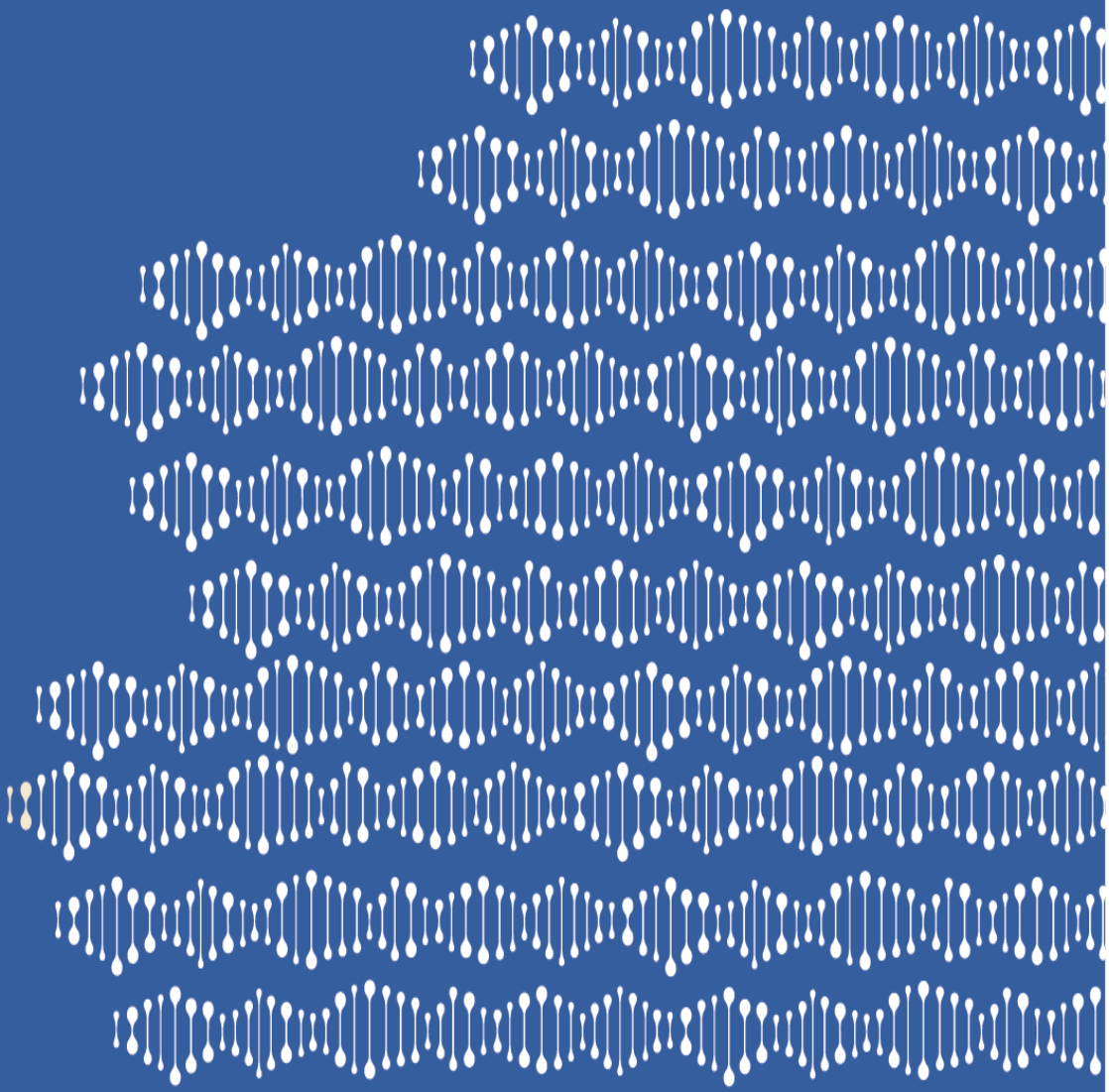
CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Meeting

November 29, 2017



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Summary Overview of the November 29, 2017, Oversight Committee Meeting

This summary provides an overview of major agenda items and background on key issues for Committee consideration at the November 29, 2017, Oversight Committee meeting.

CEO Report
Wayne Roberts will present the CEO's report and address issues including new personnel, available grant funds, preparation for the special Oversight Committee meeting in January, and other topics.

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.

Chief Scientific Officer Report and Grant Award Recommendations
Dr. James Willson will provide an update on the Academic Research Program and present the Program Integration Committee's (PIC) two award recommendations for Recruitment of First-Time, Tenure-Track Faculty Members, and one recommendation for the Recruitment of an Established Investigator totaling $10,000,000. Dr. Willson will also address the request to increase funding for Award RP170691 by $943,570 ($4,766,430 total) to accurately reflect the reduction in budget that was recommended by the Scientific Review Council on July 13, 2017.

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

Chief Prevention and Communications Officer Report and Grant Award Recommendations
Dr. Becky Garcia will update the Oversight Committee on the on the agency's communications activities and present the PIC's one award recommendation totaling $294,804.

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

Chief Product Development Officer Report
Mr. Mike Lang will provide an update on the Product Development Program, including an overview of FY 2018 Requests for Applications.

Program Priorities
Health and Safety Code Chapter 102 requires CPRIT's Oversight Committee to establish program priorities on an annual basis. Mr. Roberts will present the staff's recommendations for FY 2018 Program Priorities. The Oversight Committee will vote on final program priorities.

Appointments - Scientific Research and Prevention Programs Committee
The Chief Executive Officer has provisionally appointed three new members to CPRIT's Scientific Research and Prevention Programs Committees. CPRIT's statute requires the Oversight Committee to approve the CEO's recommendations before the appointments are final. Biographical sketches for the appointees are included for the Oversight Committee's consideration.

Internal Auditor Report
Weaver and Tidwell, CPRIT's internal auditor, will provide an internal audit update.

Amendments to 25 TAC Chapters 701 and 703
Ms. Eckel will present the final order approving an amendment to Chapter 703 that the Oversight Committee provisionally approved at the August meeting. If approved, the amendment will become effective in December.

Ms. Eckel will also present proposed changes to the agency's administrative rules in Chapters 701 and 703. Texas Health and Safety Code § 102.108 authorizes the Oversight Committee to implement rules to administer CPRIT's statute. Legal staff will bring back these rule changes to the Oversight Committee for final approval in February after the public has commented on the proposed rule changes.

Chief Operating Officer Report
Heidi McConnell will discuss the operating budget, performance measures, and debt issuance history for the fourth quarter of FY 2017.

Subcommittee Business
Three new appointments to the Oversight Committee require subcommittee assignments for fiscal year 2018-2019. The Oversight Committee must vote to approve the changes to subcommittee membership.

Public Information Act and Open Meeting Act Update Training
Texas Administrative Code § 702.21 requires Oversight Committee members to receive training on the Public Information Act (PIA) and the Texas Open Meetings Act (TOMA) after each regular session of the legislature. CPRIT's legal staff will discuss issues raised in the memos included in the meeting packet.

CANCER PREVENTION & RESEARCH
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Oversight Committee Meeting Agenda

Texas State Capitol Extension
1400 N. Congress Avenue, Austin, Texas 78701
Room E1.012

November 29, 2017
10:00 a.m.

