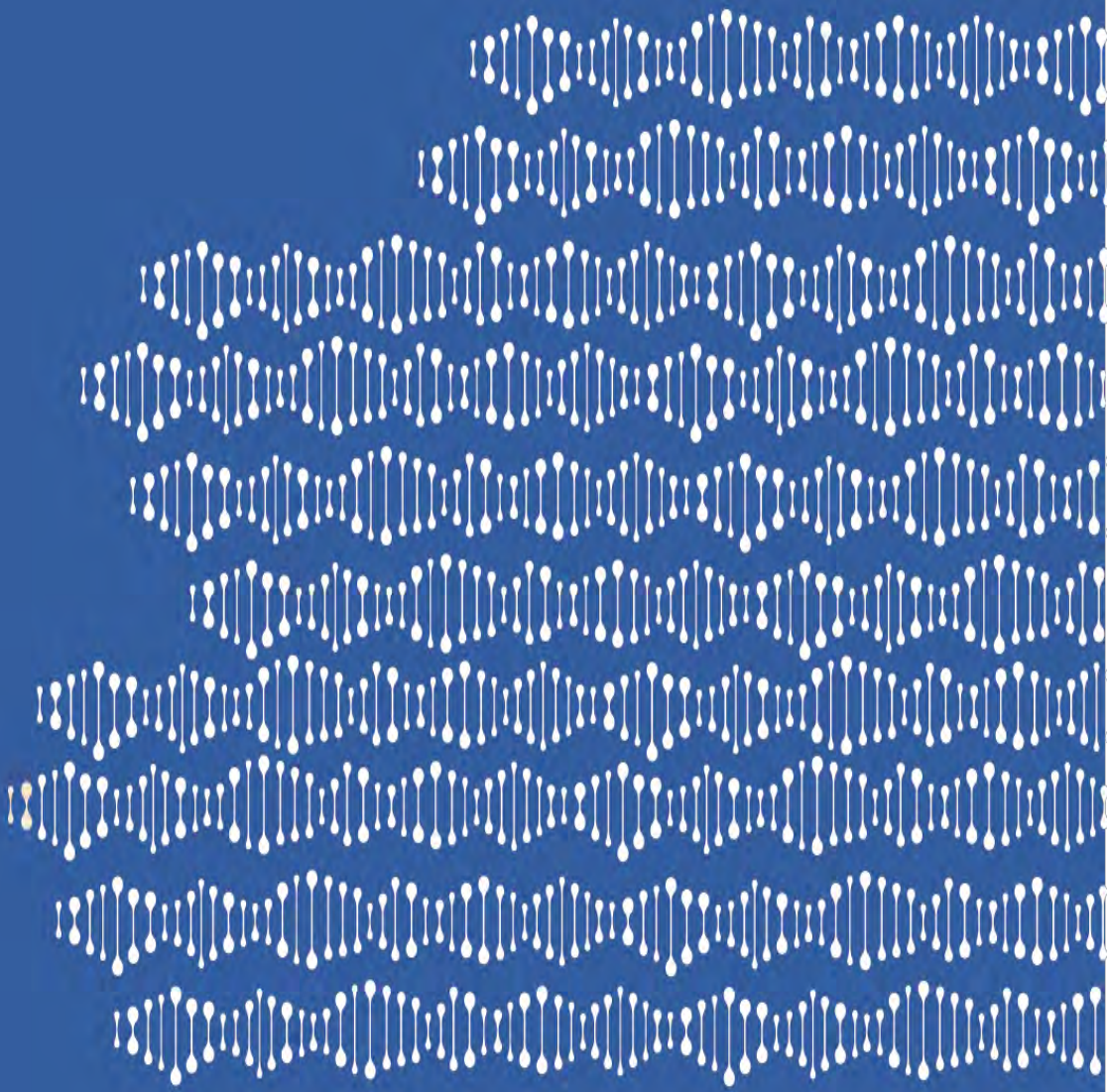
CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Meeting

November 18, 2021



CANCER PREVENTION & RESEARCH
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Summary Overview of the November 18, 2021, Oversight Committee Meeting

This summary provides an overview of major agenda items and background on key issues for Committee consideration at the November 18, 2021, Oversight Committee meeting.

Grantee Presentations
CPRIT has invited CPRIT Early Clinical Investigator Dr. Premal Lulla, Assistant Professor, Center for Cell and Gene Therapy at Baylor College of Medicine, and Dr. Michael Pignone, chair of the Department of Internal Medicine, assistant dean for Veterans Affairs, director of the program on Cancer Prevention and Control at Dell Med's Livestrong Cancer Institutes, to make presentations to the Oversight Committee about their CPRIT-funded work.

CEO Report
Wayne Roberts will present the CEO's report and address issues including grant funds available for fiscal year 2022, new personnel, and other topics as warranted.

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

Chief Scientific Officer Report and Grant Award Recommendations
Dr. Le Beau will provide an update on the Academic Research Program, including five requests for applications for fiscal year 2023. He will also present the Program Integration Committee's 12 award recommendations for Recruitment of First-Time, Tenure-Track Faculty Members, Rising Stars and Established Investigators totaling $38,000,000.

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

Chief Prevention Officer Report
Ms. Magid will present an update the Oversight Committee on the Prevention Program.

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

FY 2023 Program Priorities
Health and Safety Code Chapter 102 requires the Oversight Committee to establish program priorities on an annual basis. Mr. Roberts will present the program subcommittees'

recommendations for fiscal year 2023 Program Priorities for approval by the Oversight Committee.

Internal Auditor Report
Weaver and Tidwell, CPRIT's internal auditor, will provide an internal audit update and present an *Internal Audit Report over Information Technology General Controls*, a *Disaster Recovery and Business Continuity Planning Audit Advisory Follow-Up Procedures Report,* and FY 2022 Internal Audit Plan update. Weaver will also present the Fiscal Year 2021 Annual Internal Audit Report.

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

Appointment – Advisory Committees
Presiding Officer Dr. Mahendra Patel has provisionally appointed one new member to CPRIT's Prevention Advisory Committee. CPRIT's statute requires the Oversight Committee to approve the recommendation to finalize the appointment. CPRIT has provided the appointee's biographical sketch for the Oversight Committee's consideration.

Amendment to 25 TAC Chapter 703
Ms. Eckel will present a proposed change to Chapter 703 for Oversight Committee consideration and approval to publish in the *Texas Register*.

Texas Public Information Act (PIA) and Texas Open Meetings Act (TOMA) Legislative Update and Required Training
CPRIT's administrative rules require that the Oversight Committee receive training on TOMA and PIA after each regular legislative session. CPRIT's legal staff will present changes to the TOMA and PIA recently enacted by the 87th Legislature that are relevant to CPRIT's activities.

Chief Operating Officer Report and Contract Approvals
Ms. McConnell will discuss the operating budget, performance measures, and debt issuance history for the fourth quarter of fiscal year 2021. She will also present a recommendation to increase the FY 2022 internal audit contract amount with Weaver and Tidwell.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

Oversight Committee Meeting Agenda

November 18, 2021
9:00 a.m.

Texas Higher Education Coordinating Board
1200 E. Anderson Lane, Austin, TX 78752
Board Room 1.170

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. 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 August 18 meeting — Tab 1
4. Public Comment
5. Grantee Presentations — Tab 2
6. Chief Executive Officer Report — Tab 3
7. Chief Compliance Officer Report and Compliance Certification of Grant Award Process — Tab 4
8. Chief Scientific Officer Report — Tab 5
   - Grant Award Recommendations
   - FY 2023 Requests for Applications
9. Chief Prevention Officer Report — Tab 6
10. Chief Product Development Officer Report — Tab 7
11. FY 2023 Program Priorities — Tab 8
12. Internal Auditor Report — Tab 9
    - Internal Audit Report over Information Technology General Controls
    - Report over Disaster Recovery and Business Continuity Planning Advisory Audit Follow-up Procedures
    - FY 2022 Internal Audit Plan Update
    - FY 2021 Annual Internal Audit Report
13. Scientific Research and Prevention Program Committee Appointments — Tab 10
14. Advisory Committee Appointments — Tab 11
15. Amendment to 25 T.A.C. Chapter 703 — Tab 12
    - Proposed Amendment to Chapter 703 and Authorization to Publish in *Texas Register*
16. Texas Public Information Act and Texas Open Meetings Act Legislative Update — Tab 13
17. Chief Operating Officer Report — Tab 14
18. Contract Approval
    - FY 2022 Internal Audit Services Modification — Tab 15
19. T.A.C. §701.7(d) Training

20. Subcommittee Business
21. Compliance Investigation Pursuant to Health & Safety Code § 102.2631
22. Consultation with General Counsel
23. Future Meeting Dates and Agenda Items
24. Adjourn

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Meeting Minutes
August 18, 2021

NOTE: CPRIT conducted this meeting by videoconference in accordance with Governor Abbott's suspension of various provisions requiring government officials to be physically present at a specified meeting location. Unless the information is confidential, the reports, presentations, and grant award information referenced in the minutes are available in the "Oversight Committee Board Packet" section for the corresponding meeting date at http://ocmeetings.cprit.texas.gov.

Call to Order – Agenda Item 1

With a quorum present, Presiding Officer Dee Margo called the meeting to order at 9:04 a.m.

Roll Call/Excused Absences – Agenda Item 2

Committee Members Present
David Cummings, M.D.
Ambrosio Hernandez, M.D. (Dr. Hernandez joined after the meeting convened, as noted)
Donald (Dee) Margo
Will Montgomery
Mahendra Patel, M.D. (Dr. Patel joined after the meeting convened, as noted)
Cindy Barberio Payne
Bill Rice, M.D.
Craig Rosenfeld, M.D.

Adoption of Minutes from the May 19, 2021, Meeting – Agenda Item 3 – Tab 1

MOTION:
On a motion by Dr. Rice and seconded by Mr. Montgomery, the Oversight Committee unanimously voted to approve the minutes of the May 19, 2021, Oversight Committee meeting as presented.

Public Comment – Agenda Item 4

There were no public comments.

Chief Executive Officer Report – Agenda Item 5, Tab 2

Presiding Officer Margo recognized Mr. Roberts to present the Chief Executive Officer's Report. Mr. Roberts reported that CPRIT has sufficient funds to cover all proposed awards considered by the Oversight Committee today. He highlighted the 241 stellar recruits brought to Texas institutions of higher education since 2009. He noted that if the Oversight Committee approves the 12 proposed

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recruitment awards today and each candidate accepts their award, CPRIT will achieve the milestone 250 CPRIT Scholars recruited to Texas.

There were no questions for Mr. Roberts.

Presiding Officer Margo noted for the record that Dr. Patel joined the meeting at 9:10 a.m.

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

Presiding Officer Margo recognized Chief Compliance Officer Vince Burgess to present the Compliance Report and Compliance Certification of Grant Award Process. Mr. Burgess updated members on the compliance program activities for the past quarter. He concluded his report with an update on the FY 2022 Grantee Risk Assessment and Monitoring Plan and noted that he will share additional details at the Oversight Committee meeting in November.

An Oversight Committee member asked about potential matching errors that occurred prior to the recent matching enhancements. Mr. Burgess explained that before the enhancements, CPRIT performed several ad hoc and onsite reviews that included sampling of the matching expenditures; as a result, he felt that implementing a 100% match expenditure review was prudent.

Mr. Burgess certified the review process for the proposed academic research, prevention and product development research grant awards, confirming that the proposed awards and review process complied with all applicable state and agency requirements.

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

Presiding Officer Margo recognized Chief Scientific Officer Dr. Jim Willson to present the academic research program update and award recommendations. Presiding Officer Margo also noted for the record that Dr. Ambrosio joined the meeting at 9:26 a.m.

Dr. Willson directed members to Table 1 on page 6 of the Proposed Grant Award Book, which displayed the Scientific Review Council's (SRC) and PIC recommendations for the FY 2021.2 review cycle and recruitment cycles 2021.10, 2021.11 and 2021.12. The proposed recommendations include 62 awards from eight grant mechanisms totaling $103,416,042.

He noted that two institutions recommended for awards, Southern Methodist University and The University of Texas Rio Grande Valley, are first-time CPRIT awardees.

Dr. Willson presented an overview of the eight academic research slates. He explained that CPRIT introduced three new RFAs in the FY 2021.2 cycle and provided a summary of each new mechanism: Texas Regional Excellence in Cancer Awards; Clinical Trials Network Awards; and Texas Clinical Trials Participation Awards.

FY 2021 Cycle 2 Proposed Academic Research Grant Awards

Rank	ID	Grant	Score	Application Title	PI	Organization	Budget
1	RP210227	CFSA	**1.0**	Proteomics and Metabolomics Core Facility	Edwards, Dean	Baylor College of Medicine	$3,977,681
2	RP210176	ECI	**1.0**	CPRIT Early Clinical Investigator Award: Moran Amit	Draetta, Gulio	The University of Texas M. D. Anderson Cancer Center	$1,499,042
3	RP210208	CFSA	**1.1**	Center for Innovative Drug Discovery: Expansion of a Highly Productive Shared Cancer Drug Discovery Resource for Texas	McHardy, Stanton	The University of Texas at San Antonio	$3,087,131
4	RP210143	TCTPA	**1.5**	Dan L. Duncan Comprehensive Cancer Center Harris Health Clinical Trials Financial Support Project	Mims, Martha	Baylor College of Medicine	$1,500,000
5	RP210165	HIHRRA	**1.6**	Rapid Point-of-Care Detection of Ovarian Cancer Biomarkers Using a Common Thermometer for Low-Resource Settings	Li, Xiujun (James)	The University of Texas at El Paso	$249,999
6	RP210115	TCTPA	**1.7**	Enhancing Access to and Diversity in Cancer Clinical Trials Through a Financial Reimbursement and Outreach Program	Gerber, David	The University of Texas Southwestern Medical Center	$1,499,327
7	RP210159	ECI	**1.8**	CPRIT Early Clinical Investigator Award: Carl Gay	Draetta, Gulio	The University of Texas M. D. Anderson Cancer Center	$1,499,997
8	RP210088	CFSA	**1.9**	Targeted Therapeutic Drug Discovery and Development Program	Dalby, Kevin	The University of Texas at Austin	$3,989,441
9	RP210205	HIHRRA	**1.9**	Cytokine Factories for the Treatment of Mesothelioma	Veiseh, Omid	Rice University	$250,000
10	RP210173	HIHRRA	**1.9**	Multiplex CRISPR Genetic Modeling of Polypharmacology for Precision Medicine	Hart, Traver	The University of Texas M. D. Anderson Cancer Center	$250,000
11	RP210108	CFSA	**2.0**	The GCC Microphysiological Lead Optimization and Toxicity Screening Facility	Stephan, Clifford	Texas A&M University System Health Science Center	$3,973,083
12	RP210144	HIHRRA	**2.0**	Leveraging Glioma Stem Cell Electrophysiology for Therapy	Rostomily, Robert	The Methodist Hospital Research Institute	$248,028
13	RP210168	HIHRRA	**2.0**	Overcoming Myeloma Resistance to Proteasome Inhibitors	Yi, Qing	The Methodist Hospital Research Institute	$250,000
14	RP210062	HIHRRA	**2.0**	Protein Degradation of CDK9 for Treatment of Drug-Resistant Mantle Cell Lymphoma	Zhou, Jia	The University of Texas Medical Branch at Galveston	$250,000

15	RP210154	TREC	**2.0**	Texas Regional Excellence in Cancer Developmental Therapeutics Center at TTUHSC	Reynolds, Charles	Texas Tech University Health Sciences Center	$5,999,936
16	RP210073	HIHRRA	**2.1**	Identification of Collateral Lethal and Synthetic Lethal Targets in Pancreatic and Colorectal Cancers	DePinho, Ronald	The University of Texas M. D. Anderson Cancer Center	$249,994
17	RP210111	HIHRRA	**2.1**	Single-Cell Proteomics to Dissect Intratumor Heterogeneity	Pan, Sheng	The University of Texas Health Science Center at Houston	$250,000
18	RP210134	HIHRRA	**2.2**	High-Throughput Discovery of Anticancer Protein Degraders	Tambar, Uttam	The University of Texas Southwestern Medical Center	$250,000
19	RP210116	CFSA	**2.3**	The Genetic Design and Engineering Center (GDEC): A CPRIT Core Facility	Bao, Gang	Rice University	$4,000,000
20	RP210158	HIHRRA	**2.3**	Improving CAR T-Cell Therapy of T-ALL by Cotargeting Additional Antigens	Mamonkin, Maksim	Baylor College of Medicine	$250,000
21	RP210206	HIHRRA	**2.4**	Novel Tumor-Specific Bioactive Nanoparticles for Cancer Therapy	Nguyen, Kytai	The University of Texas at Arlington	$249,999
22	RP210180	CFSA	**2.5**	Integrated Cancer Research Core (ICRC)	Chauhan, Subhash	The University of Texas Rio Grande Valley	*$2,525,000
23	RP210126	CFSA	**2.5**	High-Parameter Analysis, Sorting, and Imaging Flow Cytometry Shared Resource	Berton, Michael	The University of Texas Health Science Center at San Antonio	$3,645,500
24	RP210122	CTNA	**2.5**	Building a Clinical Trial Network for Texas Community Affiliates	Overman, Michael	The University of Texas M. D. Anderson Cancer Center	$3,000,000
25	RP210164	ECI	**2.5**	Early Clinical Investigator Award: William Kelly	Hromas, Robert	The University of Texas Health Science Center at San Antonio	$1,499,985
26	RP210140	ECI	**2.6**	Targeting Altered Metabolism in IDH-Mutant Glioma	Arteaga, Carlos	The University of Texas Southwestern Medical Center	$1,500,000
27	RP210089	HIHRRA	**2.6**	Dissecting Therapeutic Immunomodulation of Gut Microbiome on Colorectal Cancer	Kim, Hyun Jung	The University of Texas at Austin	$250,000
28	RP210079	HIHRRA	**2.7**	Targeting Mitochondrial NAD+ in Leukemias	Cambronne, Xiaolu	The University of Texas at Austin	$250,000
29	RP210236	HIHRRA	**2.7**	Magnetomechanical Modulation of Blood-Brain Barrier Permeability	Qin, Zhenpeng	The University of Texas at Dallas	$250,000

30	RP210234	ECI	**2.7**	Targeting Src Homology-2 Domain-Containing Phosphatase to Overcome Resistance to Immune Checkpoint Blockade in Pancreatic Ductal Adenocarcinoma	Johnston, Sterling	The University of Texas at Austin	$1,443,367
31	RP210105	HIHRRA	**2.8**	Targeting Lymphotoxin Beta Receptor in Sensory Neurons for Control of Chemotherapy-Induced Neuropathic Pain	Tumanov, Alexei	The University of Texas Health Science Center at San Antonio	$249,996
32	RP210068	HIHRRA	**2.8**	Role of Aberrant Translational Quality Control in Tumorigenesis of Glioblastoma	Wu, Zhihao	Southern Methodist University	$249,272
33	RP210102	HIHRRA	**2.8**	Deciphering BRCA1-BARD1 E3 Ligase Activity in Genome Maintenance and Tumor Suppression	Zhao, Weixing	The University of Texas Health Science Center at San Antonio	$250,000
34	RP210099	CFSA	**2.8**	North Texas Multimodal Small-Animal Imaging Core Facility	Henning, Anke	The University of Texas Southwestern Medical Center	$3,999,929
35	RP210137	HIHRRA	**2.8**	Development of TCR-Based Immunotherapies Targeting Hotspot EGFR Mutations for the Treatment of Non-Small Cell Lung Cancer	Reuben, Alexandre	The University of Texas M. D. Anderson Cancer Center	$250,000
36	RP210209	CFSA	**2.9**	North Texas Clinical Pharmacology Cancer Core	Putnam, William	Texas Tech University Health Sciences Center	$2,965,226
37	RP210092	HIHRRA	**3.0**	Antibody-Drug Conjugate Combination Treatment for Targeting Colorectal Cancer Cell Plasticity	Carmon, Kendra	The University of Texas Health Science Center at Houston	$250,000
38	RP210131	HIHRRA	**3.0**	Antibody like Therapeutics That Target Polyclonal T Cells to CMV-Positive Glioblastomas	Maynard, Jennifer	The University of Texas at Austin	$250,000
39	RP210075	HIHRRA	**3.0**	Exploring the Biological Basis of Ethnic and Social Disparities in Pediatric Acute Lymphoblastic Leukemia Outcomes	Schraw, Jeremy	Baylor College of Medicine	$249,999
40	RP210199	HIHRRA	**3.0**	Treating Metastatic Cancer Using Microbubble-Assisted Ultrasound-Guided Immunotherapy of Cancer of Cancer (MUSIC)	Lux, Jacques	The University of Texas Southwestern Medical Center	$249,011

41	RP210127	HIHRRA	**3.0**	Engineered Enteric Nerve-Perineural Invasion Models to Improve Predictive Preclinical Screens in Early-Stage Colorectal Adenocarcinoma	Raghavan, Shreya	Texas A&M University	$250,000
42	RP210148	HIHRRA	**3.0**	Novel Pharmacodynamic Assay to Predict Response to CDK4/6 Inhibitor Therapy	Trivedi, Meghana	University of Houston	$250,000
43	RP210119	CFSA	**3.1**	A Preclinical Development Core for Large-Molecule Therapeutics	Liu, Qingyun	The University of Texas Health Science Center at Houston	$3,999,999
44	RP210064	CFSA	**3.1**	The Adolescent and Childhood Cancer Epidemiology and Susceptibility Service (ACCESS) for Texas	Scheurer, Michael	Baylor College of Medicine	*$4,000,000
45	RP210130	CFSA	**3.1**	Data Management and Analysis Core for Comparative Effectiveness Research on Cancer in Texas	Kuo, Yong-Fang	The University of Texas Medical Branch at Galveston	$2,936,731
46	RP210070	HIHRRA	**3.1**	Tunable Epigenetic Remodeling to Modulate CAR T-Cell-Based Immunotherapy	Zhou, Yubin	Texas A&M University System Health Science Center	$250,000
47	RP210132	HIHRRA	**3.1**	Synergy Between Epigenetic Reprogramming and Wnt Inhibition to Enhance Neuroendocrine Tumor Radionuclide Therapy	Frost, Jeffrey	The University of Texas Health Science Center at Houston	$249,999
48	RP210153	TREC	**3.1**	UTEP/UTMDACC Partnership for Hispanic Cancer Disparities Research	Cox, Marc	The University of Texas at El Paso	$5,881,734
49	RP210183	HIHRRA	**3.3**	Virulence Modulation of Helicobacter pylori, the Strongest Risk Factor for Gastric Cancer	Kearney, Christopher	Baylor University	$248,938
50	RP210213	HIHRRA	**3.3**	Therapeutic Inhibition of Cholangiocarcinoma Progression by Targeting Tumor-Lymphatic Cross Talk	Chakraborty, Sanjukta	Texas A&M University System Health Science Center	$250,000

*Note the SRC recommended reduced budgets for applications # RP210180 and #RP210064, the reductions are reflected in the table.
CFSA = Core Facility Support Awards
CTNA = Clinical Trials Network Award
ECI = Early Clinical Investigator Awards
HIHR = High-Impact/High Risk Awards
TCTPA =Texas Clinical Trials Participation Award
TREC = Texas Regional Excellence in Cancer Award

FY 2021 Cycles 10, 11 and 12 Proposed Recruitment Awards

Rank	ID	Grant	Candidate	Organization	Budget	Score
1	RR210082	RFTFM	Dr. Kyle Eagen	Baylor College of Medicine	$2,000,000	1.0
2	RR210066	RFTFM	Dr. Chad W. Johnston	Baylor College of Medicine	$2,000,000	1.0
3	RR210056	RFTFM	Dr. Xia Gao	Baylor College of Medicine	$2,000,000	1.0
4	RR210059	RFTFM	Dr. Javier Garcia-Bermudez	The University of Texas Southwestern Medical Center	$2,000,000	1.0
5	RR210067	RRS	Dr. Yong Lu	The Methodist Hospital Research Institute	$3,998,389	1.7
6	RR210085	RFTFM	Dr. Yuan Pan	The University of Texas M. D. Anderson Cancer Center	$2,000,000	1.9
7	RR210077	RFTFM	Dr. Edward J. Grow	The University of Texas Southwestern Medical Center	$2,000,000	1.9
8	RR210083	RFTFM	Dr. David Braun	The University of Texas M. D. Anderson Cancer Center	$2,000,000	2.0
9	RR210086	RFTFM	Dr. Seungwon "Sebastian" Choi	The University of Texas Southwestern Medical Center	$2,000,000	2.0
10	RR210079	RRS	Dr. Tian Zhang	The University of Texas Southwestern Medical Center	$4,000,000	2.0
11	RR210080	RFTFM	Dr. Jason George	Texas A&M Engineering Experiment Station	$1,999,309	2.0
12	RR210070	RFTFM	Dr. Shih-Han Lee	The University of Texas M. D. Anderson Cancer Center	$2,000,000	2.3

RRS = Recruitment of Rising Stars
RFTFM = Recruitment of First-Time, Tenure Track Faculty Members

Dr. Willson also presented the proposed FY 2022 and FY 2023 Requests for Applications:

Proposed FY 2022 and FY 2023 Requests for Applications

Grant Mechanism	Applications Due	Review Panel	Awards Announced	Budget Year
Core Facility Support Awards	Jan 2022	May 2022	August 2022	FY 2022
High-Impact/High Risk	Jan 2022	May 2022	August 2022	FY 2022
Early Clinical Investigator	Jan 2022	May 2022	August 2022	FY 2022
Clinical Trials Network	Jan 2022	May 2022	August 2022	FY 2022
Texas Regional Excellence in Cancer	Sept 2022	Nov 2022	Jan 2023	FY 2023

Conflict of Interest Notification

Presiding Officer Margo noted for the record that Dr. Rosenfeld reported a conflict of interest with two academic research awards, RP210140 and RP210208.

Approval Process – Academic Research Awards

Presiding Officer Margo called for a vote on the award recommendations, with the first vote addressing RP210140 and RP210208.

MOTION:
On a motion made by Dr. Rice and seconded by Mr. Montgomery the Oversight Committee members voted to approve the PIC's recommendations for RP210140 and RP210208. No members voted to disapprove the recommendations.

Presiding Officer Margo noted for the record that Dr. Rosenfeld did not vote. Presiding Officer Margo then called for a vote on the remaining eight slates of academic research award recommendations.

MOTION:
On a motion made by Dr. Rice and seconded by Mr. Montgomery the Oversight Committee members voted unanimously to approve the PIC's recommendations for the remaining proposed academic research grant awards.

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

Following the vote on the award recommendations, Presiding Officer Margo requested a motion regarding the proposed FY 2022 and FY 2023 RFAs presented by Dr. Willson.

MOTION:
On a motion made by Mr. Montgomery and seconded by Dr. Rice, the Oversight Committee members unanimously voted to approve the proposed FY 2022 and FY 2023 RFAs as presented by Dr. Willson.

Chief Prevention Officer Report – Agenda Item 8, Tab 5

Presiding Officer Margo recognized Chief Prevention Officer Ramona Magid to update the Oversight Committee on the prevention program and to present the prevention awards. Ms. Magid presented her update and introduced the nine prevention program projects in the second cycle of FY 2021, totaling $11,396,581, recommended by the Prevention Review Council and PIC. She explained that applicants submitted the recommended applications in response to four grant mechanisms: *Evidence-Based Cancer Prevention Services, Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations, Tobacco Control and Lung Cancer Screening, and Dissemination of CPRIT-Funded Cancer Control Interventions.* Ms. Magid reported that all applications address at least two of the Prevention Program priorities.

An Oversight Committee member asked if CPRIT allowed COVID-19 vaccinations as part of the clinical service delivery of prevention projects. Ms. Magid replied that grantees do not provide these vaccinations, but several grantees provide education about and navigation services to COVID-19 vaccination.

Proposed FY 2021 Cycle 2 Prevention Program Awards

ID	Grant	Application Title	PD	Organization	Score	Rank	Budget
PP210045	DI	Dissemination of a Mailed Stool Testing Program for Colorectal Cancer Prevention in Underserved Communities in Texas	Pignone, Michael	The University of Texas at Austin	1.00	1	$300,000
PP210049	EBP	Texas Southern University Breast Cancer Screening and Prevention Center	Ajewole, Veronica	Texas Southern University	1.80	2	$1,000,000
PP210020	EPS	Vaccinating Medically Underserved Women Against HPV: Expansion of Clinical Services to Increase Access	Berenson, Abbey	The University of Texas Medical Branch at Galveston	2.00	3	$1,999,988
PP210042	TCL	A Regional Expansion of Lung Cancer Screening and Patient Navigation (E-LSPAN)	Argenbright, Keith	The University of Texas Southwestern Medical Center	2.10	4	$1,999,993
PP210026	DI	Taking Texas Tobacco Free: Dissemination to and Implementation Within Agencies Serving Texans Experiencing Homelessness	Reitzel, Lorraine	University of Houston	2.70	5	$299,978
PP210027	TCL	Increasing Accessibility to Smoking Cessation and Lung Cancer Screening Services for Low-Income/Uninsured Texans	McKnight, Jason	Texas A&M University System Health Science Center	3.10	6	$999,947
PP210031	DI	Application of mHealth Technologies to Improve Latino Childhood Cancer Survivor Engagement and Use of Evidence for Personalized Follow-Up Care and Screening	Poplack, David	Baylor College of Medicine	3.30	7	$299,982
PP210007	EPS	Strengthening Safety Net Health Systems to Improve Cervical and Colorectal Cancer Screening and Follow-up among the Medically Underserved	Montealegre, Jane R	Baylor College of Medicine	3.30	8	$2,497,029
PP210044	TCL	Expansion of the Lung Cancer Screening and Tobacco Control (LCTC) Network to Rural and Medically Underserved Populations	Zoorob, Roger	Baylor College of Medicine	3.60	9	$1,999,664

DI: Dissemination of CPRIT-Funded Cancer Control Interventions
EBP: Evidence-Based Cancer Prevention Services
EPS: Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations
TCL: Tobacco Control and Lung Cancer Screening

Compliance Certification

Presiding Officer Margo reminded members that Mr. Burgess previously certified compliance of the prevention awards process.

Conflict of Interest Notification

Presiding Officer Margo noted for the record that no Oversight Committee member reported a conflict of interest with any of the proposed prevention awards.

Approval Process -Prevention Grant Award

Presiding Officer Margo called for a vote on the nine proposed award recommendations.

MOTION:
On a motion made by Mr. Montgomery and seconded by Dr. Rice, the Oversight Committee unanimously voted to approve the PIC's recommendations for the nine prevention grants recommended by the PIC.

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

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

Presiding Officer Margo recognized Chief Product Development Officer Dr. Cindy WalkerPeach to present the proposed product development research award recommendations and to provide the product development research program update.

Dr. WalkerPeach presented the PIC's two product development research award recommendations, totaling $27,565,207 for the FY 2021 review cycle: Dialectic Therapeutics, Inc. and Marker Therapeutics, Inc.

FY 2021 Proposed Product Development Research Awards

Rank	ID	Grant	Company	Project	Score	Budget
1	DP210005	Texas Company	Dialectic Therapeutics	Clinical Development of DT2216, a First-in-Class APTaD™ for Cancer Therapy	3.0	$14,449,638
2	DP210042	Texas Company	Marker Therapeutics	Efficacy of a Multi Tumor Associated Antigen Specific T Cell Therapy in AML Patients following Allogeneic Stem Cell Transplant	2.2	$13,115,569
					Total	**$27,565,207**

Dr. WalkerPeach also provided an update regarding the status of the applications under review in the first review cycle for FY 2022 and presented staff's proposal to revise CPRIT's matching funds policy for repeat product development grantees. She finished her report with the presentation of the planned review timeline and three product development research RFAs for the second review cycle in FY 2022.

Compliance Certification

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

Conflict of Interest Notification

Presiding Officer Margo noted for the record that no Oversight Committee member reported a conflict of interest with any of the proposed product development awards.

Approval Process – Product Development Research Awards

Presiding Officer Margo called for a vote on the two proposed award recommendations.

MOTION:
On a motion made by Mr. Montgomery and seconded by Dr. Hernandez, the Oversight Committee unanimously voted to approve the PIC's recommendations for product development research awards to Dialectic Therapeutics and Marker Therapeutics as presented by Dr. WalkerPeach.

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

MOTION:
On a motion made by Mr. Montgomery and seconded by Dr. Rice, the Oversight Committee unanimously voted to authorize CPRIT to disburse grant funds via advance payments to Dialectic Therapeutics and Marker Therapeutics upon execution of the award contracts and the successful completion of tranches.

Following the vote on the award recommendations, Presiding Officer Margo requested a motion regarding the proposed policy change for matching funds required for multiple product development grants, as presented by Dr. WalkerPeach.

MOTION:
On a motion made by Mr. Rosenfeld and seconded by Mr. Montgomery, the Oversight Committee unanimously voted to approve the change to CPRIT's matching funds policy for companies that have received multiple product development awards as outlined by CPRITs Chief Product Development Officer.

Presiding Officer Margo noted for the record that the Oversight Committee would leave Agenda Item 9 pending and take up the remaining point in closed session later in the meeting.

Internal Auditor Report – Agenda Item 10, Tab 7

Presiding Officer Margo recognized CPRIT internal auditor Dan Graves with Weaver and Tidwell. Mr. Graves provided an update on current internal audit activities and the FY 2022 Internal Audit Plan. He explained that the State Auditor's Office (SAO) has a requirement for the submission of an annual internal audit report and that a component of the report is the inclusion of the proposed FY 2022 Internal Audit Plan. The report is due November 1, 2021.

MOTION:
On a motion by Dr. Patel and seconded by Mr. Montgomery, the Oversight Committee unanimously voted to approve the FY 2022 Internal Audit Plan.

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

The Chair recognized Mr. Roberts to present the Scientific Research and Prevention Program Committee Appointments. Mr. Roberts presented his four appointments to the scientific research and prevention program committee, which he summarized on page 8-2 of the meeting book. The Nominations Subcommittee reviewed and recommended the appointments at their August 13, 2021, meeting.

MOTION:
On a motion by Mr. Montgomery and seconded by Dr. Patel, the Oversight Committee unanimously voted to approve the four appointments to the scientific research and prevention program committee.

Advisory Committees – Item 12, Tab 9

The Chair recognized Dr. Willson to present Dr. Osborne, Chair of the Clinical Trials Advisory Committee to present the Clinical Trial Advisory Committee's Annual Report.

<u>Clinical Trial Advisory Committee Annual Report Presentation</u>

Dr. Osborne presented the Clinical Trials Advisory Committee's report and recommendations.

In response to an Oversight Committee member's question regarding the number of patients historically enrolled in clinical trials, Dr. Osborne explained that few patients enroll in trials – approximately only 4% of eligible candidates.

Responding to an Oversight Committee member's question about how CPRIT and an institution may ensure that the early clinical investigator required 50% "protected time" for Early Clinical Investigator's awardees, Dr. Osborne noted that the institution keeps time sheets.

The Oversight Committee members thanked Dr. Osborne for the annual report presentation and his leadership as Chair of the Clinical Trials Advisory Committee. Mr. Roberts thanked Dr. Osborne for also serving on the CPRITs Chief Scientific Officer interview committee.

Appointment of Advisory Committee Members

Presiding Officer Margo recognized Mr. Roberts to present the Presiding Officer's new appointments to CPRIT's advisory committees and the proposed schedule for FY 2022 advisory committee reports.

Mr. Roberts presented the four advisory committee appointments: Lisa Tichenor (Advisory Committee on Childhood Cancer), Smita Bhaskara, M.D. (Advisory Committee on Childhood Cancer), Phillip Neff, M.D. (Advisory Committee on Childhood Cancer) and Jon Mogford, Ph.D. (Product Development Advisory Committee). Mr. Roberts also discussed the proposed schedule for FY 2022 advisory committee annual reports.

MOTION:
On a motion made by Dr. Patel and seconded by Dr. Rice the Oversight Committee members voted unanimously to approve the four new appointments to the advisory committees.

FY 2022 Honoraria Policy – Agenda Item 13, Tab 10

Presiding Officer Margo recognized Mr. Roberts to present the FY 2022 honoraria policy. Mr. Roberts reported that there are no changes to the FY 2022 honoraria policy from the FY 2021 policy approved by the Oversight Committee last year.

MOTION:
On a motion made by Mr. Montgomery and seconded by Dr. Patel the Oversight Committee members voted unanimously to approve the FY 2022 honoraria policy.

Health & Safety Code § 102.1062 Waivers – Agenda Item 14, Tab 11

Presiding Officer Margo recognized Mr. Roberts to present the Health and Safety Code Section 102.1062 waivers for FY 2022. Mr. Roberts presented the four waivers for FY 2022.

MOTION:
On a motion made by Dr. Rice and seconded by Mr. Montgomery the Oversight Committee members voted unanimously to approve the Health and Safety Code Section 102.1062 waivers for FY 2022.

Amendments to 25 T.A.C. Chapters 703 – Item 15, Tab 12

Presiding Officer Margo recognized CPRIT assistant general counsel Cameron Eckel to discuss the proposed administrative rule change. Ms. Eckel reviewed the final order approving the amendment to Chapter 703. CPRIT will file the final order with the Secretary of State for final adoption.

MOTION:
On a motion made by Dr. Rice and seconded by Mr. Montgomery, the Oversight Committee unanimously voted to approve the final order adopting rule change to the Texas Administrative Code Chapter 703.

Chief Operating Officer Report – Agenda Item 16, Tab 13

Presiding Officer Margo recognized Ms. McConnell to provide the Chief Operating Officer Report. Ms. McConnell updated the Oversight Committee regarding third quarter financial information, performance measures, debt issuance, service contract renewals, and the imminent issuance of the State Auditor's Office audit over CPRIT's grant management processes.

Ms. McConnell reported on the de-obligation of approximately $85 million from the unspent funds of closed grant awards. She explained that FY 2021 is the first year that the agency is using de-obligated funds to support the grant awards that the Oversight Committee has approved, with CPRIT applying $60 million to the grant awards in FY 2021. CPRIT may apply the remaining amount to grant awards approved in future funding years. Ms. McConnell explained other circumstances may reduce that de-obligated fund amount such as the unbudgeted draws by the Employees Retirement System (ERS) to pay post-retirement benefits of former Texas Cancer Registry employees at the Department of State Health Services or former CPRIT employees. The amount drawn annually has grown over the past 12 years from $10,000 to $380,000. There is no standard pattern to the amount drawn by ERS.

