ 254,604,570**	**$ 256,483,156**	**$ 215,838,270**	**$ 95,873,125**			$ 3,193,358,419
Agency Operations and Transfer to DSHS (Texas Cancer Registry)	$ 19,707,288	$ 20,196,337	$ 22,766,115	$ 23,277,916	$ 24,105,308	$ 24,087,820	*$ 24,270,171*		$ 297,523,089
Total Agency Expenses Obligated	$ 276,932,601	$ 258,708,146	$ 277,370,685	$ 279,761,072	$ 239,943,578	$ 119,960,945			$ 3,466,611,337
Issued Debt to Date	**$ 231,612,339**	**$ 168,235,121**	**$ 131,168,031**	**$ 98,029,883**	**$ 43,031,397**	**$ 12,063,911**	**$ -**		**$ 2,658,900,000**
Unobligated Bond Authority Appropriations	**$ 23,067,399**	**$ 43,726,910**	**$ 38,824,256**	**$ 39,070,385**	**$ 9,492,545**				**$ 390,235,813**
Remaining Balances in Closed Grant Contracts (Available for Deobligation)	**$ 10,385,637**	**$ 5,417,929**	**$ 1,462,508**	**$ -**	**$ -**	**$ -**			**$ 150,401,078**
Unbudgeted ERS Cash Transfer for DSHS Retired Employee Insurance Payments	$ (166,003)	$ (389,362)	*$ (384,886)*	$ (348,028)	$ (311,237)	$ (1,068,286)			$ (3,445,450)

*Current state fiscal year

**Upcoming state fiscal year under consideration by the 88th Texas Legislature.

^State leadership moratorium on CPRIT grant awards.

Cancer Prevention and Research Institute of Texas

Estimated Expenditure Schedule, Fiscal Year 2024

Fiscal Year 2024	September	October	November	December	January	February	March	April	May	June	July	August	Total
Bond proceeds for Indirect Administration	$ 2,455,447	$ -	$ -	$ -	$ -	$ -	$ 2,455,446	$ -	$ -		$ -	$ -	$ 4,910,893
Bond proceeds for Grant Review and Award Operations	$ 8,029,448	$ -	$ -	$ -	$ -	$ -	$ 8,029,447	$ -	$ -	$ -	$ -	$ -	$ 16,058,895
Bond proceeds for Salary Adjustments	$ 182,351												$ 182,351
Bond proceeds for Texas Cancer Registry (GAA 2024-25, Art. I, CPRIT Rider 4)	$ 1,559,016	$ -	$ -	$ -	$ -	$ -	$ 1,559,016	$ -	$ -	$ -	$ -	$ -	$ 3,118,032
Bond proceeds for Prevention and Research Grants	$ 80,573,738	$ -	$ -	$ 70,600,000	$ -	$ -	$ 63,456,091	$ -	$ -	$ 59,500,000	$ -	$ -	$ 274,129,829
Debt Issuance Subtotal, Fiscal Year 2024	$ 92,800,000	$ -	$ -	$ 70,600,000	$ -	$ -	$ 75,500,000	$ -	$ -	$ 59,500,000	$ -	$ -	$ 298,400,000
Cumulative Debt Total, Fiscal Year 2024	**$ 92,800,000**	**$ 92,800,000**	**$ 92,800,000**	**$ 163,400,000**	**$ 163,400,000**	**$ 163,400,000**	**$ 238,900,000**	**$ 238,900,000**	**$ 238,900,000**	**$ 298,400,000**	**$ 298,400,000**	**$ 298,400,000**	**$ 298,400,000**

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	HEIDI MCCONNELL, CHIEF OPERATING OFFICER
SUBJECT:	FY 2024 GRANT MANAGEMENT SUPPORT SERVICES CONTRACT RENEWAL APPROVAL
DATE:	APRIL 27, 2023

Recommendation

CPRIT staff recommends that the agency exercise the second renewal option on its contract with General Dynamics Information Technology, Inc. (GDIT) for an amount not to exceed $9,662,900 in FY 2024. This amount includes an annual payment of $1.1 million as a subscription to the electronic grant management platform (GMP) with access to the application receipt, peer review evaluation, and post-award grant contract and report management modules in the platform. The remaining $8,562,900 is an estimate of the time and materials that will be expended by GDIT on labor and direct costs. CPRIT pays only for actual services received and direct costs incurred by GDIT up to that contracted price.

All peer review meetings will be held using remote video technology, so contract pricing includes only the use of the remote video technology and honoraria payments to peer review panel members for these meetings.

The renewal will require approval from the Legislative Budget Board (LBB) before CPRIT can finalize the FY 2024 contract with GDIT.

Background

GDIT services include:

- Provision of a help desk call number and e-mail to provide assistance to grant applicants with the online grant application process or grant recipients with questions about grant report submission or use of the online grant management system;
- A Software as a Service (SaaS) subscription to the Grants Management Platform (GMP) software including maintenance and support of the application receipt module, program and peer review module, and grant management module;
- Processing all grant applications received through the application receipt system;
- Logistical support for peer review meeting arrangements using remote video technology;
- Administrative support for peer review panel honoraria payments;
- Summarized evaluation reports for each grant application including peer review chair consensus statements, budget recommendations, and noted issues in clinical trials with human subjects or animal research;

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- Incorporation of grant request for application requirements in the GMP application receipt module for electronic application submission;
- Enhancements to the GMP grant management module for improved progress reporting by redesigning the reports, restructuring the report database, and migrating the report to a report formatting technology already in use on other reports in the module;
- Administration of electronic grant application pedigrees; and
- Scientific expertise for the evaluation of the annual and final progress reports for academic research grants.