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. Oath of Office for newly appointed Oversight Committee members
4. Adoption of Minutes from the August 16, 2017, meeting **TAB 1**
5. Public Comment
6. Grantee Presentation **TAB 2**
7. Chief Executive Officer Report **TAB 3**
8. Chief Compliance Officer Report **TAB 4**
9. Chief Scientific Officer Report **TAB 5**
   - Grant Award Recommendations
10. Chief Prevention and Communications Officer Report **TAB 6**
    - Grant Award Recommendations
11. Chief Product Development Officer Report **TAB 7**
    - Proposed Request for Applications FY 2018 Process and Timeline
12. Scientific Research and Prevention Program Committee Appointments **TAB 8**
13. FY 2018 Program Priorities **TAB 9**
14. Internal Auditor Report **TAB 10**
15. Amendments to 25 T.A.C. Chapters 701 – 703 **TAB 11**
    - Final Order Approving Amendments to Chapter 703
    - Proposed Amendments to Chapters 701 and 703 and Authorization to Publish in *Texas Register*
16. Chief Operating Officer Report **TAB 12**
17. Subcommittee Business
    - New subcommittee member assignments
18. Personnel – Chief Executive Officer
19. Texas Open Meeting Act and Public Information Act Updates **TAB 13**
20. Compliance Investigation Pursuant to Health & Safety Code § 102.2631
21. Consultation with General Counsel
22. Future Meeting Dates and Agenda Items
23. Adjourn

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Meeting
August 16, 2017

Call to Order – Agenda Item 1

A quorum being present, Presiding Officer Geren called the Oversight Committee to order at 10:01 a.m.

Roll Call/Excused Absences – Agenda Item 2

Committee Members Present:
Angelos Angelou
Pete Geren
Bill Rice, M.D.
Will Montgomery
Craig Rosenfeld, M.D.

Donald (Dee) Margo was not present at roll call, but arrived at 10:45 a.m. as noted in the minutes.

Absent:
Amy Mitchell
Ned Holmes

MOTION:
On a motion made by Dr. Rice and seconded by Mr. Montgomery, the Oversight Committee unanimously voted to excuse the absence of Mr. Holmes and Mrs. Mitchell.

Adoption of Minutes from the May 17, 2017, Meeting – Agenda Item 3

MOTION:
On a motion made by Mr. Montgomery and seconded by Dr. Rice, the Oversight Committee unanimously voted to approve the minutes of the Oversight Committee meeting of May 17, 2017, as presented.

Public Comment – Agenda Item 4

Presiding Officer Geren noted that there were no requests for public comment.

Grantee Presentations – Agenda Item 5

Dr. James Willson, Chief Scientific Officer, introduced Dr. Peter Houghton, Professor, Molecular Medicine, The University of Texas Health Science Center at San Antonio, Director of the Greehey Children's Cancer Research Institute, and holder of the Greehey Distinguished Chair for the Children's Cancer Research Institute.

Dr. Houghton reported on the work of the Texas Pediatric PDX Core, a joint effort of The University of Texas Health Science Center at San Antonio and The University of Texas Southwestern Medical Center Dallas, and responded to questions from the Oversight Committee members.

Michael Lang, Chief Product Development Officer, introduced Fahar Merchant, Ph.D., Chairman, President and Chief Executive Officer of Medicenna BioPharma, Inc.

Dr. Merchant reported on the work of Medicenna BioPharma, Inc, and responded to questions from the Oversight Committee members.

Chief Executive Officer Report - Agenda Item 6

Presiding Officer Geren called Mr. Wayne Roberts, Chief Executive Officer to give his report.

Personnel

Mr. Roberts reported all the agency's 32 positions are filled with permanent or contracted personnel. CPRIT expects to fill the three contracted positions with permanent employees on September 1 after the Governor's hiring moratorium expires. The three new positions authorized by the Legislature during the last session are posted and anticipated to be filled by the end of September.

Grant Awards Funds Available

Mr. Roberts noted that if the Oversight Committee approves all recommendations presented today, there will be $2.6 million in available funds unspent for the year. The amount would have been only $636,000 had an institution not declined a $2 million recruitment award prior to this meeting. Mr. Roberts informed the Oversight Committee that in future years the agency will plan for a 1 to 1.5% reserve (equal to approximately $2.8 to $4 million) when budgeting for grant awards. Any unexpended balances in a fiscal year are rolled into the next fiscal year. Mr. Roberts stated he feels confident that by the time the agency Sunsets in 2023, all unexpended balances will be exhausted.

New Initiative

Mr. Roberts stated staff is exploring a complementary Request for Application (RFA) program related to the Academic Research Program. Because this is a new initiative and approach, Mr. Geren and Dr. Rice will participate in the scoping process. The stimulus for the initiative is Ms. Susan Dawson's presentation to the committee in February 2017 on a proposed new funding

mechanism. Mr. Roberts promised future updates for Oversight Committee members about this new initiative.

CPRIT Funding Scenarios through FY 2023

Mr. Roberts stated that the Legislature authorized the agency through FY 2023. He referred to three funding scenarios in the meeting materials that may inform the Oversight Committee when making program priority decisions.

Presiding Officer Geren noted for the record that Mr. Margo arrived at the meeting at 10:45.

Chief Compliance Officer Report – Agenda Item 7

Mr. Vince Burgess, Chief Compliance Officer, stated that his report in the meeting materials highlighted several compliance activities and initiatives, including Grant Recipient Reports, Financial Status Report Reviews, Desk Reviews, On-site Reviews, Annual Compliance Attestations, Single Audit Tracking, FY18 Grantee Risk and Assessment, and Training and Support. Mr. Burgess also noted that grantee delinquent/missing reports continue to be under the 5% threshold.

Chief Scientific Officer Report and Grant Award Recommendations – Agenda Item 8

Dr. James Willson, Chief Scientific Officer, presented the proposed awards recommended by the Program Integration Committee (PIC). He noted that the PIC recommended 52 awards, however a grant applicant withdrew one recruitment award after the PIC meeting but before the Oversight Committee meeting. Therefore, the Oversight Committee will consider 51 awards presented in 6 slates corresponding to grant mechanism and totaling approximately $79,481,933. Dr. Willson also noted that the PIC recommendations include 8 Individual Research Awards (IIRA) totaling $7,034,189, and 3 Early Translational Research Awards (ETRA) totaling $2,998,914 that the PIC originally deferred at its October 28, 2016, meeting. To meet the FY17 budget allocation, Dr. Willson reported that the PIC recommended reducing the deferred IIRA and ETRA budgets by 8.5%.

Grant Mechanism	SRC Recommendations		Program Integration Committee Recommendations	
	Awards	Funding	Awards	Funding
Early Translational Research Awards (Deferred 17.1)	3	$2,998,914	3	$2,744,006
Individual Investigator Initiated Research Awards (Deferred 17.1)	8	$7,034,189	8	$6,436,283
High Impact/High Risk Research Awards	19	$3,799,366	19	$3,799,366
Core Facility Support Awards	7	$30,502,278	7	$30,502,278

Recruitment of Established Investigators	2	$12,000,000	2	$12,000,000
Recruitment of First-Time, Tenure Track Faculty Members*	13	$26,000,000	13	$26,000,000
Total*	**52**	**$82,334,747**	**52**	**$81,481,933**

* The total includes one grant application, RR170064, which the PIC recommended for funding before the applicant withdrew the application.