Oversight Committee members discussed the de-obligated grant funds with Ms. McConnell.

Contract Approvals – Agenda Item 17, Tab 14

Presiding Officer Margo recognized Ms. McConnell to present proposed contract approvals. Ms. McConnell summarized the four contract renewals exceeding $100,000 that require Oversight Committee approval: Icon, Hahn Public, Perryman Group, and Weaver. She noted that Oversight Committee approval is not necessary for outside counsel services because CPRIT will contract with two separate law firms and each contract will be less than $100,000. Ms. McConnell reminded members that she will send out financial disclosure forms.

MOTION:
On a motion made by Dr. Rice and seconded by Dr. Patel, the Oversight Committee unanimously voted to approve contracts with The Perryman Group, Weaver and Tidwell, Hahn Public, and ICON Clinical Research.

Subcommittee Business – Agenda Item 18, Tab 15

Presiding Officer Margo informed the committee members that CPRIT included the proposed subcommittee assignments, including subcommittee chair positions, for FY 2022 - 2023.

In addition, Presiding Officer Margo explained that the Oversight Committee will move the responsibilities originally assigned to the Nominations subcommittee to the Board Governance subcommittee in FY 2022. CPRIT included a revised Board Governance subcommittee charter that reflects the new duties in the meeting packet.

MOTION:
On a motion made by Dr. Rosenfeld and seconded by Mr. Montgomery, the Oversight Committee unanimously voted to approve the new subcommittee assignments for FY 2022 and 2023.

MOTION:
On a motion made by Dr. Rosenfeld and seconded by Dr. Patel, the Oversight Committee unanimously voted to approve the proposed changes to the Board Governance charter.

Election of Board Officers – Agenda Item 20, Tab 16

Presiding Officer Margo informed the committee members that the Nominations Subcommittee met August 13 and unanimously recommended a slate of officers to serve two-year terms ending in August 2023. The proposed slate is Dr. Mahendra Patel as presiding officer, Dr. David Cummings as vice presiding officer, and Cindy Payne as board secretary.

MOTION:
On a motion made by Mr. Margo and seconded by Dr. Rosenfeld, the Oversight Committee unanimously voted to approve Dr. Mahendra Patel as Presiding Officer, Dr. David Cummings as Vice Presiding Officer, and Cindy Payne as Board Secretary to serve the Oversight Committee for FY 2022 and 2023.

Wayne Roberts and CPRIT staff thanked Mr. Margo for his service as the Presiding Officer.

Future Meeting Dates and Agenda Items – Agenda Item 23, Tab 17

Taking agenda item 23 out of order, Presiding Officer Margo presented the proposed dates for the Oversight Committee's regular quarterly meetings and subcommittee meetings for FY 2022.

MOTION:
On a motion made by Dr. Rice and seconded by Mr. Montgomery, the Oversight Committee unanimously voted to approve the proposed meeting dates for the regular meetings of the Oversight Committee and the subcommittees for FY 2022.

Tribute to Jim Willson

Presiding Officer Margo announced that this is Dr. Jim Willson's last meeting as Chief Scientific Officer. Presiding Officer Margo thanked Dr. Willson for serving as a remarkable advocate for the academic research program and for CPRIT's mission and spoke for the board and for CPRIT staff in appreciation of Dr. Willson's tremendous work on behalf of Texans. CPRIT played a short video of several CPRIT grantees and colleagues conveying gratitude for his five years at CPRIT.

Mr. Roberts presented Dr. Willson with a Governor's proclamation. Presiding Officer Margo recognized committee members for remarks. Oversight Committee members made remarks. Presiding Officer Margo read the honorary resolution.

WHEREAS, James K.V. Willson, M.D. has served as the Chief Scientific Officer of the Cancer Prevention and Research Institute of Texas since March 1, 2016; and

WHEREAS, Dr. Willson worked selflessly for and on behalf of CPRIT, giving his time, reputation, wisdom, expertise, and energy to extend lives and improve the health of Texans; and

WHEREAS, Dr. Willson earned the respect and admiration of the Oversight Committee, his CPRIT colleagues, and the greater cancer research community through his leadership of CPRIT's academic research program; and

WHEREAS, Dr. Willson was instrumental in the passage of Proposition 6 in November 2019, ensuring an additional $3 billion to accelerate the momentum in the state's historic fight against cancer through the next decade;

WHEREAS, Dr. Willson provided steadfast guidance to the cancer research community and CPRIT during the unprecedented challenges presented by the global COVID-19 pandemic;

WHEREAS, Dr. Willson faithfully performed the duties of his position with equanimity, persistence, and poise; and

WHEREAS, CPRIT's mission of promoting academic research, prevention, and product development research progressed under Dr. Willson's guidance and leadership to the benefit of all Texans; now, therefore, be it

RESOLVED, THAT the Oversight Committee of CPRIT hereby recognizes James K.V. Willson, M.D. for his distinguished service to the citizens of the State of Texas, and expresses its gratitude for his many and lasting contributions to CPRIT; and, be it further

RESOLVED, THAT an official copy of this resolution be prepared for Dr. Willson as an expression of high regard by Oversight Committee members and CPRIT staff.

MOTION:
On a motion made by Dr. Rosenfeld and seconded by Dr. Rice, the Oversight Committee unanimously voted to approve the honorary resolution.

Personnel – Chief Scientific Officer – Agenda Item 19
Chief Product Development Officer Report (pending discussion item) – Agenda Item 9

Turning the Agenda Item 19, Presiding Officer Margo informed the Oversight Committee that they will convene in closed session for discussion regarding the Chief Scientific Officer position pursuant to Texas Open Meetings Act Section 551.074. He explained that the Oversight Committee will also take up in closed session the pending discussion under Agenda Item 9 related to managing, acquiring, or selling securities or other revenue sharing obligations pursuant to Texas Health & Safety Code Section 102.107(b). He asked Mr. Roberts, Ms. Lisa Nelson, Ms. Doyle, Dr. WalkerPeach, and Ms. Tracey Davies to join the Oversight Committee in closed session

The Oversight Committee convened in closed session via a secure video channel at 11:26 a.m. Presiding Officer Margo reconvened the open meeting at 12:13 p.m.

MOTION:
On a motion made by Mr. Montgomery and seconded by Dr. Rice, the Oversight Committee unanimously voted to set the exempt salary for the Chief Scientific Officer position to the legislatively authorized $608,850 effective on or after September 1, 2021.

Adjournment – Agenda Item 24

MOTION:
There being no further business, the Oversight Committee unanimously voted to approve a motion to adjourn made by Presiding Officer Margo and seconded by Dr. Rice.

Meeting adjourned at 12:14 a.m.

_____ _____

Signature Date

Michael Pignone, M.D., MPH, is the chair of the Department of Internal Medicine, assistant dean for Veterans Affairs, director of the program on Cancer Prevention and Control at Dell Med's Livestrong Cancer Institutes and professor in the Departments of Internal Medicine, Oncology and Population Health.

Dr. Pignone's research is focused on chronic disease screening, prevention, and treatment, and on improving medical decision making. His main areas of interest include heart disease prevention, colorectal cancer screening, and management of common chronic conditions such as diabetes and heart failure. He has developed and tested interventions, including decision aids, to mitigate literacy-related health disparities and to improve the use of appropriate preventive services. He has published more than 300 peer-reviewed journal articles.

Improving cancer screening and prevention in primary care populations

Michael Pignone, MD, MPH
Professor and Chair, Department of Internal Medicine
Co-Director, Cancer Prevention and Control Program, Livestrong Cancer Institutes
Dell Medical School, University of Texas Austin

Funding and Acknowledgements

- No conflicts to report
- Funding:
  - American Cancer Society
  - Cancer Prevention and Research Institute of Texas
  - Centers for Disease Control and Prevention
  - National Cancer Institute
  - Livestrong Foundation
- Thanks to many collaborators: Ascension, CommUnity Care, LoneStar Circle of Care, UNC Lineberger

Former member of the USPSTF – the views expressed here are mine and not necessarily those of the TF

CPRIT grants: PP210045, PP200066, PP200036, PP190063 and PP170082

Objectives

1. Outline rationale for our program of research.

2. Describe our current programs in cancer screening and prevention for primary care populations.

1. Examine future directions for our work (and for CPRIT-funded work in screening and prevention).

Current CPRIT funded work

Cancer type	Program type	Grant durations
Colorectal cancer	Mailed FIT in Central Texas FQHC systems	Pt 1 2017-2022* Pt 2 2021-2024*
Lung cancer	Intensive smoking cessation and CT screening in high risk patients	2019 - 2022
Multiple cancers	Screening for risky drinking and brief counseling / pharmacotherapy to reduce alcohol-related cancer risk	2020 - 2023
Colorectal cancer	Dissemination of mailed FIT in Texas FQHCs through geo-spatial-guided consultation	2021 - 2023

Rationale- 1

- Several cancer screening and prevention services are effective but sub-optimally implemented
- Gaps are larger for vulnerable populations
- Increasing screening in FQHCs can both improve overall levels and potentially reduce disparities

Rationale - 2

- Primary care is time-starved – especially for FQHCs with limited resources and high needs patient populations
- Taking some prevention work out of the traditional MD-patient encounter can increase effectiveness and reduce burdens for patients and providers

Mailed FIT

Advantages of Mailed FIT

- Convenient for patients
- Low initial test cost
- Conserves colonoscopy resources
- Scalable
- Frees up face to face visit time

Gupta et al CA Cancer J Clin. 2020;70(4):283-298

Mailed FIT Response Summary

10/29/2021	Total Mailings	TOTAL RESULTS	TOTAL RESPONSE RATE	Total Positive results	Pos Rate
All	**44,232**	**10,730**	**24%**	**570**	**5.3%**
Year 1 Only	37,915	7,466	20%	428	5.7%
Year 2/3/4	6,317	3,203	51%	142	4.4%
Year 3 Only	1,439	886	62%	41	4.6%
Year 4 Only	135	92	68%	2	2%
Non-Responders to Year 1	855	21	3%	1	4.8%

Few differences in participation across demographic groups

	% completing at least one FIT
Age < 60	19%
Age > 60	21%
Female	22%
Male	18%
White, NH	17%
Black, NH	18%
Hispanic	21%

	% completing at least one FIT
Commercial	19%
MAP	20%
Medicaid	18%
Medicare	20%
Sliding scale	23%
Other	16%

2-11

Colonoscopy Navigation Status

Outcomes of Positive FITs (as of 10/29/2021)	
Evaluation Scheduled	24
Colonoscopy Scheduled	11
Colonoscopy Completed	399
Referred to PCP/Other Provider	14
Pending/Rescheduling	40
Refused/Difficulty Contacting	75
Deceased	8
TOTAL	571
Median time to colonoscopy	**55 days**

Total "On Track" 434 (76%)

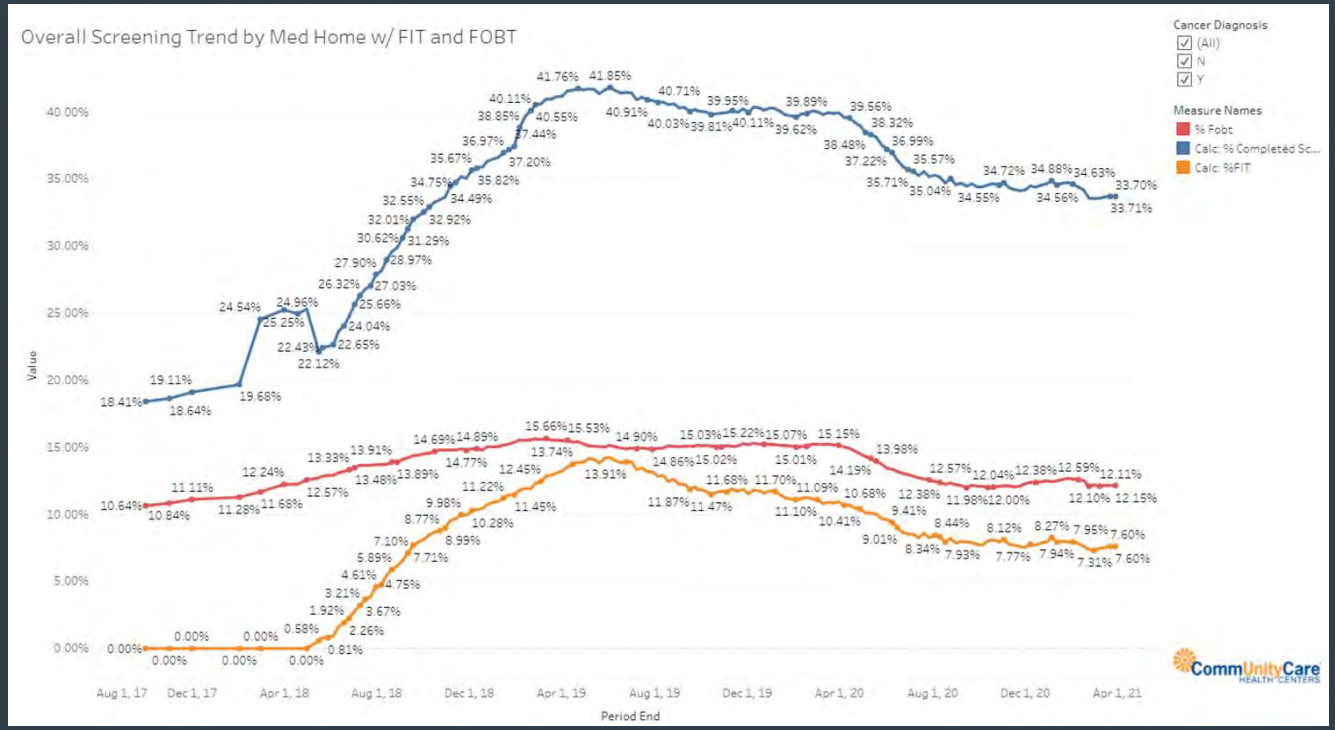
Colonoscopy results

Colonoscopies Completed (10/29/2021)	399
Normal	141
Cancer	11
Adenomas	128
Hyperplastic Polyps	57
No biopsy	13
Benign Mucosa	8
Path report not available	12
Inconclusive	5
Pathology Pending/Unknown	24

Patients Identified with Cancer

Age at Dx	Sex	Race	Time:FIT to Colonoscopy	Location of Cancer	Pathology	Stage	Tx/Status
69	M	W	145 days	Anal Canal/rectum	SCC	T3N1M0	chemo 2018-2019; disease progressed in 2020; hospice (deceased)
68	F	H	54 days	Rectum	Adeno	T2N0M0	chemo/RT 2019; normal surv col 2020; 2021 MRI no recurrence
53	M	W	51 days	Sigmoid	Adeno	T2N0M0	sigmoid colectomy; normal surv col 2020
73	M	W	98 days	Sigmoid colon	Adeno	IV	chemo 2019-2020; cardiac arrest 2020 (deceased)
56	M	H	34 days	Ascending colon	Adeno	IV	palliative resection; chemo in 2020; 2021 worsening mets
63	M	H	101 days	Sigmoid colon	Adeno	T3N0	robotic LAR 2020; surv COL (polyps – repeat in 3 yrs)
62	M	W	459 days	Rectum	Adeno	T3	chemo 2019-2020; LAR; surv col 2021 (poor prep); rpt COL ordered
66	F	H	271 days			II	partial colectomy; normal surv col 2020
56	F	Unk	89 days	ascending colon	adeno	T1N0M0	Hemicolectomy; CT negative for mets; flex sig ordered
56	M	H	79 days	sigmoid	adeno		Malignant polyp completely removed
53	F	H	49 days	Sigmoid	Adeno	T1N0M0	Sigmoidectomy 2021

CRC Screening Rate at CUC has improved but room for improvement- especially post-COVID



2018 CRC Screening Rates

- National: 69%
- Texas: 62%
- National FQHCs: 44%

2020 Comparative Data

- National FQHCs: 40%
- Texas FQHCs: 34%

2-15

Data through 4/1/2021

Mailed FIT Response Summary - LSCC

As of 10/26/2021

	Total Mailed	Negative Results	Positive Results	Pos Rate	Total Results	TOTAL RESPONSE RATE
Total	1,208	309	21	6.4%	330	27.3

Outcomes of Positive FITs	
Evaluation Scheduled	0
Colonoscopy Scheduled	2
Colonoscopy Completed	8
Pending/Rescheduling	4
Refused/Difficulty Contacting	7
TOTAL	21

CRC screening in the COVID era

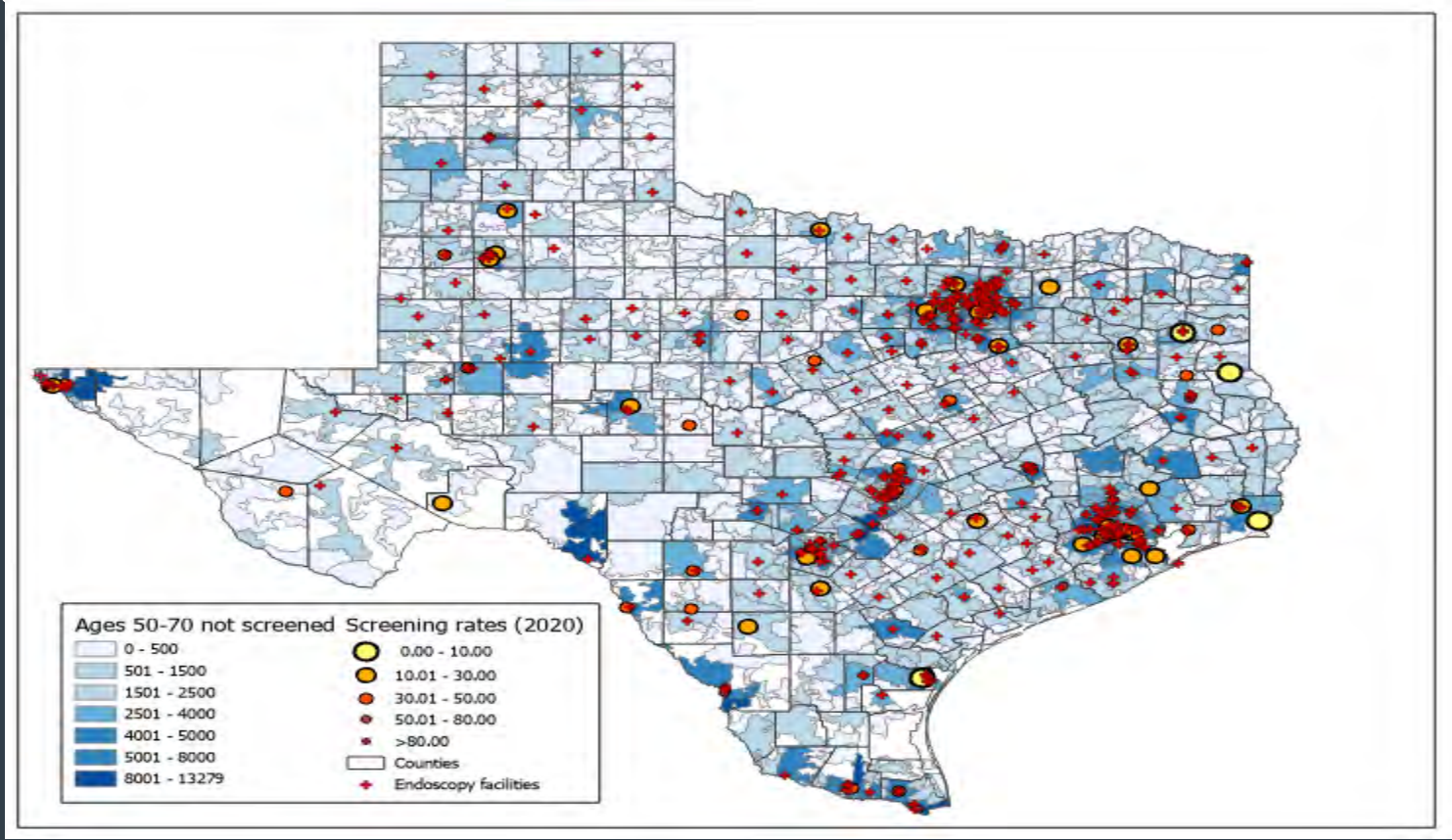
- March 18, 2020: CMS halts colonoscopies
  - Iatrogenic risk, lack of PPE
- Ongoing concern about delays in screening / early detection and worsening of health disparities
- Mailed FIT helpful: allowed colonoscopies to be prioritized for those at higher risk
- Still significant gap in screening that will need to be closed!

Issaka and Somsouk JAMA Health Forum 2020

What's next?

- Expand mailed FIT (including 45-49 ages)
- State-wide collaboration with FQHCs
- Centralized testing support with local navigation?

Geographic Distribution of Endoscopy Facilities, Estimated Age-Eligible Population, and Screening Rates of FQHCs in Texas

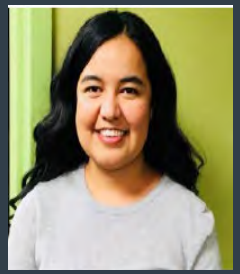


Lung Cancer Risk Reduction: intensive tobacco cessation and LDCT screening

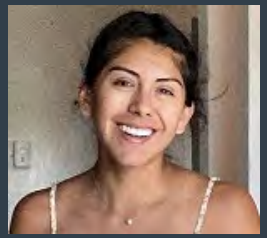
- Started smoking cessation services - March 2020
- Started mailed outreach in Sept 2020
- Started lung cancer screening in Nov 2020
- Scaling up full range of services in 2021

Program Team

LaTasha Vanin, LCSW
Patient Navigator/Educator
LaTasha.Vanin@communitycaretx.org



Karen Mendoza, LCSW-S
Bilingual Navigator/Educator
karen.mendoza@communitycaretx.org

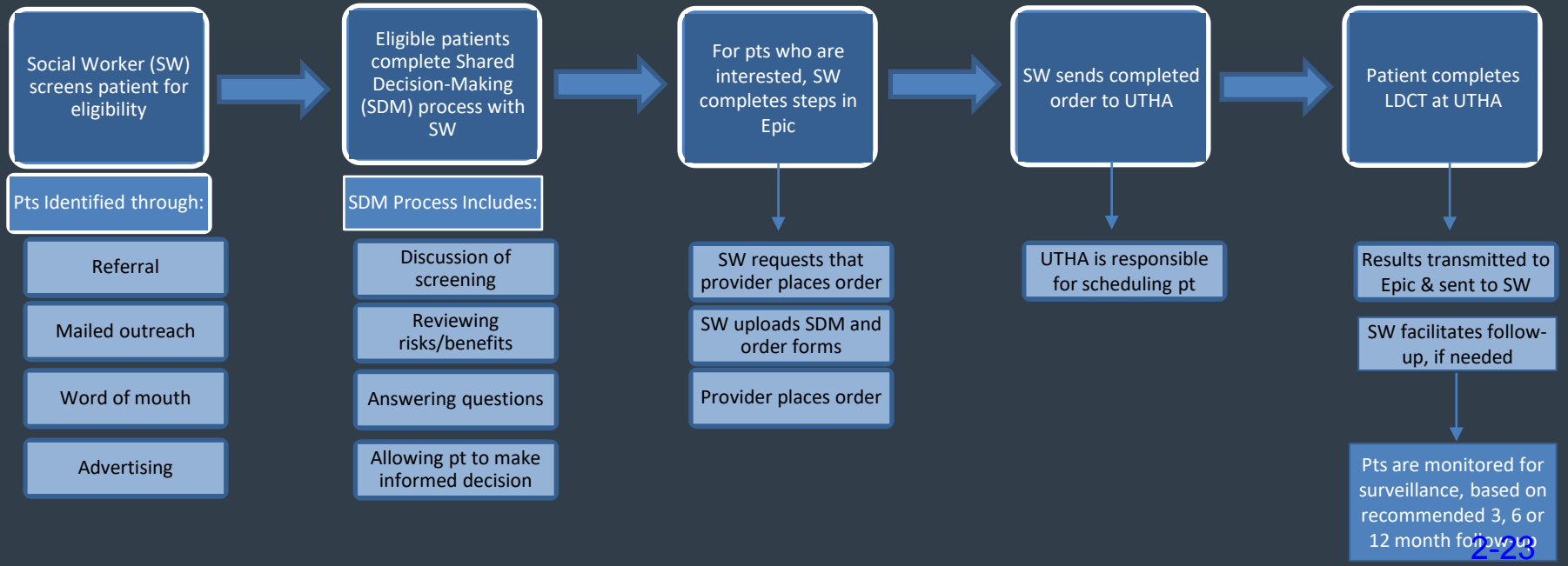


Amaris Martinez, BA
Program Coordinator
amaris.martinez@austin.utexas.edu

Mailed Outreach Responses

Total Mailed	Total Responses	TOTAL RESPONSE RATE	Patients Interested in Quitting	Eligible for Smoking Cessation	Patients Eligible for LDCT
6,775	445	7%	138	113	168

LDCT Referral Workflow



Smoking Cessation and LDCT Program

Smoking Cessation			
Referrals for Smoking Cessation	Patients Engaged in Smoking Cessation	# Pts Quit Smoking	% Quit (of total in cessation)
334	**198**	**42**	**21%**

Lung Cancer Screening		
Completed SDM Process	Agreed to LDCT	# Completed LDCT
161	**153**	**91**

Data updated 10/29/2021

LDCT Patient Outcomes

# of patients	LungRADS	Description	F/U Interval
57	1	No abnormalities	12 months
22	2	Benign appearance	12 months
7	3	Probably benign	6 months
5	4	Abnormal	Immediate

LungRADS Score	Current Status/Notes
4a	Nodules resolved at f/u scan (LungRADS Score 2)
4x	Bx indeterminate; repeat scan reassuring – close follow-up
4a	cancer; referred to onc and surg consult; surgery scheduled for localized cancer
4b	Cancer; referred to onc; PET and genetic testing suggest metastatic disease
4b	Pulm recommended Sputum for TB (neg); recommend bx; pulm consult pending

Screening and brief intervention for risky drinking

- Alcohol is a major risk factor for multiple cancers
- Risk increases at levels of drinking below those often associated with alcohol use disorder
- Screening and brief intervention recommended but not widely implemented

AUD Screening Program Outcomes

Patients Screened	
Total Screened (via SDOH forms)	524
% Screened Positive	18%

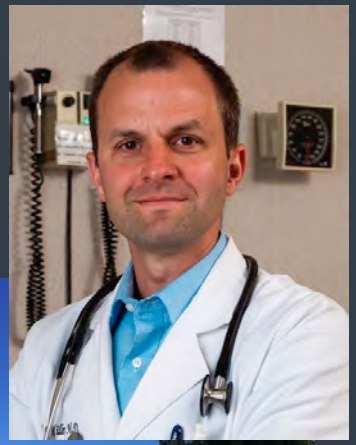
Data updated 10/25/2021

Initial AUDIT Score	# Completed AUDIT	# Completed BI
4-7	35	34
8-12	16	15
12+	37	34
TOTAL	**88**	**83**

Conclusions

- Successful implementation of multiple cancer screening and prevention services in Central Texas FQHC populations
- Only possible with CPRIT support!
- Work to build sustainable systems statewide to reduce cancer burden and disparities

Special Thanks



Questions?

Premal Lulla, M.D.,
Assistant Professor,
Center for Cell and Gene Therapy
Baylor College of Medicine

I am a clinical investigator at the Center for Cell and Gene Therapy (CAGT) at Baylor College of Medicine (BCM) with a central focus on improving the outcomes for patients with hematological malignancies. I completed my medical school training in Mumbai, India, where I am from, before moving to Houston in 2009 to seek cutting-edge training in cancer medicine and research at Baylor College of Medicine (BCM). At BCM, I completed most of my post-doctoral training at a county hospital with a large population of patients with HIV-related cancers. This exposure narrowed my research interests to exploring the close interaction between the immune system and hematological malignancies. I approached Dr. Helen Heslop, the director of CAGT and an authority in the field of cancer immunology, with the aim of understanding the effects of the immune system on cancers. I published our initial work to determine the effects of immune reconstitution on lymphomas in patients with HIV.

I spent the last year of my fellowship training on a NIH-T32 award where I sought to build upon these early positive research experiences by seeking “bench-side” training in the laboratory of Dr. Ann Leen, also at CAGT. There, for the first time in my training, I was introduced to laboratory science. My project was to clinically translate a novel tumor-associated antigen (TAA)-specific T cell therapy that was developed by Dr. Leen for patients with leukemia. Under the close supervision of Drs. Heslop and Brenner, who are accomplished clinical investigators, I have since translated this project into an early phase clinical trial (NCT02494167) that has now been published. The rewarding experience of conducting my first trial as Principal Investigator (PI), as well as witnessing the impact of this treatment on patients, has confirmed my decision to pursue a clinical research career in cancer cellular therapy. So, the CPRIT opportunity was quite timely for my career path and so I jumped at the opportunity to apply in early 2020.

Now as faculty at CAGT/BCM, I remain deeply committed to translating both gene modified and non-gene modified cellular immunotherapies from the laboratory bench to cancer patients who have failed conventional therapies. Another key aspect my research is to study the biological correlates of clinical responses and toxicities from treatment with these novel cellular immunotherapies. In my early career, so far, I have published results from these trials in high impact journals highlighting my early contributions to the field of cancer immunotherapy. Furthermore, some of these therapies have entered advanced phase clinical testing with the eventual goal of commercializing them. Currently, and as a direct consequence of the CPRIT Early Career Clinical Investigator Award, I have been able to expand the repertoire of investigator-initiated “first-in-human” clinical trials from 2 to now 4 trials for which I am the principal investigator.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	AGENDA ITEM 6: CHIEF EXECUTIVE OFFICER REPORT
DATE:	NOVEMBER 11, 2021

I will address the items detailed below in my Chief Executive Officer Report presented at the November 18 Oversight Committee meeting. I have attached copies of the August/September and October 2021 CPRIT Activity Updates behind this memo for your reference.

FY 2022 Grant Awards Funds Available and CPRIT Dashboard (Attachments 1 and 2)

Today's awards will be the first from FY 2022 appropriations. If the Oversight Committee approves the 12 recruitment awards at the recommended level of $38.0 million, $235.1 million will remain for additional awards this fiscal year.

I have also included CPRIT's dashboard of metrics the agency tracks on a regular basis.

CPRIT's Response to COVID-19 Related Issues

CPRIT staff now works both in the office and remotely. Most staff work from home pursuant to our new remote work policy.

Personnel

CPRIT currently has 39 of our 44 full-time equivalent (FTE) positions filled.

Mr. Mark Loeffler began as Communications Director on November 16. Mr. Loeffler has extensive state communications experience in the Department of Agriculture, General Land Office as well as in the legislature.

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

CPRIT has awarded **1,679** grants totaling **$2855 billion**

- 258 prevention awards totaling $300.3 million
- 1,421 academic research and product development research awards totaling $2.555 billion

Of the $2.555 billion in academic research and product development research awards,

- 30.3% of the funding ($775.4 million) supports clinical research projects
- 24.4% of the funding ($622.5 million) supports translational research projects
- 28.7% of funding ($733.6 million) supports recruitment awards
- 13.1% of the funding ($333.5 million) supports discovery stage research projects
- 3.5% of funding ($90.4 million) supports training programs.

CPRIT has 10 open Requests for Applications (RFAs)

- 3 Research Recruitment
- 5 Research
- 3 Prevention
- 3 Product Development

FY 2022 GRANT AWARD FUNDS AVAILABLE

General Obligation Bond Proceeds

	Prevention	Academic / Product Development Research	1% Grant Funding Buffer	Operating Budget	Total Appropriations
Available Appropriated Funds	**$ 27,659,031**	**$ 251,353,693**		**$ 20,987,276**	**$ 300,000,000**
Appropriations Transfer to DSHS		**$ (3,118,032)**		**$ 3,118,032**	
Adjusted Appropriations	**$ 27,659,031**	**$ 248,235,661**		**$ 24,105,308**	**$ 300,000,000**
Total Available for All Grants			**$ 275,894,692**		
1% of Total Available Grant Funding			**$ 2,758,947**		
Adjusted Grant Award Funding	**27,659,031**	**$ 245,476,714**			**$ 273,135,745**

	Prevention Grants	Academic Research Grants	PD Research Grants		
Total Available for Grant Awards (Total GO Bond Proceeds Less Operating Budget)	**$ 27,659,031**	**$ 173,764,963**	**$ 74,470,698**		**$ 275,894,692**
Total Available for Grant Awards Incorporating 1% Grant Funding Buffer	**$ 27,659,031**	**$ 171,833,700**	**$ 73,643,014**		**$ 273,135,745**
Announced Grant Awards					
	$ -	$ -	$ -		
	$ -	$ -	$ -		
Announced Grant Award Subtotal	**$ -**	**$ -**	**$ -**	$ -	**$ -**
Available Grant Funds as of September 1, 2021	**$ 27,659,031**	**$ 171,833,700**	**$ 73,643,014**		**$ 273,135,745**
Pending Grants-PIC Recommendations					
Recruitment Awards (12)	$ -	$ 38,000,000	$ -		
Pending Award Subtotal	**$ -**	**$ 38,000,000**	**$ -**		**$ 38,000,000**
Available Grant Funds as of November 19, 2021	**$ 27,659,031**	**$ 133,833,700**	**$ 73,643,014**		**$ 235,135,745**
1% Grant Funding Buffer	**$ -**	**$ 1,931,263**	**$ 827,684**		**$ 2,758,947**
Total Remaining Funds	**$ 27,659,031**	**$ 135,764,963**	**$ 74,470,698**		**$ 237,894,692**

Operating Budget Detail		
Indirect Administration	$	4,928,381
Grant Review & Award Operations	$	16,058,895
Subtotal, CPRIT Operating Costs	$	20,987,276
Cancer Registry Operating Cost Transfer	$	3,118,032
Total, Operating Costs		24,105,308

CPRIT MANAGEMENT DASHBOARD
FISCAL YEAR 2021

	SEPT	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	CUMULATIVE (ANNUAL)	CUMULATIVE (TO DATE)
ACCOUNTABILITY														
Announced Grant Awards			62			2			26			73	163	
New Grant Contracts Signed	13	33	6	5	10	4	2	6	0	1	7	9	96	
New Grant Contracts In Negotiation			12			5			15			21	53	
Grant Reimbursements Processed (#)	208	195	209	142	128	119	242	171	181	158	130	135	2018	
Grant Reimbursements Processed ($)	$ 24,277,590	$ 21,609,925	$ 11,437,454	$ 25,234,475	$ 14,976,404	$ 13,896,416	$ 21,383,991	$ 27,269,422	$ 13,590,778	$ 23,027,043	$ 13,846,005	$ 13,831,162	$ 224,380,666	
Revenue Sharing Payments Received	$ -	$ -	$ 44,809	$ -	$ -	$ 22,845	$ 100,000	$ 4,550	$ 27,439	$ 45,100	$ 17,153	$ 26,134	$ 288,031	$ 4,952,530
Grants Awarded (#)/ Applications Rec'd (#)	18%	18%	19%	18%	18%	18%	18%	18%	18%	18%	18%	18%		
Grantee Compliance Trainings	0	4	2	1	0	0	4	1	1	4	4	0	21	
Grantee Compliance Monitoring Visits	0	0	2	2	3	2	5	6	4	3	4	1	32	
Awards with Delinquent Reimbursement Submission (FSR)			14			2			2			1		
Awards with Delinquent Matching Funds Verification			0			3			2			3		
Awards with Delinquent Progress Report Submission			4			1			2			2		
MISSION														
Open RFAs	11	13	13	13	16	7	8	8	5	15	10	10		
Prevention Applications Received	0	12	0	0	0	22	0	0	0	0	0	0	34	903
Product Development Applications Received	0	0	0	0	36	0	0	0	0	0	0	13	49	610
Academic Research Applications Received	0	17	2	4	162	6	11	9	0	403	0	6	620	8,165
Help Desk Calls/Emails	85	123	72	94	225	124	139	137	235	106	143	152	1,635	
Number of Research Grants Announced (Annual)	0		52			2			21			62	137	
Recruited Scientists Contracted														246
Number of Product Development Grants Announced (Annual)			2			0			0			2	4	
Life Science Companies Recruited (in TX)													1	12
Number of Product Development Jobs Created & Maintained														738
Number of Prevention Grants Announced (Annual)			8			0			5			9	22	
Total Number of Education, Navigation and Training Services			177,077			132,058			174,101			133,208	616,444	
Total Number of Clinical Services			57,327			40,111			58,900			60,712	217,050	
Published Articles on CPRIT-Funded Projects (#)													1371	
Clinical Studies (#)														202
Number of Patent Applications													47	
Number of Patents Resulting from Research													27	
TRANSPARENCY														
Total Website Hits (Sessions)	8,582	8,651	10,366	6,975	9,422	6,775	9,172	8,372	11,413	8,484	8,841	11,848		
Total Unique Visitors to Website (Users)	6,409	6,646	8,474	5,351	6,762	5,601	7,130	6,326	8,392	6,608	7,084	8,864		

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	CPRIT ACTIVITIES UPDATE FOR AUGUST AND SEPTEMBER
DATE:	SEPTEMBER 30, 2021

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

Recent Milestones in the Fight Against Cancer

CPRIT Grantees in the News

- *U.S. News & World Report* Best Hospitals for Cancer ranked four Texas cancer centers among the top 25 cancer centers in the 2021-2022 rankings released July 27. The University of Texas MD Anderson Cancer Center retained its distinction as the No. 1 adult cancer hospital in the country. Houston Methodist Hospital (23), The University of Texas Southwestern Medical Center (24) and the Dan Duncan Comprehensive Cancer Center at Baylor St Luke's Medical Center (25) all ranked among the top 25 cancer centers for the first time. The rankings reflect patient outcomes measurements, patient satisfaction, the availability of advanced technologies, nursing quality, specialty-specific certifications, services for patients and their families and expert opinions of specialists in the field.

- Dr. Mamta Jain of The University of Texas Southwestern Medical Center discussed the sharp increases in hepatitis A and hepatitis C virus infections between 2015 – 2019, as well as the hepatitis A vaccine and treatment options for hepatitis C on fighting hepatitis on KERA radio in an interview that aired June 7. She also published an opinion piece about eliminating hepatitis C in the June 28 edition of the *Austin American Statesman* and an article "The Epidemic No One is Talking About" in the July issue of *D Magazine*. Dr. Jain is the director of the CPRIT project "Evidence-Based Hepatocellular Cancer Prevention through Targeted Hepatitis C Screening and Navigation" and its expansion (PP170121 and PP180091).