The FY 2023 contract renewal with GDIT is $9,984,746.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: MARK DALLAS LOEFFLER
SUBJECT: COMMUNICATIONS UPDATE
DATE: MAY 8, 2022

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

UTRGV Visit

The CPRIT communications team worked with The University of Texas Rio Grande Valley to put on a media event highlighting the recent CPRIT TREC award to create the South Texas Center of Excellence in Cancer Research in McAllen. The February 24 media event, held adjacent to the UTRGV Administration offices, was well attended by local media. Oversight Committee member Dr. Ambrosio Hernandez, Chief Executive Officer Wayne Roberts, Chief Scientific Officer Dr. Michelle Le Beau, Senator Juan Hinojosa and Representative Bobby Guerra spoke at the event. The press conference was followed by a tour of the UTRGV research facility.

CPRIT Symposium on Computational Oncology

CPRIT co-sponsored the symposium "Expanding Texas Leadership in Computational Oncology Throughout the Cancer Continuum," held April 20 at The University of Texas Austin Dell Medical School. The CPRIT communications team helped promote and cover the symposium, including website and email promotion and social media coverage.

CPRIT Conference

The CPRIT communications team helped launch the official CPRIT Innovations VI Conference website at www.texascancerconference.org. We created a new "Conference Sponsorship Opportunities" packet, which has already led to several potential sponsors for the event. We are also coordinating with conference speakers to compile online and print program information. The communications team will conduct sit-down interviews with grantees at the conference.

Direct Communication with CPRIT Stakeholders

We distributed listserv notifications regarding new Academic Research, Prevention, and Product Development RFAs, a training webinar for the new Academic Research funding mechanism (Texas Connect for Cancer Prevention Study), mandatory compliance webinars for funding

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applicants, and several messages in support of various CPRIT events (symposium and conference).

Media Relations

We posted and distributed two media advisories and press releases related to CPRIT programs and news:

- Media advisory (February 10 and 14, 2023): CPRIT may award more than $90 million for cancer research, prevention on Wednesday
- Press release (February 15, 2023): CPRIT approves $90 million to boost cancer research, prevention efforts across Texas
- Media advisory (February 23, 2023): CPRIT to join UTRGV and area legislators in McAllen to spotlight historic state cancer research grant
- Press release (Feb. 24, 2023): CPRIT joins UTRGV and area legislators in McAllen to spotlight historic state cancer research grant
- Press release (April 20, 2023): CPRIT symposium to expand Texas leadership in computational oncology

In addition, the CPRIT communications team facilitated a news package for the February 15, 2023, Oversight Committee meeting that aired 16 times in seven television markets (Abilene, Amarillo, Harlingen, Houston, Lubbock, Shreveport, and Wichita Falls).

Newsclips

We shared 675 articles and social media posts through CPRIT ENews from February 16 through May 5, 2023.

Social Media Statistics

Social Media from February 15, 2023 – May 8, 2023

Facebook	Twitter	LinkedIn
7.99% post engagement rate	**3.59%** engagement rate	**6.87%** engagement rate
1,235 Fans (**+16**)	**3,473** followers (**+51**)	**2,731** followers (**+252**)
Top Post: **17.44%** engagement (3/22)	Top Tweet: **25,000** impressions (2/15)	Top Post: **1,972** impressions (3/15)

Website Hits and Visitors February 15 to May 8, 2023

Users	New Users	Sessions (Visits)	Pageviews	Pages / Session
33,456	**31,945**	**42,913**	**78,815**	**1.84**

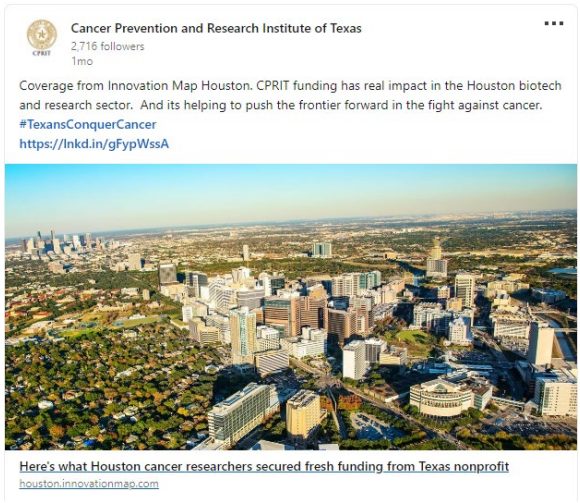
Top Performing Posts

FACEBOOK: 3/22

"Our Chief Scientific Officer Dr. Michelle Le Beau & Chief Prevention Officer Ramona Magid joined #CPRIT grantees Drs. Michael Pignone & Navkiran Shokar at Dell Medical School - UT Austin today for the Livestrong Cancer Institutes Cancer Prevention & Control Research Symposium. #TexansConquerCancer"

TWITTER: 2/15

"eBREAKING NEWS: CPRIT approved over $90 million in new cancer research and prevention grants today, funding a wide range of innovative research and prevention efforts across Texas. #TexansConquerCancer Read more: http://ow.ly/ZkA650MTa2G"



LINKEDIN:

"Coverage from Innovation Map Houston. CPRIT funding has real impact in the Houston biotech and research sector. And its helping to push the frontier forward in the fight against cancer. #TexansConquerCancer https://lnkd.in/gFypWssA"