Program Priorities Addressed by Grant Recommendations		
# Awards	**Program Priorities**	**Funding**
15	Recruitment of outstanding cancer researchers to Texas	$38,000,000
7	Investment in core facilities	$30,502,278
30	A broad range of innovative, investigator-initiated research projects	$12,979,656
5	Prevention and early detection	$3,514,005
7	Computational biology and analytic methods	$25,345,097
11	Childhood cancers	$22,887,206
5	Cancers of importance in Texas	$9,847,000
5	Disparities	$8,138,500
*Some grants awards address more than one program priority.		

Academic Research Grant Award Recommendations

Core Facility Support Awards					
App ID	**Award Mechanism**	**Application Title**	**PI**	**PI Organization**	**Recommended Budget**
RP170638	CFSA	Cyclotron and Radiochemistry Core Facility for Pediatric Oncology	Sun, Xiankai	The University of Texas Southwestern Medical Center	$5,648,027
RP170644	CFSA	Establish a New Cryo-Electron Microscopy Core Facility and Service for Structure Determination at UT Southwestern Medical Center	Nicastro, Daniela	The University of Texas Southwestern Medical Center	$5,498,714
RP170628	CFSA	The University of Texas M.D. Anderson Cancer Center Science	Richie, Ellen	The University of Texas M. D. Anderson	$3,693,219

Core Facility Support Awards					
App ID	**Award Mechanism**	**Application Title**	**PI**	**PI Organization**	**Recommended Budget**
		Park Flow Cytometry and Cell Imaging Core		Cancer Center	
RP170691	CFSA	Patient-Derived Xenograft and Advanced in Vivo Models (PDX-AIM) Core Facility	Lewis, Michael	Baylor College of Medicine	$3,822,860
RP170719	CFSA	GCC Center for Advanced Microscopy and Image Informatics	Mancini, Michael	Texas A&M University System Health Science Center	$5,793,075
RP170675	CFSA	Individualized Pediatric Tumor Analysis Center of Texas (INPACT)	Allen, Carl	Baylor College of Medicine	$200,000
RP170668	CFSA	Data Science and Informatics Core for Cancer Research	Zheng, Wenjin	The University of Texas Health Science Center at Houston	$5,846,383

High-Impact/High-Risk Research Awards					
App ID	**Award Mechanism**	**Application Title**	**PI**	**PI Organization**	**Recommended Budget**
RP170674	HIHRRA	Regulation of Cancer Cell Migration by Secreted Protein Phosphorylation	Tagliabracci, Vincent	The University of Texas Southwestern Medical Center	$200,000
RP170640	HIHRRA	Capitalizing on Therapeutic Liabilities in RAS-Mutant Cancers with a Rational Combination Therapy with PARP and MEK Inhibitors	Mills, Gordon	The University of Texas M. D. Anderson Cancer Center	$200,000
RP170686	HIHRRA	A Novel Chemical Strategy to Target EGFR for Destruction	Rao, Hai	The University of Texas Health Science	$200,000

High-Impact/High-Risk Research Awards					
App ID	**Award Mechanism**	**Application Title**	**PI**	**PI Organization**	**Recommended Budget**
				Center at San Antonio	
RP170660	HIHRRA	Optogenetic Toolkit for Precise Epigenome Editing in Cancer Cells	Zhou, Yubin	Texas A&M University System Health Science Center	$200,000
RP170734	HIHRRA	Mitochondrial DNA Instability Engages a Cancer-Related Interferon Program to Modify the Immune Microenvironment and NAD+ Metabolome and Enhance Melanoma Growth	West, Andrew	Texas A&M University System Health Science Center	$199,795
RP170699	HIHRRA	Targeting a Metabolic Reprogramming Event for the Early Prevention of Pancreatic Cancers	Tu, Benjamin	The University of Texas Southwestern Medical Center	$200,000
RP170671	HIHRRA	Targeting a Novel Nuclease PAAN in Triple-Negative Breast Cancer	Wang, Yingfei	The University of Texas Southwestern Medical Center	$200,000
RP170714	HIHRRA	Optimization of a Novel Class of Microtubule Stabilizers That Circumvent Multiple Drug Resistance Mechanisms Through Crystal-Structure Guided Total Synthesis	Frantz, Douglas	The University of Texas at San Antonio	$200,000
RP170817	HIHRRA	Isolation and in Situ Profiling of Circulating Tumor Cell Subpopulations Using a Hyperuniform Structured Microchip	Li, Wei	Texas Tech University	$200,000
RP170633	HIHRRA	The Role of the CACNA1D Calcium Channel in Melanoma	Morrison, Sean	The University of Texas Southwestern	$199,828

High-Impact/High-Risk Research Awards					
App ID	**Award Mechanism**	**Application Title**	**PI**	**PI Organization**	**Recommended Budget**
				Medical Center	
RP170752	HIHRRA	Radiation-Induced Release of Chemotherapeutic Agents in Vivo	Gassensmith, Jeremiah	The University of Texas at Dallas	$200,000
RP170805	HIHRRA	Etiology and Prevention of Gastric Cancers by Mitigation of H pylori Mechanosensing	Lele, Pushkar	Texas A&M University	$200,000
RP170797	HIHRRA	The Preparation of Novel Phage-Displayed Macrocyclic Peptide Libraries for the Identification of Anticancer Agents	Liu, Wenshe	Texas A&M University	$200,000
RP170696	HIHRRA	Targeting Cathepsin L as a Selective Mechanism for the Release of Potent Anticancer Agents from Drug-Linker Conjugates	Pinney, Kevin	Baylor University	$200,000
RP170721	HIHRRA	Enhancing Immunotherapy of Pancreatic Cancer by Disrupting Mutant K-Ras Using CRISPR/Cas9	Bao, Gang	Rice University	$200,000
RP170619	HIHRRA	An Unexpected Oncometabolic Axis: Exposing Novel Regulators of Cardiac Remodeling in Leukemia	Taegtmeyer, Heinrich	The University of Texas Health Science Center at Houston	$199,744
RP170747	HIHRRA	Noninvasive Lung Cancer Screening by Rapid Chemical Profiling of Exhaled Breath	Sun, Yuze	The University of Texas at Arlington	$199,999
RP170653	HIHRRA	Identify Streptococcus gallolyticus Factors Important for Promoting Colorectal Tumor Development	Xu, Yi	Texas A&M University System Health Science Center	$200,000
RP170722	HIHRRA	Identification of Critical Dependencies and Actionable Therapeutic	Draetta, Giulio	The University of Texas M. D.	$200,000

High-Impact/High-Risk Research Awards					
App ID	**Award Mechanism**	**Application Title**	**PI**	**PI Organization**	**Recommended Budget**
		Options in Smarcb1-Deficient Pediatric Tumors		Anderson Cancer Center	