- Aravive, Inc. announced August 9 that it had dosed the first patient in a phase 1b/2 clinical trial of AVB-500 for the treatment of pancreatic adenocarcinoma. The company, based in Houston and Palo Alto, received a $20 million CPRIT Product Development Research award in 2015 to develop AVB-500.

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- In an August 12 announcement, the American College of Obstetrics and Gynecology recognized Abbey Berenson, M.D., Ph.D., of The University of Texas Medical Branch at Galveston as a 2021 Immunization Champion. The acknowledgement recognizes individuals that have demonstrated exceptional progress in increasing immunization rates among adults and pregnant women in their communities through leadership, innovation, collaboration, and educational activities. Dr. Berenson has received multiple CPRIT grants focusing on HPV vaccinations to promote collaborations among the UTMB Health System, the Department of Ob/Gyn, the Department of Pediatrics, and 12 Regional Maternal Child Health clinics, as well as external partners, The University of Texas-Rio Grande Valley and a hospital in the Valley. Dr. Berenson credits this award to her extraordinarily successful work on the CPRIT Prevention program projects.

- A drug funded by CPRIT, belzutifan, received FDA approval on August 13. Belzutifan will help patients with the rare cancer disorder known as von Hippel-Lindau disease. CPRIT provided $3.2 million to Dallas-based Peloton Therapeutics, Inc. (formerly Damascus Pharmaceuticals) in 2010 to fund early drug development of three small molecule drug programs sourced from leading investigators at The University of Texas Southwestern Medical Center. This is the first drug funded by CPRIT to receive FDA approval. Merck & Co., Inc. acquired Peloton in 2019.

- On September 2, the National Cancer Institute renewed the designation as a comprehensive cancer center for the Harold C. Simmons Comprehensive Cancer Center at The University of Texas Southwestern Medical Center for the next five years. Carlos Arteaga, M.D., leads the Harold C. Simmons Cancer Center. UT Southwestern recruited him from Vanderbilt in 2017 with a CPRIT Established Investigator recruitment award.

  There are 51 NCI designated comprehensive cancer centers. The comprehensive designation recognizes the centers' leadership in fighting cancer and includes them in a nationwide infrastructure that advances cancer discovery and patient care by integrating laboratory, clinical, and population-based research as well as community outreach, education, and training. The University of Texas MD Anderson Cancer Center and Baylor College of Medicine are also NCI-designated comprehensive cancer centers. The University of Texas Health Science Center at San Antonio is an NCI-designated cancer center.

- On September 13 KTSM News 9 featured Texas Tech University Health Sciences Center El Paso breast cancer (PP180003 and PP210004) and colorectal cancer (PP170068 and PP210005) screening projects. Dr. Jennifer Molokwu directed the CPRIT-funded projects.

- DNAtrix, Inc. appointed David Liebowitz, M.D., Ph.D., as Chief Medical Officer on September 14. The company, based in Houston and San Diego, received a $10.8 million CPRIT Product Development Research award in 2014 to develop an oncolytic adenovirus for the treatment of malignant glioma.

- On September 22, Salarius Pharmaceuticals, Inc. announced a research partnership with the Cancer Epigenetics Institute at Fox Chase Cancer Center. The Institute's director, Johnathan

Whetstine, Ph.D., will lead the research efforts to identify new indications and potential biomarkers for Salarius' lead drug candidate, seclidemstat. The Houston-based company received an $18.7 million CPRIT Product Development Research Award in 2014 to support their clinical trials of seclidemstat in Ewing sarcoma.

- The Howard Hughes Medical Institute (HHMI) named CPRIT Scholar Vincent Tagliabracci, Ph.D., a HHMI Investigator on September 23.

  Dr. Tagliabracci, Associate Professor of Molecular Biology at The University of Texas Southwestern Medical Center, will receive $9 million over seven years, which is renewable pending a scientific review by HHMI, a philanthropic organization created to advance basic biomedical research and science education for the benefit of humanity. According to UT Southwestern's President Daniel Podolsky, Dr. Tagliabracci has uncovered an unexpected and novel family of pseudokinases that alter protein form and function in a way that is categorically distinct from canonical kinases. His work shines a new light on a diverse array of physiological processes that rely on these enzymes.

  UT Southwestern recruited Dr. Tagliabracci to Texas from the University of California, San Diego in 2015 with a $2 million First-Time, Tenure-Track CPRIT recruitment grant award. UT Southwestern has 14 HHMI investigators, nine of which receive CPRIT research awards; the institution recruited three HHMI investigators to Texas with CPRIT recruitment grants.

- OncoNano Medicine, Inc. announced a multi-year collaboration with The University of Texas Southwestern Medical Center on September 23. The collaboration will conduct translational research on novel cancer therapeutics that leverage OncoNano's core nanotechnology platform. The Southlake-based company will sponsor UT Southwestern's Dr. Jinming Gao's research identifying new cancer therapies that benefit from OncoNano's ultra pH-sensitive polymeric micelles. The company has an exclusive option to license new technology arising from the research conducted under this agreement.

  OncoNano received two CPRIT Product Development Research awards to fund the development of ONM-100 for the detection of breast, head and neck, and skin cancers, including a $6 million award in 2014 and a $10 million award in 2020. In addition, the company received a $15.4 million CPRIT Product Development Research award in 2019 to develop a novel T-cell activating cancer vaccine for solid tumors.

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

- Houston-based ImmunoGenesis, Inc. reported positive preclinical glioblastoma and pancreatic cancer data for its STimulator of INterferon Genes (STING) agonist in the September 10 publication of *Clinical Cancer Research* and the August edition of the *Journal for ImmunoTherapy of Cancer*. The company received a $15.4 million CPRIT Product Development Research award in 2020 to develop a novel immunotherapy drug active across immune "hot" and "cold" cancers.

- A team of investigators led by C. Patrick Reynolds, M.D., Ph.D., director of the Texas Tech University Health Sciences Center School of Medicine Cancer Center, published findings in the August 18 edition of *Science Translational Medicine* showing that neuroblastoma develops resistance to chemotherapy by adopting an alternative lengthening of telomeres (ALT) mechanism to continue replicating. Telomeres are repetitive sequences of non-coding DNA at the end of a chromosome that protect the chromosome from damage.

  Using patient-derived cell lines, Dr. Reynolds' team determined that this telomere dysfunction promotes organic activation of an enzyme, ATM kinase, which, in turn, promotes resistance to chemotherapy. They found that a clinical-stage small-molecule inhibitor of the ATM kinase, under development by AstraZeneca, reversed chemotherapy resistance in patient-derived xenografts, suggesting a potential strategy to target ALT neuroblastoma chemoresistance. The findings are important because neuroblastoma patients with this phenotype do not respond well to treatment. Scientists also report the ALT mechanism in many other types of cancers; it is likely what makes those cancers resistant to chemotherapy.

  Dr. Reynolds explains that understanding how ALT works and how to target it will shape future clinical trials that may benefit patients with tumors that depend on the ALT mechanism. An individual investigator research award in childhood cancers (RP170510) supported Dr. Reynolds' research.

- A new discovery from researchers at The University of Texas MD Anderson Cancer Center clarifies the long-established connection between inflammation and pancreatic cancer development. The study led by Andrea Viale, M.D., Assistant Professor of Genomic Medicine, found that pancreatic cells display an adaptive response to repeated inflammatory episodes that initially protects against tissue damage but can promote tumor formation in the presence of mutant KRAS. In research published in the September 17 edition of the journal *Science*, Dr. Viale's team demonstrated that mutant KRAS, present in almost all pancreatic cancers, supports this adaptive response and leads to selective pressure to maintain the cancer-causing mutation. A CPRIT High Risk/High Impact Award (RP190599) funded Dr. Viale's research.

- Rice University chemist Han Xiao, Ph.D., and Baylor College of Medicine biologist Xiang Zhang, Ph.D., received a $2.3 million Department of Defense grant announced August 19. The award expands their efforts to halt bone cancer metastasis by coupling a molecule used to treat osteoporosis, alendronate, with the HER2-targeting antibody trastuzumab, which oncologists use to treat breast cancer. Their study, published in June 23 edition of *Science Advances*, showed the antibody conjugate they developed called "BonTarg" significantly enhances the concentration of trastuzumab at tumor sites. The new grant will allow the team to expand their study to a wider patient population. Rice recruited Dr. Xiao to Texas from Stanford University in 2017 with a $2 million First Time, Tenure-Track CPRIT Scholar award.

- Researchers from The University of Texas MD Anderson Cancer Center reported in the September 23 edition of *Cancer* that 127 breast cancer survivors participating in the "Active Living After Cancer" program between 2014 and 2017 markedly increased their physical ability and capacity to accomplish the basic activities of daily life. The evidence-based 12-week group program measured changes in participants' six minute walk and 30 second sit-to-stand test results as well as self-reported physical activity.

  The program is free to breast cancer survivors who had completed primary cancer treatment. Trained facilitators from community organizations lead the sessions following a 12-week curriculum developed by MD Anderson researchers that introduces a different low-impact exercise, cognitive/behavioral skill and survivorship resource each week. The program helps participants increase their physical activity at home, learn how to build healthier habits and cope with the challenges of survivorship. The MD Anderson research team focused on recruiting minority and medically underserved cancer survivors because these populations tend to exercise less and have less access to physical activity resources.

  Since 2017, Active Living After Cancer programs have expanded to include survivors of all cancer types and broadened to serve the El Paso, Beaumont and Tyler communities. Due to the COVID-19 pandemic, Active Living After Cancer programs meet virtually; more than 1,000 cancer survivors have completed the program.

  CPRIT supported the project with a $628,680 Evidence-Based Prevention Programs and Services grant (PP130079) awarded to Dr. Karen Basen-Engquist, Ph.D., M.P.H., a Professor of Behavioral Science and the Director of the Center for Energy Balance in Cancer Prevention and Survivorship at The University of Texas MD Anderson Cancer Center.

Personnel

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

The posting for the new director of communications closed September 24. We will conduct interviews in October and plan to fill the position by November. We posted the product development manager position September 17; CPRIT will accept applications until October 22.

CPRIT's Chief Due Diligence and Patent Officer Ken Smith, Ph.D., joined CPRIT September 1. Michelle Le Beau, Ph.D., will begin work as CPRIT's new Chief Scientific Officer on October 11. Dr. Willson has graciously agreed to remain on board with CPRIT through October to assist in the transition.

CPRIT Outreach

Staff outreach activities during August and September include:

- On August 25 I updated a representative of Baylor College of Medicine on CPRIT personnel and award schedules and exchanged legislative insights.

- Chief Product Development Officer Dr. Cindy WalkerPeach presented CPRIT Product Development Research funding opportunities and illustrated the importance of trainees to startups during the Gulf Coast Consortium's virtual event "Foundations of Cancer Therapeutics Crash Course" held August 26.

- Chief Prevention Officer Ramona Magid presented a CPRIT Prevention program update to the American Cancer Society's Texas Cancer Control Strategic Partnerships team on August 30. Many of these team members work closely with CPRIT Prevention grantees in Texas communities.

- On September 8 Dr. Willson spoke at the virtual event "Texas Legislative Briefing: The Promise of Precision Medicine and Biomarker Testing in Oncology." The American Cancer Society Cancer Action Network hosted the event, which several CPRIT staff members attended.

- I met with representatives of the Texas Foundation for Innovative Communities on September 13 to continue discussions about possible future research collaboration opportunities and other initiatives.

- Deputy Executive Officer and General Counsel Kristen Doyle and Chief Strategic Initiatives and Intellectual Property Officer Tracey Davies provided an overview of CPRIT and its product development program to the University of Houston Bauer College of Business Information Systems Project Management course on September 15.

- Ms. Magid attended the September 17 meeting of the Association of Community Cancer Centers' nationwide program, "3, 2, 1 Go! Practical Solutions for Addressing Cancer Care Disparities." Ms. Magid serves as an invited member of the Texas Society of Clinical Oncology committee that will focus on the Latino/Hispanic population. Arizona and Hawaii are also participating in this initiative. The states will develop and implement a community-based educational initiative that will identify and address disparities among groups specific to their population.

- Between September 20 and 25 I attended several video conferenced panels and keynotes during the Tribfest hosted by the *Texas Tribune*. Topics included state fiscal matters, upcoming legislative issues and election forecasts, higher education, and federal issues and politics.

- I updated Senator Jane Nelson on September 21 about CPRIT activities, personnel and prospects for legislative support after her retirement from the Texas Senate.

- On September 22 CPRIT Director of Cancer Research Dr. Patty Moore represented CPRIT at the State Agency Counsel's quarterly meeting.

- Ms. Magid provided a CPRIT Prevention program overview on September 27 to the UTHealth Center for Health Promotion & Prevention Research, Texas' only CDC Prevention Research Center.

2021 Legislative Session

The Third Called Session of the 87th Texas Legislature began September 20. No item on the governor's call affects CPRIT.

Compliance Program Update

Submission Status of Required Grant Recipient Reports

CPRIT has $1.4 billion in active grants under management, with 560+ grants that are either active or wrapping up grant activities. We receive an average of 560 grantee reports each month. As of September 23, two entities had not filed one Academic Research report and one Product Development Research 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 file the required reports.

Financial Status Report Reviews

CPRIT's compliance specialists performed 244 second-level reviews of grantee Financial Status Reports (FSRs) in August and September. Twenty-two FSRs (9%) needed resubmission due to insufficient or inaccurate documentation sent by the grantee. CPRIT's grant accounting staff completes the first review of the FSRs and supporting documentation before routing them to the compliance specialists for final review and disposition.

Single Audit Tracking

Compliance specialists track the submission of the grantees' independent audit reports and the resolution of issues named in these reports. A grantee who spends $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 supplied required audits. Grantees are unable to receive reimbursements or advances if they are delinquent in filing the required audit and corrective

action plan unless the grantee requests more time by the due date of the required audit and I approve the request.

Desk Reviews

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

Onsite Reviews

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

Match Expenditures Review

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

Product development grantees 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 the grantees' match expenditures for appropriateness and allowability and work with CPRIT's grant accountants and the grantee to address any deficiencies. Compliance staff performed three annual match expenditure reviews for three grantees in August and September. The total amount of match expenses reviewed by compliance staff for FY 2021 was $14,919,352.48. The total amount of match expenses reviewed by compliance staff for FY 2022 is currently $1,905,888.18.

Training and Support

CPRIT staff conducted two new Authorized Signing Official (ASO) training webinars in August and September for The University of Texas Health Center at Tyler and Texas A&M University - Corpus Christi. The trainings covered grant reporting requirements, administrative rule changes,

grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. Per Texas Administrative Code §703.22, CPRIT requires new ASOs to complete a compliance training program within 60 days of the change.

Academic Research Program Update

FY 2021 Recruitment Applications

Dr. Michelle Le Beau, in her role as CPRIT's new Chief Scientific Officer, will present the Scientific Research Council's (SRC) recruitment award recommendations to the Program Integration Committee (PIC) and the Oversight Committee in November.

Cycle 22.1 Mechanism	Received	Funds Requested	Proposed by SRC	Funds Proposed by SRC
Recruitment of Established Investigators	2	$12,000,000	2	$12,000,000
Recruitment of Rising Stars	3	$12,000,000	1	$4,000,000
Recruitment of First-Time, Tenure Track Faculty Members	5	$10,000,000	4	$8,000,000
TOTAL	**10**	**$34,000,000**	**7**	**$24,000,000**

Academic Research FY 2022 Review Cycle 1 (22.1)

CPRIT released the first five RFAs for FY 2022 grant awards on January 13. CPRIT received 403 applications for the 22.1 review cycle by the June 2 deadline. Peer review panels will meet virtually in October to evaluate the applications and make grant recommendations. Dr. Le Beau will present the SRC's recommendations to the PIC and the Oversight Committee in February 2022.

Cycle 22.1 Mechanism	Received	Funds Requested
Individual Investigator Research Awards	282	$285,494,299
Individual Investigator Research Awards for Cancer in Children and Adolescents	50	$67,884,165
Individual Investigator Research Awards for Clinical Translation	27	$52,079,326
Individual Investigator Research Awards for Computational Systems Biology of Cancer	21	$23,825,931
Individual Investigator Research Awards for Prevention and Early Detection	23	$44,112,406
TOTAL	**403**	**$473,396,127**

Product Development Research Program Update

Product Development Research FY 2022 Review Cycle 1 (22.1)

CPRIT released three Product Development Research RFAs on May 27 for the first review cycle of FY 2022. Dr. WalkerPeach and Ms. French hosted a webinar June 23, giving an overview of the Cycle 22.1 Product Development RFAs and tips for putting together a good application. The application portal opened June 24 – August 4 to receive applications. CPRIT received 13 proposals that the peer review panels evaluated September 28-29. CPRIT will invite three selected applicants to present their proposed projects to the entire peer review panel via Zoom in late October. Following the completion of peer review due diligence, Dr. WalkerPeach will present the Product Development Review Council's (PDRC) Cycle 22.1 award recommendations to the PIC and the Oversight Committee in February 2022.

Cycle 22.1 Mechanism	Applications	Funds Requested
Texas Company	4	$38,258,557
Relocation Company	3	$43,856,191
Seed Company	6	$17,712,522
TOTAL	**13**	**$99,827,270**

Product Development Research FY 2022 Cycle 2 (22.2)

CPRIT will release three product development RFAs in October for the second review cycle of FY 2022. Applications will be due in January 2022 and Dr. WalkerPeach will present the PDRC's grant recommendations for cycle 22.2 to the PIC and the Oversight Committee in August 2022.

Prevention Program Update

Prevention FY 2022 Review Cycle 1 (22.1)

CPRIT released four RFAs on May 7 for the first review cycle of FY 2022. CPRIT received 16 applications requesting $22.7 million by the September 1 deadline. Peer review panels will meet December 6 - 7 to discuss the applications. Ms. Magid will present the Prevention Review Council's (PRC) recommendations for Cycle 22.1 awards to the PIC and the Oversight Committee in February 2022.

Cycle 22.1 Mechanism	Applications	Funds Requested
Evidence-based Cancer Prevention Services	6	$ 5,654,148
Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations	8	$15,427,264
Tobacco Control and Lung Cancer Screening	1	$ 898,707
Prevention Program Assessment	1	$ 748,236
TOTAL	**16**	**$22,728,355**

- *Evidence-Based Cancer Prevention Services*
  Seeks projects that will deliver evidence-based cancer prevention and control clinical services. CPRIT will give priority to projects that propose to address CPRIT areas of emphasis and serve areas of the state not covered by current CPRIT funded projects.
  Award: Up to $1 million over 3 years.

- *Tobacco Control and Lung Cancer Screening*
  Seeks programs on tobacco prevention and cessation, as well as screening for early detection of lung cancer. Through release of this RFA, CPRIT's goal is to stimulate more programs across the state, thereby supplying greater access for underserved populations and reducing the incidence and mortality rates of tobacco-related cancers. This RFA promotes the delivery of evidence-based programming designed to significantly increase tobacco cessation among adults and/or prevent tobacco use by youth.
  New Award: Up to $1 million over 3 years.

- *Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations*
  Seeks to support coordination and expansion of evidence-based services to prevent cancer in underserved populations who do not have adequate access to cancer prevention interventions and health care, bringing together networks of public health and community partners to carry out programs tailored for their communities. Projects should name cancers that cause the most burden in the community and use evidence-based models shown to work in similar communities to prevent and control these cancers. Currently funded CPRIT projects should propose to expand their programs to include more types of prevention clinical services and/or an expansion of current clinical services into more counties. In either case, the expansion must include delivery of services to nonmetropolitan and medically underserved counties in the state.
  Initial Expansion Award: Up to $2 million over 3 years.
  Subsequent Expansion Award: Up to $2.5 million over 5 years.

- *Prevention Program Assessment*
  Seeks applications for one project to assess the progress of the CPRIT Prevention Program since 2010 and to develop an assessment plan for the next stage of the CPRIT Prevention Program. The evaluation will use a mixed-methods approach that combines quantitative and qualitative data to supply evidence of effectiveness and information about how organizations and populations implement and sustain CPRIT-related changes. CPRIT will use evaluation findings to improve program effectiveness and to inform decisions about future program development.
  Award: Up to $750,000 over 2 years.

<u>Prevention FY 2022 Review Cycle 2 (22.2)</u>

CPRIT will release three RFAs on October 19. Applications are due February 9, 2022. Peer review panels will meet by teleconference in April 2022. The PRC will meet in June 2022 to make award recommendations. Ms. Magid will present the PRC's recommendations to the PIC

and the Oversight Committee in August 2022. Note: The Dissemination mechanism is undergoing revision and CPRIT will not release a Dissemination RFA in the 22.2 cycle.

Advisory Committee Meetings

- The Advisory Committee on Childhood Cancer met August 23 and September 27.
- The Geographic Diversity Advisory Committee met September 15.

Operations, Audit and Finance Update

On September 20, the State Auditor's Office released *An Audit Report on Grants Management at the Cancer Prevention and Research Institute of Texas*. The conclusion of the audit is that CPRIT has processes and related controls in place to help ensure that it awards and monitors grants in accordance with state law, rules, and CPRIT policies and procedures. It also concluded that the controls are adequate to ensure that CPRIT follows its processes and procedures consistently. The single finding was that CPRIT needs to perform a needs assessment for each service contract, which is not related to any grant management processes or procedures.

Weaver, CPRIT's internal auditor, continued field work on the IT general computer controls audit, governance audit follow-up, business continuity planning advisory follow-up, and the records management (grantee compliance records) audit advisory. Weaver will finalize these audit reports by the November Oversight Committee meeting.

CPRIT released the request for proposal (RFP) for a conference planner on the Electronic State Business Daily website on September 16. Proposals are due by October 14. Once CPRIT selects a conference planner, staff will work with the planner to release an RFP for a conference venue for the preferred fall 2022 conference timeframe.

Upcoming Subcommittee Meetings

Listed below are the subcommittee meetings in advance of the November 18 Oversight Committee meeting. (Please note that CPRIT has changed the meeting date from November 17 to November 18 due to meeting room availability.) Unless pandemic developments dictate otherwise, the November 18 meeting will be an in-person meeting at the Texas Higher Education Coordinating Board in Austin.

Board Governance	November 4 at 10:00 a.m.
Audit	November 8 at 10:00 a.m.
Prevention	November 9 at 10:00 a.m.
Academic Research	November 10 at 10:00 a.m.
Product Development	November 10 at 1:00 p.m.

We will send instructions for signing onto the Zoom platform along with the subcommittee agenda and meeting materials one week prior to the meeting date. Please plan to join the subcommittee meeting a few minutes early so we can address any technology issues before the meeting start time.

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CPRIT has awarded **1,679** grants totaling **$2.855 billion**

- 258 prevention awards totaling $300.3 million
- 1,421 academic research and product development research awards totaling $2.555 billion

Of the $2.555 billion in academic research and product development research awards,

- 30.3% of the funding ($775.4 million) supports clinical research projects
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- 13.1% of the funding ($333.5 million) supports discovery stage research projects
- 3.5% of funding ($90.4 million) supports training programs.

CPRIT has 7 open Requests for Applications (RFAs)

- 3 Research Recruitment
- 4 Prevention

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS
FROM: WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT: CPRIT ACTIVITIES UPDATE FOR OCTOBER
DATE: NOVEMBER 1, 2021

Topics in this memo address the upcoming November 18 Oversight Committee meeting and CPRIT activities in October, including recent milestones in our fight against cancer, a staffing summary, outreach efforts, FY 2023 Program Priorities, and updates from Compliance, Programs, and Operations.

Planning for the November 18 Oversight Committee Meeting

The Oversight Committee will meet in person on Thursday, November 18 in the board room at the Texas Higher Education Coordinating Board, 1200 E. Anderson Lane. (Please note that CPRIT has changed the meeting date from November 17 to November 18 due to meeting room availability.) I would appreciate if you would notify me as soon as possible if you are unable to attend the November 18 meeting or have schedule constraints that require you to arrive at the meeting after 9:00 a.m. or leave prior to 11:30 a.m.

You will receive an email from CPRIT by November 6 with a link and password to access the Program Integration Committee's recruitment award recommendations via the grant award portal. The portal has a summary of the award slate, as well as supporting documentation for each proposed award, including the application, CEO affidavit, summary statement, and grant pedigree. Please allow some time to complete the individual conflict of interest checks and review the supporting material.

I have attached a draft meeting agenda. CPRIT will post the final agenda for the Oversight Committee meeting by November 10. Oversight Committee members will receive an electronic copy of the agenda packet by November 11. We will provide hard copies of the agenda and proposed award packets at the meeting.

Recent Milestones in the Fight Against Cancer

CPRIT Grantees in the News

- Dr. Jane Montealegre, director of Baylor College of Medicine's "Expanding a Community Network for Cancer Prevention to Increase HPV Vaccine Uptake and Tobacco Prevention in

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a Medically Underserved Pediatric Population" (PP190051), gave a Spanish-language interview with Univision and Harris Health System on the importance of vaccinating for HPV, which aired just before the school year began for students in Harris County.

- B.J. Fregly, Ph.D., CPRIT Established Investigator and Rice University professor of mechanical engineering and bioengineering, received a $2.4 million grant from the National Institute of Biomedical Imaging and Bioengineering on September 16. The four-year award supports development of open-source software for designing individualized treatments for movement impairments using computational modeling and simulation. The software makes it easy to create personalized computer models of individual patients and optimize treatment. The personalized models account for each patient's unique movement control, muscular and skeletal characteristics, while optimization makes it possible to identify better treatment solutions as opposed to clinical intuition. Clinical applications of the software include the design of custom-tailored neurorehabilitation protocols orthopedic surgery plans for childhood bone cancer as well as physical therapy interventions for osteoarthritis and stroke. Rice recruited Dr. Fregly to Texas from the University of Florida in 2017 with a $5.1 million Established Investigator recruitment award (RR170026).

- AlloVir, Inc. announced October 4 that the U.S. Food and Drug Administration has granted Orphan Drug Designation to posoleucel (Viralym-M, ALVR105) for the treatment of virus-associated hemorrhagic cystitis (HC). An inflammatory disease of the bladder, virus-associated HC is a serious complication of stem cell transplantation that prolongs hospital stays and increases mortality. There are currently no approved or effective antiviral treatment options. AlloVir, formerly known as ViraCyte, received a Product Development Research award (DP170043) in 2017 to test the safety and effectiveness of Viralym-M in adults and children with severe viral infection after a stem cell transplant.

- NIH announced October 5 that Jian Zhou, Ph.D., Assistant Professor at The University of Texas Southwestern Medical Center's Lyda Hill Department of Bioinformatics, received a highly competitive $1.5 million Director's award to investigate the three-dimensional structure of DNA and its impact on health. UT Southwestern recruited Dr. Zhou from the Flatiron Institute and Princeton University to Texas in 2019 with a CPRIT First Time Tenure Track faculty award (RR 190071.)

- On October 6 Dialectic Therapeutics, Inc. announced that clinicians had dosed the first patient in a first-in-human, dose escalation Phase 1 trial evaluating DT2216 in patients with relapsed or refractory solid tumor and hematologic malignancies. The Dallas-based company received two CPRIT Product Development Research awards to develop DT2216, including a $3 million Seed award in 2020 and a $14.4 million award in 2021.

- Hummingbird Bioscience, Inc. presented pre-clinical data on novel biomarkers for HER3-driven cancers at the AACR-NCI-EORTC 2021 Virtual International Conference on Molecular Targets and Cancer Therapeutics on October 7. The company, based in Houston and Woodlands, Singapore, received a $13.1 million CPRIT Product Development Research

award in 2019 to develop a first-in-class anti-VISTA monoclonal antibody for the treatment of MDSC-mediated suppression of anti-tumor immunity in solid tumors and lymphomas.

- Apollo Endosurgery, Inc. closed its previously announced underwritten public offering on October 15. Apollo sold 9,660,000 shares of its common stock, including 1,260,000 shares sold pursuant to the underwriters' exercise-in-full of their option to purchase additional shares, at a public offering price of $7.75/share. Gross proceeds totaled ~$75 million. Austin-based Apollo received a $5 million CPRIT Product Development Research award in 2010 (RP101216) to develop a flexible surgical device for the treatment of cancerous legions in the gastrointestinal tract.

- On October 18, the National Academy of Medicine elected two Texans as members, Helen Heslop, M.D., director of the Center for Cell and Gene Therapy and interim director of the Dan Duncan Comprehensive Cancer Center at Baylor College of Medicine and Anil Sood, M.D., professor of Gynecologic Oncology and Reproductive Medicine at The University of Texas MD Anderson Cancer Center. Election to the National Academy of Medicine is one of the highest honors in the fields of health and medicine and recognizes individuals who have demonstrated outstanding professional achievement and commitment to service. CPRIT grants have supported both physician scientists (RP110553 and RP110595.)

  The National Academy of Medicine recognized Dr. Heslop's work developing and conducting transplant studies and cell and gene therapy studies to improve hemopoietic stem cell transplantation and cancer therapy. Similarly, Dr. Sood's election recognizes his discovery of the basis for effects of chronic stress on cancer and identification of the mechanisms behind paraneoplastic thrombocytosis, as well as his research focused on improving the understanding of the mechanisms underlying ovarian cancer growth and progression, developing new biologically targeted therapies and the role of non-coding RNAs as biomarkers and for therapeutic applications.

- On October 19, The University of Texas Southwestern Medical Center announced its research partnership in a new $185 million National Institutes of Health initiative to build on findings of the Human Genome Project. NIH awarded a team of UT Southwestern faculty led by CPRIT Scholar Gary Hon, Ph.D., Assistant Professor in the Cecil H. and Ida Green Center for Reproductive Biology Sciences, a five-year, $8.8 million grant to participate in the National Human Genome Research Institute's Impact of Genomic Variation on Function (IGVF) Consortium. Dr. Hon created a genome engineering technique called Mosaic-seq, which helped UT Southwestern secure the NIH partnership. UT Southwestern recruited Dr. Hon to the Harold C. Simmons Cancer Center from the Ludwig Institute for Cancer Research in San Diego in 2014 with a $2 million First-Time, Tenure-Track recruitment award (RR140023).

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

- The University of Texas MD Anderson Cancer Center and the Rare Cancer Research Foundation launched a collaboration designed to accelerate development of new treatments

for rare cancers. The collaboration, announced September 30, enables patients to contribute tumor samples directly to MD Anderson for translational research efforts.

This initiative helps overcome a major obstacle - the lack of available samples - that prevents significant progress in rare cancer research. Rare cancers are those with fewer than 40,000 new cases diagnosed annually in the U.S. Taken together, rare cancers represent roughly 25% of all cancer cases and are the leading cause of cancer-related deaths.

The Rare Cancer Research Foundation will use its online engagement platform to allow patients to donate tumor biopsies and surgical samples for research purposes. With these samples, MD Anderson researchers will perform comprehensive analyses and work to develop laboratory models used to pursue new therapeutic strategies for rare cancers. Researchers can use the discoveries to design and launch clinical trials to evaluate these new strategies for patients in need. CPRIT Scholar Andy Futreal, Ph.D., Chair of Genomic Medicine at MD Anderson will lead the institution's research efforts. In 2011 MD Anderson recruited Dr. Futreal from the Wellcome Trust Sanger Institute to Texas with a CPRIT Established Investigator recruitment award (R1205.)

- OncoNano Medicine, Inc. announced October 8 positive results from its preclinical study of ONM-501, a novel dual-activating polyvalent STING agonist for immuno-oncology applications. The data, presented at The American Association for Cancer Research (AACR) Virtual Conference on Tumor Immunology and Immunotherapy, demonstrate strong efficacy in multiple tumor models.

  The Southlake-based company also announced results from a Phase 2 study of its lead clinical development candidate, pegsitacianine, on October 14 in a presentation at the 2021 World Molecular Imaging Congress (WMIC). The presentation by Dr. Jason Newman of the University of Pennsylvania Health System reported that the fluorescent nanoprobe pegsitacianine provided real-time surgical imaging in a tumor-agnostic manner for the accurate identification of malignant tissue in the operating room.

  OncoNano received two CPRIT Product Development Research awards to fund the development of ONM-100 to detect breast, head and neck, and skin cancers, including a $6 million award (DP140072) in 2014 and a $10 million award (DP200081) in 2020. The company also received a $15.4 million CPRIT Product Development Research award (DP190066) in 2019 to develop a novel T-cell activating cancer vaccine for solid tumors.

Personnel

CPRIT has filled 39 of our 44 full-time equivalent (FTE) positions.

- Michelle Le Beau, Ph.D. began as CPRIT's new Chief Scientific Officer on October 11.

- Mark Loeffler accepted the position of Communications Director. He has broad communications experience with the state and private sector, including high-level communications positions with the Department of Agriculture and the General Land Office. Mr. Loeffler will join CPRIT November 16.

CPRIT Outreach

Staff outreach activities during October include:

- Chief Strategic Initiatives and Intellectual Property Officer Tracey Davies was a panelist addressing CPRIT and investment opportunities in life science in Texas at the North Texas Bio conference in Dallas on September 30.

- Chief Product Development Officer Dr. Cindy WalkerPeach spoke on a panel at the Texas Healthcare & Bioscience Institute (THBI) virtual events *2021 Innovation Tour*: *Building the Texas Life Science Economy* on October 7 (Austin) and October 14 (Houston). Dr. WalkerPeach highlighted regional assets and challenges association with early-stage cancer-focused companies and CPRIT funding opportunities.

- Several CPRIT staff attended the American Cancer Society Cancer Action Network (ACS CAN) "Texas Policy Forum Series: The Future of Cancer Care" on October 13.

- Ms. Davies spoke about CPRIT's programs at the Texas Economic Development Conference held in Fort Worth on October 13.

- Dr. WalkerPeach and Senior Program Manager for Product Development Rosemary French attended an information session "Device Product Realization Hub" hosted by Bio El Paso-Juarez on October 13.

- On October 19 I participated on a THBI videoconference panel highlighting the El Paso life science industry. Other panelists included State Representative Mary González, Jackie Butler from Bio El Paso-Juarez, Emma Schwartz from Medical Center of the Americas, and Tom Kowalski of THBI.

- Deputy Executive Director and General Counsel Kristen Doyle, Dr. Jim Willson, Chief Scientific Officer Dr. Michelle Le Beau, CPRIT Academic Research Director Dr. Patty Moore, and I met with Dr. Larry Peterson of the Texas Foundation for Innovative Communities on October 21 to discuss possible future research opportunities.

- Chief Prevention Officer Ramona Magid attended the three-day virtual Healthier Texas Summit October 27 - 29. The event provides a forum for health champions to learn alongside thought leaders at a national, state, and local level about emerging insights to transform health and health equity in Texas.

- Dr. WalkerPeach, Ms. French, and Ms. Davies attended the TMCi Accelerator for Cancer Therapeutics Summit on October 28 in Houston. Dr. WalkerPeach spoke at the event, which was an opportunity to meet the 2022 accelerator cohort and network with possible applicants.

- On October 29, Oversight Committee member Dee Margo and I participated in a public celebration of The University of Texas at El Paso receiving one of the initial Texas Regional Excellence in Cancer awards on the UTEP campus

- On November 1, Ms. Doyle and I met with Joel Williams regarding potential collaboration opportunities for pediatric cancer research funding.

- On November 3 Chief Due Diligence and Patent Officer Dr. Ken Smith, Ms. Doyle and Ms. Davies will tour the newly opened Pegasus Park, a state-of-the-art redevelopment in Dallas designed to accelerate life science and healthcare discoveries and boost nonprofit resiliency. In addition to touring the campus with executives from the American Cancer Society and its BrightEdge fund, they will discuss issues related to the Texas biotech ecosystem.

- Ms. Davies, Ms. Doyle, and Dr. Smith will visit the TMC^3 campus in Houston on November 4 and meet with executives from TMC^3's venture partners to discuss CPRIT.

- Dr. WalkerPeach and Ms. French will attend an event at JLabs in Houston on November 4.

- Dr. Moore will speak at the National Council of University Research Administrators (NCURA) Region V Conference on November 8 in Fort Worth.

2021 Legislative Session

The Third Called Session of the 87th Texas Legislature adjourned early October 19. No item on the governor's call affected CPRIT.

FY 2023 Program Priorities

The three program subcommittees will discuss program priorities for FY 2023 in their upcoming subcommittee meetings in preparation for the Oversight Committee's vote to adopt the priorities at the November 18 meeting.

Compliance Program Update

<u>Submission Status of Required Grant Recipient Reports</u>

CPRIT has $1.4 billion in active grants under management, with 560+ grants that are either active or wrapping up grant activities. We receive an average of 560 grantee reports each month.

As of October 25, three entities had not filed four Academic Research reports. CPRIT's grant accountants and compliance specialists review and process incoming reports and reach out to grantees to resolve filing issues. In most cases, CPRIT does not disburse grant funds until the grantee files the required reports. In some instances, grantee institutions may be ineligible to receive a future award if the grantee does not file the required reports.

Financial Status Report Reviews

CPRIT's compliance specialists performed 114 second-level reviews of grantee Financial Status Reports (FSRs) in October. Eight FSRs (7%) needed resubmission due to insufficient or inaccurate documentation sent by the grantee. CPRIT's grant accounting staff completes the first review of the FSRs and supporting documentation before routing them to the compliance specialists for final review and disposition.

Single Audit Tracking

Compliance specialists track the submission of the grantees' independent audit reports and the resolution of issues named in these reports. A grantee who spends $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 supplied required audits. Grantees are unable to receive reimbursements or advances if they are delinquent in filing the required audit and corrective action plan unless the grantee requests more time by the due date of the required audit and I approve the request.

Desk Reviews

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

Onsite Reviews

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

Match Expenditures Review

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

Product development grantees plus those academic research grantees whose indirect cost rate credit does not fully offset the required match must supply a detailed match expenditure report that includes the amount and date paid, vendor, description, and budget category. Compliance staff review the 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 grantee reviews in October totaling $1,644,204.19.

Training and Support

CPRIT staff conducted a series of Annual Compliance Training webinars on October 6-7 for 250 grantee staff. Trainings are specific to each program area (Academic Research, Product Development Research, and Prevention) and allow for an interactive experience and opportunity to focus on topics relevant to each program. The trainings covered grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. This was the third training series offered this year for the annual compliance training requirement which requires the Authorized Signing Official and at least one other employee from each grantee organization to attend an annual compliance training by December 31 of each year.

Academic Research Program Update

FY 2022 Recruitment Applications

CPRIT's Chief Scientific Officer Dr. Michelle Le Beau will present the Scientific Research Council's (SRC) recruitment award recommendations to the Program Integration Committee (PIC) and the Oversight Committee in November.