Previously Deferred Individual Investigator Research Awards and Early Translational Research Awards					
App ID	**Award Mechanism**	**Application Title**	**PI**	**PI Organization**	**Recommended Budget**
RP170373	IIRA	HTS for covalent GTP-competitive inhibitors of KRAS G12C	Westover, Kenneth	The University of Texas Southwestern Medical Center	$823,500
RP170086	IIRA	Tumor suppression, p53 and retrotransposons	Abrams, John	The University of Texas Southwestern Medical Center	$816,171
RP170572	IIRA	Probing Novel Concepts of the NF-kappaB Transcriptional Program In Human Cancer	D'Orso, Ivan	The University of Texas Southwestern Medical Center	$679,458
RP170267	IIRA	Chemically based disruption of oncogenic beta-catenin activity in liver tissue	Lum, Lawrence	The University of Texas Southwestern Medical Center	$823,500
RP170407	IIRA	Role of HDAC8 and higher order chromatin structure in melanoma metastasis and therapy	Rai, Kunal	The University of Texas M.D. Anderson Cancer Center	$823,154
RP170179	ETRA	Chemoablation of High-Risk Oral Premalignant Lesions for Sustained Cancer Prevention	Tsai, Robert	Texas A&M University System Health Science Center	$915,000
RP170500	ETRA	Development of next generation steroid receptor coactivator small molecule inhibitors as novel agents to target therapy-resistant breast cancer	O'Malley, Bert	Baylor College of Medicine	$914,006
RP170090	IIRA	Novel Regulation and Function of TAK1 in	Chiao, Paul	The University of Texas M.D.	$823,500

Previously Deferred Individual Investigator Research Awards and Early Translational Research Awards					
App ID	**Award Mechanism**	**Application Title**	**PI**	**PI Organization**	**Recommended Budget**
		Mutant Kras-driven Development of Pancreatic Ductal Adenocarcinoma		Anderson Cancer Center	
RP170333	ETRA	Targeting ubiquitination for cancer therapy	Zhang, Shuxing	The University of Texas M.D. Anderson Cancer Center	$915,000
RP170180	IIRA	Mechanistic Roles of Long Non-Coding RNA in Glioblastoma Development and Treatment	Huang, Suyun	The University of Texas M.D. Anderson Cancer Center	$823,500
RP170172	IIRA	Targeting Therapy Resistance using Epithelial to Mesenchymal Transition (EMT) Pathways in Preclinical Claudin Low Breast Cancer Models	Rosen, Jeffrey	Baylor College of Medicine	$823,500

Academic Research Recruitment Grant Awards				
App ID	**Candidate**	**Mechanism**	**Organization**	**Budget**
RR170048	Amos, Christopher	REI	Baylor College of Medicine	$6,000,000
RR170063	Woodruff, Jeffrey	RFTFM	The University of Texas Southwestern Medical Center	$2,000,000
RR170079	Li, Bo	RFTFM	The University of Texas Southwestern Medical Center	$2,000,000
RR170061	Arteaga, Carlos	REI	The University of Texas Southwestern Medical Center	$6,000,000
*RR170064	Obeng, Esther	RFTFM	The University of Texas Southwestern Medical Center	$2,000,000
RR170076	Wu, Jun	RFTFM	The University of Texas Southwestern Medical Center	$2,000,000

RR170054	Dickinson, Daniel	RFTFM	The University of Texas at Austin	$2,000,000
RR170059	Tsai, Kuang-Lei	RFTFM	The University of Texas Health Science Center at Houston	$2,000,000
RR170068	Kim, Daehwan	RFTFM	The University of Texas Southwestern Medical Center	$2,000,000
RR170051	Aguilera, Todd	RFTFM	The University of Texas Southwestern Medical Center	$2,000,000
RR170047	Hancks, Dustin	RFTFM	The University of Texas Southwestern Medical Center	$2,000,000
RR170055	Zheng, Siyuan	RFTFM	The University of Texas Health Science Center at San Antonio	$2,000,000
RR170075	Reddy, Rohith	RFTFM	University of Houston	$2,000,000
RR170062	Uribe, Rosa	RFTFM	Rice University	$2,000,000
RR170050	Mu, Ping	RFTFM	The University of Texas Southwestern Medical Center	$2,000,000

* RR170064 recommended by the PIC was withdrawn by the applicant after the PIC meeting.

Compliance Certification

Mr. Vince Burgess, Chief Compliance Officer, presented his certification of the review process for the proposed Academic Research Awards, Prevention Awards, and Product Development Research Awards recommendations presented to the Oversight Committee at this meeting. He stated he had reviewed the compliance pedigrees for the grant applications submitted to CPRIT for the six Academic Research Award mechanisms, the one Product Development Research Award mechanism, and four Prevention Award mechanisms. Further, Mr. Burgess stated he had conferred with staff at CPRIT and CSRA, International (CSRA), CPRIT's contracted third-party grants administrator and studied the supporting grant review documentation, including third-party observer reports for the peer review meetings.

Mr. Burgess reported he was satisfied that the application review process that resulted in the above mechanisms recommended by the PIC followed applicable laws and agency administrative rules and certified the award recommendations for the Oversight Committee's consideration.

Conflict of Interest Notification

Presiding Officer Geren noted for the record that Mr. Angelou has reported a conflict of interest with the awards recommended for The University of Texas at Austin.

Vote on Recommended Awards

Presiding Officer Geren noted for the record that the applicant withdrew application RR170064 after the PIC meeting. That award recommendation is not included as part of the awards voted on by the Oversight Committee.

MOTION:
On a motion made by Mr. Margo and seconded by Dr. Rice, the Oversight Committee unanimously voted to approve the PIC's recommendation for RR170054 to The University of Texas at Austin.

Presiding Officer Geren noted for the record that Mr. Angelou did not vote on this recommendation.

MOTION:
On a motion made by Mr. Margo and seconded by Mr. Montgomery, the Oversight Committee unanimously voted to approve the PIC's recommendations for the remaining 50 academic research awards.

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

Program Priorities Impact Report and Active and Proposed Academic Research RFA Mechanisms FY18 and FY19.1

Dr. Willson presented the Program Priorities Impact report for 2015 – 2017 academic research awards and made several observations:

- The CPRIT portfolio represents the priorities of "Cancers of Importance in Texas" as evidenced by the academic research community's work done in lung, liver, and cervical cancer. The number of awards represented in the program priorities chart is low because the chart only covers the preceding six months.

- Seventeen percent of the academic research awards have been made in the priority area of "Disparities," and more work will continue in this area. CPRIT has ongoing initiatives with strategies to stimulate accrual in traditionally under-represented populations.

- In prevention and early detection, Texas has strong prevention research programs throughout the state, yet prevention does not see the same number of applications as from traditional biology. To stimulate those applications, CPRIT initiated a targeted RFA and assembled a targeted panel to review the resulting applications. CPRIT encourages communities that are addressing prevention service delivery to think about ways to interact with the academic researchers. A recent RFA under review now includes a

special call for taking advantage of population demonstration projects supported by CPRIT's Prevention Program.

Dr. Willson responded to a question about quantifying the residual benefits of academic research awards, noting that CPRIT could use statistics such as NIH grant dollars, the number of corporate grants or graduate students that CPRIT research grantees bring to Texas. For instance, to date 135 CPRIT scholars who have come to Texas have brought follow-on funding that exceeds $225 million. A less tangible but important parameter to consider is the halo effect of the reputations that these individuals have when they bring their already achieved recognition with them to Texas.

Transitioning to the presentation of proposed FY 2018 and FY 2019 requests for applications (RFAs), Dr. Willson stated that since CPRIT has limited funding available for awards, staff seeks the Oversight Committee's input regarding RFAs with consideration of realistic budget projections. He restated the 2017 Academic Research Program Priorities and discussed the announced and proposed RFAs for FY 2018.