Cycle 22.1-22.3 Mechanisms	Received	Funds Requested	Proposed by SRC	Funds Proposed
Recruitment of Established Investigators	4	$24,000,000	2	$12,000,000
Recruitment of Rising Stars	6	$24,000,000	3	$12,000,000
Recruitment of First-Time, Tenure Track Faculty Members	11	$22,000,000	7	$14,000,000
TOTAL	**21**	**$70,000,000**	**12**	**$38,000,000**

Academic Research FY 2022 Review Cycle 1 (22.1)

CPRIT released the first five RFAs for FY 2022 grant awards on January 13. CPRIT received 403 applications for the 22.1 review cycle by the June 2 deadline. Peer review panels met virtually in October to evaluate the applications and make grant recommendations. Dr. Le Beau will present the SRC's recommendations to the PIC and the Oversight Committee in February 2022.

Cycle 22.1 Mechanism	Received	Funds Requested
Individual Investigator Research Awards	282	$285,494,299
Individual Investigator Research Awards for Cancer in Children and Adolescents	50	$67,884,165
Individual Investigator Research Awards for Clinical Translation	27	$52,079,326
Individual Investigator Research Awards for Computational Systems Biology of Cancer	21	$23,825,931
Individual Investigator Research Awards for Prevention and Early Detection	23	$44,112,406
TOTAL	**403**	**$473,396,127**

Academic Research FY 2022 Review Cycle 2 (22.2)

CPRIT released the four RFAs listed below for the second cycle of FY 2022 on August 30. The application portal opened October 13 and will accept proposals through January 12, 2022. Peer review panels will meet in late Spring 2022. Dr. Le Beau will present the SRC's recommendations to the PIC and the Oversight Committee in August 2022.

- *Core Facility Support Awards (CFSA)*
  Seeks applications to establish or enhance core facilities (laboratory, clinical, population-based, or computer-based) that will directly support cancer research programs to advance knowledge of the causes, prevention, and/or treatment of cancer or improve quality of life for patients with and survivors of cancer.
  Award: Up to $4,000,000 over 5 years

- *Clinical Trial Network Award (CTNA)*
  Seeks applications from Lead Institutions (LI) to develop and oversee a network of two cancer care facilities to extend access to a select group of LI cancer clinical trials. Once the LI establishes an initial network in the first stage of the project, it will be eligible to receive additional CPRIT funding in the second stage of the project to expand its network to two additional facilities located outside the LI current catchment area.
  Award: Up to $600,000 annually (stage 1); up to $900,000 annually (stage 2) over 4 years

- *Early Clinical Investigator Award (ECI)*
  Seeks applications to provide cancer physicians early in their academic career the opportunity to develop clinical research skills and to gain experience in advanced methods and experimental approaches needed to become clinical investigators; to provide an

opportunity to establish a partnership with a laboratory-based collaborator in order to design and conduct correlative studies needed to interpret the outcome of an interventional trial; to provide the protected time from clinical responsibilities required to develop and conduct investigator initiated clinical trials; and to increase the pool of clinical investigators at Texas academic institutions who are conducting patient-oriented studies, capitalizing on basic discoveries and translating them through the conduct of innovative clinical trials involving cancer patients or individuals at risk for cancer.
Award: Up to $1,5000,000 over 5 years

- *High Impact/High Risk Research Awards (HIHR)*
  Seeks applications to explore the feasibility of high-risk projects that, if successful, would contribute major new insights into the etiology, diagnosis, treatment, or prevention of cancers.
  Award: Up to $250,000 over 2 years

Product Development Research Program Update

Product Development Research FY 2022 Review Cycle 1 (22.1)

CPRIT released three Product Development Research RFAs on May 27 for the first review cycle of FY 2022. Dr. WalkerPeach and Ms. French hosted a webinar June 23, giving an overview of the Cycle 22.1 Product Development RFAs and tips for putting together a good application. The application portal opened June 24 – August 4 to receive applications. CPRIT received 13 proposals that the peer review panels evaluated September 28-29. The review panels selected three applicants to present their proposed projects to the entire peer review panel via Zoom on October 25 and 27. Following the presentations, the review panels decided that two companies will proceed to due diligence review by the Product Development Review Council (PDRC). Chief Product Development Officer Dr. WalkerPeach will present the PDRC's Cycle 22.1 award recommendations to the PIC and the Oversight Committee in February 2022.

Cycle 22.1 Mechanism	Applications	Funds Requested	Presenting	Funds Requested	Due Diligence	Funds Requested
Texas Company	4	$38,258,557	1	$17,404,980	0	N/A
Relocation Company	3	$43,856,191	0	N/A	0	N/A
Seed Company	6	$17,712,522	2	$5,998,261	2	$5,998,261
TOTAL	**13**	**$99,827,270**	**3**	**$23,403,241**	**2**	**$5,998,261**

Product Development Research FY 2022 Cycle 2 (22.2)

CPRIT will release three product development RFAs in October for the second review cycle of FY 2022. Applicants may submit proposals beginning December 1, 2021, through January 26,

2022. Dr. WalkerPeach will present the PDRC's grant recommendations for cycle 22.2 to the PIC and the Oversight Committee in August 2022.

Prevention Program Update

Prevention FY 2022 Review Cycle 1 (22.1)

CPRIT released four RFAs on May 7 for the first review cycle of FY 2022. CPRIT received 16 applications requesting $22.7 million by the September 1 deadline. Peer review panels will meet December 6 - 7 to discuss the applications. Chief Prevention Officer Ramona Magid will present the Prevention Review Council's (PRC) recommendations for Cycle 22.1 awards to the PIC and the Oversight Committee in February 2022.

Cycle 22.1 Mechanism	Applications	Funds Requested
Evidence-based Cancer Prevention Services	6	$ 5,654,148
Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations	8	$15,427,264
Tobacco Control and Lung Cancer Screening	1	$ 898,707
Prevention Program Assessment	1	$ 748,236
TOTAL	**16**	**$22,728,355**

Prevention FY 2022 Review Cycle 2 (22.2)

The Prevention Program released three RFAs on October 19. CPRIT will open the application portal November 15 to receive proposals through the February 9, 2022, deadline. Peer review panels will meet by teleconference in April 2022. The PRC will meet in June 2022 to finalize recommendations. Ms. Magid will present the PRC's recommendations to the PIC and the Oversight Committee in August 2022. (NOTE: CPRIT is currently revising the Dissemination RFA and will not release that RFA in the 22.2 cycle.)

- *Evidence-Based Cancer Prevention Services*
  Seeks projects that will deliver evidence-based cancer prevention and control clinical services. CPRIT will give priority to projects that propose to address CPRIT areas of emphasis and serve areas of the state not covered by current CPRIT funded projects.
  Award: Up to $1 million over 3 years.

- *Tobacco Control and Lung Cancer Screening*
  Seeks programs on tobacco prevention and cessation, as well as screening for early detection of lung cancer. Through release of this RFA, CPRIT's goal is to stimulate more programs across the state, thereby supplying greater access for underserved populations and reducing the incidence and mortality rates of tobacco-related cancers. This RFA promotes the delivery of evidence-based programming designed to significantly increase tobacco cessation among adults and/or prevent tobacco use by youth.
  New Award: Up to $1 million over 3 years.

- *Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations*
  Seeks to support coordination and expansion of evidence-based services to prevent cancer in underserved populations who do not have adequate access to cancer prevention interventions and health care, bringing together networks of public health and community partners to carry out programs tailored for their communities. Projects should name cancers that cause the most burden in the community and use evidence-based models shown to work in similar communities to prevent and control these cancers. Currently funded CPRIT projects should propose to expand their programs to include more types of prevention clinical services and/or an expansion of current clinical services into more counties. In either case, the expansion must include delivery of services to nonmetropolitan and medically underserved counties in the state.
  Initial Expansion Award: Up to $2 million over 3 years.
  Subsequent Expansion Award: Up to $2.5 million over 5 years.

Advisory Committee Meetings

- The Advisory Committee on Childhood Cancer met October 25.

- The Prevention Advisory Committee will meet November 1.

Operations, Audit and Finance Update

Merck notified CPRIT on October 28 that they will be sending quarterly royalty payments from the sale of WELIREG™ pursuant to CPRIT's contract with Peloton. The royalty distribution due to CPRIT is $2,442.37 based on sales of more than $1.6 million during calendar quarter ending September 30, 2021. The company recorded first sales of the product in the last week of August.

Weaver, CPRIT's internal auditor, is finalizing reports over the IT general computer controls audit and business continuity planning advisory follow-up. They will present the audit reports at the November Oversight Committee meeting.

CPRIT is evaluating the proposals submitted in response to the request for proposals (RFP) for a conference planner. Ms. McConnell anticipates that CPRIT will select the conference planning vendor by the next Oversight Committee meeting. Once CPRIT selects the conference planner, staff will work with the planner to release an RFP for a conference venue for the preferred fall 2022 conference timeframe.

Upcoming Subcommittee Meetings

Listed below are the subcommittee meetings in advance of the November 18 Oversight Committee meeting.

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- 3 Research Recruitment
- 4 Academic Research
- 3 Prevention

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	VINCE BURGESS, CHIEF COMPLIANCE OFFICER
SUBJECT:	COMPLIANCE PROGRAM UPDATE
DATE:	NOVEMBER 8, 2021

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

Submission Status of Required Grant Recipient Reports

CPRIT has $1.4 billion in active grants under management, with 560+ grants that are either active or wrapping up grant activities. We receive an average of 560 grantee reports each month. As of October 29, three entities had not filed four Academic Research reports. CPRIT's grant accountants and compliance specialists review and process incoming reports and reach out to grantees to resolve filing issues. In most cases, CPRIT does not disburse grant funds until the grantee files the required reports. In some instances, grantee institutions may be ineligible to receive a future award if the grantee does not submit the required reports.

Financial Status Report Reviews

CPRIT's compliance specialists performed 450 second-level reviews of grantee Financial Status Reports (FSRs) in August, September, and October. Forty-one FSRs (9%) needed resubmission due to insufficient or inaccurate documentation sent by the grantee. CPRIT's grant accounting staff completes the first review of the FSRs and supporting documentation before routing them to the compliance specialists for final review and disposition.

Single Audit Tracking

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

Desk Reviews

Compliance specialists performed 13 enhanced desk-based financial monitoring reviews in August, September, and October. Enhanced desk reviews verify that grantees spend funds in compliance with specific grant requirements and guidelines and may target an organization's internal controls, current and past fiscal audits, and timeliness of required grantee report submission. Compliance specialists are working with one grantee to remediate enhanced desk review findings.

Onsite Reviews

CPRIT completed five virtual onsite reviews in August, September, and October. Onsite reviews examine 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 single audit compliance. Compliance specialists are working with two grantees to remediate onsite review findings.

Match Expenditures Review

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

Product development grantees 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 annual match expenditure reviews for six grantees in August, September, and October totaling $5,694,374.55.

Training and Support

CPRIT staff conducted two new Authorized Signing Official (ASO) training webinars in August and September: The University of Texas Health Center at Tyler, and Texas A&M University - Corpus Christi. 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.

CPRIT staff conducted a series of Annual Compliance Training webinars on October 6-7 for 250 grantee staff. Trainings are specific to each program area (Academic Research, Product Development Research, and Prevention) and allow for an interactive experience and opportunity to focus on topics relevant to each program. The trainings covered grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. This was the second training series offered this year for the annual compliance training requirement which requires the Authorized Signing Official (ASO) and at least one other employee from each grantee organization to attend an annual compliance training by December 31 of each year.

Grantee Risk Assessment and FY22 Monitoring Plan

CPRIT's compliance staff finalized the FY22 Grantee Risk Assessment and Monitoring Plan (Attachment A). Risk Assessments are performed on a quarterly and annual basis. The Risk Assessment Model considers several factors in determining grantee risk including:

- Financial exposure,
- Entity maturity, and
- Prior experience administering grants.

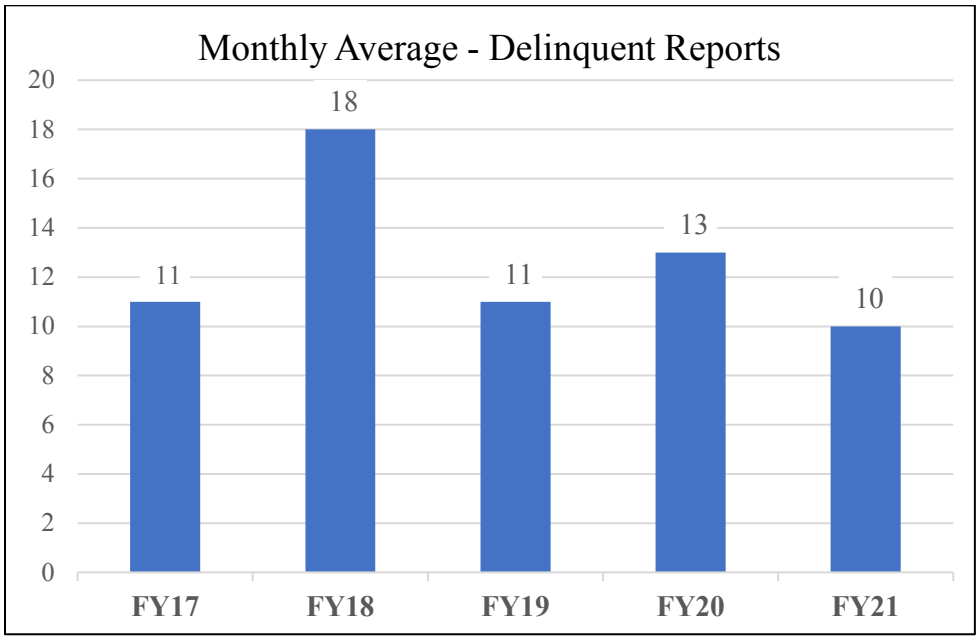
Risk Assessments assign a priority ranking (1, 2, or 3) to grant recipients, which is used to determine monitoring and training needs for the coming fiscal year. Based on the results of the Risk Assessment, grantees will receive a desk review, or an onsite monitoring review completed by CPRIT staff. Compliance monitoring reviews are designed to evaluate a grantee's

compliance with grant requirements included in the Texas Administrative Code, Texas Health and Safety Code, CPRIT Policies and Procedures, Uniform Grant Management Standards, and terms of the grant contract.

FY21 Compliance Program Activities Summary

CPRIT's Compliance Program functions are designed to actively support the integrity and transparency of CPRIT's agency processes. FY21 Compliance Program highlights include:

- Grant Recipient Report Monitoring – CPRIT receives approximately 560 required grantee reports each month. The number of delinquent reports in FY21 decreased slightly from FY20, to an average of 10 reports per month. CPRIT staff meets weekly to review and discuss delinquent reporting and actively work with grantees to submit required reports timely. The average number of delinquent reports for the past five fiscal years are represented in the chart below:

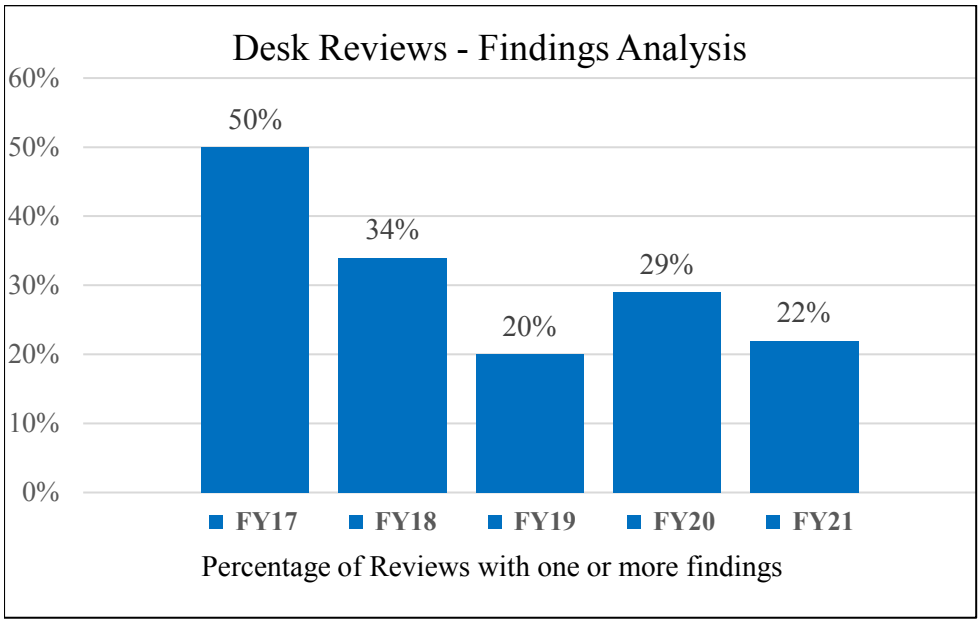


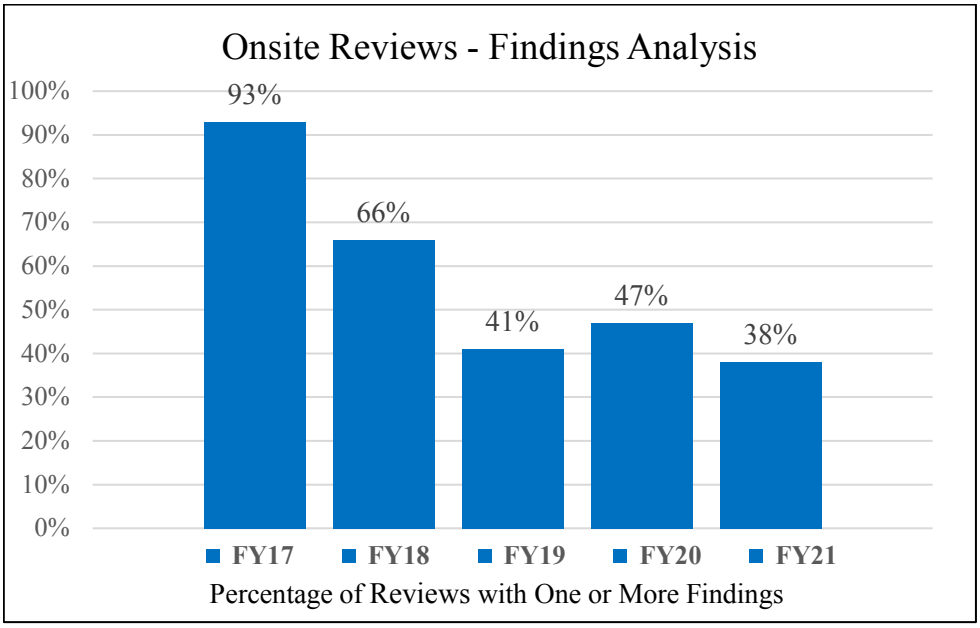
- Training and Education – In FY21, CPRIT staff provided 22 grantee trainings including annual compliance trainings, new grantee trainings, and trainings for new Authorized Signing Officials (ASOs). Over 660 grantee staff attended these training opportunities provided to our active grantees.

- Annual Compliance Attestation – The compliance team reviewed and processed 49 attestations submitted by grantees. The comprehensive Attestation Form outlines statutory and administrative grant requirements, grant contract terms, and Uniform Grant Management Standards/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.

- Compliance Monitoring Reviews (Enhanced Desk and Onsite) – The compliance team performed 92 compliance reviews (60 enhanced desk reviews, 32 onsite reviews) in FY21. Findings analyses are represented in the charts below:





- Second-level Reviews of Financial Status Reports (FSRs) – The compliance team performed a second-level review of over 2,200 FSRs in FY21. FSRs are grantee

expenditure reports that detail how project costs from the previous quarter were incurred. CPRIT's grant accounting staff completes the initial review of the FSRs and supporting documentation before routing them to the compliance specialists for final review and disposition.

- Single Audit Reviews – The compliance team reviewed 37 audits and agreed upon procedures (AUP) reports and actively worked with one grantee to remediate audit findings. Grantees who expend $750,000 or more in state awards in the grantee's fiscal year must submit a single independent audit, a program specific audit, or an agreed upon procedures engagement. The grantee submits 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.

- Match Expenditure Reviews – Compliance staff reviewed grantees' match expenditures for appropriateness and allowability and worked with CPRIT's grant accountants and the grantee to address any deficiencies. Compliance staff completed annual match expenditures reviews for 17 grantees totaling $15 million in FY 2021.

ATTACHMENT A

FY22 Grantee Risk Assessment Rankings

Grant Recipient	Priority Ranking
Baylor College of Medicine	Priority 3
Baylor University	Priority 3
Rice University	Priority 3
Texas A&M Engineering Experiment Station	Priority 3
Texas A&M University	Priority 3
Texas A&M University Health Science Center Institute of Biosciences and Technology	Priority 3
Texas AgriLife Research	Priority 3
Texas Medical Center Foundation	Priority 3
Texas Southern University	Priority 3
Texas State University	Priority 3
Texas Tech University	Priority 3
Texas Tech University Health Sciences Center	Priority 3
Texas Tech University Health Sciences Center at El Paso	Priority 3
The University of Texas at Arlington	Priority 3
The University of Texas at Austin	Priority 3
The University of Texas at Dallas	Priority 3
The University of Texas at San Antonio	Priority 3
The University of Texas Health Center at Tyler	Priority 3
The University of Texas Health Science Center at Houston	Priority 3
The University of Texas Health Science Center at San Antonio	Priority 3
The University of Texas M. D. Anderson Cancer Center	Priority 3
The University of Texas Medical Branch at Galveston	Priority 3
The University of Texas Southwestern Medical Center	Priority 3
University of Houston	Priority 3
University of North Texas Health Science Center at Fort Worth	Priority 3
Centro San Vicente	Priority 2
Legacy Community Health Services	Priority 2
Light and Salt Association	Priority 2
Texas A&M University - Corpus Christi	Priority 2
Texas A&M University System Health Science Center	Priority 2
The Rose	Priority 2
University Health System	Priority 2
Allterum Therapeutics, LLC	Priority 1
ANOVAC, INC.	Priority 1
Asylia Therapeutics	Priority 1
Barricade Therapeutics, Corp.	Priority 1
Curtana Pharmaceuticals, Inc.	Priority 1
Dialectic Therapeutics, Inc.	Priority 1
Hummingbird Bioscience, Incorporated	Priority 1
Immatics US Inc.	Priority 1
Immunogenesis, Inc.	Priority 1
Instapath Inc.	Priority 1
Invectys USA Inc	Priority 1
Iterion Therapeutics Inc	Priority 1
Magnolia Tejas Corporation	Priority 1
Molecular Templates, Inc.	Priority 1
OncoNano Medicine	Priority 1
Pelican Therapeutics	Priority 1
Perimeter Medical Imaging Corp	Priority 1
Rapamycin Holdings Inc.	Priority 1
Salarius Pharmaceuticals, Inc.	Priority 1
The Methodist Hospital Research Institute	Priority 1

CANCER PREVENTION & RESEARCH
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MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	MICHELLE LE BEAU, PH.D., CHIEF SCIENTIFIC OFFICER
SUBJECT:	ACADEMIC RESEARCH PROGRAM UPDATE
DATE:	NOVEMBER 18, 2021

Proposed Academic Research RFAs for Fiscal Year 2023 Cycle 1 (23.1) – Action Item

The Academic Research Program proposes the following RFAs for FY23.1:

- **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 in total costs per year for up to 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.

- **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 in total costs per year for up to 4 years. Applicants that plan on conducting a clinical trial as part of the project may request up to $500,000 in total costs.

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- **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 $500,000 per year in total costs per year for up to 4 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 in total costs per year for up to 4 years.

FY 2023 Program Priorities – Action Item

The Oversight Committee Academic Research Program Subcommittee met November 10, 2021 and recommends to the Oversight Committee approval of the FY 2023 Academic Research Program priorities.

Established Principles:

- Scientific excellence and impact on cancer
- Increasing the life sciences infrastructure
- Achieving health equity

The proposed program priorities for academic research include:

- Recruitment of outstanding cancer researchers to Texas
- Investment in core facilities
- A broad range of innovative, investigator-initiated research projects
- Implementation research to accelerate the adoption and deployment of evidence-based prevention and screening interventions.
- Computational biology and analytic methods
- Childhood cancers
- Hepatocellular cancer
- Expand access to innovative clinical trials

FY 2022 Cycle 1 (22.1) RFA Submission data and review status

Table 1 displays the number of applications submitted by mechanism for the 22.1 RFAs. CPRITs Application Receipt System (CARS) opened for 22.1 applications on March 3, 2021 and closed on June 2, 2021. Virtual Peer Review was conducted in October. Dr. Le Beau will present the Scientific Review Council's recommendations to PIC and the Oversight Committee in February 2022.

Table 1: FY2022 Cycle 1 (22.1) Submission Data and requested funding

RFA Mechanism	# Applications Submitted	Requested Funding
Individual Investigator Research Awards (IIRA)	282	$285,494,299
Individual Investigator Research Awards for Cancer in Children and Adolescents (IIRACCA)	50	$67,884,165
Individual Investigator Research Awards for Clinical Translation (IIRACT)	27	$52,079,326
Individual Investigator Research Awards for Computational Systems Biology of Cancer (IIRACSBC)	21	$23,825,931
Individual Investigator Research Awards for Prevention and Early Detection (IIRAP)	23	$44,112,406
Total	**403**	**$473,396,127**

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: RAMONA MAGID, CHIEF PREVENTION OFFICER

SUBJECT: PREVENTION PROGRAM UPDATE

DATE: NOVEMBER 10, 2021

FY 2022 Cycle 1 (22.1) Prevention Applications

CPRIT released four (4) RFAs in August for the first grant cycle of FY 2022. Sixteen (16) applications were received by the October 5 deadline. The sixteen applications requesting $22,728,355 will undergo peer review, scheduled for December 6, 2021. Ms. Magid will present the PIC recommendations to the Oversight Committee in February 2022.

Mechanism	Apps Received	Funds Requested
Evidence-based Cancer Prevention Services	6	$ 5,654,148
Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations	8	$15,427,264
Tobacco Control and Lung Cancer Screening	1	$ 898,707
Prevention Program Assessment	1	$ 748,236
TOTAL	**16**	**$22,728,355**

FY 2022 Cycle 2 (22.2) Prevention RFAs

CPRIT released three (3) RFAs on October 19 for the second cycle of FY 2022. Applications are due on February 9, 2022, peer review is scheduled for April 2022, and presentation of the PIC recommendations to the Oversight Committee in August 2022.

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RFA Descriptions

Evidence-Based Cancer Prevention Services

Evidence-Based Cancer Prevention Services - This award mechanism seeks to fund projects that will deliver evidence-based cancer prevention and control clinical services. Priority will be given to projects that propose to address CPRIT areas of emphasis and serve areas of the state not well addressed by current CPRIT funded projects.

Award: Maximum of $1M; Maximum duration of 36 months.

Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations

This award mechanism seeks to support the coordination and expansion of evidence-based services to prevent cancer in underserved populations who do not have adequate access to cancer prevention interventions and health care, bringing together networks of public health and community partners to carry out programs tailored for their communities. Projects should identify cancers that cause the most burden in the community and use evidence-based models shown to work in similar communities to prevent and control these cancers. Currently funded CPRIT projects should propose to expand their programs to include additional types of prevention clinical services and/or an expansion of current clinical services into additional counties. For projects requesting a maintenance expansion, expansion of clinical services or geographic area is optional; however, the number of clinical services delivered should be substantially increased.

Initial Expansion Award: Maximum of $2M; Maximum duration of 36 months.
Maintenance Expansion Award: Maximum of $2.5M; Maximum duration of 60 months.

Tobacco Control and Lung Cancer Screening

This award mechanism seeks to fund programs on tobacco prevention and cessation, as well as screening for early detection of lung cancer. Through release of this RFA, CPRIT's goal is to stimulate more programs across the state, thereby providing greater access for underserved populations and reducing the incidence and mortality rates of tobacco-related cancers. This RFA seeks to promote and deliver evidence-based programming designed to significantly increase tobacco cessation among adults and/or prevent tobacco use by youth.

Award: Maximum of $1M for new projects and $2M for expansion projects; Maximum duration of 36 months.

Prevention Program Assessment

This award mechanism solicits applications for one project to assess the initial progress of the CPRIT Prevention Program since 2010 and to develop an assessment plan for the next stage of the CPRIT Prevention Program. The evaluation will use a mixed-methods approach, which combines quantitative and qualitative data to provide evidence of effectiveness and information about how CPRIT-related changes are embedded and sustained in organizations and populations. Evaluation findings will be used to improve program effectiveness and to inform decisions about future program development.

Award: Maximum of $750,000; Maximum duration of 24 months.

FY 2023 Program Priorities

The Oversight Committee Prevention Subcommittee met November 9 and recommends to the Oversight Committee approval of the FY 2023 Prevention Program priorities.

FY 2023 Prevention Program Priorities
Populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence
Geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence
Underserved populations
Program assessment to identify best practices, use as a quality improvement tool and guide future program direction

Geographic Coverage – Historical Maps

CPRIT Prevention projects have been implemented across the state of Texas; since 2015, each of the 254 counties has been covered by at least one project. The maps illustrate the cumulative Prevention projects from FY 2010 through FY 2021 in each county, ranging from 1 project to 57 projects (Harris County).

Other Activities

Ramona attended the virtual Healthier Texas Summit, hosted by It's Time Texas and the University of Texas at Austin on October 27-29. CPRIT partnered with It's Time Texas to promote the annual summit.

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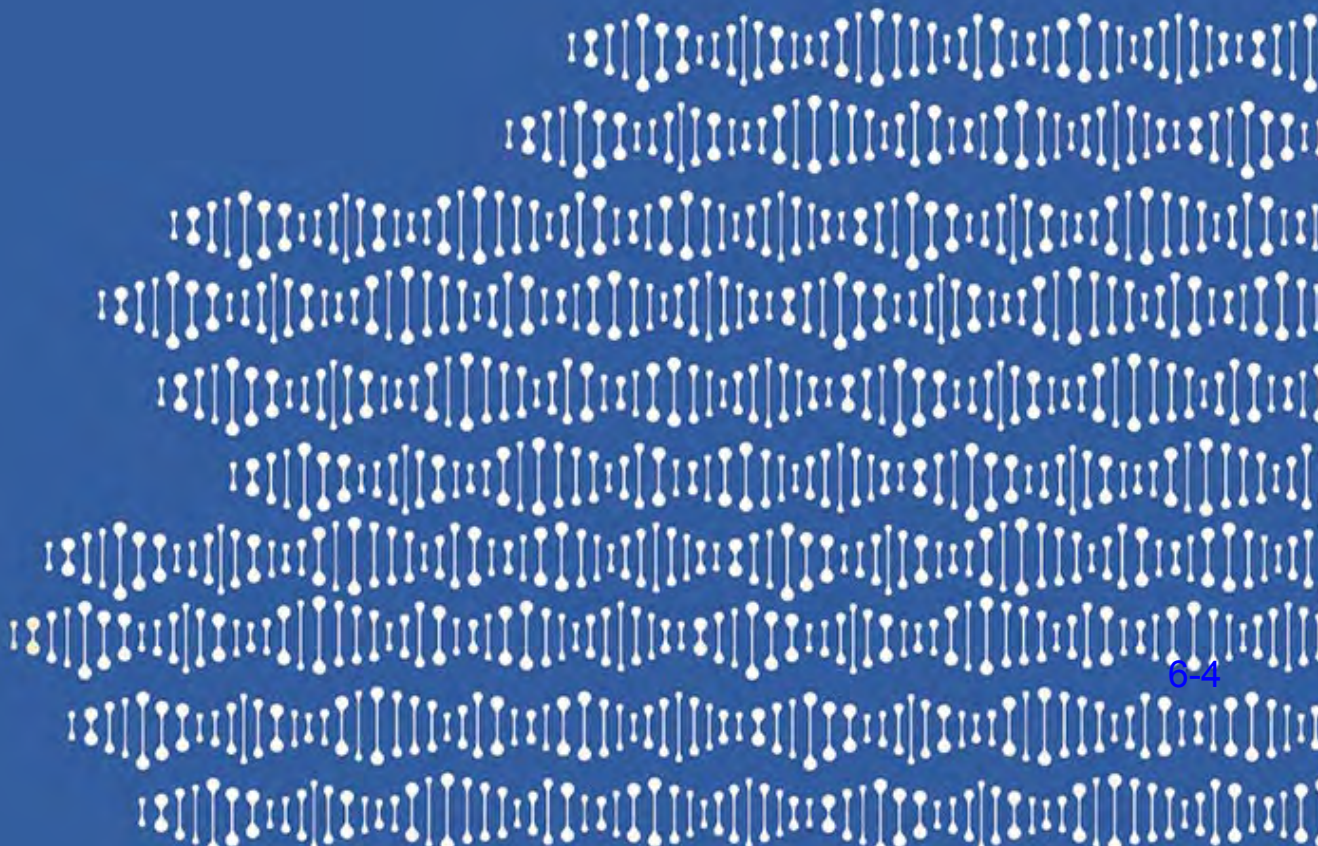
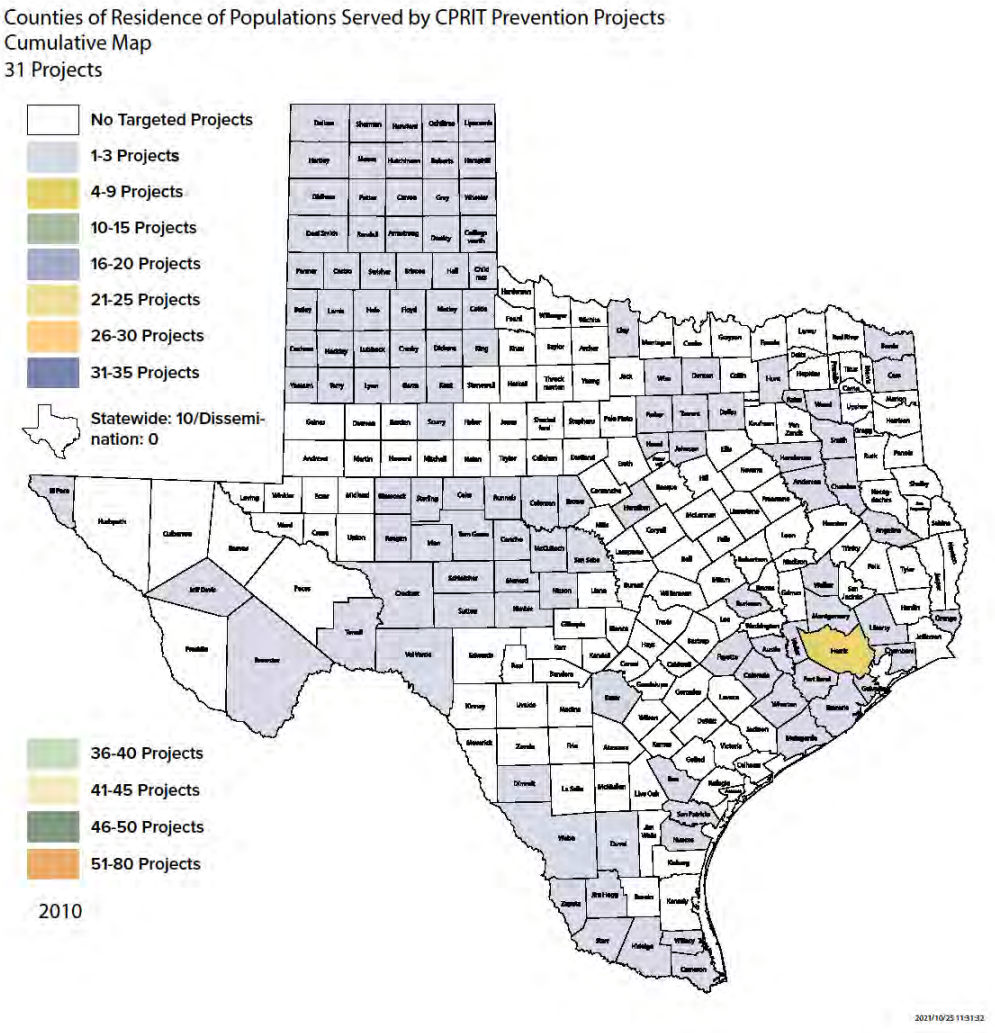
CPRIT Prevention Program Geographic Coverage

FY2010 - FY2021



FY2010 Geographic Coverage – 31 Projects



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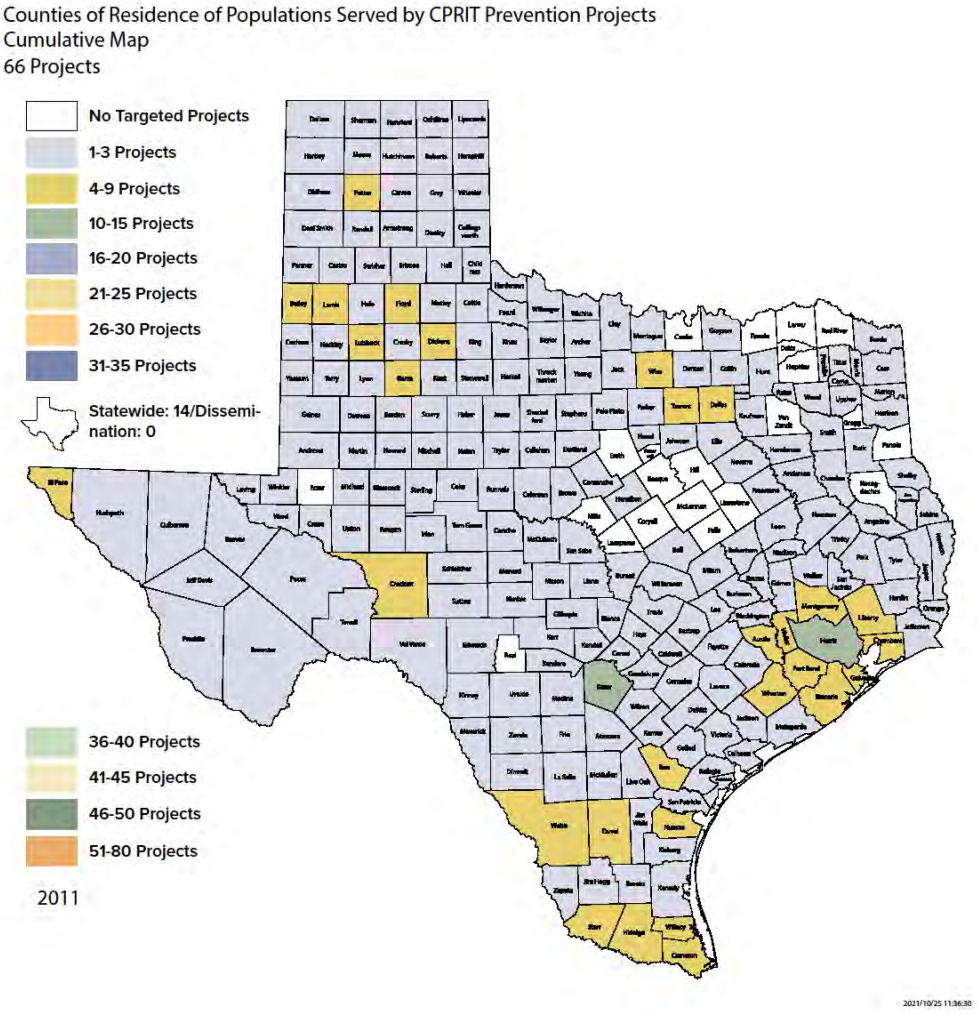
FY2011 Geographic Coverage – 66 Projects