FY 2018 Academic Research Requests for Applications

- Recruitment of Established Investigators (FY18)
- Recruitment of Rising Stars (FY18)
- Recruitment of First-Time Tenure Track Faculty Members (FY18)
- Core Facilities Support Awards (CFSA) (RFA R-18.2 CFSA)
- High Impact/High Risk Research Awards (HIHR) (RFA R-18.2 HIHR)
- Early Translational Awards (ETA) (RFA-R-18.2 ETA)

For the purposes of discussion, Dr. Willson projected the anticipated budgets for the announced and proposed FY 2018 RFAs.

Announced RFA Mechanisms	**Anticipated Budget**
Recruitment (25-30 @ 2,000,000 - 6,000,000)	$80,000,000
Individual Investigator Research Award (IIRA)	$45,600,000
IIRA - Individual Investigator Research Awards (18 @ 900,000)	$16,200,000
IIRA - Childhood & Adolescent Cancers (6 @ 1,000,000)	$6,000,000
IIRA - Computational Biology (6 @ 900,000)	$5,400,000
IIRA - Prevention & Early Detection (6 @ 1,000,000)	$6,000,000
IIRA - Clinical Translation (6 @ 2,000,000)	$12,000,000

Proposed RFA Mechanisms	**Anticipated Budget**
Core Facilities Support Award (6 @ 6,000,000)	$36,000,000

High Impact/High Risk (20 @ 200,000)	$4,000,000
Early Translational Award (5 @ 2,000,000)	$10,000,000
Multi-Investigator Research Award (4 @ 6,000,000)	$24,000,000
Total Announced & Proposed	**$199,600,000**

Presiding Officer Geren clarified that the Oversight Committee's vote on the direction of the FY 2018 - 2019 RFAs would not be a vote for or against the anticipated budgeted amounts as presented by Dr. Willson. Those budget amounts will vary according to applications received and recommendations made in each of the program areas, and according to on-going discussions among the professional staff and the Oversight Committee.

Mr. Roberts added that CPRIT has funded all projects that the peer reviewers and the PIC have recommended so far. In some years, CPRIT has scheduled a special September meeting to approve some of the proposed grants to take advantage of the start of a new fiscal year. CPRIT has also made funding adjustments at the time of award approval for some grants when the adjustments do not affect the viability of the projects.

Discussing the split between academic research and product development research funding, Mr. Roberts referenced an Oversight Committee workshop on May 19, 2016. At that meeting the Oversight Committee did not set a formal funding allocation for each program but instead stated the intent that CPRIT fund more product development awards than previously. Historically the funding split was 80% academic research and 20% product development research. Mr. Roberts reported that internal targets set over the course of the last two years projected product development funding at 25% to 30% of the annual award budget, respectively. CPRIT did not reach the 30% target for product development in FY 2017. As a result, CPRIT was able to fund recommendations for academic research awards that exceeded the original FY 2017 target of 70% of the annual award budget. Mr. Roberts noted that while he is not concerned about CPRIT's ability to fund recommendations in the coming fiscal year, he is watching the number of product development applications that make it through the peer review process for indication of a trend or a one-time event. It is a testament to the peer review process that the review panels are not recommending applications just to meet a funding quota.

Dr. Willson responded to a question, explaining that CPRIT did not list the "population disparities and cancers of importance in Texas" separately as a RFA mechanism because this priority is integrated into all RFAs.

An Oversight Committee member expressed the desire to have further discussion on funding Early Translational Research Awards (ETRA) with CPRIT monies before voting on an RFA. Another member suggested holding a meeting with CPRIT staff and interested Oversight Committee members to discuss the proposed ETRA RFA further and bringing the results to a future Oversight Committee meeting.

MOTION:

On a motion made by Mr. Montgomery and seconded by Mr. Margo, the Oversight Committee unanimously voted to approve the Academic Research Program's plan for active and proposed Requests for Applications (RFAs) for FY 2018 and early 2019, except for Early Translation Research RFAs.

Internal Auditor Report - Agenda Item 16

Ms. Alyssa Martin and Daniel Graves, Internal Auditors, presented the Internal Audit Reports on Pre-Award Grant Management and on Procurement and P-Cards. Additionally, Ms. Martin presented follow-up procedures reports for three previous audits in which CPRIT had remediated all findings.

Ms. Martin presented the Fiscal Year 2017 Annual Internal Report for approval of the Oversight Committee. She reported that the Audit Subcommittee reviewed the annual report.

Ms. Martin indicated that the last issue to discuss with the Oversight Committee was the follow up procedures on the internal audit on information security.

Closed Session

Pursuant to the Texas Open Meetings Act, Section 551.076, Presiding Officer Geren announced that the Oversight Committee would move into closed session to discuss a security audit. Presiding Officer Geren asked Alyssa Martin and Dan Graves (Internal Auditors), Heidi McConnell, Kristen Doyle, Therry Simien, and Wayne Roberts to join the Oversight Committee in the closed session.

Presiding Officer Geren convened in closed session at 1:15 p.m.

Presiding Officer Geren reconvened the open meeting at 2:11 p.m.

Presiding Officer Geren stated the Audit Subcommittee met on August 7, 2017, and recommended the Oversight Committee approve the audits and annual report.

MOTION:
On a motion made by Mr. Angelou and seconded by Mr. Montgomery, the Oversight Committee unanimously voted to approve the internal audit on Pre-Award Grant Management and the internal audit on Procurement and P-Cards and the four follow up procedures for prior year audit findings.

MOTION:
On a motion made by Dr. Rosenfeld and seconded by Dr. Rice, the Oversight Committee unanimously voted to approve CPRIT's Fiscal Year 2017 Annual Internal Report.

Chief Prevention and Communications Officer Report - Agenda Item 9

Prevention Program Awards Recommendations

Dr. Rebecca Garcia, Chief Prevention and Communications Officer, reported that the PIC recommended eight projects totaling $14,019,137 for approval. She presented the grant recommendations in 4 slates. Dr. Garcia noted that the PIC agreed with the Prevention Review Council's recommendation to reduce all budgets by 10% to assure that sufficient funds are available to support all recommended applications for this cycle. She also noted that the Competitive Continuation/Expansion award was a deferred application.

Mr. Margo reported that the Prevention Subcommittee recommended that the Oversight Committee approve the four Prevention slates.

# of Apps Recommended	Grant Mechanism Slate	Award Amount
2	Colorectal Cancer Prevention Coalition	$ 5,972,794
1	Competitive Continuation/Expansion for Evidence-Based Cancer Prevention Services	$ 1,350,000
3	Evidence-Based Cancer Prevention Services	$ 4,044,851
2	Tobacco Control and Lung Cancer Screening	$ 2,651,492

Number of Recommended Applications* Addressing Priorities	
5	Prioritize populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence
5	Prioritize geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence
8	Prioritize underserved populations

* Some applications fulfill more than one priority.