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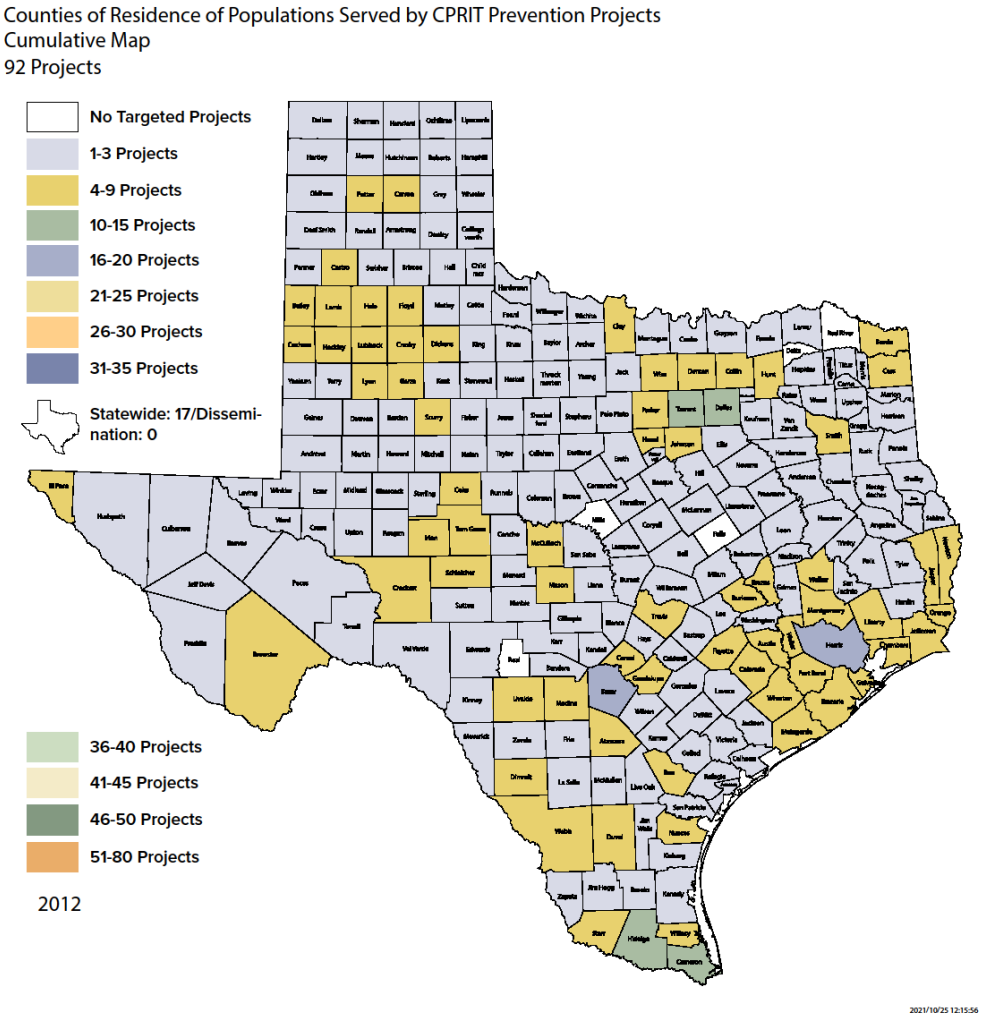
FY2012 Geographic Coverage – 92 Projects



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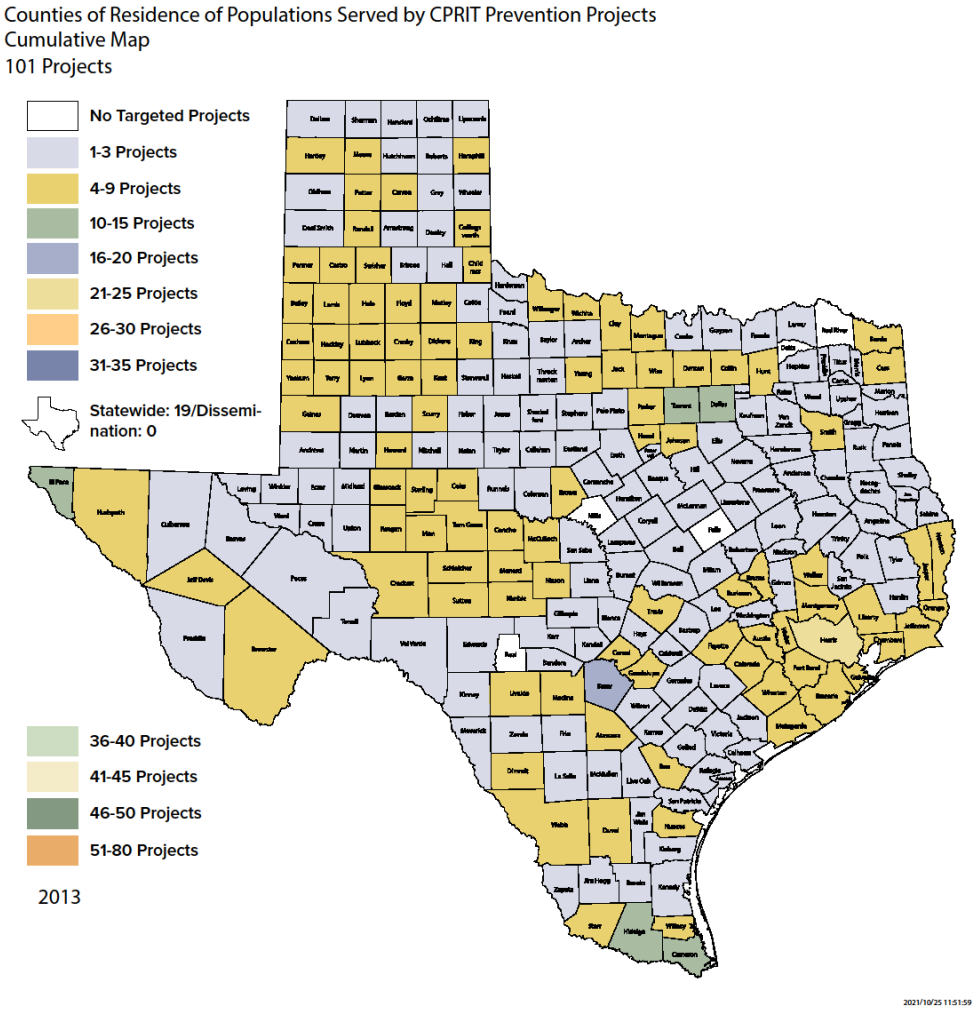
FY2013 Geographic Coverage – 101 Projects



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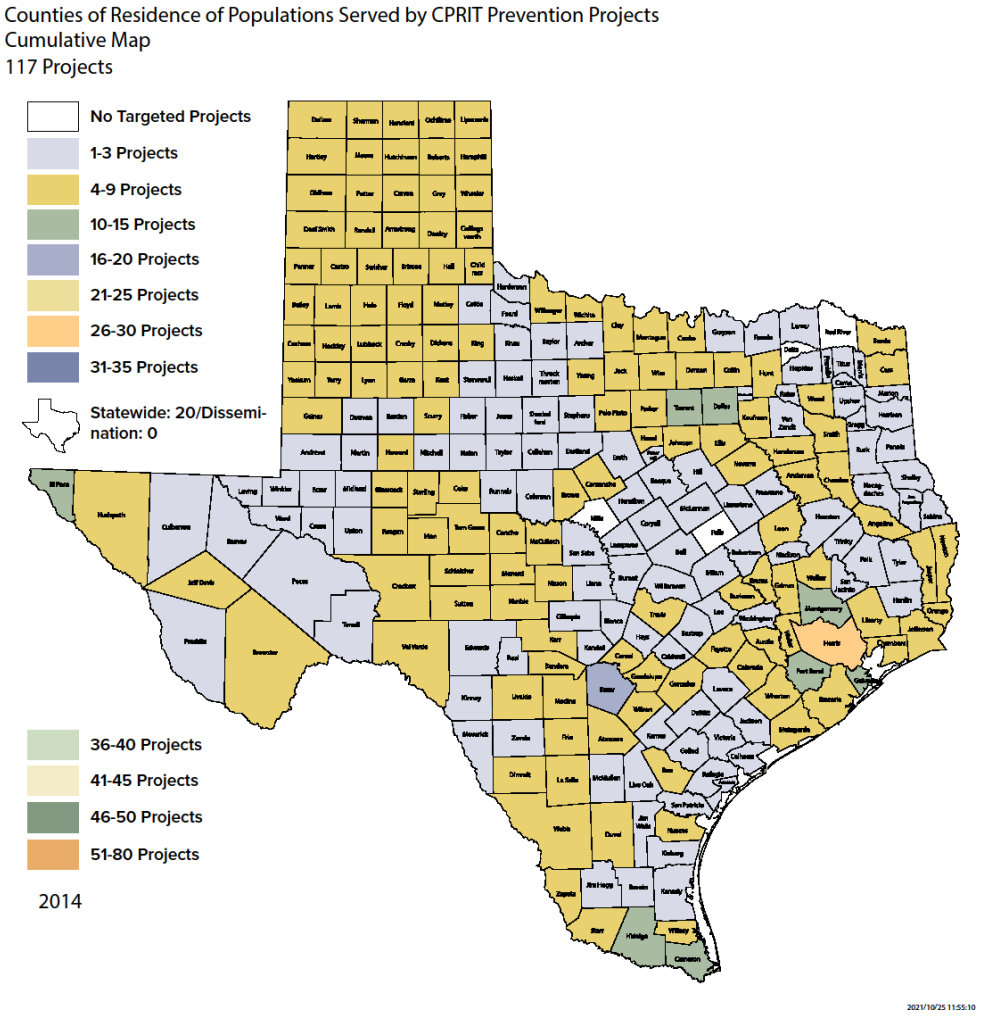
FY2014 Geographic Coverage – 117 Projects



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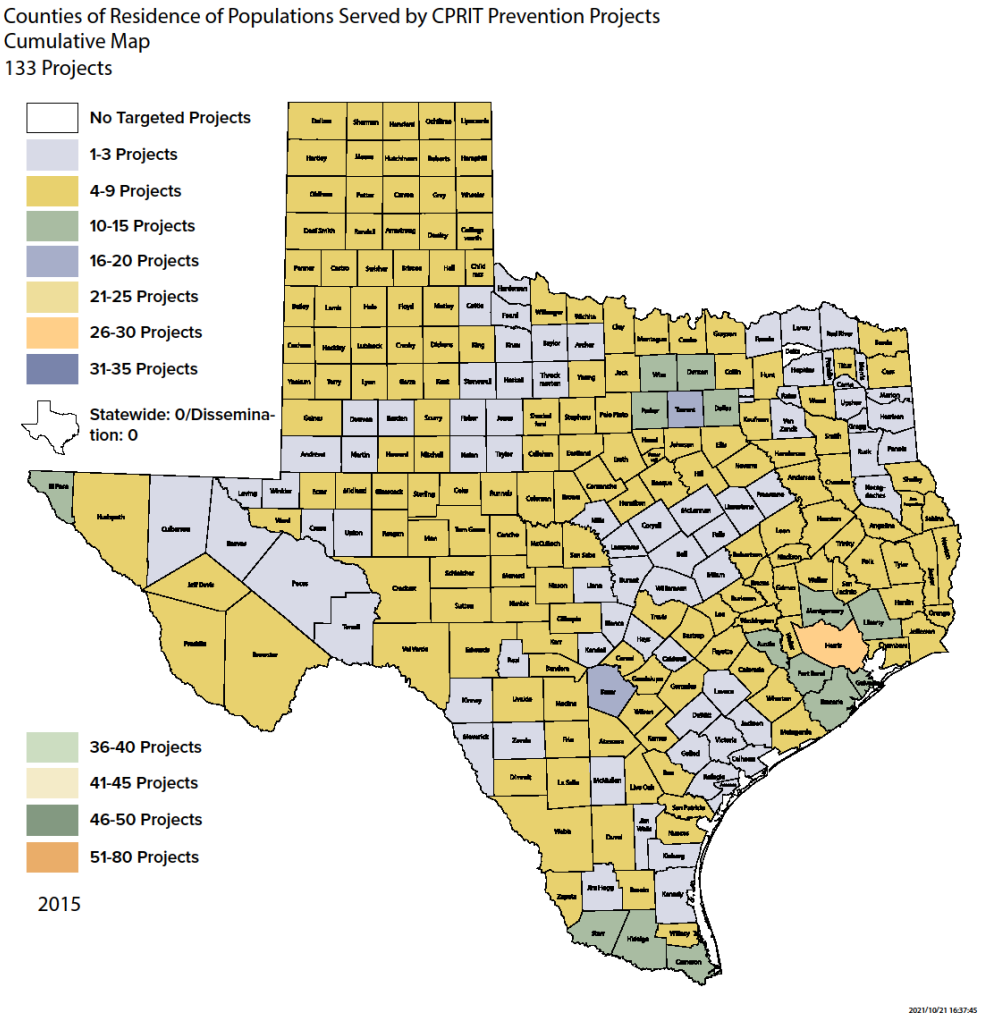
FY2015 Geographic Coverage – 133 Projects



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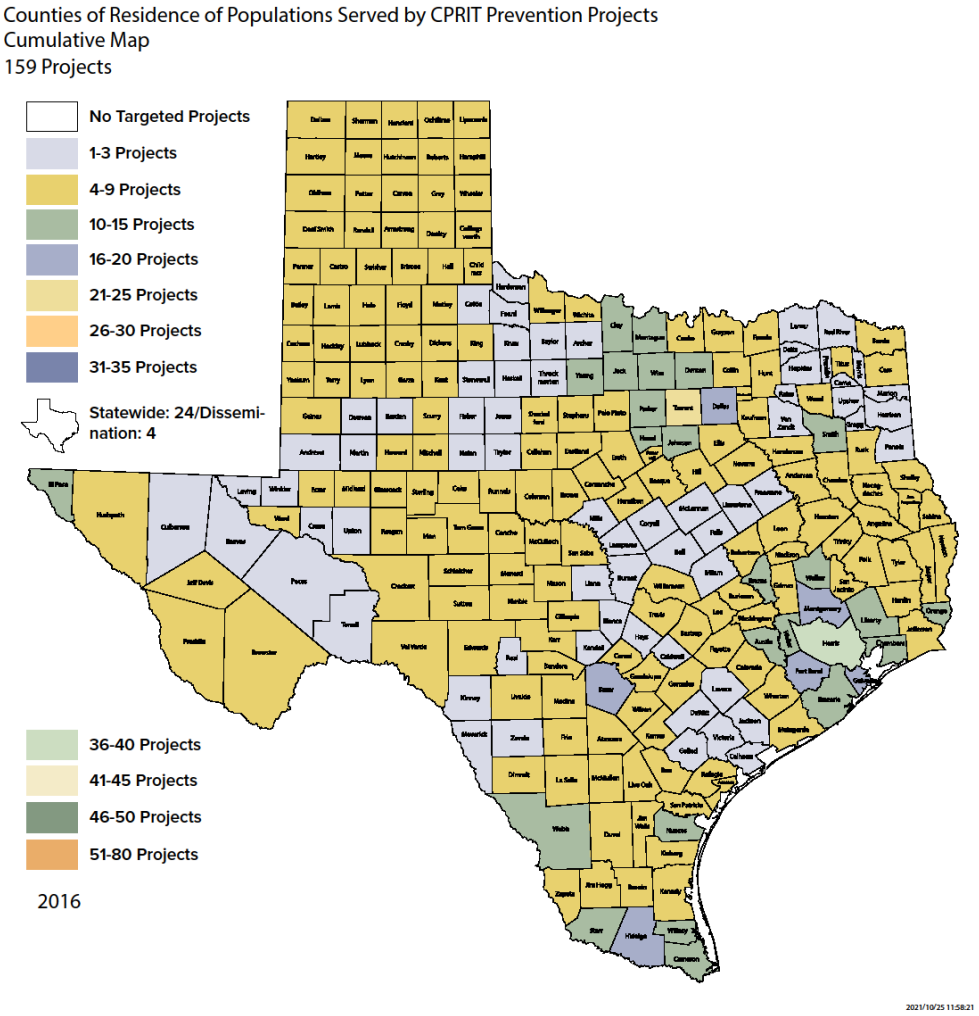
FY2016 Geographic Coverage – 159 Projects



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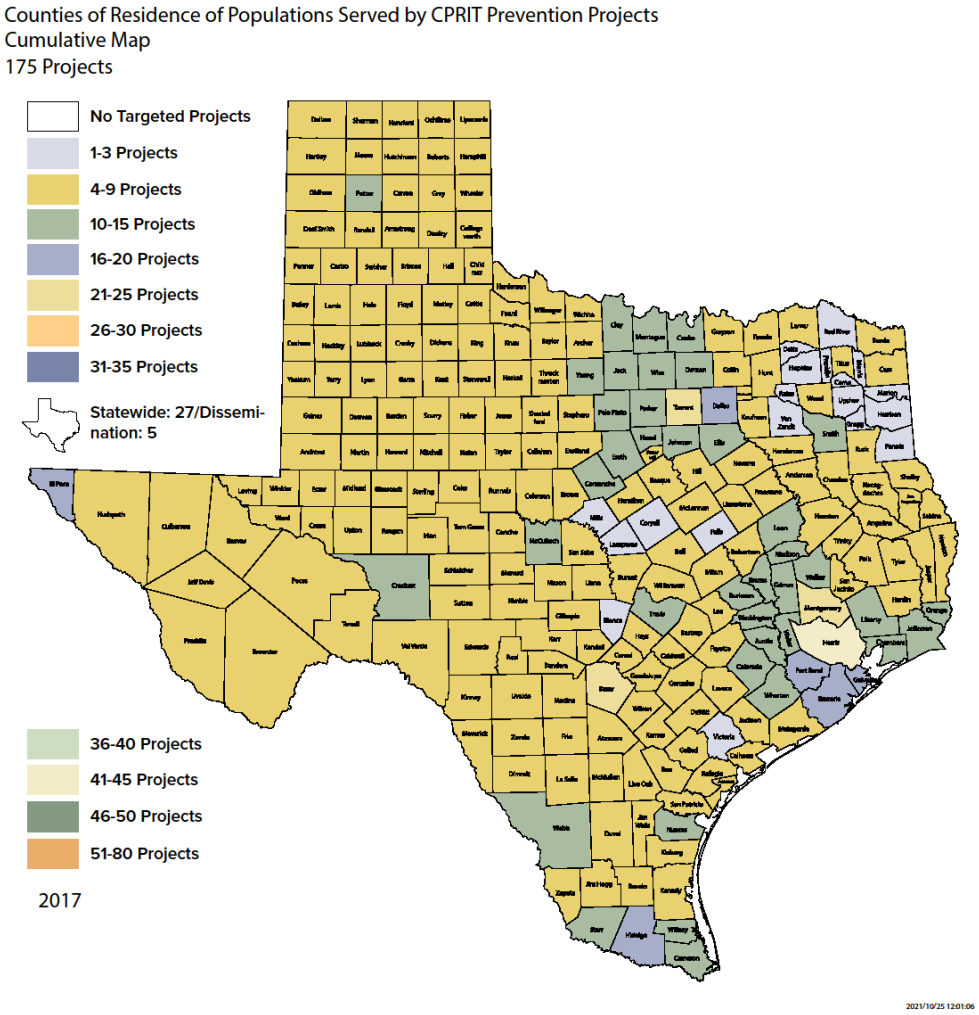
FY2017 Geographic Coverage – 175 Projects



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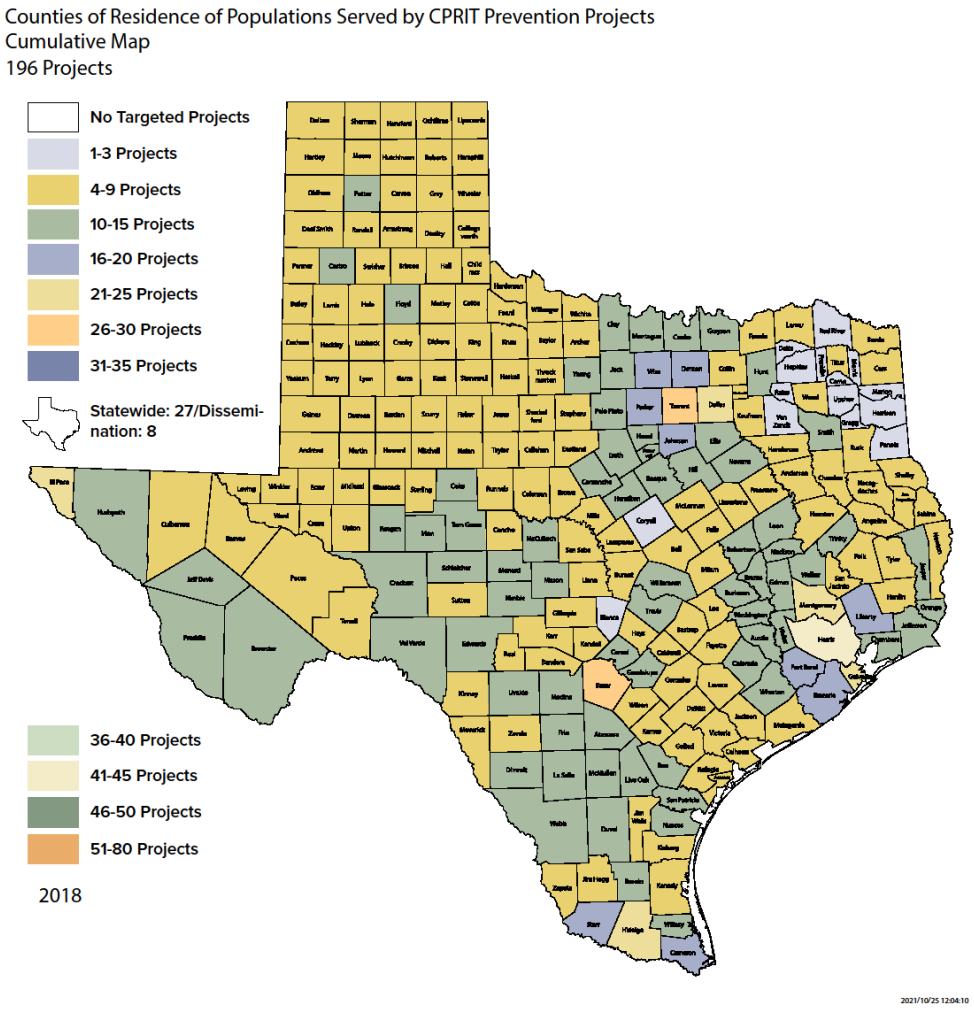
FY2018 Geographic Coverage – 196 Cumulative Projects



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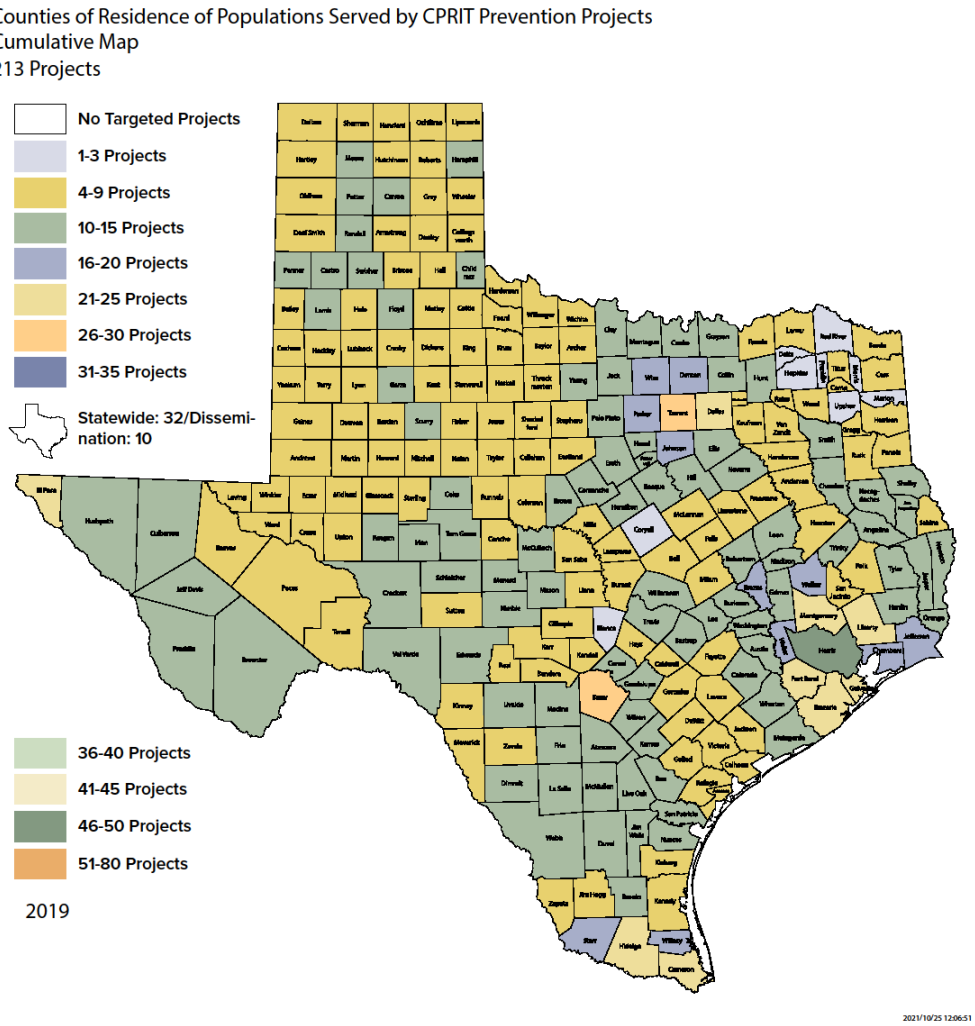
FY2019 Geographic Coverage – 213 Cumulative Projects



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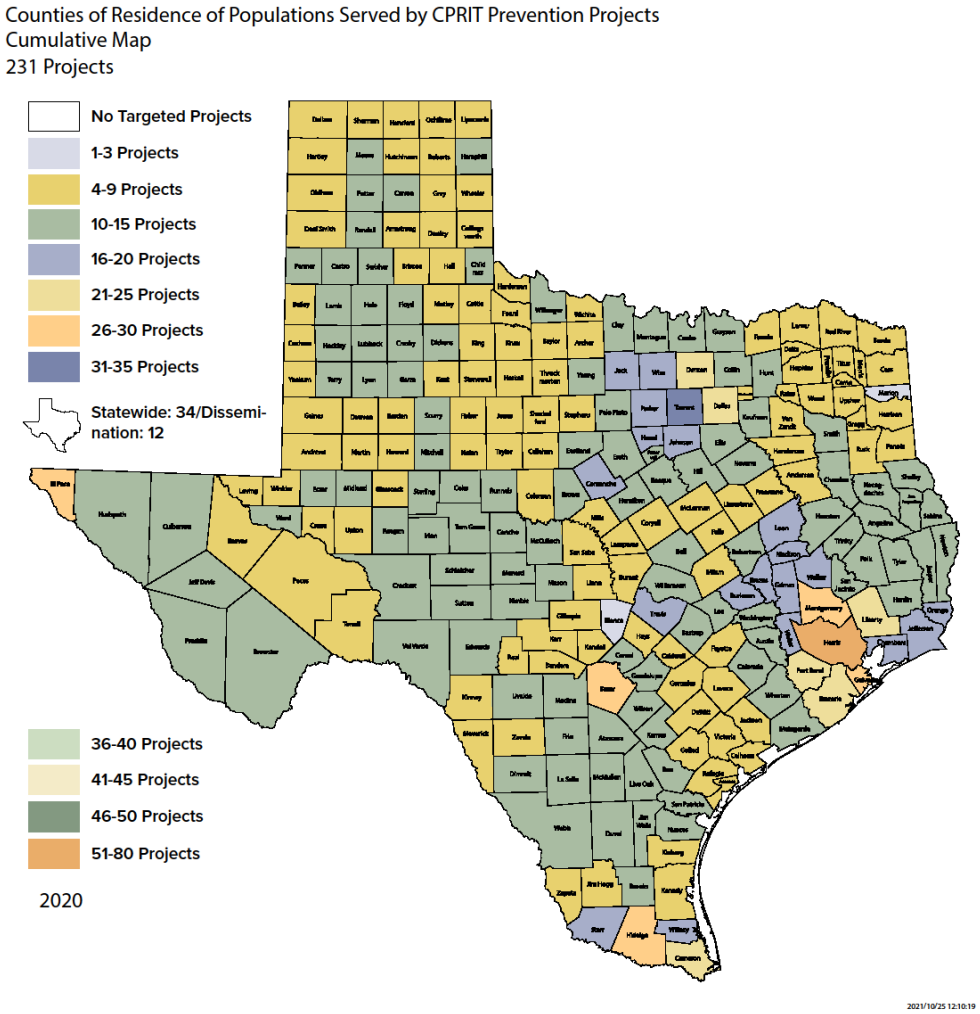
FY2020 Geographic Coverage – 231 Cumulative Projects



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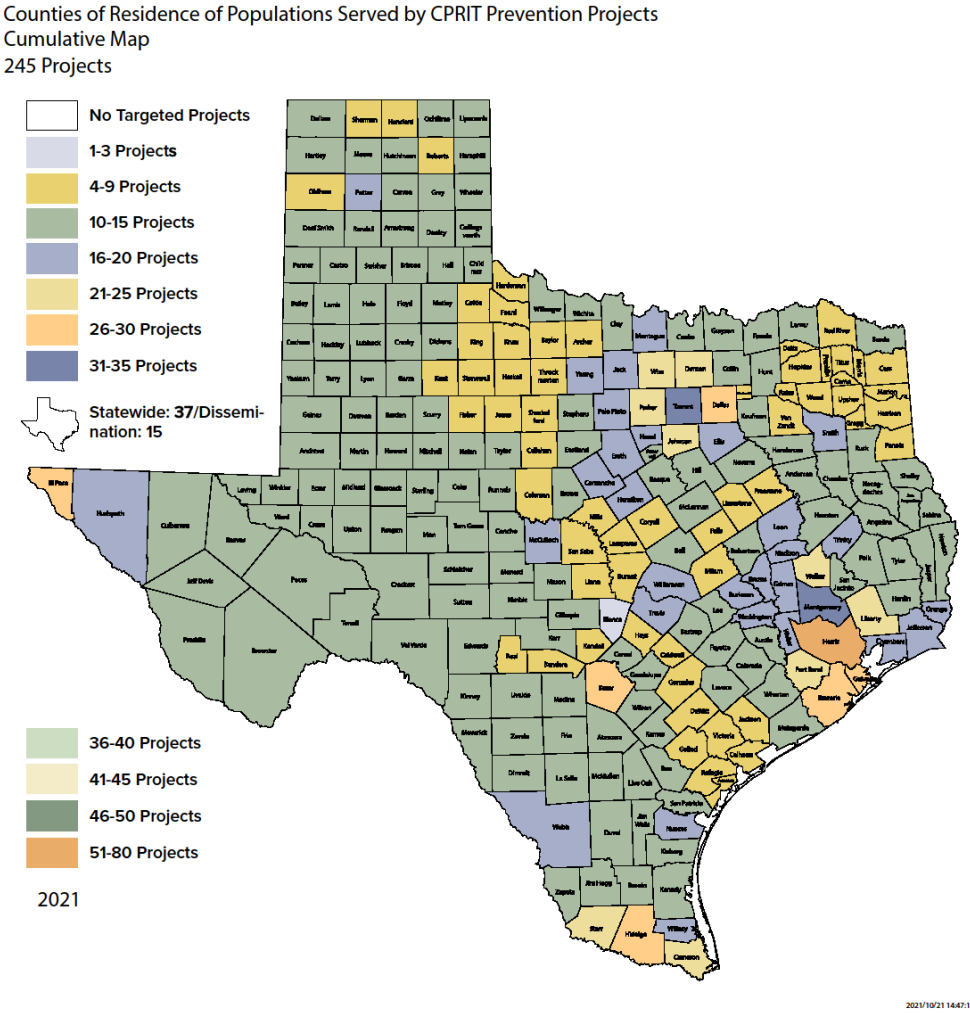
FY2021 Geographic Coverage – 245 Cumulative Projects



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MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	CINDY WALKERPEACH, PHD CHIEF PRODUCT DEVELOPMENT OFFICER
SUBJECT:	PRODUCT DEVELOPMENT RESEARCH UPDATE
DATE:	01 NOVEMBER 2021

Product Development Research Review Cycle Updates

Product Development Research FY 2022 Cycle 1

CPRIT Product Development Research released the TXCO, RELCO and SEED RFAs on June 24, 2021, and accepted applications through August 4, 2021. Twelve (12) applications and three (3) application submission extension requests were submitted by the deadline. As a result of an approved application extension, one (1) additional application was received, resulting in a total of thirteen (13) applications for Review Cycle 22.1. All thirteen (13) applications successfully passed administrative review and moved into peer review. As a result of the initial peer review conducted on September 28-29, three (3) applicants were invited to in-person (via Zoom) presentations conducted on October 25-28, 2021. The outcome of the Peer Review Meeting, the peer review panels recommended two (2) applications for diligence evaluation. Following the completion of peer review due diligence, Dr. Cindy WalkerPeach, Chief Product Development Officer, anticipates presenting any PDRC recommendations to the Program Integration Committee and Oversight Committee for approval at the February 2022 Oversight Committee meeting.

Application metrics for FY2022 Cycle 1 applications can be found in the table below.

Table 1: Review Cycle 22.1 Application Data by Mechanism

Mechanism	Applications Received	Funds Requested	Invited to Peer Review Meeting	Funds Requested	Rec'd for Diligence Review	Funds Requested
Texas Company	4	$38,258,557	1	$17,404,980	0	$0
Relocation Company	3	$43,856,191	0	$0	0	$0
Seed Company	6	$17,712,522	2	$5,998,261	2	$5,998,261

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TOTAL	**13**	**$99,827,270**	**3**	**$23,403,241**	**2**	**$5,998,261**

Product Development Research FY 2022 Cycle 2

Dr. WalkerPeach presented, and the Oversight Committee approved, the following three (3) RFAs during the February 2021 OC meeting for FY2022 Cycles 1 and 2:

- *Texas Company Product Development Research Award* (TXCO):
  RFA supporting TX based company product development research projects
  Award: Up to $20 million over a maximum timeline of three years.

- *Company Relocation Product Development Award* (RELCO):
  RFA supporting product development research projects for companies relocating to TX
  Award: Up to $20 million over a maximum timeline of three years.

- *Seed Award for Product Development Research* (SEED):
  RFA supporting product development research projects from newly formed companies
  Award: Up to $3 million over a maximum timeline of three years.

For Review Cycle 22.2, Product Development Research anticipates opening the application portal on December 1, 2021 with a January 26, 2022 deadline. Any Review Cycle 22.2 award recommendation would be presented during the August 2022 OC Meeting.

Proposed Product Development Research Program Priorities for FY 2023

The Product Development Research program priorities were established based on the following principles:

- Support commercial product development of novel technologies that address unmet cancer healthcare services and treatment needs;
- Stimulate the Texas life sciences ecosystem by supporting product development funding gaps that lack adequate private investment;
- Invest in projects based on sound scientific and business merit, with potential to attract additional private funding necessary to launch cancer healthcare related products and services.

With the Oversight Committee's approval, Product Development Research recommends continuing with the current program priorities for FY 2023, as detailed below:

Product Development Research Program Priorities
• Funding novel projects that offer therapeutic or diagnostic benefits not currently available; i.e., disruptive technologies • Funding projects addressing large or challenging unmet medical needs • Investing in early stage projects when private capital is least available • Stimulating commercialization of technologies developed at Texas institutions • Supporting new company formation in Texas or attracting promising companies to Texas that will recruit staff with life science expertise, especially experienced C-level staff to lead to seed clusters of life science expertise at various Texas locations • Providing appropriate return on Texas taxpayer investment

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE
FROM:	WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	2023 PROGRAM PRIORITIES
DATE:	NOVEMBER 11, 2021

Summary and Recommendation

I recommend that the Oversight Committee approve the fiscal year 2023 program priorities as presented behind this memo. Texas Health and Safety Code § 102.107 requires the Oversight Committee to set priorities for the grant programs annually. Each program officer discussed the priorities proposed for fiscal year 2023 with their respective subcommittee in meetings earlier this month. The 2023 program priorities are the same as the priorities adopted by the Oversight Committee last November for fiscal year 2022.

FY 2023 Priorities

Legislation adopted in 2013 requires the Oversight Committee to establish program priorities on an annual basis. CPRIT uses the priorities to provide transparency in how it directs the orientation of the agency's funding portfolio between and within its three programs. The program priorities also guide CPRIT staff and the peer review panels on the development and issuance of program-specific Requests for Applications (RFAs) and the evaluation of applications submitted in response to those RFAs.

The Oversight Committee reviews its priorities annually and adjusts as circumstances change and to incorporate the latest information concerning cancer-related advances in prevention, academic research, and product development research. In January 2018, the Oversight Committee decided to approve program priorities at November meetings to provide CPRIT staff more lead time for preparing and releasing RFAs. Adopting the 2023 program priorities at the November 18, 2021, Oversight Committee meeting allows the priorities to guide the fiscal year 2023 RFA process.

Each of the program subcommittees discussed the program priorities proposed for fiscal year 2023. The Prevention, Product Development Research, and Academic Research Subcommittees recommend proposed fiscal year 2023 priorities for their respective programs unchanged from the priorities adopted for fiscal year 2022.

In addition to the priorities specific to each grant program, the proposed fiscal year 2023 program priorities also reflect priorities across CPRIT's three programs. These overarching

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priorities, which also remain the same as those adopted for fiscal year 2022, inform the Program Integration Committee on balancing the portfolio across the academic research, prevention, and product development research programs.

CPRIT staff will use the newly adopted program priorities to develop RFAs for the fiscal year 2023 CPRIT grant review cycles.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Program Priorities 2023

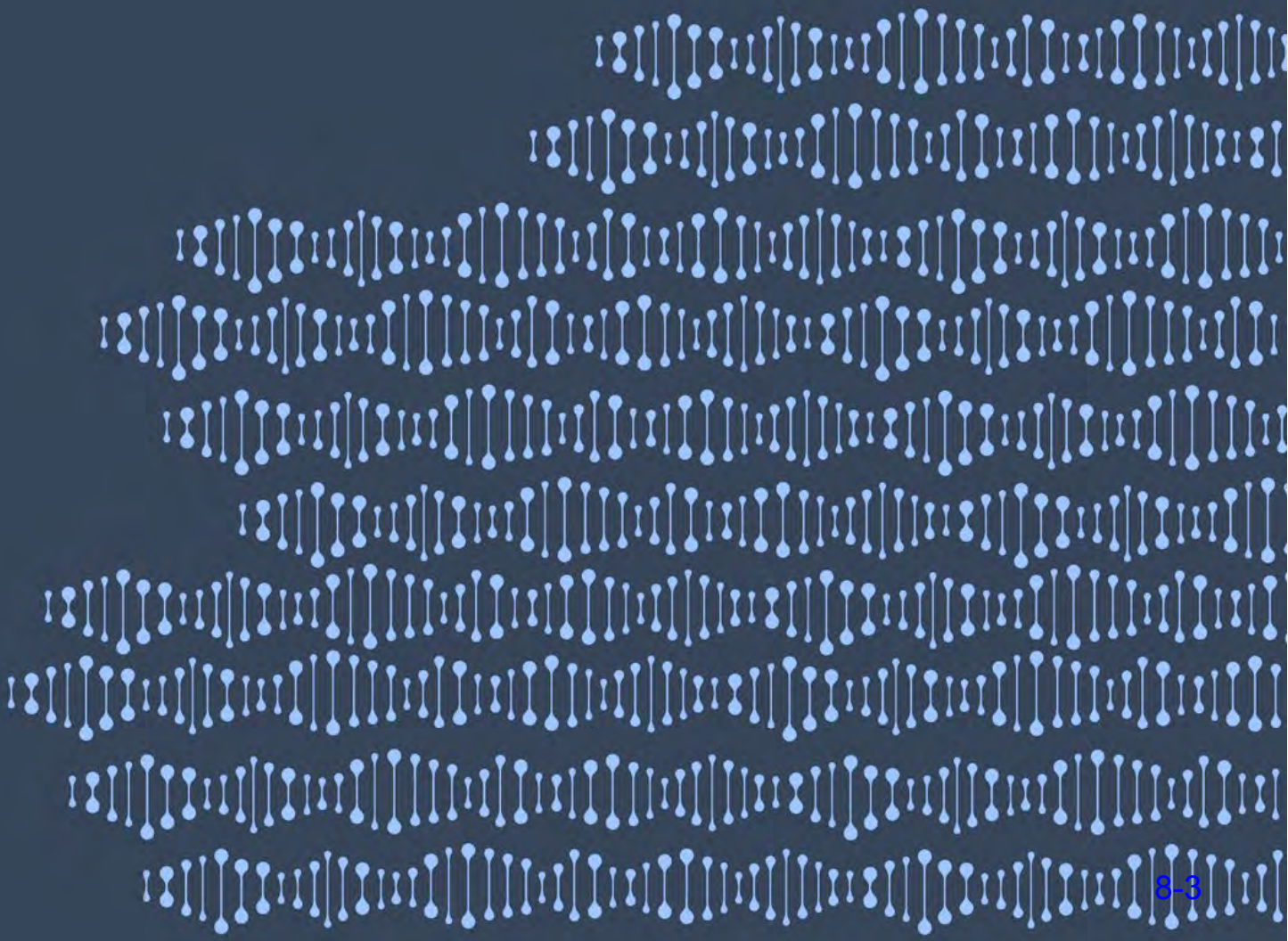


TABLE OF CONTENTS

ABOUT CPRIT'S PROGRAM PRIORITIES PROJECT

Legislation adopted in 2013 modified CPRIT's governing statute, Texas Health & Safety Code Chapter 102, to include enhancements to the agency's governance and operations. One of the statutory changes adopted in 2013 requires CPRIT's Oversight Committee to establish program priorities on an annual basis. The Oversight Committee uses the priorities to provide transparency in how it directs the orientation of the agency's funding portfolio between and within its three programs as well as guide CPRIT staff and the peer review panels on the development and issuance of program-specific Requests for Applications (RFAs) and the evaluation of applications submitted in response to those RFAs.

The Oversight Committee reviews its priorities annually and adjusts as circumstances change to incorporate the latest information concerning cancer-related advances in prevention, academic research, and product development research.

CPRIT Purpose

Texas Health & Safety Code, Chapter 102
Sec. 102.002. PURPOSES. The Cancer Prevention and Research Institute of Texas is established to:
(1) create and expedite innovation in the area of cancer research and in enhancing the potential for a medical or scientific breakthrough in the prevention of cancer and cures for cancer;
(2) attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in this state; and
(3) develop and implement the Texas Cancer Plan.

Program Priorities Legislative Mandate

Texas Health & Safety Code, Chapter 102
Sec. 102.107. POWERS AND DUTIES. The oversight committee shall:
(1) hire a chief executive officer;
(2) annually set priorities as prescribed by the legislature for each grant program that receives money under this chapter; and
(3) consider the priorities set under Subdivision (2) in awarding grants under this chapter.

PROCESS TO DEVELOP PROGRAM PRIORITIES

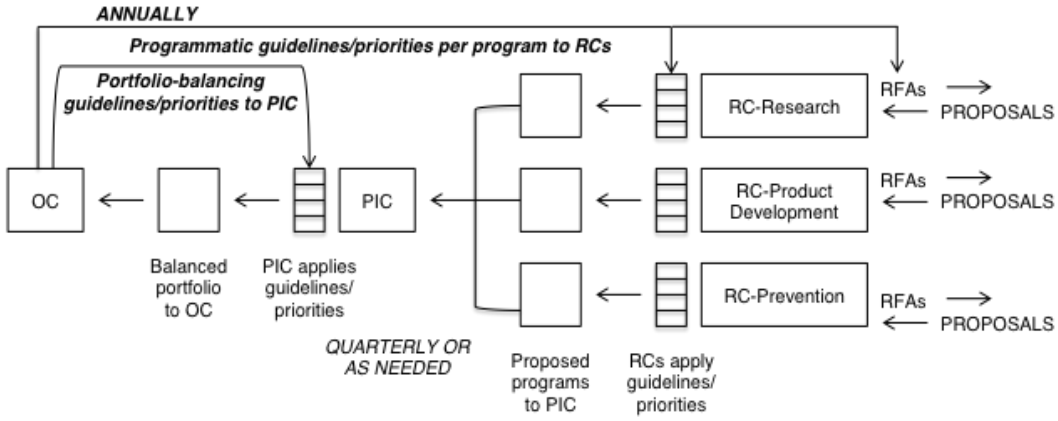
The Oversight Committee initially approved the program priorities in November 2014 after a six-month process that included public input. The fiscal year 2015 program priorities were subsequently incorporated into the RFAs released by each program. The Oversight Committee continues to annually approve priorities for each program every year, most recently adopting the program priorities for fiscal year 2022 at the November 18, 2020, meeting.

SCOPE OF PROGRAM PRIORITIES PROJECT

The Program Priorities Project establishes priorities at two levels of CPRIT's grant making process:

- **Priorities Within Each of CPRIT's Programs** – priorities to inform staff and respective Peer Review Councils (RCs) on the development and issuance of program-specific Requests for Applications (RFAs) and evaluation of applications submitted in response to those RFAs.
- **Priorities Across CPRIT's Three Programs** – priorities to inform the Program Integration Committee (PIC) on balancing the portfolio across the academic research, prevention, and product development research programs.

Priorities and CPRIT's Grant Making Process



CPRIT'S LONG TERM VISION

As the Oversight Committee established its program priorities, it began by defining the long-term vision for the agency and each of the three programs in alignment with CPRIT's mandated purpose.

Innovative projects funded by CPRIT will result in:

- A decrease in the burden of cancer in Texas through preventive measures, new diagnostics and treatments, and effective translation of discoveries into products;
- A recognition of and focus on disparities in cancer incidence, mortality, and access to care;

- Significant advancements in the scientific understanding of cancer; and
- An enhanced and expanded life sciences infrastructure in the state because of recruiting researchers, training health care/science professionals, attracting companies and supporting investigator startups.

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

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

PRIORITIES WITHIN EACH OF CPRIT'S PROGRAMS

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

Established key principles essential to executing CPRIT's purpose guide each of CPRIT's three programs. The main principle underlying all three programs is that each will continue to ensure only applications with scientific merit moves forward in CPRIT's peer review grant process. In addition, each program has established unique program principles. The program priorities supplement these principles to guide the selection of meritorious applications to address CPRIT's strategic priorities as set annually by the Oversight Committee.

It is important to note that these priorities do not exclude funding in areas outside of the identified priorities.

Academic Research Program

Background

The goal of CPRIT's academic research program is to discover new insights about cancer that can lead to prevention, early detection, and more effective treatments; translate new and existing discoveries into practical advances in cancer diagnosis, treatment, and survivorship; and increase the prominence and stature of Texas in the fight against cancer. CPRIT's strategy is to support the most creative ideas and the most meritorious projects brought forward by the cancer research community in Texas. The overarching principles for awarding CPRIT funds will continue to be scientific excellence and impact on reducing the burden of cancer.

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

Finally, it is critically important to add to the life sciences infrastructure in the State of Texas. This will enable CPRIT's impact on cancer research to extend for years beyond the lifetime of the program. Most important to increasing infrastructure is the recruitment of preeminent researchers and the investment in core facilities. New researchers will bring additional resources to the State, including research funding and new expertise, as well as help build the critical mass of science needed to attract investments in the development of products for cancer prevention, diagnosis, and treatment. Investments in core facilities will assure that these and other cancer researchers in Texas have access to the most up-to-date technologies needed for cutting-edge cancer research. Also critical are the training programs that aim to produce the next generation of cancer researchers and increase the diversity of the cancer research workforce.

Established Principles

- Scientific excellence and impact on cancer
- Increasing the life sciences infrastructure

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

Prevention Program

Background:

The following principles have guided the prevention program since its inception in 2009. These principles have informed the development of the requests for applications (RFAs) and the evaluation of applications submitted in response to the RFAs. Through the prevention program, CPRIT seeks to fund projects that:

- Offer effective prevention interventions based on the existing body of knowledge about and evidence for cancer prevention ("evidence based"); and
- Deliver primary, secondary, or tertiary (includes survivor care) prevention interventions that provide state of the art preventive clinical services and tailored, culturally appropriate, and accurate information to the public and health professionals.

In addition, the program has focused on providing access to underserved populations and serving the populations in most need including underinsured and uninsured individuals and those disproportionately affected by cancer.

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

- Potential for impact;
- Geographic distribution;

- Cancer type; and
- Type of program or service

While these principles provide guidance for the program, identifying priorities based on areas where significant cancer incidence and mortality disparities exist focuses the program further on areas of greatest need and greatest potential for impact.

The prevention program reviews data on cancer incidence, mortality, and disparities (geographic, ethnic, etc.) annually to identify priorities and identify areas of emphasis. This information informs the development of RFAs and informs programmatic decisions during the PRC level of review.

Established Principles:

- Fund evidence-based interventions and their dissemination
- Support the prevention continuum of primary, secondary, and tertiary (includes survivorship) prevention interventions

Prevention Program Priorities
• Populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence • Geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence • Underserved populations • Program assessment to identify best practices, use as a quality improvement tool, and guide future program direction

Product Development Research Program

Background

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

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

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

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

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

Established Principles

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

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

CPRIT's Product Development Research Program is also interested in catalyzing the Texas life science ecosystem by:

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

Product Development Research Program Priorities
• Funding novel projects that offer therapeutic or diagnostic benefits not currently available; i.e., disruptive technologies • Funding projects addressing large or challenging unmet medical needs • Investing in early stage projects when private capital is least available • Stimulating commercialization of technologies developed at Texas institutions • Supporting new company formation in Texas or attracting promising companies to Texas that will recruit staff with life science expertise, especially experienced C-level staff to lead to seed clusters of life science expertise at various Texas locations • Providing appropriate return on Texas taxpayer investment

PRIORITIES ACROSS CPRIT'S THREE PROGRAMS

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

CPRIT's structure, which includes programs in academic research, prevention, and product development research, presents a unique opportunity for funding projects that span the continuum from discovery to delivery to the public and creating synergy across the spectrum. While CPRIT programs would continue to fund a broad range of programs and cancer types, selecting areas of emphasis where CPRIT may have an impact distinguishing it from other funding sources provides a basis for focusing resources and guiding decisions for limited resources. The recommended areas of emphasis outlined below also correspond to unmet needs – places in the cancer research and care continuum where existing institutions have not provided strong programs or results.

It is important to note that these priorities serve as strategic areas of emphasis and do not exclude funding in areas outside of the identified priorities.

Prevention and Early Detection Initiatives

Rationale

Nowhere is there greater potential to reduce the burden of cancer than by reducing its incidence. This spares people and families from the psychological and emotional trauma of a cancer diagnosis, the often-devastating physical consequences of cancer therapies, and the financial burden associated with cancer treatment. In addition, the current emphasis in cancer research on finding cures for advanced cancers has serious limitations. Thus far, the ability of cancer cells to develop resistance to chemotherapy, radiation, and even targeted therapy has thwarted attempts to control cancer by these treatment modalities. Detecting cancer early in its development is a more desirable approach to cancer control. Despite the potential impact of prevention and early detection on reducing the cancer burden, these areas of cancer research receive little funding relative to funding devoted to curing advanced cancer.

Emphasis

Ideally, academic research will create the evidence base for novel approaches to prevention and early detection. Product development research will provide new methods, diagnostics, imaging, or devices, for early cancer detection. The prevention program will implement interventions to put these innovative approaches into practice once a solid evidence base of effectiveness exists.

Strategies include each program issuing either a targeted RFA or listing prevention or early detection as an area of emphasis (among others) within current RFAs. In addition, the programs can explore RFAs that could span programs, e.g. RFAs that would support a research component to a prevention project.

Early Translational Research

Rationale

One well-documented impediment to bringing the results of basic research to bear on cancer is the shortage of funding to translate new discoveries into practical advances for cancer patients. Funds for research and development are needed between the stages of discovery science, which is funded traditionally by grants from federal sources and foundations, and late term development and commercialization of drugs, devices, diagnostic tests, and biologicals, which is funded often by private sector industries. Data indicate that translational research is underfunded and would benefit from additional investment. Funding such research and development by CPRIT could have the added benefit of stimulating public-private partnerships and bringing new commercial investments to Texas.

Emphasis

Funding translational research that bridges the gap between basic research and product development, and between research on preventive measures and innovative technologies for early detection and adaptation of tested interventions represents opportunities for inter-program strategic investment by CPRIT. The time needed to move some projects from research to products is often lengthy and may limit the role of the prevention program in this area of emphasis.

Enhance Texas' Research Capacity and Life Science Infrastructure

Rationale

CPRIT's statute emphasizes enhancing research superiority, increasing applied science and technology research capabilities and increasing high-quality jobs in the state. All three programs contribute to enhancing the research, life science and cancer control workforce and infrastructure in the state.

Emphasis

Establishing a critical mass of cancer researchers in Texas is possible by supporting the recruitment of cancer scientists and clinicians, at all career levels, to academic institutions in Texas and through training programs that educate pre- and post-doctoral fellows to become cancer researchers. The recruitment program has been successful in enhancing Texas' cancer research efforts and increasing the external visibility of the state in the medical and scientific communities.

CPRIT's investments in product development help to build Texas' life-science industry. While bringing a product to market takes time, the process generates jobs and economic activity. Every CPRIT award includes intellectual property requirements that specify a revenue return to Texas through the successful development of CPRIT-funded drugs, devices, diagnostics, or services.

The prevention program supports the education and training of health care professionals and community workers, thereby increasing the state's capacity for cancer prevention and control activities. By requiring collaborative partnerships, the program also creates incentives for organizations and individuals to collaborate to tackle community problems through networks that can mobilize resources and avoid duplication of efforts. Implementing system changes (such as reducing wait times between screening and diagnostics, implementing patient reminder systems) by CPRIT funded programs also improves the infrastructure for the delivery of preventive interventions.

Summary: Priorities across CPRIT's Three Programs

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

	Prevention and Early Detection Initiatives	Early Translational Research	Enhance Texas' Research Capacity and Life Science Infrastructure
Academic Research Program Implementation	Create the evidence base for novel approaches to prevention and early detection.	Identify CPRIT funded basic research that could translate new discoveries into practical advances.	Increase workforce and infrastructure: researcher recruitment, training grants and core facilities.
Prevention Program Implementation	Implement programs to put these innovative approaches into practice and continue to fund what is known to work (evidence based).	Due to long lead-time to product development, there may be limited role for prevention to implement programs resulting from this research.	Implementing systems change, developing partnerships and collaborations, training of community and healthcare providers, and creating new jobs.
Product Development Research Program Implementation	Fund new tools, technologies, methods and devices for early cancer detection and prevention.	Fund translational research that bridges the gap between basic research and product development.	Build up life sciences infrastructure and industry in Texas and create new high paying jobs.

November 2021 Oversight Committee
Internal Audit Status Report
As of November 8, 2021

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 and Alyssa Martin, Partner.

2021 Internal Audit Plan and Schedule

Based on the approved 2021 Internal Audit Plan by the Oversight Committee, we have completed the internal audits and follow-up procedures for the 2021 Internal Audit Plan.

2021 INTERNAL AUDITS		
Internal Audit	**Description**	**Status**
Sunset Self-Assessment Advisory Audit	The advisory audit was planned to provide CPRIT a risk-based framework and an overlay of internal audits and controls in preparation for the Self-Assessment Report for the Sunset Commission Review. The advisory audit has been cancelled because there is a bill, SB 73, moving quickly through the legislature that changes CPRIT's sunset date from 2023 to 2029. Planning for the advisory audit, and the creation of the framework and mapping of audits to the Self-Assessment Report criteria were complete when SB 713 was voted out of the Senate Committee on Administration on April 14, 2021. It passed the Senate on April 19, and was voted out of the house State Affairs Committee on April 29	Cancelled
Information Technology General Computer Controls	Fieldwork for the audit was completed on September 24, 2021. We issued the report on October 25, 2021. The audit resulted in an overall assessment of "Unsatisfactory" with eight total findings. Follow-up procedures on the remediation of the findings will be included in the audit plan for fiscal year 2022.	Complete
Records Management – Grantee Compliance Records Advisory Audit	Due to CPRIT staffing considerations and conflicts as a result of the COVID-19 pandemic, this advisory audit was delayed until 2022.	Rescheduled for FY 2022

2021 INTERNAL AUDIT FOLLOW-UPS		
Information Security Follow-Up • 2 findings	Due to CPRIT staffing considerations and conflicts as a result of the COVID-19 pandemic, this advisory audit was delayed until 2022	Rescheduled for FY 2022
Communications Follow-Up • 1 High Finding • 2 Moderate Findings	Due to CPRIT staffing considerations and conflicts as a result of the COVID-19 pandemic, this advisory audit was delayed until 2022.	Rescheduled for FY 2022
Governance Follow-up • 1 Moderate Finding	Due to CPRIT staffing considerations and conflicts as a result of the COVID-19 pandemic, this advisory audit was delayed until 2022.	Rescheduled for FY 2022
Disaster Recovery and Business Continuity Planning Advisory Follow-up	Fieldwork for the Advisory Audit Follow-up procedures was completed on September 28, 2021. Twenty-five of the 30 recommendations from the prior advisory audit were remediated. We will perform follow-up procedures on the remaining five recommendations as part of the fiscal year 2022 Internal Audit Plan.	Complete

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

Based on the outcomes from the current year's internal audit plan, we have also drafted proposed changes to the fiscal year 2022 internal audit plan. The changes include the addition of the IT General Computer Controls Remediation Assistance Audit Advisory project, as well as an update to the scope of the Records Management – Grantee Compliance Records Audit Advisory project to focus on validating the completeness and accuracy of the records and data migrated to the CPRIT –hosted system. The revised audit plan is attached.

We also completed the annual internal audit report required by the Texas Internal Audit act. This report is required to be filed with the Governor's Office – Budget and Policy Division, the State Auditor's Office, and the Legislative Budget Board.

Daniel Graves

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 November 8, 2021

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

Open Items Summary

					Findings				Closed Findings				Total Open Findings				
Audit	**Fiscal Year**	**Status/Timing**	**Report Date**	**Report Rating**	**High**	**Mod**	**Low**	**Total**	**High**	**Mod**	**Low**	**Total**	**High**	**Mod**	**Low**	**Total**	**Timing of Follow-Up Procedures by IA**
Information Technology General Computer Controls	2021	September 2021	September 24, 2022														**FY 2022**
2020 Governance	2020	July 2020	October 30, 2020	Strong	-	1	-	1	-	-	-	-	-	1	-	1	**FY 2022**
2016 Information Security Follow-Up	2020	August 2020	N/A														**FY 2022**
2018 Communications Follow-Up	2020	November 2020	N/A	N/A	1	4	-	5	-	2	-	2	1	2	-	3	**FY 2022**
Total Findings For Internal Audit Follow-Up					**1**	**5**	**-**	**6**	**-**	**2**	**-**	**2**	**1**	**3**	**-**	**4**	

Cancer Prevention and Research Institute of Texas

IA #2-2021 Report over Disaster Recovery and Business Continuity Planning Advisory Audit Follow-Up Procedures

Report Date: September 28, 2021

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 internal audit follow-up procedures performed for the Cancer Prevention and Research Institute of Texas (CPRIT) during September 2021 relating to the recommendations for improvement from the Advisory Audit Report over Disaster Recovery and Business Continuity Planning (September 2020).

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

To accomplish this objective, we obtained updated disaster recovery and business continuity planning documentation from CPRIT personnel responsible for their maintenance. This documentation was reviewed to verify that the advisory audit improvement opportunities were addressed. Procedures were performed remotely and completed on September 30, 2020.

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

Weaver and Tidwell, L.L.P.

WEAVER AND TIDWELL, L.L.P.

Austin, Texas
September 28, 2021

Cancer Prevention and Research Institute of Texas

IA #2-2021 Report over Disaster Recovery and Business Continuity Planning
Advisory Audit Follow-Up Procedures
September 28, 2021

Background

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

Of the 121 required and best practice criteria elements to be included in the DR/BCP documents, 30 items were identified to improve and better align CPRIT's planned processes and procedures including:

- 24 to augment or revise information related to required criteria; and
- 6 to improve general clarity and better align the planning documents.

To address these instances, the 2020 advisory audit report proposed:

- 23 draft revisions to augment or update the existing documentation; and
- 7 recommendations for updates to technical information about IT platforms in the planning documentation.

The 2021 Internal Audit Plan included performing follow-up procedures to validate that CPRIT management has taken steps to address the advisory audit improvement opportunities.

Follow-Up Objective and Scope

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

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

Executive Summary

Through our review of updated DR/BCP documentation, we determined that 25 of 30 recommendations were addressed and five of 30 to be underway. Thereby resulting in the overall recommendation as partially remediated.

Cancer Prevention and Research Institute of Texas

IA #2-2021 Report over Disaster Recovery and Business Continuity Planning Advisory Audit Follow-Up Procedures
September 28, 2021

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

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

Conclusion

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

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

Follow-up procedures should be conducted in Fiscal Year 2022 to validate the implementation of the remaining remediation efforts taken to address the open items in the recommendations.

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

Cancer Prevention and Research Institute of Texas

IA #2-2021 Report over Disaster Recovery and Business Continuity Planning
Advisory Audit Follow-Up Procedures
September 28, 2021

Detailed Follow-Up Results, Recommendations and Management Response

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

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

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

DR/BC Component	Total Criteria	Improvement Opportunity		Nature of Improvement Opportunity			Partially Remediated
		Count	Type	Content Addition	Content Revision	Reference Update	Content Addition
Incident Evaluation	31	8	R	5	2	1	2
		1	OA	1	-	-	-
Incident Management	30	10	R	3	4	3	-
		1	OA	1	-	-	1
Disaster Recovery	37	1	R	1	-	-	1
		-	OA	-	-	-	-
Business Resumption	23	5	R	4	-	1	1
		4	OA	2	2	-	-
Total	**121**	**30**		**17**	**8**	**5**	**5**

Results: **Recommendations are partially addressed**

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

Responsible Party: Chief Operating Officer, Operations Manager, IT Manager
Implementation Date: March 15, 2022

Cancer Research and Prevention Institute of Texas

Proposed Internal Audit Plan (Updated)

Draft - For Discussion Purposes Only

Audit Area	Risk Rating	Summary Procedures	Audit Focus	Timing
2022 Planned New Internal Audits				
Vendor Contract Compliance	High	Internal Audit will evaluate the risk of significant vendor contracts in place at CPRIT. Based on the risk evaluation, vendor contracts will be evaluated for compliance with key provisions, terms and conditions of the contract, as well as on the performance with the delivery of goods and/or services in alignment with the contract.	Internal Audit	December 2021- January 2022
IT Remediation Assistance	High	Internal Audit will assist CPRIT in designing control procedures and templates to implement and execute the IT gengeral controls necessary to align with TAC 202 standards and to remediate the findings identified in the FY 2021 ITGC Internal Audit. Where needed, we will assist CPRIT in staff training and transitioning responsibility for the execution of controls to new staff and/or third-party assistance.	Audit Advisory	December 2021- March 2022
Records Management - Grantee Compliance Records	High	Internal Audit will provide audit advisory services to evaluate the grantee compliance record migration from a third-party designed system to the integrated CPRIT system. Consulting services will include the validation of the system configuration, verification of the completeness of the data migration and testing the accuracy of data classification and mapping.	Audit Advisory	April 2022 - May 2022
Procurement	High	Internal Audit will validate CPRIT's compliance with the requirements for procurements specified in the State of Texas Procurement and Contract Management Guide.	Internal Audit	May/June 2022
2022 Planned Internal Audit Follow-up				
Information Technology General Computer Controls	High	Internal Audit will perform possible follow-up procedures on the findings from the 2021 internal audit to ensure corrective action has been taken.	Follow-up	April 2022
Information Security	High	Internal Audit will perform possible follow-up procedures on the findings from the 2021 internal audit advisory project to validate changes in operations.	Follow-up	April 2022
Communications	High	Internal Audit will perform possible follow-up procedures on the findings from the 2021 internal audit advisory project to validate changes in operations.	Follow-up	April 2022
Governance	High	Internal Audit will perform possible follow-up procedures on the findings from the 2021 internal audit advisory project to validate changes in operations.	Follow-up	April 2022
Disaster Recovery/Business Continuity Audit Advisory	High	Internal Audit will perform possible follow-up procedures on the findings from the 2021 internal audit advisory project to validate changes in operations.	Audit Advisory Follow-up	June 2022

Cancer Research and Prevention Institute of Texas

Proposed Internal Audit Plan (Updated)

Draft - For Discussion Purposes Only

2022 Planned Annual Requirements				
Project Management	NA	Track overall internal audit procedures, coordinate audit activities, and reporting to management.	Project Management	Ongoing
Update Risk Assessment	NA	Perform required annual update of risk assessment	Policy Compliance	Ongoing
Annual and Quarterly Board Reports	NA	Prepare and submit required Annual Internal Audit Report and quarterly reports of internal audit activities to the Audit Sub-Committee and Oversight Committee.	Policy Compliance	Ongoing
2023 Potential Audit Topics				
TAC 202 Alignment and Strategic Roadmap	High	Internal Audit will evaluate the alignment of the IT environment with the state agency IT requirements of Texas Administrative Code (TAC) 202 and its underlying control frameworks. The scope of the audit will also include the development and monitoring of the long-term strategic initiatives of information technology and its alignment with the strategic goals and initiatives of CPRIT.	Internal Audit	FY 2023

Cancer Prevention & Research Institute of Texas

Fiscal Year 2021 Annual Internal Audit Report
August 31, 2021

weaver
Assurance • Tax • Advisory

CONTENTS

Cancer Prevention and Research Institute of Texas

Fiscal Year 2021 Annual Internal Audit Report
August 31, 2021

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

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

The Cancer Prevention and Research Institute of Texas (CPRIT or the agency) will post this report which includes the Fiscal Year 2022 Internal Audit Plan on its website at www.cprit.texas.gov. CPRIT's Oversight Committee reviewed and approved the Annual Internal Audit Report as part of their regular meeting held on August 2, 2021. In accordance with Texas Government Code, Section 2102.015, CPRIT will post this report on its website within 30 days of the Oversight Committee's approval.

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

II. Internal Audit Plan for Fiscal Year 2021

The internal audits planned and performed for fiscal year 2021 were selected to address the agency's highest risk areas, based on the risk assessment update conducted in 2020, which included input from CPRIT management. The audits conducted during fiscal year 2021 are listed below.

Internal Audit	Report Date	Current Status
Sunset Self-Assessment Advisory Audit	NA	Due to legislative changes in reporting requirements for the Sunset Self-Assessment, this advisory audit was cancelled.
Information Technology General Computer Controls	September 24, 2021	The report was issued October 25, 2021. Follow-up procedures to verify that recommendations have been addressed are included in the proposed 2022 Internal Audit Plan.
Records Management – Grantee Compliance Records Advisory Audit	NA	Due to CPRIT staffing considerations and conflicts as a result of the COVID-19 pandemic, this advisory audit was delayed until 2022.
Information Security Follow-Up	NA	Due to CPRIT staffing considerations and conflicts as a result of the COVID-19 pandemic, follow-up procedures were delayed until FY 2022.
Communications Follow-Up	NA	Due to CPRIT staffing considerations and conflicts as a result of the COVID-19 pandemic, follow-up procedures were delayed until FY 2022.
Governance Follow-Up	NA	Due to CPRIT staffing considerations and conflicts as a result of the COVID-19 pandemic, follow-up procedures were delayed until FY 2022.

III. Consulting Services and Non-audit Services Completed

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

Audit	Report Date	Current Status
Disaster Recovery and Business Continuity Planning Advisory Follow-Up	September 28, 2021	This advisory follow-up audit is complete. Follow-up procedures to verify that corrective action has been performed on the remaining open findings are included in the proposed 2022 Internal Audit Plan.

IV. External Quality Assurance Review

In accordance with professional standards, and to meet the requirements of the Texas Internal Auditing Act, Internal Audit is required to undergo an external quality assurance review at least once every three years. Weaver's review was issued in October 2019.

EideBailly

CPAs & BUSINESS ADVISORS

Report on Firm's System of Quality Control

October 16, 2019

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

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

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

Firm's Responsibility

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

Peer Reviewer's Responsibility

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

Required Selections and Considerations

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

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

Opinion

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

Eide Bailly LLP

Eide Bailly LLP

V. Internal Audit Plan for Fiscal Year 2022

The Internal Audit Plan was submitted to the Audit Subcommittee of the CPRIT Oversight Committee. The Audit Subcommittee approved the plan on August 9, 2021, and the Oversight Committee subsequently approved the plan on August 18, 2021. Prior to November 1, 2021, it was identified that the FY 2022 internal audit plan would need to be modified. Below is the Fiscal Year 2022 Internal Audit Plan as modified and submitted to the agency's Oversight Committee based on the results of the 2021 Internal Audit Risk Assessment Update. The internal audit plan will be submitted to the State Auditor's Office upon approval by CPRIT's Oversight Committee during their November 18, 2021 meeting.

Fiscal Year 2022 Internal Audit Plan		
Audit Area	**2021 Risk Rating**	**Estimated Hours**
Vendor Contract Compliance	High	280
IT Remediation Assistance	High	210
Records Management – Grantee Compliance Records Advisory Audit	High	200
Procurement	High	150

Planned follow-up procedures for fiscal year 2022 to verify and communicate with Management the remediation efforts of prior Internal Audit Recommendations.

Fiscal Year 2022 Follow-up Procedures		
Audit Area	2021 Risk Rating	Estimated Hours
Information Technology General Computer Controls	High	280
Information Security	High	100
Communications	Moderate	50
Governance	High	40
Disaster Recovery and Business Continuity Advisory	High	30

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

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

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

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

The 2021 Internal Audit Risk Assessment Update resulted in ten (10) Significant Activities rated as "High" risk. Six (6) of the ten (10) Significant Activities are not included in the Fiscal Year 2022 Internal Audit Plan. Those activities are as follows:

- Pre-Award Grant Management
- Post-Award Grant Monitoring
- Commodity and Service Contracts
- Procurement and P-Cards
- Internal Agency Compliance
- Application Development and Management

VI. External Audit Services Procured in FY 2021

CPRIT engaged McConnell & Jones, LLP, a certified public accounting and consulting firm, as their external auditors for FY 2021.

VII. Reporting Suspected Fraud, Waste and Abuse

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

- The CPRIT Chief Compliance Officer is the designated staff member within the agency to receive written or verbal allegations of suspected fraud, waste, and abuse. The Chief Compliance Officer has the authority to examine and investigate those allegations and turn over information of verified instances of fraud, waste, or abuse to the State Auditor's Office.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	CAMERON ECKEL, ASSISTANT GENERAL COUNSEL
SUBJECT:	APPOINTMENT TO THE SCIENTIFIC RESEARCH AND PREVENTION PROGRAMS COMMITTEE
DATE:	NOVEMBER 4, 2021

Summary and Recommendation

The Chief Executive Officer has appointed five experts to CPRIT's Scientific Research and Prevention Programs Committee. CPRIT's statute requires Oversight Committee approval for the appointments. At their November 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 Nominations Subcommittee charter assigns the subcommittee with the responsibility "to circulate to Oversight Committee members in advance of a public meeting written notification of the committee's intent to make the nomination, along with such information about the nominee as may be relevant."

The Board Governance Subcommittee reviewed the appointees at its November 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 Committee (SRPP) Appointments
November 2021

Appointee	CPRIT Program	Organization
Elisa V. Bandera, MD, PhD	Prevention	Professor and Chief, Cancer Epidemiology and Health Outcomes; Co-Leader, Cancer Prevention and Control, and Interim Director of the Population Science Research Support Shared Resource at Rutgers Cancer Institute of New Jersey
Chien-Ching Li, PhD, MPH	Prevention	Associate Professor of Health Systems Management and a health services researcher at Rush University
Jesse Nodora, DrPH	Prevention	Associate Professor in the UC San Diego Herbert Wertheim School of Public Health & Human Longevity Science and a member of the Moores UC San Diego Cancer Center
Jennifer Sanchez-Flack, PhD, MPH	Prevention	Tenure-track Assistant Professor in the Department of Pediatrics at the University of Illinois at Chicago (UIC)
Karl Whitney, PhD, RAC	Product Development Research	Vice President Regulatory Affairs at Precision Biosciences, Inc.

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Elisa V. Bandera, MD, PhD

Dr. Bandera is Professor and Chief, Cancer Epidemiology and Health Outcomes; Co-Leader, Cancer Prevention and Control, and Interim Director of the Population Science Research Support Shared Resource at Rutgers Cancer Institute of New Jersey; Professor of Medicine, Robert Wood Johnson Medical School and Professor of Epidemiology at Rutgers School of Public Health.

Her major research interests include the impact of obesity and body composition and related factors on breast and ovarian cancer risk, treatment outcomes and survival, with a focus on cancer health disparities. She is leading several cancer epidemiologic studies and has served in numerous advisory boards and expert panels for several organizations, including the American Cancer Society, the National Cancer Institute, the International Agency for Research on Cancer (IARC), the American Institute for Cancer Research (AICR) and the World Cancer Research Fund International (WCRF). She also served as Chair of the American Society of Preventive Oncology (ASPO)'s Lifestyle Behaviors, Energy Balance and Chemoprevention Special Interest Group and in 2021 she was co-chair of the 2021 ASPO Meeting: Health Equity, Culture, and Cancer.

Chien-Ching Li, MPH, PhD

I am an Associate Professor of Health Systems Management and a health services researcher at Rush University. I have expertise in behavioral risk research, quantitative/qualitative research, and epidemiological research, and health services and outcomes research. My current program of research is focused on the reduction of cancer-related health disparities among vulnerable and underserved population groups. Specifically, I target tobacco use as a modifiable determinant of cancer-related health disparities among minority populations. Currently, I am leading a study to develop and evaluate a web-based and interactive decision aid tool for lung cancer screening with low-dose computed tomography (LDCT) for older Chinese American smokers and their providers.

Jesse Nodora, DrPH

Dr. Nodora is currently Associate Professor in the UC San Diego Herbert Wertheim School of Public Health & Human Longevity Science and a member of the Moores UC San Diego Cancer Center. He is also Director of Community Engagement with the UC San Diego Altman Clinical and Translational Research Institute. He received a doctor of public health (DrPH) from the University of Texas School of Public Health in 1995 with an emphasis on health promotion. After 10 years of public health practice in state-level tobacco control, he transitioned to cancer prevention research at the Arizona Cancer Center and the University of Arizona School of Medicine. Dr. Nodora's research focus is in informed decision-making, patient-provider communication, health literacy, language and cultural concordant care, and dissemination and implementation science among poor and underserved populations. His work seeks to produce products and information that can be used by individuals and a variety of systems (e.g., communities, health care, government, non-profits) to promote healthy lifestyles, increase access to care, and improve health outcomes for chronic disease, especially cancer. His primary grants include research on colorectal cancer screening interventions in federally qualified health centers, bladder health for women (PLUS Consortium), COVID-19 testing and vaccination, HPV vaccination, and underserved population accrual into therapeutic cancer clinical trials.