Prevention Program Awards Recommendations					
App ID	Mech.	Application Title	PD	Organization	Rec Budget
PP170094	EBP	Expanding a Community Network for Cancer Prevention to Improve Cervical and Colorectal Screening and Follow-Up Among an Urban Medically Underserved Population	Jibaja-Weiss, Maria L	Baylor College of Medicine	$1,347,590
PP170068	CRC	Southwest Coalition for Colorectal Cancer Screening (SuCCCeS)	Shokar, Navkiran K	Texas Tech University Health Sciences Center at El Paso	$3,679,823

Prevention Program Awards Recommendations					
App ID	**Mech.**	**Application Title**	**PD**	**Organization**	**Rec Budget**
PP170070	TCL	Taking Texas Tobacco Free: Increasing Tobacco Cessation in Substance Use Treatment Centers via an Evidence-based, Comprehensive Tobacco-free Workplace Program	Reitzel, Lorraine R	University of Houston	$1,348,851
PP170082	CRC	Improving Colorectal Cancer Screening in Vulnerable Populations in Travis County	Pignone, Michael	The University of Texas at Austin	$2,292,971
PP170099	TCL	Mobile Cessation Services for Young Adult Rural, Low-Income, and Spanish-Speaking Smokers	Ramirez, Amelie G	The University of Texas Health Science Center at San Antonio	$1,302,641
PP170088	EBP	Access to Breast and Cervical Care for West Texas (ABC24WT)	Layeequr Rahman, Rakhshanda	Texas Tech University Health Sciences Center	$1,349,730
PP170091	EBP	Empower Her To Care Expansion(EHC4): Increasing Access to Breast Cancer Screening and the Continuum of Care for Underserved Texas Women	Joseph, Bernice	The Rose	$1,347,531
PP170037 Deferred from 17.1	CCE-EBP	Continuation/Expansion of Texas A&M's Breast and Cervical Cancer Prevention Program for Underserved Women through a Family Medicine Residency	McClellan, David A	Texas A&M University System Health Science Center	$1,350,000

Compliance Certification

Presiding Officer Geren noted that Mr. Burgess previously certified compliance of the Prevention awards process.

Conflict of Interest Notification

Presiding Officer Geren indicated that Mr. Angelou reported a conflict of interest with application PP170082 submitted by The University of Texas at Austin.

Vote on Recommended Awards

MOTION:
On a motion made by Mr. Montgomery and seconded by Dr. Rice, the Oversight Committee unanimously voted to approve the Program Integration Committee's recommendation for PP170082 to The University of Texas at Austin.

Presiding Officer Geren noted for the record that Mr. Angelou did not vote on this recommendation.

MOTION:
On a motion made by Mr. Margo and seconded by Mr. Montgomery, the Oversight Committee unanimously voted to approve the Program Integration Committee's recommendations for the remaining 7 prevention awards.

MOTION:
On a motion made by Mr. Margo and seconded by Mr. Montgomery, the Oversight Committee unanimously voted to approve the delegation of contract negotiation authority to the Chief Executive Officer and CPRIT staff, and authorized the Chief Executive Officer to sign the contracts on behalf of CPRIT.

Program Priorities Impact Report and Active and Proposed Prevention RFA Mechanisms for FY 2018

Dr. Garcia presented the Program Priorities Impact Report for the Prevention Program and directed the Oversight Committee to the report under Item 11 in their agenda books.

She reported that FY 2018 Cycle 1 is underway. CPRIT released three RFAs for this cycle:

- Evidence-Based Cancer Prevention Services
- Tobacco Control and Lung Cancer Screening
- Dissemination of CPRIT-Funded Cancer Control Intervention (DI)

Dr. Garcia indicated that the DI RFAs will be continuously open and the Prevention Review Council will generally review applications on a quarterly basis in order to expedite the dissemination of successful CPRIT funded projects. CPRIT will present successful applications to the Oversight Committee at a scheduled quarterly meeting.

Dr. Garcia presented the proposed FY 2018 Cycle 2 RFA, "Expansion of Cancer Prevention Services to Rural (nonmetropolitan) and Medically Underserved Areas." She reported that this is a new RFA to encourage applicants to add a service to a CPRIT project currently in progress, such as adding cervical cancer services to a breast cancer screening project, with a requirement that the services be delivered to those from medically underserved and rural areas of the state.

She noted that other mechanisms under consideration for FY 2018 Cycle 2 RFAs are:

- Evidence-Based Cancer Prevention Services
- Tobacco Control and Lung Cancer Screening
- Dissemination of CPRIT-Funded Cancer Control Interventions (DI)

Dr. Garcia will notify the Oversight Committee through the Prevention Subcommittee about the intention to release any RFAs after assessing the type and volume of applications submitted for Cycle FY18.1. She noted that these are RFAs that CPRIT has released in the past and are updated about a month before the next release.

Presiding Officer Geren noted that the county-by-county data grantees are now reporting and the new Expansion RFA will allow the CPRIT Oversight Committee and staff to examine the services provided in rural areas of the state more closely.

Presiding Officer Geren also noted that Dr. Willson presented RFAs for FY 2018 and FY 2019, while Dr. Garcia presented for FY 2018.

MOTION:
On a motion made by Mr. Montgomery and seconded by Mr. Margo, the Oversight Committee unanimously voted to approve the Prevention Program's plan for active and proposed Requests for Applications (RFAs) for FY 2018.

Communications Program Update

Dr. Garcia stated that registration for the conference opened at the end of July. By August 15, 76 people registered, and 204 abstracts were submitted. Staff is working with speakers to finalize the titles and descriptions of their topics.

Chief Product Officer Report and Grant Awards Recommendations - Agenda Item 10

Mr. Michael Lang, Chief Product Development Officer, reported that CPRIT received 20 applications for the FY 17.2 review cycle. CPRIT invited six applicants to make in-person presentations, and peer reviewers selected two for due diligence. The Review Council recommended one for a grant award, which the PIC has also for Oversight Committee approval.

For the FY 18.1 review cycle, CPRIT received 19 applications and the review process will be starting.

Dr. Rosenfeld reported that the Product Development Subcommittee reviewed this application and recommended approval.

Product Development Research Awards Recommendations

Application ID	Company Name	Project	Maximum Recommended Budget

DP170043	ViraCyte, LLC	Improving the Outcome of Stem Cell Transplants for Cancer Treatment Using Multi-Virus Specific T cells	$8,998,067

Compliance Certification and Conflict of Interest Notification

Presiding Officer Geren noted that Mr. Burgess had previously certified compliance of the Product Development Awards process and that no member had reported a conflict of interest.

Vote on Recommended Award

MOTION:
On a motion made by Mr. Angelou and seconded by Dr. Rosenfeld, the Oversight Committee unanimously voted to approve the Program Integration Committee's recommendation for ViraCyte, LLC.

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

MOTION:
On a motion made by Mr. Montgomery and seconded by Mr. Angelou, the Oversight Committee unanimously voted to authorize CPRIT to disburse grant funds via advance payments to ViraCyte, LLC, upon execution of the award contract and the successful completion of tranches, pursuant to the General Appropriations Act, Article IX, Section 4.03(a).

Contract Approvals - Agenda Item 21

Chief Operating Officer Heidi McConnell presented staff's recommendation that the Oversight Committee approve the following contracts for FY 2018:

- Contract renewal with The Perryman Group for $150,000 to perform an internal audit assessment of the cost of cancer in Texas.
- Contract renewal with Weaver and Tidwell for $243,750 to provide internal audit services; and
- Contract renewal with Hahn Public Communications for $149,975 to provide strategic communications services.