Jesse Nodora, DrPH
He/Him/El
Associate Professor, Herbert Wertheim School of Public Health & Human Longevity Science
Moores UC San Diego Cancer Center
Director, Community Engagement, Altman Clinical and Translational Research Institute
3855 Health Sciences Dr. #0901
La Jolla, CA 92093
Phone: (858) 822-3686
jnodora@ucsd.edu

El Dr. Nodora es actualmente Profesor Asociado en la escuela de Salud Pública Herbert Wertheim de la Universidad de California, San Diego y miembro del Centro Oncológico UC San Diego Moores. Tambien es director del programa para enlaces comunitarios en el Instituto de investigación traslacional Altman en la UC San Diego. Recibió su doctorado en salud pública (DrPH) de la Escuela de Salud Pública de la Universidad de Texas en 1995 con un énfasis en la promoción de la salud. Después de 10 años de práctica de salud pública en el control del tabaco a nivel estatal, pasó a la investigación de prevención del cáncer en el Arizona Cancer Center y la Universidad de Arizona School of Medicine. La investigación del Dr. Nodora se centra en la toma de decisiones informadas, la comunicación paciente-proveedor, la alfabetización de la salud, la atención concordante del lenguaje y la cultura, y la difusión y la implementación de la ciencia entre las poblaciones pobres y desatendidas. Su trabajo busca producir productos e información que puedan ser utilizados por individuos y una variedad de sistemas (por ejemplo, comunidades, sistemas de salud, gobierno, organizaciones sin fines de lucro) para promover estilos de vida saludables, aumentar el acceso a servicios de salud y mejorar los resultados de salud para enfermedades crónicas, especialmente el cáncer. Sus subvenciones primarias incluyen investigaciones sobre intervenciones de detección del cáncer colorrectal en centros de salud comunitarios, salud de la vejiga en mujeres (Plus Consortium), vacunación y pruebas de COVID-19, vacunación contra el VPH y acumulación de población desatendida en ensayos clínicos de cáncer.

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Jennifer Sanchez-Flack, PhD, MPH, is a tenure-track Assistant Professor in the Department of Pediatrics at the University of Illinois at Chicago (UIC). Dr. Sanchez-Flack first joined UIC as a T32 Postdoctoral Research Fellow in the NCI-funded Cancer Education and Career Development Program. Dr. Sanchez-Flack has an academic background in behavioral sciences and public health with experience in qualitative and quantitative research methodology, implementation of behavioral-based interventions to prevent obesity and cancer in multiple settings and with diverse populations, and in dissemination and implementation science. As a recipient of training fellowships from the National Cancer Institute (NCI), she has been able to train with distinguished researchers from various disciplines, including public health, medicine, maternal and child health, cancer epidemiology, marketing, psychology, nutrition, and kinesiology. Her research focuses on using dissemination and implementation science principles to examine the external validity of obesity prevention interventions to translate and replicate behavioral-based interventions in "real-world" settings (e.g., clinics, communities, schools). She is particularly interested in how multilevel interventions, including digital health interventions, can improve Latinxs and African American families' food and beverage purchasing behaviors to reduce obesity and cancer inequities. This research aims to identify sustainable approaches to reach and engage underserved families in obesity prevention and cancer risk reduction that can be applied in clinical settings and in policy research to reduce health disparities. Dr. Sanchez-Flack received her PhD in Public Health from the joint-doctoral program at San Diego State University/University of California, San Diego, and her Master's in Public Health (MPH) from the University of Michigan.

Karl Whitney, PhD, RAC

Vice President Regulatory Affairs
Cell: 919-491-7147; e-mail: karl.d.whitney@gmail.com

Summary

Highly effective solutions-oriented regulatory affairs professional with 20 years' experience executing and leading integrated pharmaceutical product development programs, including multiple IND and NDA filings. Seeking a leadership position with an innovative biotech where my regulatory strategy, scientific, and business operations contributions can help the company realize its important human-health mission. Therapeutic area experience includes oncology, infectious disease, metabolic disease, dermatology, hemophilia, ADHD, pain, schizophrenia, and other CNS indications. Product development experience spans small-molecule, cell therapy, and gene therapy programs.

Education

1999 Ph.D.	**Duke University** Pharmacology (Thesis: "Autoantibodies, Complement, and Rasmussen's Encephalitis")
1991 BA Summa Cum Laude	**Yale University** Psychology
1991 Immersion Training	**Peace Corps, Costa Rica** Spanish and Tropical Forestry

Professional Experience

October 2020 – present
Vice President and Head of Regulatory Affairs
Precision BioSciences, Inc.

February 2020 – October 2020
Senior Director and Head of Regulatory Affairs
Precision BioSciences, Inc.

As Vice President and Head of Regulatory Affairs I am responsible for successful implementation of regulatory strategies and ensuring regulatory compliance for company manufacturing, preclinical, and clinical programs. More specifically, the Vice President Regulatory Affairs:

- *Works within the multi-disciplinary Operations Team to develop and lead corporate regulatory strategies and execute tactical regulatory functions.*
- *Serves as Regulatory Affairs subject matter expert and program team member for the design and implementation of regulatory strategy for cell and gene therapy programs.*
- *Develops plans for health authority meetings and expedited development programs and other special designations; develops summary document contents and manages meetings with FDA (e.g. pre-IND, EOPI/II, pre-BLA) and other health authorities.*
- *Plans content and timelines for, and guides subject matter experts (SMEs) on the preparation of, IND and BLA submissions and amendments to FDA with an overall objective to receive approval within the shortest time frames possible.*
- *Serves as primary liaison with FDA and other health authorities. Represents Precision perspectives in proactive and collaborative interactions with health authority representatives. Negotiates with health authority representatives to achieve optimal outcomes for development program topics and issues.*
- *Leads and oversees all activities of the Regulatory Affairs group at Precision BioSciences.*

- *Recruits, develops, and retains regulatory affairs talent. Mentors and supports staff on scientific, regulatory, and project management issues.*
- *Nurtures internal and external partnerships to ensure a proactive, successful regulatory plans are implemented in each program and in concert with other disciplines such as CMC, Nonclinical, Clinical, and Quality.*

August 2014 – January 2020

Assistant Vice President, Operations

Rho, Inc., Chapel Hill, NC

The Assistant Vice President is accountable for fostering staff professional development, project excellence, and strong client relationships for projects performed within Rho's regulatory group. Key responsibilities:

- *Provided leadership, guidance, and support to teams, programs, and projects across the development spectrum from pre-IND to Phase IV, focusing on regulatory submissions and integrated product development programs.*
- *Facilitated achievement of strategic goals for client programs. Monitored ongoing progress of key deliverables against Global Integrated Product Development Plan goals, including helping project leads identify potential risks and develop contingency plans.*
- *Served as regulatory advisor and expert regulatory and scientific document reviewer for regulatory applications and other submissions. As needed, liaised with FDA for client projects.*
- *Nurtured client and partner relationships through outreach and support in the escalation context.*
- *Recruited, developed, and retained talent. Mentored staff on scientific, regulatory, and project management issues. Jointly managed the Integrated Product Development Associate training program and the Research Scientist staff pipeline.*
- *Supported business development efforts by leading proposal development and jointly representing Rho at bid defenses.*

August 2010– August 2014

Director, Product Development

Rho, Inc., Chapel Hill, NC

- *Led integrated product development programs consisting of clinical, preclinical, chemistry, manufacturing and controls, and regulatory components (including INDs, Agency meetings, and NDA/BLA submissions, etc.).*
- *Managed external vendors, including consultants, contract manufacturers, packagers and labelers, preclinical toxicology houses, clinical facilities, and central laboratories.*
- *Proactively identified and critically analyzed problems affecting projects. Developed viable and long-lasting solutions to cross-program, cross-functional or organizational issues. Developed and implemented risk assessment, mitigation, and contingency plans.*
- *Provided regulatory and scientific consultation on drug development challenges for projects throughout the company.*
- *Ensured effective, accurate and timely communication of key issues and progress to the team, Sponsor, and Rho Senior Management.*

May 2006- August 2010

Regulatory Program Director

RTI, International, Durham, NC

March 2005- April 2006

Regulatory Program Manager

RTI, International, Durham, NC

- *Designed and executed multidisciplinary development plans in close collaboration with the client project team and consultants as needed.*
- *Planned, directed, and tracked all CMC, nonclinical, clinical, and regulatory activities for multiple preclinical and clinical-stage drug projects.*
- *Served as official contact to FDA for client INDs.*

- *Identified contract research organizations (CROs) to perform specific development activities. Helped negotiate contracts. Planned and provided oversight to CRO projects to ensure teams conduct high-quality work on-time and within budget. Identified and monitored corrective action plans when CRO services do not meet expectations.*
- *Reviewed written work product of all CROs, including method validation protocols and reports, drug substance/product manufacturing protocols and records, nonclinical study protocols and reports, GCP site monitoring reports, clinical study reports, etc.*
- *Authored regulatory documents such as initial and serial IND submissions and other required communications to FDA. Authored clinical documents such as protocols, study procedure manuals, management plans, communications plans, etc.*
- *Presented research findings to the research community. Authored summary documents and presentations for use by the client with its funding agencies and collaborators.*

January 2003-March 2005

Regulatory Scientist

Cato Research, Durham, NC

- *Led multidisciplinary teams in completing concurrent projects related to the development of two pharmaceutical products.*
- *Developed, reviewed, and implemented project budgets and timelines.*
- *Interfaced with clients to negotiate contracts, plan projects, and ensure that project deliverables met client quality, time, and budget specifications.*
- *Wrote regulatory, clinical, and scientific documents such as sections of integrated development plans, initial IND submissions, IND annual reports, pre-NDA meeting packages, study monitoring protocols, clinical and nonclinical final study reports, and cover letters for IND safety reports and information amendments.*
- *Guided and reviewed the technical writing by other team members of regulatory, clinical, and scientific documents such as IND amendments, IND annual and safety reports, an end-of-phase 2 meeting package, an NDA in eCTD format, informed-consent documents, CTM release processes, SOPs, and presentations.*
- *Helped manage the Cato Fellows program, a clinical-research training program aimed at Ph.D.-level scientists. Duties included recruiting, mentoring, managing, and training fellows; coordinating a weekly seminar series; and developing program budgets and performance goals.*

2001-2002

Scientific Analyst

Cogent Neuroscience, Durham, NC

- *Participated in study design and strategy concerning preclinical development of lead compounds.*
- *Analyzed, interpreted, and managed screening data for patent submissions; participated in preparing patents.*
- *Employed HTML, JavaScript, XML, XSL, PHP, and MySQL to implement an intranet website providing data storage, search, and presentation capabilities.*
- *Conceptualized and helped develop a program that rapidly scans biomedical literature for chemical genetics information about gene products of interest.*

1999-2001

Postdoctoral Fellow

GlaxoWellcome, RTP, NC

- *Participated in a matrix-managed drug discovery team that identified a novel, potent liver X receptor (LXR) agonist.*
- *Designed and conducted microarray experiments, in vitro functional assays, and in vivo proof-of-concept studies on the role of LXR in atherosclerosis.*
- *Conceptualized and performed the initial in vitro and in vivo studies to demonstrate the value of LXR agonists in treating Alzheimer's disease.*

1994-1999 **Graduate Student**
Duke University, Durham, NC

- *Conceived, designed, and performed independent research on epilepsy.*
- *Performed statistical analysis and interpretation of data.*
- *Presented results in journal articles, departmental seminars, and at conferences.*
- *Assisted in writing NIH grant proposals for laboratory funding.*

1991-1994 **Community Development Worker**
US Peace Corps, Costa Rica

- *Bridged cultural and language barriers in Costa Rica and the United States.*
- *Educated rural Costa Rican community groups about reforestation.*
- *Motivated and facilitated planning, financing, and implementation of tree nursery businesses and watershed reforestation projects.*
- *Collaborated with Costa Rican teachers to develop, evaluate, and execute an environmental education curriculum for fifth- and sixth-grade children.*

Professional Certifications

2003-present **Regulatory Affairs Certification**

Professional Associations

Drug Information Association

Regulatory Affairs Professional Society

North Carolina Regulatory Affairs Forum

Awards, Honors & Special Recognition

1995-1999 **Predoctoral Fellow**
Howard Hughes Medical Institute

1994-1998 **James B. Duke Fellow**
Duke University

1994-1995 **Graduate Fellow**
Pharmacological Sciences Training Program, Duke University

1987 **Eagle Scout**
Boy Scouts of America

Current Volunteer and Personal Activities

FOXP1 Syndrome Advocacy

Co-founder, Co-president, and Board of Directors member, International FOXP1 Foundation, a 501(c)(3) charitable non-profit organization (www.foxp1.org), 2021-present

Co-founder, international FOXP1 syndrome parents' group (https://www.rareconnect.org/en/community/foxp1), 2014-present

Member of the Associates' Board, Seaver Autism Center for Research and Treatment at the Icahn School of Medicine at Mount Sinai, 2017-present

Planning committee member, 2019 National FOXP1 Syndrome Parent/Researcher Congress

Avid lathe woodworker and furniture builder

Competencies

~20 years' experience in pharmaceutical development from target identification to NDA/BLA, focused on clinical development, regulatory strategy, and regulatory affairs

Educational background in neuroscience through Ph.D.

Leadership and management of company initiatives, staff pipelines, client accounts, and project execution across a diverse range of therapeutic areas, developmental stage, and project scope

Management and mentorship of junior colleagues

Positive, solution-oriented interactions with client peer scientists and regulatory agency representatives

Track record of successfully leading multidisciplinary drug development teams by relying on excellent project planning, consensus building, and team motivation skills

Authorship of numerous high-quality regulatory and clinical documents for use in clinical trials or FDA submission

Experience reviewing and providing feedback on regulatory and clinical documents prepared by colleagues

Excellent oral and written communication skills

Extensive experience with and appreciation for diverse cultures and peoples; strong desire to work towards the improvement of human health worldwide

Preference for energetic, self-motivated, and matrix-managed work environments

Thorough knowledge of and facility with Microsoft Office and other productivity software

Patents

2003 **Patent No. WO 03/082198A2**
GlaxoSmithKline
Methods of Treatment with LXR Modulators

Selected Publications

Refereed Journal Articles

H Winter, A Ginsberg, E Egizi, N Erondu, **K Whitney**, E Pauli, D Everitt. (2013) Effect of a High-Calorie, High-Fat Meal on the Bioavailability and Pharmacokinetics of PA-824 in Healthy Adult Subjects. Antimicrob. Agents Chemother. Nov;57(11):5516.

AH Diacon, R Dawson, M Hanekom, K Narunsky, SJ Maritz, A Venter, PR Donald, C van Niekerk, **K Whitney**, DJ Rouse, MW Laurenzi, AM Ginsberg, MK Spigelman. (2010) Early bactericidal activity and pharmacokinetics of PA-824 in smear-positive tuberculosis patients. Antimicrob Agents Chemother. Aug;54(8):3402-7

AM Ginsberg, MW Laurenzi, DJ Rouse, **KD Whitney**, MK Spigelman. (2009) Safety, tolerability, and pharmacokinetics of PA-824 in healthy subjects. Antimicrob. Agents Chemother. 2009 Sep;53(9):3720-5.

AM Ginsberg, MW Laurenzi, DJ Rouse, **KD Whitney**, MK Spigelman. (2009) Assessment of the effects of the nitroimidazo-oxazine PA-824 on renal function in healthy subjects. Antimicrob. Agents Chemother. 2009 Sep;53(9):3726-33.

KD Whitney, MA Watson, JL Collins, WG Benson, TM Stone, MJ Numerick, TK Tippin, JG Wilson, DA Winegar, and SA Kliewer. (2002) Regulation of Cholesterol Homeostasis by the Liver X Receptors in the Central Nervous System. Mol. Endo. 16:1378-1385.

JL Collins, AM Fivush, MA Watson, CM Galardi, MC Lewis, LB Moore, DJ Parks, JG Wilson, TK Tippin, JG Binz, KD Plunket, DG Morgan, EJ Beaudet, **KD Whitney**, SA Kliewer, and TM Willson. (2002) Identification of a Nonsteroidal Liver X Receptor Agonist through Parallel Array Synthesis of Tertiary Amines. J. Med. Chem. 45:1963-1966.

KD Whitney, MA Watson, B Goodwin, CM Galardi, JM Maglich, JG Wilson, TM Willson, JL Collins, and SA Kliewer. (2001) Liver X Receptor (LXR) Regulation of the *LXR*α Gene in Human Macrophages. J. Biol. Chem. 276:43509-43515.

KD Whitney and JO McNamara (2000) GluR3 autoantibodies destroy neural cells in a complement-dependent manner modulated by complement regulatory proteins. J. Neuroscience 20:7307-7316.

KD Whitney, PI Andrews and JO McNamara. (1999) Immunoglobulin G and complement immunoreactivity in the cerebral cortex of patients with Rasmussen's encephalitis. Neurology 53:699-708.

X-P He, M Patel, **KD Whitney**, S Janumpalli, A Tenner and JO McNamara. (1998) Glutamate receptor GluR3 antibodies and death of cortical cells. Neuron 20:153-163.

S Shafqat, M Velaz-Faircloth, VA Henzi, **KD Whitney**, TL Yang-Feng, MF Seldin and RT Fremeau, Jr. (1995) Human brain-specific L-proline transporter: molecular cloning, functional expression, and chromosomal localization of the gene in human and mouse genomes. Mol. Pharm. 48:219-229.

KD Whitney, FJ Seidler and TA Slotkin. (1995) Developmental neurotoxicity of chlorpyrifos: cellular mechanisms. Toxicol. Appl. Pharm. 134:53-62.

Review Articles

D Fordyce, S Truocchio, and **K Whitney**. (2006) Assembling and Filing the Common Technical Document. In: Expediting Drug and Biologics Development: A Strategic Approach, 3rd Edition (S. E. Linberg, ed.), pp. 289-297. PAREXEL International Corporation: Waltham, MA.

KD Whitney and JO McNamara. (1999) Humoral autoimmunity and modulation of synaptic transmission. Annu. Rev. Neurosci. 22:175-195.

JO McNamara, **KD Whitney**, PI Andrews, X-P He, S Janumpalli, MN Patel. (1999) Evidence for glutamate receptor autoimmunity in the pathogenesis of Rasmussen's encephalitis. In: Jasper's Basic Mechanisms of the Epilepsies. 3rd Edition: Advances in Neurology, Volume 79 (A.V. Delgado-Escueta, W.A. Wilson, R.J. Porter, eds.), pp. 543-550. Lippincott, Williams & Wilkins: Philadelphia.

JO McNamara, M Patel, XP He, S Janumpalli and **KD Whitney**. (1996) Glutamate receptor autoimmunity in Rasmussen's encephalitis. Cold Spring Harbor Symp. Quant. Biol. 61:327-332.

Abstracts and Presentations

KD Whitney and JO McNamara. (1998) GluR3 antiserum cytotoxicity occurs by an indolent, atypical complement-dependent mechanism. Soc Neurosci Abstr 24:1858.

CJ Oliver, M Inoue, JH Connor, R Terry, T Haystead, **KD Whitney**, R Gupta and S Shenolikar. (1998) Identification of neurofilament-L as the 68 kDa protein phosphatase-1-binding protein associated with neuronal plasma membranes. 1998 FASEB Summer Conference on Protein Phosphatases.

KD Whitney and JO McNamara. (1997) Immunohistochemical evidence of IgG and complement activity in the brains of Rasmussen's encephalitis patients. Soc. Neurosci. Abstr. 23:816.

KD Whitney and JO McNamara (1997) Complement deposition in the brains of patients with Rasmussen's encephalitis : an immunohistochemical analysis. Epilepsia 38:209.

M Patel, X-P He, **KD Whitney**, S Janumpalli and JO McNamara. (1997) IgG immunoreactive labeling of cortical neurons in a GluR3-induced rabbit model of Rasmussen's encephalitis. Epilepsia 38:106.

M Patel, X-P He, **KD Whitney**, S Janumpalli and JO McNamara. (1997) Increased IgG immunoreactive labeling of cortical neurons in a GluR3-induced animal model of Rasmussen's encephalitis. Soc. Neurosci. Abstr. 23:1666.

JO McNamara, X-P He, S Janumpalli, **KD Whitney** and M Patel. (1996) Glutamate receptor antibodies and death of cortical neurons. Epilepsia 37:78.

M Patel, X-P He, S Janumpalli, **KD Whitney** and JO McNamara. (1996) Glutamate receptor antibodies destroy cortical neurons by a complement-dependent mechanism. Soc. Neurosci. Abstr. 22:1203.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	CAMERON ECKEL, ASSISTANT GENERAL COUNSEL
SUBJECT:	APPOINTMENTS TO ADVISORY COMMITTEES
DATE:	NOVEMBER 4, 2021

Summary and Recommendation

At its November 4 meeting, the Board Governance subcommittee discussed Presiding Officer Dr. Mahendra Patel's proposed appointment to the Prevention Advisory Committee (PAC) and recommends approval of the appointment by the Oversight Committee.

Discussion

Texas Health and Safety Code Section 102.155 allows the Oversight Committee to create ad hoc committees of experts to advise the Oversight Committee. The PAC advises the Oversight Committee on important issues surrounding cancer prevention and control. The members of the PAC, appointed by the Oversight Committee, share their advice on opportunities to increase CPRIT's impact on cancer prevention and control in Texas.

CPRIT's administrative rules dictate that the presiding officer of the Oversight Committee is responsible for appointing experts to serve on CPRIT's advisory committees, including the PAC. Appointments to the PAC must be approved by the Oversight Committee.

The Nominations subcommittee reviewed the PAC appointment and recommends approval by the Oversight Committee.

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CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

CPRIT Advisory Committee Appointments
November 2021

Appointee	Advisory Committee	Organization
Ernest Hawk, M.D., MPH	Prevention Advisory Committee	Vice President and Head of the Division of Cancer Prevention and Population Sciences at The University of Texas MD Anderson Cancer Center

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BIOGRAPHICAL SKETCH

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

NAME: Hawk, Ernest T.

eRA COMMONS USER NAME (credential, e.g., agency login): EHAWK1

POSITION TITLE: Vice President and Division Head, Division of Cancer Prevention and Population Sciences / Boone Pickens Distinguished Chair for Early Prevention of Cancer

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

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Wayne State University, Detroit, MI	BS	06/1981	Biological Sciences
Wayne State University School of Medicine, Detroit, MI	MD	06/1985	Medicine
Emory University Affiliated Hospitals, Atlanta, GA	Clinical Residency	06/1988	Internal Medicine Internship/Residency
University of California, San Francisco, San Francisco, CA	Clinical Fellowship	06/1993	Medical Oncology Clinical Fellowship
National Cancer Institute, Bethesda, MD	Research Fellowship	06/1996	Cancer Prevention Fellowship
Johns Hopkins University School of Hygiene & Public Health, Baltimore, MD	MPH	05/1994	Epidemiology/ Biostatistics

A. Personal Statement

I am the current Vice President and Head of the Division of Cancer Prevention and Population Sciences at The University of Texas MD Anderson Cancer Center (MDACC), I hold the Boone Pickens Distinguished Chair for Early Prevention of Cancer, and serve as a Professor in the Department of Clinical Cancer Prevention. I also serve as the Cancer Center Support Grant (CCSG) Associate Director for Cancer Prevention and Population Sciences, Director of the CCSG Community Outreach and Engagement component, and co-leader of the CCSG Gastrointestinal Cancer Program. My background includes research, education, training, and practice in medicine, epidemiology, cancer prevention, clinical trials, disparities and drug development at several different institutions. Before coming to MDACC, I worked at the National Cancer Institute (NCI) for 12 years in chemopreventive drug identification, preclinical testing, and clinical development, participating in phase I-III trials of several agents including calcium, aspirin, celecoxib, DFMO, and combinations. From 2005-2007, I oversaw the NCI's Cancer Centers SPORE, training, and disparities programs; and also served as a co-leader of the NCI's Translational Research Working Group. At MDACC, I have gained experience in T1-T4 research through oversight and collaborations with the division's five academic departments (i.e., epidemiology, behavioral science, clinical cancer prevention, disparities, and health services research), the last of which, I founded; through my leadership of the Duncan Family Institute for Cancer Prevention and Risk Assessment; and my co-leadership of the institution's cancer prevention and control platform which advances health promotion and cancer control through evidence-based public policy, public and professional education, and community-based service implementation and dissemination. Beyond MDACC, I serve as a deputy editor for American Association for Cancer Research's (AACRs) *Cancer Prevention Research*, co-chair of the AACR's Prevention Committee. I serve or have served as an invited external advisor regarding cancer prevention and control, population sciences, and community outreach and engagement to more than ten NCI-designated cancer centers and as an internal advisor to several SPOREs, and two disparities-focused centers.

B. Positions, Scientific Appointments, and Honors

Positions and Employment

2012-present Co-director, Cancer Prevention & Control Platform, The University of Texas MD Anderson Cancer Center, Houston, TX

2009-present Boone Pickens Distinguished Chair for Early Prevention of Cancer, The University of Texas MD Anderson Cancer Center, Houston, TX

2008-present Executive Director, Duncan Family Institute for Cancer Prevention & Risk Assessment, The University of Texas MD Anderson Cancer Center, Houston, TX

2007-present Division Head, Division of OVP, Cancer Prevention and Population Sciences, The University of Texas MD Anderson Cancer Center, Houston, TX

2007-present Professor, Department of Clinical Cancer Prevention, Division of OVP, Cancer Prevention and Population Sciences, The University of Texas MD Anderson Cancer Center, Houston, TX

2007-present Vice President, Division of OVP, Cancer Prevention and Population Sciences, The University of Texas MD Anderson Cancer Center, Houston, TX

2004-2007 Director, Office of Centers, Training and Resources, Office of the Director, National Cancer Institute, Bethesda, MD

1999-2004 Chief & Medical Officer, Gastrointestinal and Other Cancers Research Group, Division of Cancer Prevention, National Cancer Institute, Bethesda, MD

1997-1999 Medical Officer, Chemoprevention Branch, National Cancer Institute, Bethesda, MD

Honors

2015 ASCO-American Cancer Society Award and Lecture in Cancer Prevention and Control – given for significant contributions to cancer prevention and control research or practice

2014 Cancer Prevention Fellowship Distinguished Alumni Award, National Cancer Institute

2011 Outstanding Leading Mentor in Cancer Prevention, Division of Cancer Prevention and Population Sciences, The University of Texas MD Anderson Cancer Center

2007 The Nancy Terner Behrman Lecture in Honor of Betty Flehinger, PhD, Weill Cornell Medical School, NYC

2002 Research Award, Distinguished Achievement in Cancer Prevention, National Cancer Institute

C. Contributions to Science

The primary focus of my career has been on chemopreventive drug identification, preclinical testing, and clinical development. Specifically, I am interested in the potential of non-steroidal anti-inflammatory drugs (NSAIDs) to prevent cancer because of their well-documented and broad efficacy in prevention, yet very real safety concerns. Additionally, I have worked to advance participation of diverse groups in clinical cancer prevention trials. Recently, as I have become more active in cancer control efforts, my interests have expanded to include the design, implementation, dissemination, and evaluation of evidence-based interventions that can significantly reduce the burden of cancer at the population level.

1. Identification, testing, and development of cancer chemopreventive agents. While at the NCI, my work involved pre-clinical and translational research investigations to develop novel chemopreventive agents as well as biomarkers of risk or response. As part of this work, I was actively involved in the initial design, implementation, monitoring, and analysis of a number of phase II and III trials testing the safety and efficacy of celecoxib for the prevention of colorectal cancer in individuals at increased risk. These trials demonstrated that celecoxib was, in fact, effective in the prevention of colorectal adenomas, but that it was associated with serious cardiovascular events among individuals at increased risk of cardiovascular disease, precluding its use in the general population.
   a. Bertagnolli MM, Eagle CJ, Zauber AG, Redston M, Solomon SD, Kim K, Tang J, Rosenstein RB, Wittes J, Corle D, Hess TM, Woloj GM, Boisserie F, Anderson WF, Viner JL, Bagheri D, Burn J, Chung DC, Dewar T, Foley TR, Hoffman N, Macrae F, Pruitt RE, Saltzman JR, Salzberg B, Sylwestrowicz T, Gordon GB, **Hawk ET**; APC Study Investigators. Celecoxib for the prevention of sporadic colorectal adenomas. N Engl J Med. 2006 Aug 31;355(9):873-84. PMID: 16943400.
   b. Bertagnolli MM, Eagle CJ, Zauber AG, Redston M, Breazna A, Kim K, Tang J, Rosenstein RB, Umar A, Baheri D, Collins NT, Burn J, Chung DC, Dewar T, Foley TR, Hoffman N, Macrae F, Pruitt RE, Saltzman JR< Salzberg B, Sylwestrowicz T, **Hawk ET**; Adenoma Prevention with Celexocib Study Investigators. Five-year efficacy and safety analysis of the adenoma prevention with celecoxib trial. Cancer Prev Res (Phila). 2009 Apr;2(4):310-21. PMID: 19336730; PMCID: PMC2976587.

c. Steinbach G, Lynch PM, Phillips RK, Wallace MH, **Hawk E**, Gordon GB, Wakabayashi N, Saunders B, Shen Y, Fujimura T, Su LK, Levin B, Godio L, Patterson S, Rodriguez-Bigas MA, Jester SL, King KL, Schumacher M, Abbruzzese J, DuBois RN, Hittelman WN, Zimmerman S, Kelloff G. The effect of celecoxib, a cyclooxygenase-2 inhibitor, in familial adenomatous polyposis. N Engl J Med. 2000 Jun 29;342(26):1946-52. PMID: 10874062.
d. Maresso KC, Tsai KY, Brown PH, Szabo E, Lippman S, **Hawk ET**. Molecular cancer prevention: current status and future directions. CA Cancer J Clin. 2015 Sep-Oct;65(5):345-83. PMID: 26284997; PMCID: PMC4820069.

2. Promotion of translational research and translation of scientific evidence into clinical and public health practice. Along with the research described above, I led the NCI's Translational Research Working Group (TRWG), formed in 2005. Over two years, the TRWG reviewed the NCI's intramural and extramural translational research portfolio and made recommendations regarding how the NCI could optimize its investment in further translational research. At MDACC, I've been involved in establishing goals, metrics, and infrastructures for translation of prevention science into cancer control actions. The Cancer Prevention and Control Platform was developed over the last few years to advance evidence-based cancer control actions in public policy, public/professional education, and delivery of community-based services to reduce the cancer burden broadly, but most especially in the underserved. The platform has developed and implemented several projects to advance evidence-based, community-oriented cancer control actions to promote human papillomavirus (HPV) vaccination, tobacco prevention and cessation, the adoption/maintenance of healthy lifestyles (including healthy diets, physical activity, and UV protection), cancer screening, and survivorship in Houston, across Texas, and with partnering cancer institutions nationally and globally. These have resulted in new collaborative relationships and more than $13M in financial support from individual philanthropists, major corporations, state/federal agencies, and private foundations. Additionally, we've gained support from a peer-reviewed funding agency within our state (e.g., CPRIT prevention award).
   a. http://www.cancer.gov/aboutnci/organization/ccct/reports/trwg-report.pdf
   b. **Hawk ET**, Greenwood A, Gritz ER, McTiernan A, Sellers T, Hursting SD, Leischow S, Grad O; Translational Research Working Group. The Translational Research Working Group developmental pathway for lifestyle alterations. Clin Cancer Res. 2008 Sep 15;14(18):5707-13. PMID: 18794079.
   c. Srivastava S, Gray JW, Reid BJ, Grad O, Greenwood A, **Hawk ET**; Translational Research Working Group. Translational Research Working Group developmental pathway for biospecimen-based assessment modalities. Clin Cancer Res. 2008 Sep 15;14(18):5672-7. PMID: 18794074; PMCID: PMC2737183.
   d. **Hawk ET**, Matrisian LM, Nelson WG, Dorfman GS, Stevens L, Kwok J, Viner J, Hautala J, Grad O; Translational Research Working Group. The Translational Research Working Group developmental pathways: introduction and overview. Clin Cancer Res. 2008 Sep 15;14(18):5664-71. PMID: 18612047.

3. Promotion, development, and implementation of prevention and control science. At MDACC, I lead the Division of Cancer Prevention and Population Sciences, which includes 60+ faculty members and 420+ employees. During my thirteen years here, I have promoted the work of our four existing departments (i.e, epidemiology, behavioral science, clinical cancer prevention, and health disparities) and developed the fifth department, Health Services Research. Through my oversight of these departments, I have had the opportunity to expand my research interests and work in both the genetic epidemiology and clinical prevention of various cancers, primarily colorectal cancer. I have initiated, coordinated, and/or participated in the design and analysis of a number of genetic association studies and both pre-clinical and clinical research seeking to identify risk factors, potential chemopreventive targets, and novel chemopreventive agents or regimens. This work has uncovered novel genetic loci that may potentially serve as risk biomarkers, and in the case of Wen, et al. (below), has resulted in a powerful risk prediction model for liver cancer in the general population.
   a. Hassan MM, Abdel-Wahab R, Kaseb A, Shalaby A, Phan AT, El-Serag HB, **Hawk E**, Morris J, Singh Raghav KP, Lee JS, Vauthey JN, Bortus G, Torres HA, Amos CI, Wolff RA, Li D. Obesity early in adulthood increases risk but does not affect outcomes of hepatocellular carcinoma. *Gastroenterology*. 2015 Jul;149(1):119-29. PMID: 25836985; PMCID: PMC4778392.

b. Wu X, Ajani JA, Gu J, Chang DW, Tan W, Hildebrandt MA, Huang M, Wang KK, **Hawk E**. MicroRNA expression signatures during malignant progression from Barrett's esophagus to esophageal adenocarcinoma. Cancer Prev Res (Phila). 2013 Mar;6(3):196-205. PMID: 23466817; PMCID: PMC3608471.
c. Dai J, Gu J, Huang M, Eng C, Kopetz ES, Ellis LM, **Hawk E**, Wu X. GWAS-identified colorectal cancer susceptibility loci associated with clinical outcomes. Carcinogenesis. 2012 Jul;33(7):1327-31. PMID: 22505654; PMCID: PMC4072910.
d. Wen CP, Lin J, Yang YC, Tsai MK, Tsao CK, Etzel C, Huang M, Hsu CY, Ye Y, Mishra L, **Hawk E**, Wu X. Hepatocellular carcinoma risk prediction model for the general population: the predictive power of transaminases. J Natl Cancer Inst. 2012 Oct 17;104(20):1599-611. PMID: 23073549; PMCID: PMC3692381.

4. Disparities in cancer, cancer care, and cancer outcomes. My positions at NCI and MDACC have also allowed me to examine barriers to the recruitment of underserved communities (especially, racial and ethnic minorities) in preventive and therapeutic cancer trials. These individuals have been historically underrepresented in such trials, which hinders scientific and medical advances in the prevention and treatment of cancer among these populations. In addition, each NCI-designated cancer center must ensure a proportional mix of racial and ethnic minorities in their therapeutic trials that is representative of the center's catchment area. I served as co-PI on an NIH U24 grant focused on enhancing minority participation in clinical trials (EMPaCT) and this team published its preliminary findings along with potential steps to improve rates of participation for this historically underrepresented group in therapeutic trials.
   a. **Hawk ET**, Habermann EB, Ford JG, Wenzel JA, Brahmer JR, Chen MS Jr, Jones LA, Hurd TC, Rogers LM, Nguyen LH, Ahluwalia JS, Fouad M, Vickers SM. Five National Cancer Institute-designated cancer centers' data collection on racial/ethnic minority participation in therapeutic trials: a current view and opportunities for improvement. Cancer. 2014 Apr 1;120 Suppl 7:1113-21. PMID: 24643649; PMCID: PMC4322861.
   b. Volk RJ, **Hawk E**, Bevers TB. Should CMS cover lung cancer screening for the fully informed patient? JAMA. 2014 Sep 24;312(12):1193-4. PMID: 25247511; PMCID: PMC4367127.

Complete List of Published Works in My Bibliography:

https://www.ncbi.nlm.nih.gov/sites/myncbi/1lQulfxZwpEQc/collections/44299012/public/

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	KRISTEN PAULING DOYLE, DEPUTY EXECUTIVE OFFICER & GENERAL COUNSEL CAMERON L. ECKEL, ASSISTANT GENERAL COUNSEL
SUBJECT:	CHAPTER 703 - PROPOSED RULE CHANGE
DATE:	NOVEMBER 4, 2021

Summary and Recommendation

The Board Governance Subcommittee met November 4 and recommends that the Oversight Committee approve the proposed administrative rule change for publication in the *Texas Register*. The suggested change affects Texas Administrative Code Chapter 703. Publication of the anticipated rule change in the *Texas Register* is the first step in the agency rulemaking process. CPRIT Staff will bring back the proposed rule amendment and any public comments to the Oversight Committee in February for final approval.

Discussion

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

The Board Governance Subcommittee met on November 4 to discuss the proposed rule change to § 703.26 with legal staff. The subcommittee voted to recommend that the Oversight Committee approve publication of the suggested rule change.

There are both substantive and non-substantive proposed amendments to § 703.26. First, the proposed amendment to § 703.26(f) adds "parking" to the list of allowable grantee reimbursements for clinical trial participation costs. The Oversight Committee recently approved subsection (f) at its August 2021 meeting to authorize reimbursement for costs of participation incurred by cancer clinical trial participants, including transportation, lodging, and costs reimbursed under a program established pursuant to the "Cancer Clinical Trial Participation Program."

A second proposed change to § 703.26 changes the statutory reference of the "Cancer Clinical Trial Participation Program" to Texas Health and Safety Code Chapter 51. During the 87th regular session, the Legislature approved the redesignation of the "Cancer Clinical Trial

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Participation Program" from Chapter 50 to Chapter 51. The redesignation did not result in any substantive changes to the "Cancer Clinical Trial Participation Program."

The remaining amendments to § 703.26 are structural rulemaking and grammatical changes recommended by Texas Register staff at the Secretary of State's Office.

Next Steps

Once approved by the Oversight Committee, CPRIT will publish the proposed rule change 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 change on our website and announce the opportunity for public comment via CPRIT's electronic list serve. CPRIT legal staff will summarize any comments received from the public for the Oversight Committee's consideration when approving the final rule changes in February.

The Cancer Prevention and Research Institute of Texas ("CPRIT" or "the Institute") proposes amendments to 25 Tex. Admin. Code § 703.26 relating to reimbursement of clinical trial participation costs to grantees, a statutory reference to the Cancer Clinical Trial Participation Program, and non-substantive edits.

Background and Justification

Section 703.26(f) became effective in September 2021 and relates to the reimbursement of certain costs that are part of a grant recipient's approved budget and incurred by a cancer clinical trial participant. The proposed amendment to § 703.26(f)(1) adds parking as a reimbursable clinical trial participation cost. In § 703.26(f)(3), the Institute proposes changing the statutory reference of the Cancer Clinical Trial Participation Program ("the Program") to Texas Health and Safety Code Chapter 51. During the 87th regular session, the Legislature redesignated the Program from Chapter 50 to Chapter 51.