Ms. McConnell noted that the contracts for the Oversight Committee's consideration are not-to-exceed amounts, and payment is based on the delivery of actual services from the vendor, either time and materials or a unit cost. She also noted that the renewal of the Weaver and Tidwell contract will require the State Auditor's Office to provide audit delegation authority to CPRIT prior to contract execution.

There were no questions for Ms. McConnell.

MOTION:
On a motion made by Mr. Montgomery and seconded by Dr. Rice, the Oversight Committee unanimously voted to approve FY 2018 contracts with The Perryman Group, Weaver and Tidwell, and Hahn Public Communications.

Mirna Shareholder Vote - Agenda Item 19

Ms. Kristen Doyle, Deputy Executive Officer and General Counsel, reported that Mirna Therapeutics announced in May plans to merge with Synlogic, Inc., via a reverse merger arrangement to maximize value for its shareholders. There will be an annual shareholder meeting on August 24, 2017, to vote on approval of the merger. CPRIT is a shareholder via the revenue sharing agreement in Mirna's award contract. Ms. Doyle presented staff's request that the Oversight Committee delegate authority to the Chief Executive Officer to vote CPRIT's shares at the annual meeting.

MOTION:
On a motion made by Dr. Rice and seconded by Mr. Montgomery, the Oversight Committee unanimously voted to delegate authority to CPRIT's Chief Executive Officer to take all actions necessary to vote CPRIT's shares in Mirna at the company's upcoming annual shareholder meeting.

Amendments to 25 T.A.C. Chapter 703 - Agenda Item 17

Ms. Cameron Eckel, Staff Attorney, presented the following rules changes for Oversight Committee action:

- Final approval of a rule change first presented at the May 2017, Oversight Committee meeting that eliminates the fifth reporting period for grantees. Ms. Eckel reports that CPRIT received no public comments regarding the proposed rule change.
- Approval to publish two proposed rule changes in the *Texas Register* to seek public comment. Ms. Eckel reports that one change clarifies that grantees need to maintain grant records for a period of three years and one change prohibits grantee payments to a subcontractor that employs a relative of the grantee unless CPRIT grants an exception.

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

MOTION:

On a motion made by Mr. Angelou and seconded by Mr. Margo, the Oversight Committee unanimously voted to approve the proposed changes to Texas Administrative Code Chapter 703 for publication in the *Texas Register*.

1. Subcommittee Business - Agenda Item 22

Presiding Officer Geren presented the Board Governance Subcommittee's proposed subcommittee assignments for FY 2018-2019 for Oversight Committee approval. He noted that CPRIT provided the proposed assignments in the Oversight Committee meeting packet.

MOTION:
On a motion made by Mr. Montgomery and seconded by Mr. Angelou, the Oversight Committee unanimously voted to approve the new subcommittee assignments for FY 2018-2019.

Election of Board Officers - Agenda Item 23

Presiding Officer Geren reported that the Nominations Subcommittee unanimously recommended the following slate of officers:

Will Montgomery – Presiding Officer
Dee Margo – Vice Presiding Officer
Amy Mitchell - Secretary

MOTION:
On a motion made by Mr. Angelou and seconded by Dr. Rice, the Oversight Committee unanimously voted to approve the slate of officer recommendations: Will Montgomery as Presiding Officer, Dee Margo as Vice Presiding Officer, and Amy Mitchell as Secretary.

Special Resolution Honoring Outgoing Chair Pete Geren

Mr. Montgomery presented a resolution from the Oversight Committee honoring the service of Mr. Geren as Presiding Officer for Fiscal Years 2016-2017.

Health & Safety Code Section 102.1062 Waivers - Agenda Item 14

Mr. Roberts presented a request for conflict of interest waivers for Dr. Rebecca Garcia, Dr. John Hellerstedt, Mr. Don Brady, Mr. Will Montgomery, and Ms. Amy Mitchell.

MOTION:
On a motion made by Mr. Angelou and seconded by Mr. Montgomery, the Oversight Committee unanimously voted to approve the requested conflict of interest waivers pursuant to Health & Safety Code Section 102.1062.

Scientific Research and Prevention Program Comm. Appointments - Agenda Item 12

Mr. Roberts presented the list of four appointees to CPRIT review panels for Oversight Committee approval. He stated the Nominations Subcommittee discussed the appointments and recommended approval.

MOTION:
On a motion made by Mr. Angelou and seconded by Mr. Montgomery, the Oversight Committee unanimously voted to approve the Scientific Research Program Committee appointments.

FY 2018 Honoraria Policy - Agenda Item 13

Mr. Roberts presented the proposed honoraria policy for FY 2018 for Oversight Committee approval. He reported that the policy was the same as the honoraria policy for FY 2017.

MOTION:
On a motion made by Mr. Angelou and seconded by Dr. Rice, the Oversight Committee unanimously voted to approve the FY 2018 honoraria policy.

Resolution Transferring Management Authority to the Texas Treasury Safekeeping Trust Company - Agenda Item 15

Ms. Kristen Doyle, Deputy Executive Officer and General Counsel, presented a resolution transferring management authority to the Texas Treasury Safekeeping Trust Company and delegating authority to the Chief Executive Officer to take necessary actions to complete the transfer of certain assets, including negotiating a fee for the Trust Company's reasonable and necessary expenses involved with managing the transferred assets.

Presiding Officer Geren introduced Mr. Paul Ballard, Chief Executive Officer and Chief Investment Officer of the Texas Treasury Safekeeping Trust Company to provide background on the Trust Company. There were no questions for Mr. Ballard.

MOTION:
On a motion made by Mr. Angelou and seconded by Dr. Rice, the Oversight Committee unanimously approved the resolution transferring management authority to the Texas Treasury Safekeeping Trust Company for the assets named in the resolution.

Amendment to the Oversight Committee Bylaws - Agenda Item 18

Ms. Doyle presented the Board Governance Subcommittee's recommended changes to the bylaws and the Code of Conduct regarding new member training. She noted that one change provides for a 30-business day deadline to complete new member training. The other change allows a new member to participate in Oversight Committee meetings before completing the required training, with the exception that they cannot vote on awards until conflict of interest training is completed.

MOTION:

On a motion made by Dr. Rosenfeld and seconded by Mr. Angelou, the Oversight Committee unanimously voted to approve the proposed changes to the Oversight Committee bylaws and Code of Conduct.

Program Priorities - Agenda Item 11

Presiding Officer Geren stated item will be added to the November 2017 Oversight Committee meeting agenda.

Chief Operating Officer Report - Agenda Item 20

Ms. McConnell stated her report was in the Oversight Committee meeting materials along with the CPRIT's Operating Budget for 2018. There were no questions for Ms. McConnell.

Compliance Investigation Pursuant to Health & Safety Code § 102.2631; Consultation with General Counsel - Agenda Items 24 and 25

The Oversight Committee did not discuss items 24 and 25.

Future Meeting Dates - Agenda Item 26

Presiding Officer Geren announced that CPRIT has moved the next regular Oversight Committee meeting to November 29, 2017, due to CPRIT's upcoming biennial conference. Subcommittee meetings will remain on their regular schedule for the November meeting.