In addition, the Institute proposes a new structure to § 703.26(e)(15) and a grammatical edit to § 703.26(f)(2). Neither of these proposed amendments change the substance or requirements found in § 703.26.

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 ensuring that companies receiving product development grants from the Institute are Texas-based entities and clarifying the process for meeting, maintaining, and documenting that status.

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 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 January 3, 2022. 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>

§703.26. Allowable Costs.

(a) A cost is an Allowable Cost and may be charged to the Grant Award if it is reasonable, allocable, and adequately documented.

(1) A cost is reasonable if the cost does not exceed that which would be incurred by a prudent individual or organization under the circumstances prevailing at the time the decision was made to incur the cost; and is necessary for the performance of the Grant Award defined in the Scope of Work in the Grant Contract.

(2) A cost is allocable if the cost:

(A) Benefits the Grant Award either directly or indirectly, subject to Indirect Cost limits stated in the Grant Contract;

(B) Is assigned the Grant Award in accordance with the relative benefit received;

(C) Is allowed or not prohibited by state laws, administrative rules, contractual terms, or applicable regulations;

(D) Is not included as a cost or used to meet Matching Fund requirements for any other Grant Award in either the current or a prior period; and

(E) Conforms to any limitations or exclusions set forth in the applicable cost principles, administrative rules, state laws, and terms of the Grant Contract.

(3) A cost is adequately documented if the cost is supported by the organization's accounting records and documented consistent with §703.24 of this title (relating to Financial Status Reports).

(b) Grant Award funds must be used for Allowable Costs as provided by the terms of the Grant Contract, Chapter 102, Texas Health and Safety Code, the Institute's administrative rules, and the Uniform Grant Management Standards (UGMS) adopted by the Comptroller's Office. If guidance from the Uniform Grant Management Standards on a particular issue conflicts with a specific provision of the Grant Contract, Chapter 102, Texas Health and Safety Code or the Institute's administrative rules, then the Grant Contract, statute, or Institute administrative rule shall prevail.

(c) An otherwise Allowable Cost will not be eligible for reimbursement if the Grant Recipient incurred the expense outside of the Grant Contract term, unless the Grant Recipient has received written approval from the Institute's Chief Executive Officer to receive reimbursement for expenses incurred prior to the effective date of the Grant Contract.

(d) An otherwise Allowable Cost will not be eligible for reimbursement if the benefit from the cost of goods or services charged to the Grant Award is not realized within the applicable term of the Grant Award. The Grant Award should not be charged for the cost of goods or services that benefit another Grant Award or benefit a period prior to the Grant Contract effective date or after the termination of the Grant Contract.

(e) Grant Award funds shall not be used to reimburse unallowable expenses, including, but not limited to:

(1) Bad debt, such as losses arising from uncollectible accounts and other claims and related costs.

(2) Contributions to a contingency reserve or any similar provision for unforeseen events.

(3) Contributions and donations made to any individual or organization.

(4) Costs of entertainment, amusements, social activities, and incidental costs relating thereto, including tickets to shows or sports events, meals, alcoholic beverages, lodging, rentals, transportation and gratuities.

(5) Costs relating to food and beverage items, unless the food item is related to the issue studied by the project that is the subject of the Grant Award.

(6) Fines, penalties, or other costs resulting from violations of or failure to comply with federal, state, local or Indian tribal laws and regulations.

(7) An honorary gift or a gratuitous payment.

(8) Interest and other financial costs related to borrowing and the cost of financing.

(9) Legislative expenses such as salaries and other expenses associated with lobbying the state or federal legislature or similar local governmental bodies, whether incurred for purposes of legislation or executive direction.

(10) Liability insurance coverage.

(11) Benefit replacement pay or legislatively-mandated pay increases for eligible general revenue-funded state employees at Grant Recipient state agencies or universities.

(12) Professional association fees or dues for an individual employed by the Grant Recipient. Professional association fees or dues for the Grant Recipient's membership in business, technical, and professional organizations may be allowed, with prior approval from the Institute, if:

(A) the professional association is not involved in lobbying efforts; and

(B) the Grant Recipient demonstrates how membership in the professional association benefits the Grant Award project(s).

(13) Promotional items and costs relating to items such as T-shirts, coffee mugs, buttons, pencils, and candy that advertise or promote the project or Grant Recipient.

(14) Fees for visa services.

(15) Payments to a subcontractor if the subcontractor working on a Grant Award project employs an individual who is a Relative of the Principal Investigator, Program Director, Company Representative, Authorized Signing Official, or any person designated as Key Personnel for the same Grant Award project (collectively referred to as "affected Relative"), and[~~:~~] the Grant Recipient will be paying the subcontractor with Grant Award funds for any portion of the affected Relative's salary or the Relative submits payment requests on behalf of the subcontractor to the Grant Recipient for payment with Grant Award funds.

[~~(A) the Grant Recipient will be paying the subcontractor with Grant Award funds for any portion of the affected Relative's salary; or~~

~~(B) the Relative submits payment requests on behalf of the subcontractor to the Grant Recipient for payment with Grant Award funds.~~]

(A) [~~(C)~~] For exceptional circumstances, the Institute's Chief Executive Office may grant an exception to allow payment of Grant Award funds if the Grant Recipient notifies the Institute prior to finalizing the subcontract. The Chief Executive Officer must notify the Oversight Committee in writing of the decision to allow reimbursement for the otherwise unallowable expense.

(B) [~~(D)~~] Nothing herein is intended to supersede a Grant Recipient's internal policies, to the extent that such policies are stricter.

(16) Fundraising.

(17) Tips or gratuities.

(f) Pursuant to Texas Health and Safety Code Section 102.203(b) the Institute may authorize reimbursement for one or more of the following expenses incurred by a cancer clinical trial participant that are associated with participating in a clinical trial and included in the Grant Recipient's Approved Budget:

(1) transportation, including car mileage, parking, bus fare, taxi or ride hailing fare exclusive of tips, and commercial economy class airfare within the borders of the State of Texas;

(2) lodging; [~~,~~] and

(3) any cost reimbursed under a cancer clinical trial participation program established pursuant to Texas Health and Safety Code Chapter 51 ~~50~~ (relating to Cancer Clinical Trial Participation Program).

(g) The Institute is responsible for making the final determination regarding whether an expense shall be considered an Allowable Costs

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	KRISTEN DOYLE, DEPUTY EXECUTIVE OFFICER & GENERAL COUNSEL CAMERON ECKEL, ASSISTANT GENERAL COUNSEL
SUBJECT:	TEXAS OPEN MEETINGS ACT AND PUBLIC INFORMATION ACT UPDATES – T.A.C. § 702.21 TRAINING
DATE:	NOVEMBER 9, 2021

Summary

Texas Administrative Code § 702.21 requires that Oversight Committee members receive training on the Texas Public Information Act (PIA) and the Texas Open Meetings Act (TOMA) after each regular session of the legislature. This memo summarizes notable changes made to the PIA and TOMA during the 87th Legislative Session that are applicable to state agencies or CPRIT activities. The information supplements the comprehensive overview of the TOMA (attached), provided to Oversight Committee members in November 2019.

CPRIT legal staff reviewed the recent changes to the PIA and TOMA and consulted a 2021 legislative session update prepared by the Attorney General's Office (attached). Most of the recent amendments to the PIA do not directly impact Oversight Committee members or the agency. One piece of legislation of interest, SB 1225, defines when a governmental body may suspend adherence to the PIA in the event of a catastrophe. It also sets expectations of a governmental body's efforts to respond to a PIA request if its physical office is closed and staff is working remotely.

Legal staff reviewed the legislative changes and determined that the amendments to TOMA made in the 2021 session do not affect Oversight Committee open meetings. While there is not a comprehensive legislative update from the Attorney General regarding TOMA, CPRIT will continue to monitor any publications and relay relevant information to the Oversight Committee.

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

Notable Changes to the Texas Public Information Act Affecting CPRIT – Senate Bill 1225

SB **1225** (Author: Huffman; Sponsors: Paddie, Raymond, Canales): In response to COVID-19 and the shift to remote work, SB 1225 defines what constitutes a "catastrophe" and when a governing body may suspend the applicability of the PIA because of it. A catastrophe is an event that directly interferes with the ability of a governmental body to comply with the PIA and

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includes, but is not limited to, a fire, hurricane, power failure, and epidemic. A catastrophe does not include a period when staff are working remotely but can still access information in order to respond a PIA request. If an agency suspends applicability of the PIA due to a catastrophe, it must submit notice to the Office of Attorney General (OAG) using the form provided on the OAG's website. An agency must also provide notice to the public following the posting requirements found in TOMA. SB 1225 details the permissible duration of a suspension of the PIA. If an agency receives a PIA request during a declared catastrophe, the request will be considered received under the PIA on the first day after the PIA suspension expires.

SB 1225 further amends the PIA to require a governmental body to make good faith efforts to respond to any requests under the PIA during a period when the physical offices are closed but staff still has access to information while working remotely. Even with this change, the PIA states that a current or former employee does not have a personal or property right to any public information the employee may create or receive in their official capacity.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Texas Open Meetings Act – An Overview

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

Background – Texas Open Meetings Act

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

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

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

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

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When Does the Act Apply to Communications Between Members?

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

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

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

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

Are There Any Situations When the Act Does Not Apply?

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

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

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

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

Does the Act Apply to Closed Sessions?

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

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

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

Does the Act Apply to Oversight Committee Subcommittee Meetings?

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

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

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

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

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

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

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

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

What is a "Walking" Quorum?

A walking quorum occurs when:

(1) a series of smaller group meetings (less than a quorum) occur; and
(2) members use the smaller group meetings to intentionally avoid constituting a quorum and evade the requirements of the Act.[9]

[7] *See Hitt v. Mabry*, 687 S.W.2d 791 (Tex. App. B San Antonio 1985, no writ) (school trustees violated Act by telephone conferencing). *But see Harris County Emergency Serv, Dist. #1 v. Harris County Emergency Corps*, 999 S.W.2d 163 (Tex. App. B Houston [14th Dist.] 1999, no writ) (evidence that one board member of a five-member county emergency service district occasionally used telephone to discuss agenda for future meetings with one other board member did not amount to Act violation).
[8] Tex. Gov't Code Ann. § 551.143.
[9] Tex. Govt. Code Ann. § 551.143.

Texas courts have not limited their interpretation of a walking quorums to physical meetings. It may be a criminal violation if the members meet or communicate by phone, memo, text, or email in numbers less than a quorum if the specific intent for doing so is to hold secret deliberations and circumvent the Act.

In February 2019, the Texas Court of Criminal Appeals struck down the provision relating to the "walking quorum" stating the law was too vague.[10] After this ruling, Senator Watson introduced SB 1640 to revise the "walking quorum" provision in TOMA with the goal to clearly prohibit the practice. Senate Bill 1640 passed both chambers with near-unanimous votes; Governor Abbott signed it to take effect immediately. Notably, state law now defines "deliberation" include both verbal and written exchanges between a quorum of members or a quorum and another person on an issue under the body's jurisdiction.

Can an Oversight Committee Member Participate in an Open (or Closed) Meeting by Phone or Video Conference?[11]

Yes, in limited circumstances. Participation by phone may occur in the event of an emergency when convening a quorum is difficult or impossible. The Act also permits a governing board member to participate in an open or closed meeting by video conference even when there is no emergency.

- Participating in a Meeting by Phone – A governing body may not conduct meetings subject to the Act by phone unless it meets the following two requirements:

  (1) an emergency or public necessity exists;

  An emergency or public necessity exists only if the governmental body must take immediate action resulting from an imminent threat to public health or safety or a reasonably unforeseeable situation. Whether an emergency exists is a fact-based question subject to judicial review.

  AND

  (2) convening a quorum in one location is difficult or impossible.[12]

  A member may not participate by phone even in an emergency scenario if a quorum of the governing body is able to meet in one location. A requirement to justify participation by telephone is that it is difficult or impossible for the agency to convene a quorum in one location.

[10] *See State v. Doyal*, No. PD-0254-18 (Tex. Crim. App. Feb. 27, 2019).
[11] During the COVID pandemic, Governor Abbott issued an executive order suspending some provisions of the Texas Open Meetings Act, including the provision that members of the governing body meet in person. The governor's executive order expired August 31, 2021.
[12] Tex. Govt. Code Ann. §§ 551.121 - .126.

If the governing body properly convenes an open meeting where one or more members participate by phone, then the meeting must be audible to the public at the location specified in the notice with two-way communication available during the entire meeting. The governing body must record the meeting, with every party identified before speaking.

- Participating by Video Conference – A governing body may hold an open or closed meeting by video conference. [13] The Attorney General provided in guidance late 2019 that clarifies the statutory requirements for videoconference participation. One principal issue of confusion related to whether the governing board's elected/appointed presiding officer must physically attend the open meeting. The Attorney General's interpretation is that the person presiding over the open meeting must attend the meeting in person; however, that role is not exclusive to the elected presiding officer if there is a process in place to delegate the presiding officer's role to another member. Texas law also allows a member of the public to testify at a meeting from a remote location by video conference.

  How is quorum determined when members are participating via videoconference?
  Members participating by videoconference will count toward the number of members needed for quorum. For the nine-member Oversight Committee, a quorum is five members present in person or participating via live videoconference.

  If the member participating by videoconference loses audio and/or video connection with the meeting site, then that member does not count for purposes of the quorum. If the remote member's attendance via videoconference is necessary to achieve quorum, the Oversight Committee may take no action until the remote member restores the connection. The meeting may recess up to six hours to allow time for resolving technical issues. If the remote member is not back online within six hours, then the presiding officer must adjourn the meeting.

  Who must be physically present at the open meeting when one or more members are participating by videoconferencing?
  At least one member of governmental body must be physically present to preside over the open meeting at the location specified in the published meeting notice.

  Is the member attending by videoconference required to be visible to the public?
  Yes. The video and audio quality must be such that the public and other board members must be able to see the facial expressions of the member participating by videoconference as well as hear the member's questions and input. State law requires the governing body to have a monitor (at least 27-inches) at the physical location for each member participating remotely. The monitor's screen should be fully visible to the public at the meeting site and on the meeting livestream, with the volume loud enough to hear the remote member.
  Are there any special notice requirements to hold a meeting via videoconference?

[13] Tex. Govt. Code Ann. 551.127

Yes. In addition to following the regular open meeting notice requirements, the meeting notice must state that one or more members may participate via videoconference and that the member presiding over the meeting will be present at the location listed in the notice. Governing body members may not participate via videoconference if the meeting notice does not contain the required notice.

Should the Oversight Committee decide that videoconference participation may be an option for its members, Legal will include a standing notice in all future published meeting agendas regarding the possibility of videoconference participation.

May the governmental body's elected or appointed presiding officer attend a meeting by videoconference?
Yes, but TOMA prohibits any member that participates in a meeting by videoconference from presiding over that meeting. According to the Attorney General, the governing body's presiding officer may delegate the role to another member who is physically present at the meeting site if the presiding officer is unable to attend the meeting in person and will participate by videoconference instead.

Oversight Committee bylaws allow for the delegation of the chairperson's role to another member when the chairperson participates by videoconference.

Are There Other Ways for the Entire Oversight Committee to Communicate Electronically?

Yes. The Act permits communications about public business between members of a governmental body and its staff to take place electronically so long as the governmental body posts the written communication to an online message board that is accessible to the public. Such a discussion "does not constitute a meeting or deliberation," under the Act.

An electronic message board is an example of using technology to aid effective functioning of the governmental body without sacrificing transparency. It provides a forum for governing board members to discuss agency business in between traditional meetings. The governmental body must own or control the online message board, which must be publicly accessible within one click from the governmental body's home page. The message board should display the communication in real time, attributable by the name and title of the member or staff. The governmental body may not vote or take any action via posting to the online message board. The communication should be viewable for at least 30 days and retained as an agency record for six years.

The Austin City Council uses an electronic message board to communicate among the members and staff. You can see the city's bulletin board here (click on "View Active Topics" on the message board landing page to see discussion topics.)

Does the Act Apply to Social Media?

Yes, although the Act does not provide much guidance specifically addressing social media. Modern technologies such as Twitter, Facebook, Instagram, texting, and instant messaging make it easier for governmental body members to inadvertently (or intentionally) conduct a meeting that is subject to the Act's requirements. Other than authorizing the online electronic message board, the Texas Legislature has not addressed social media issues affecting open meetings. The Senate Committee on State Affairs' Interim Report to the 82nd Legislature opined, "…under the current interpretations of the Act, a quorum would exist if a majority of the governmental body discusses public business on a Facebook wall…A similar situation could arise with Twitter where members can have public or private accounts."[14]

What are the Consequences for Violating the Act?

Actions taken in violation of the Act are voidable. Certain violations of the Act may result in criminal penalties for board members if prosecutors prove an intent to evade or violate the Act's requirements. Criminal violations include knowing participation in a walking quorum or an unauthorized closed meeting.

[14] SENATE COMMITTEE ON STATE AFFAIRS, INTERIM REPORT TO THE 82D LEGISLATURE at 59 (Dec. 2010).

2021 Legislative Session Update: Changes to the Texas Public Information Act

Statute	Bill	Change Made
Gov't Code § 552.1331	HB 872	Adds section 552.1331 of the Government Code, which makes certain utility customer information confidential.
Gov't Code §§ 552.003, 552.117, 552.1175, 552.161, 552.162, 552.2325	HB 3607	Redesignates certain sections of the Act to correct the numbering of these sections.
Ch. 1703 Occ. Code	HB 1560	Repeals Chapter 1703 of the Occupations Code.
Gov't Code §§ 552.117, 552.1175; Tax Code § 25.025	HB 1082	• Adds elected public officers to sections 552.117 and 552.1175 of the Government Code, as well as section 25.025 of the Tax Code. • Redesignates certain subsections.
Gov't Code § 552.1315	HB 2357	Adds section 552.1314 of the Government Code, which makes certain crime victim information confidential.
Gov't Code §§ 552.117, 552.1175; Tax Code § 25.025	SB 56	• Adds federal public defender, deputy federal public defender, and assistant federal public defender and the spouse or child of the current or former attorney or public defender to sections 552.117 and 552.1175 of the Government Code. • Adds a current or former United States attorney and assistant United States attorney to section 552.1175 of the Government Code. • Adds federal public defender, deputy public defender, and assistant federal public defender and the spouse and child of the attorney or public defender to section 25.025 of the Tax Code.
Gov't Code § 552.149	SB 334	Revises the right of access under section 552.149.
Gov't Code §§ 552.003, 552.117, 552.1175; Tax Code § 25.025	SB 841	• Adds definition for "honorably retired" to section 552.003 of the Government Code and section 25.05 of the Tax Code. • Revises certain subsections of sections 552.117 and 552.1175 of the Government Code and 25.025 of the Tax Code.
Tex. Parks & Wildlife Code § 11.030; Transp. Code §§ 204.011, 548.601; Ch. 730 Transp. Code	SB 15	Amends certain provisions relating to the Texas Consumer Privacy Act.
Elec. Code §§ 13.0021, 13.004, 15.0215; Fin. Code §§ 254.0313,	SB 1134	Amends provisions relating to the confidentiality of certain information for certain federal officials and

411.179; Gov't Code §§ 552.117, 572.035; Local Gov't Code § 159.071; Prop. Code § 11.008; Tax Code § 25.025; Transp. Code §§ 521.054, 521.121, 521.142		family members of certain federal officials and federal or state court judges.
Gov't Code §§ 552.2325; 552.2211	SB 1225	• Revises requirements for submitting catastrophe notices. • Adds section 552.2211.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: HEIDI MCCONNELL, CHIEF OPERATING OFFICER

SUBJECT: CHIEF OPERATING OFFICER REPORT

DATE: NOVEMBER 8, 2021

CPRIT Financial Overview for FY 2021 Quarter 4

FY 2021, Quarter 4 Operating Budget

CPRIT encumbered or expended 82% of the almost $4.5 million budgeted in Indirect Administration and 97% of the almost $18 million budgeted in Grant Review and Award Operations. The Grant Review and Award Operations budget includes the majority of the agency's vendor contracts, including the $9.9 million contract for grant management support services with GDIT.

CPRIT received $88,387 in revenue sharing payments during the fourth quarter for a total of approximately $275,118 deposited into the Cancer Prevention and Research Interest and Sinking Fund 5168 during FY 2021. At the end of FY 2021, the cumulative total of payments received over the agency's lifetime exceeded $4.9 million.

During September and October, CPRIT received almost $2.4 million in revenue sharing payments, the majority of which was an approximately $2.3 million payment received on September 27 from Merck for the August 13, 2021, milestone event achieved by Peloton for the FDA approval of WELIREG™ (belzutifan) for the treatment of patients with certain types of Von Hippel-Lindau (VHL) disease-associated tumors. With these additional payments, the revenues CPRIT has received exceeded $7.3 million at the end of October 2021. Furthermore, Merck notified CPRIT on October 28 that the agency would begin receiving quarterly royalty payments from the sales of this product. The first sales were recorded the last week of August 2021, so the first royalty payment of $2,442 is based on sales through September 30, 2021.

FY 2021, Quarter 4 and Annual Performance Measure Report

CPRIT reported on its two quarterly and three annual key performance measures to the Legislative Budget Board. During the fourth quarter, there were no company relocations to the state, but the annual target for this measure was already met in the prior quarter with one company relocation. For the number of people served through CPRIT's prevention and control grants, CPRIT exceeded the 500,000-person served annual target with a total of 833,494 people served.

In addition, CPRIT within range of the 145.2 annual age-adjusted cancer mortality rate target with 141.4 reported by the Texas Cancer Registry at the Department of State Health Services.

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CPRIT exceeded the 1,000 published articles on CPRIT-funded cancer research projects target with a reported number of 1,351 published articles and the 1,500 new jobs created and maintained target with a reported number of 3,265 jobs created and maintained.

Debt Issuance History

On August 12, TPFA issued the final tranche of $57.4 million in commercial paper notes. This brought the total issued for FY 2021 to $260.3 million. On September 28, TPFA issued first FY 2022 tranced of commercial paper notes in the amount of $87 million. The total debt issued on CPRIT's behalf is approximately $2.3 billion.

Other Items

Audit of CPRIT's FY 2021 Financial Statements

On October 6, CPRIT staff the McConnell & Jones audit team held a meeting to kick off the annual audit of CPRIT's financial statements. The audit is progressing with CPRIT staff responding to numerous document requests. The draft audit will be completed by December 6, and the McConnell & Jones audit team will discuss the audit results with the Audit Subcommittee at a meeting on December 13.

2022 Conference Update

CPRIT has selected a vendor, Swift Solutions, to provide conference planning services. The next step will be to issue a request for proposal for a conference venue in the Austin area with the preferred meeting dates during fall 2022. The selection of the conference venue will determine the actual meeting dates on which the conference program will be planned.

Cancer Prevention and Research Institute of Texas
Quarterly Financial Report
As of August 31, 2021

Indirect Administration (B.1.1.)

		2021 Appropriated	2021 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
1001	Salaries and Wages	$ 1,787,425	$ 1,604,399		$ 1,343,501	260,899	84%	$ 1,343,501	$ 260,899
1002	Other Personnel Costs	38,785	38,785		23,959	14,826	62%	23,959	14,826
2001	Professional Fees and Services	1,808,662	1,818,809		1,326,199	492,610	73%	1,326,199	492,610
2003	Consumable Supplies	24,000	24,000		2,664	21,336	11%	2,664	21,336
2004	Utilities	58,600	58,600		33,085	25,515	56%	33,085	25,515
2005	Travel	45,000	4,481		4,481	0	100%	4,481	0
2006	Rent-Building	11,000	11,000		2,191	8,809	0%	2,191	8,809
2007	Rent-Machine and Other	32,172	32,172		26,000	6,172	81%	26,000	6,172
2009	Other Operating Expenses	554,409	1,377,613		1,312,731	64,882	95%	1,312,731	64,882
	Subtotal - Indirect Administration (B.1.1.)	**$ 4,360,053**	**$ 4,969,859**	**1.66%**	**$ 4,074,809**	**$ 895,050**	**82%**	**$ 4,074,809**	**$ 895,050**

Grant Review and Award Operations (A.1.3.)

		2021 Appropriated	2021 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
1001	Salaries and Wages	$ 2,993,084	3,393,326		$ 3,393,326	$ 0	100%	$ 3,393,326	$ 0
1002	Other Personnel Costs	45,000	57,839		57,839	0	0%	57,839	0
2001	Professional Fees and Services	9,436,363	14,391,335		13,914,513	476,822	97%	13,914,513	476,822
2003	Consumable Supplies	-	-		-	-	0%	-	-
2004	Utilities	12,000	14,660		14,660	(0)	100%	14,660	(0)
2005	Travel	65,000	624		624	-	100%	624	-
2009	Other Operating Expenses	355,283	121,337		15,150	106,188	12%	15,150	106,188
	Subtotal - Grant Operations (A.1.3.)	**$ 12,906,730**	**$ 17,979,121**	**6.00%**	**$ 17,396,112**	**$ 583,009**	**97%**	**$ 17,396,112**	**$ 583,009**

Grants

		2021 Appropriated	2021 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
4000	Grants - Prevention (A.1.2)	$ 28,050,081	$ 28,080,479		$ 22,599,530	$ 5,480,949	80%	$ 22,599,530	$ 5,480,949
4000	Grants - Research (A.1.1.)	251,620,104	$ 248,687,003		219,302,169	$ 29,384,834	88%	219,302,169	29,384,834
	Subtotal - Grants	**$ 279,670,185**	**$ 276,767,482**	**92.34%**	**$ 241,901,699**	**$ 34,865,783**	**87%**	**$ 241,901,699**	**$ 34,865,783**
	Grand Totals	**$ 296,936,968**	**$ 299,716,462**	**100.00%**	**$ 263,372,620**	**$ 36,343,842**	**88%**	**$ 263,372,620**	**$ 36,343,842**

Cancer Prevention and Research Institute of Texas
Cancer Prevention and Research Institute Fund Account - 5136
As of August 31, 2021

	8/01/2021-8/31/2021	AY 21 Year to Date as of 8/31/2021
Beginning Balance : 9/01/2020		**$ 600,506**
Increases:		
(1)	$ -	$ -
(2)	-	
Total Increases	**$ -**	**$ 600,506.00**
Reductions:		
Expenditures - Appropriated	$ -	$ -
	$ -	$ -
	$ -	$ -
Total Reductions	**$ -**	**$ -**
Ending Balance: 8/31/2021		**$ 600,506.00**

Note: (1) The Institute received a settlement from the Texas Cancer Coalition (TCC). This amount represents the final distribution and transfer of all funds ($303,877) from the TCC which ceased operations in May 2013. These funds are in the State Treasury but are not appropriated to CPRIT. The beginning balance reflects the transfer of all TCC funds.

Cancer Prevention and Research Institute of Texas

License Plate Trust Fund Account - 0802

As of August 31, 2021

	8/01/2021-8/31/2021	AY 21 Year to Date as of 8/31/2021
Beginning Balance : 9/01/2020		**$ 30,397.95**
Increases:		
(1) License Plate Revenue Received	$ 852.47	$ 9,175.59
Total Increases	**$ 852.47**	**$ 39,573.54**
Reductions:		
Expenditures - Appropriated	$ -	$ -
	-	-
Total Reductions	**$ -**	**$ -**
Ending Balance: 8/31/2021		**$ 39,573.54**

Note:

Balance forward from 2020 License Plate $30,397.95

Cancer Prevention and Research Institute of Texas

Appropriated Receipts - 0666

As of August 31, 2021

		8/01/2021-8/31/2021	AY 21 Year to Date as of 8/31/2021
Beginning Balance : 9/01/2020			**$ 83,996.90**
Increases:			
(1)	Product Development Application Fees Received	$ 7,500.00	$ 32,000.00
(2)	Appropriated Receipts applied to payments	$ -	$ -
(3)	Conference Registration Fees	$ -	$ -
(4)	Conference Registration Fees-Credit Card	$ -	$ -
Total Increases		**$ 7,500.00**	**$ 32,000.00**
Reductions:			
	Conference Expenditures - Appropriated	$ -	$ -
	Credit Card Fees Expended	$ -	$ -
	Refund-Application Fees	$ -	$ -
	Legal Services Expenses (Application Fees)	$ (104,750.00)	$ (104,750.00)
Total Reductions		**$ (104,750.00)**	**$ (104,750.00)**
Ending Balance: 8/31/2021			**$ 11,246.90**

Forward balance for FY 2020 is $83,896.90
Application Fees + $100 Donation

Cancer Prevention and Research Institute of Texas

Interest & Sinking Fund Account - 5168

As of August 31, 2021

		8/01/2021-8/31/2021	AY 21 Year to Date as of 8/31/2021
Beginning Balance : 9/01/2020			**$ 2,237,500.68**
Increases:			
(1)	Revenue Sharing / Royalties	$ 26,133.66	$ 288,030.57
Total Increases		**$ 26,133.66**	**$ 2,525,531.25**
Reductions:			
	Expenditures - Appropriated	$ -	$ -
		$ -	
		$ -	$ -
Total Reductions		**$ -**	**$ -**
Ending Balance: 8/31/2021			**$ 2,525,531.25**

Balance forward from FY 2020 is $2,237,500.68

Cancer Prevention and Research Institute of Texas
FY 2021, Quarter 4 Performance Measure Report

Measure	Targeted Performance	QTR 1	QTR 2	QTR 3	QTR 4	Sum of QTRs	% of Mandate Attained
Number of People Served by Institute Funded Prevention and Control Activities	500,000	234,404	172,169	233,001	193,920	833,494	166.70%
Number of Entities Relocating to TX for Cancer Research Related Projects	1	0	0	1	0	1	100.00%
Annual Age-adjusted Cancer Mortality Rate	145.2	N/A	N/A	N/A	N/A	141.4	97.38%
Number of Published Articles on CPRIT-Funded Research Projects	1,000	N/A	N/A	N/A	N/A	1,351	135.10%
Number of New Jobs Created and Maintained	1,500	N/A	N/A	N/A	N/A	3,265	217.67%

Variance Explanations

Number of People Served by Institute Funded Prevention and Control Activities
CPRIT prevention grantees have continued to be successful at delivering cancer prevention education and clinical services to more people than they anticipated, stretching their CPRIT-grant funds further to serve Texans. During the COVID-19 pandemic, they found alternative means through the use of remote technologies such as the telephone, electronic messages, and videoconferencing, to continue delivering cancer prevention education to Texans. They have also resumed providing cancer prevention clinical services, such as mammograms and colonoscopies, following COVID-19 precautions which include the use of COVID-19 tests and a greater amount of PPE.
Number of Entities Relocating to TX for Cancer Research Related Projects
CPRIT met the target in the third quarter of the year with the relocation of Invectys USA, Inc. This output is dependent on the number of companies applying for CPRIT Company Awards that can successfully advance through CPRIT's rigorous review and evaluation process, receive an award and actually relocate operations to Texas. Therefore, the results vary. A company must meet 4 of CPRIT's 7 criteria for a relocation to be considered complete.
Number of Published Articles on CPRIT- Funded Research Projects
The number reflects that CPRIT-funded research projects have yielded numerous results and breakthroughs which grantees have been successful in reporting through scientific publications.
Number of New Jobs Created and Maintained
The number of new jobs created and maintained reported by academic and product development research grantees exceeded the projection because CPRIT has a portfolio with more than 500 active grants and several scientific staff are required for each project. In addition, the measure includes jobs maintained which is proportionally double the number of new jobs created in a given year. Grantees conduct CPRIT-funded research projects over multiple years and must maintain the scientific expertise to do so.

CPRIT Commercial Paper and G.O. Bond Issuance

Fiscal Year	Amount Appropriated	Dated Issued	Amount Issued	Amount Issued for Fiscal Year	Commercial Paper or GO Bond Issuance	Series	Comments	Interest Rate
2010	$ 225,000,000	September 9, 2009	$ 9,100,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2010		September 9, 2009	$ 3,600,000		Commercial Paper Notes	Series B, Tax-Exempt	Defeased with cash July 2011	
2010		March 12, 2010	$ 63,800,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2010		August 26, 2010	$ 148,500,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
				$ 225,000,000				
2011	$ 225,000,000	September 7, 2010	$ 11,800,000		Commercial Paper Notes	Series A, Taxable		
2011		August 10, 2011	$ 51,000,000		G.O. Bonds	Taxable Series 2011	Par amount of new money	Fixed Rate Bonds All-In-True Interest Cost 4.0144%
2011		August 10, 2011	$ 232,045,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2011	Par amount of refunding; Refunded $233.2M of GOCP CPRIT Series A (9/9/09, 3/12/09, 8/26/09, 9/7/10)	Fixed Rate Bonds All-In-True Interest Cost 4.0144%
				$ 62,800,000				
2012	$ 300,000,000	September 7, 2011	$ 3,200,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2012		December 8, 2011	$ 3,200,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2012		March 2, 2012	$ 12,300,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2012		June 21, 2012	$ 15,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2012		August 16, 2012	$ 42,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
				$ 75,700,000				
2013	$ 300,000,000	September 6, 2012	$ 9,600,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2013		May 16,2013	$ 13,400,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
				$ 23,000,000				
2014	$ 300,000,000	November 25, 2013	$ 55,200,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2014		March 13, 2014	$ 47,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2014		June 17, 2014	$ 60,300,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2014		July 8, 2014	$ 233,280,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2014	Par amount of refunding; Refunded $237.88M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 3.327184%
				$ 162,500,000				
2015	$ 300,000,000	November 5, 2014	$ 57,600,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2015		April 29, 2014	$ 112,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2015		June 26, 2015	$ 75,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
				$ 244,600,000				

CPRIT Commercial Paper and G.O. Bond Issuance

Fiscal Year	Amount Appropriated	Dated Issued	Amount Issued	Amount Issued for Fiscal Year	Commercial Paper or GO Bond Issuance	Series	Comments	Interest Rate
2016	$ 300,000,000	September 22, 2015	$ 55,400,000		Commercial Paper Notes	Series A, Taxable		
2016		October 29, 2015	$ 300,000,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2015C	Par amount of refunding; Refunded $300M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 3.299867%
2016		October 29, 2015	$ 69,800,000		G.O. Bonds	Taxable Series 2015C	Par amount of new money: Disbursed to CPRIT January 2016	Fixed Rate Bonds All-In-True Interest Cost 3.299867%
2016		May 16, 2016	$ 92,100,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2016		August 29, 2016	$ 60,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
				$ 277,300,000				
2017	$300,000,000	October 19, 2016	$ 58,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2017		January 5, 2017	$ 58,900,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2017		February 8, 2017	$ 269,000,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2017	Par amount of refunding: Refunded $269M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 3.4622%
2017		February 8, 2017	$ 106,000,000		G.O. Bonds	Taxable Series 2017	Par amount of new money	Fixed Rate Bonds All-In-True Interest Cost 3.4622 %
				$ 222,900,000				
2018	$300,000,000	September 29, 2017	$ 68,200,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2018		March 8, 2018	$ 99,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
2018		July 11, 2018	$ 55,000,000		Commercial Paper Notes	Series A, Taxable	Refunded as G.O. Bonds	
				$ 222,200,000				
2019		September 21, 2018	$ 222,200,000		G.O. Bond (Refunding Bonds)	Taxable Series 2018	Par amount of refunding: Refunded $222.2M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 3.720632%
2019	$300,000,000	September 21, 2018	$ 75,975,000		G.O. Bonds	Taxable Series 2018	Par amount of new money	Fixed Rate Bonds All-In-True Interest Cost 3.720544%
2019		March 28, 2019	$ 77,725,000		Commercial Paper Notes	Series A, Taxable		Interest rates between 1.90% - 2.55%
2019		July 12, 2019	$ 54,000,000		Commercial Paper Notes	Series A, Taxable		Interest rates between 1.95% - 2.35%
				$ 207,700,000				

CPRIT Commercial Paper and G.O. Bond Issuance

Fiscal Year	Amount Appropriated	Dated Issued	Amount Issued	Amount Issued for Fiscal Year	Commercial Paper or GO Bond Issuance	Series	Comments	Interest Rate
2020		September 16, 2019	$ 64,300,000		Commercial Paper Notes	Series A, Taxable		Interest rate of 2.10%
2020		January 9, 2020	$ 52,000,000		Commercial Paper Notes	Series A, Taxable		
2020		April 23, 2020	$ 248,025,000		G.O. Bond (Refunding Bonds)	Taxable Series 2018	Par amount of refunding: Refunded $243.025M 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 2018	Par amount of new money	Fixed Rate Bonds All-In-True Interest Cost 2.644360%
				$ 231,300,000				
2021	$300,000,000	September 11, 2020	$ 75,000,000		Commercial Paper Notes	Series A, Taxable		Interest rate of 0.23% for 90 days
		January 14, 2021	$ 59,000,000		Commercial Paper Notes	Series A, Taxable		Interest rate of 0.23% for 118 days
		April 29, 2021	$ 68,900,000		Commercial Paper Notes	Series A, Taxable		Interest rate of 0.18% for 90 days
		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		
				$ 87,000,000				
TOTAL ISSUED TO DATE				**$ 2,302,300,000**				

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

To:	AUDIT SUBCOMMITTEE
From:	HEIDI MCCONNELL, CHIEF OPERATING OFFICER
Subject:	FY 2021 INTERNAL AUDIT SERVICE CONTRACT MODIFICATION
Date:	NOVEMBER 9, 2021

Recommendation

CPRIT staff recommends the Audit Subcommittee approve an amendment to the FY 2022 contract with Weaver and Tidwell to increase the contract amount by $55,000 to $241,000. The Oversight Committee approved the original FY 2022 contract for $186,000 on August 18, 2021.

Background

This contract amendment in conjunction with the agency extending the current FY 2021 contract under at no cost to allow the expenditure of those remaining funds will provide Weaver and Tidwell with sufficient budget to address the projects scheduled in the modified FY 2022 internal audit plan being considered by the Audit Subcommittee.

The modified annual internal audit plan will include an advisory audit to assist CPRIT with information technology general controls remediation activities, an audit over CPRIT procurement compliance, an adjusted records management advisory audit, and an audit over vendor contract compliance. In addition, there will be follow-up procedures performed over the outstanding findings from the information technology general computer controls, information security, communications, and governance audits and over the outstanding recommendations from the disaster recovery and business continuity planning advisory audit.

The audit over the alignment of the agency's IT environment with Texas Administrative Code, Chapter 202, and the state's strategic IT goals which was originally on the FY 2022 audit plan will be incorporated in the FY 2023 internal audit plan.

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