Adjourn - Agenda Item 27

MOTION:
There being no further business, the Oversight Committee unanimously approved a motion to adjourn made by Presiding Officer Geren and seconded Mr. Montgomery.

Meeting adjourned at 2:55 p.m.

_____ _____

Signature Date

Dr. Jane Bolin

Dr. Bolin has served as PI or Co-PI on five cancer prevention, education, and screening grants from the Cancer Prevention and Research Institute of Texas including: (1) *Colorectal Cancer Screening in a Family Medicine Residency Program Serving Low-Income & Underserved: Translating Research into Practice; renewed as an expansion grant;* (2) *Enhanced Breast and Cervical Cancer Prevention for Low-income and Underserved Women Using Transdisciplinary Collaboration in a Family Medicine Setting; also renewed as an expansion and continuation grant, and (3) a CPRIT Dissemination Grant known as the CHW ACTION grant. Dr. Bolin has also served as PI on multiple* chronic disease and diabetes grants, including Co-PI on a P-20 diabetes self-management study from the NIH National Center for Minority Health Disparities. She was Co-PI for a CTSA planning grant to conduct an investigation on the feasibility of establishing a Center for Clinical and Translational Science at Texas A&M. As Director of the HRSA funded Southwest Rural Health Research Center at Texas A&M's School of Public Health, Dr. Bolin has led several projects for the benefit of rural and underserved areas of Texas. Dr. Bolin received her BSN degree from the Oregon Health Sciences University (1978) and, after nursing school, attended law school receiving her JD from the University of Oregon in 1982. After practicing law for 10 years, Dr. Bolin attended Penn State University and received a PhD in health services research in 2002.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

TEXAS C-STEP
Cancer Screening, Training, Education & Prevention

PUBLIC HEALTH
TEXAS A&M UNIVERSITY

CANCER SCREENING, TRAINING, EDUCATION AND PREVENTION PROGRAM (TEXAS C-STEP) OUTCOMES

Jane N. Bolin, RN, JD, PhD

Professor, Texas A&M School of Public Health

Director, Southwest Rural Health Research Center

PI/PD or Co-PD/PI, 5 CPRIT Prevention Grants, 2011-current

Original Funding Credits

PUBLIC HEALTH
TEXAS A&M UNIVERSITY

Cancer Prevention & Research Institute of Texas

- **Grant PP110176:** $2.78M over 3 years for Colorectal Cancer Screening, Training, Education and Prevention in 7 counties (09/2011 - 02/2015)
- **Grant PP130090**: $1.5M over 3 years for Breast & Cervical Cancer Screening and Prevention in 9 counties (12/2013 - 11/2016)
- **Grant PP160048: $**300,000 over 2 years for Dissemination of CPRIT-Funded Cancer Control Interventions - Training CHWs for More Effective Cancer Education & Navigation in 44 counties (12/2015 – 11/2017)

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Continuation/Expansion Grants

PUBLIC HEALTH
TEXAS A&M UNIVERSITY

Cancer Prevention & Research Institute of Texas

- **Grant PP150025:** $1.5M over 3 years for Continuation/Expansion of the Colorectal Cancer Screening Program from 7 to 17 counties (12/2014 – 11/2017)
- **Grant PP170037:** $1.35M over 3 years for Continuation/Expansion of the Breast & Cervical Cancer Screening and Prevention from 9 to 17 counties (12/2013 - 11/2016)

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Interdisciplinary Collaborations

PUBLIC HEALTH
TEXAS A&M UNIVERSITY

- **Co-PD/PI Jane Bolin, RN, JD, PhD Texas A&M School of Public Health**
- **PD/PI: David McClellan, MD, Texas A&M College of Medicine & Family Medicine Residency Program**
  - Co-PD/PI, Women's Health Grant: Anna Lichorad, MD (A&M-COM)
  - Co-PD/PI, Colorectal Screening Grant: Robert Pope, MD (A&M-COM)
  - Co-I, Women's Health Grant: Cynthia Weston, DNP, RN, FNP-BC (A&M Nursing)
  - Co-I, Community Health Worker Training Grant: Katy Nimmons, MPH (A&M SPH)

Presentation Outline

PUBLIC HEALTH
TEXAS A&M UNIVERSITY

- **Colorectal Cancer Prevention Program (Texas C-STEP)**
  - Screening
  - Education
  - Training
  - Outcomes
- **Breast and Cervical Cancer Prevention Program (Texas C-STEP)**
  - Screening
  - Education
  - Training
  - Outcomes
- **CHW Training Programs (i.e., ACTION)**
  - Curriculum Development
  - Dissemination
- **Lessons Learned**
- **Sustainability**

Goals of Texas C-STEP

PUBLIC HEALTH
TEXAS A&M UNIVERSITY

- To provide prevention education and critical colorectal, breast, and cervical cancer safety-net services, such as screenings and related diagnostics, to low-income uninsured/underinsured Texas residents

- To provide cancer prevention-related training for:
  - Family Medicine Residents (FMRs) (Post Graduate Training)
  - Bachelor of Science Nursing Students (BSNs) (Undergraduate Training)
  - Family Nurse Practitioner Students (FNPs) (Graduate Training)
  - Graduate Students in Public Health (PhD, DrPH, MPH) (Graduate Training)
  - Community Health Workers (CHWs) (Technical Assoc. degree level training)

Original Texas C-STEP Service Area

PUBLIC HEALTH
TEXAS A&M UNIVERSITY

12 of these 17 counties are considered rural

11 of 17 have CRC incidence rates higher than TX state average

9 of 17 have higher CRC morality rates than TX state average

Results: Colonoscopy Screening (12/2011 – 8/2017)

PUBLIC HEALTH
TEXAS A&M UNIVERSITY

- 1,992 total colonoscopy screenings provided to 1,914 people, with 1,500 CPRIT-funded procedures
- 34% of colonoscopies had abnormal pathology
- 25% of all colonoscopies revealed cancer precursors
- 18 people diagnosed with colorectal cancer

Note: Fecal immunochemical tests (FIT) available for patients medically disqualified for clinic-based colonoscopy.

Results: CRC Education & Training (12/2011 – 8/2017)

PUBLIC HEALTH
TEXAS A&M UNIVERSITY

- 177,033 *lay* persons reached indirectly*
- 12,265 lay persons educated directly (face-to-face)
- 41,491 professionals reached indirectly*
- 1,873 students and professionals received training, including:
  - 46 family medicine residents trained in endoscopy
  - 12 new CHWs trained and state-certified on C-STEP CRC team

**Examples of indirect reach include TV interviews, radio, newspaper, social media, PSAs.*
***Examples of indirect reach to professionals include conferences, e-newsletters, publications.*

FMR Endoscopy (Colonoscopy) Training

PUBLIC HEALTH
TEXAS A&M UNIVERSITY

Curriculum Components include:

- **Endoscopy Simulator**
- **Didactics (Classroom)**
- **Clinical Training with Faculty 1:1-2**

Results: Quality Indicators

PUBLIC HEALTH
TEXAS A&M UNIVERSITY

	C-STEP Result	ASGE Recommends
Cecum attained (%)	96%	≥95
Overall adenoma detection rate (%)	27%	≥20
Adenoma detection rate among females >50 years (%)	26%	≥15
Adenoma detection rate among males >50 years (%)	38%	≥25
Mean total withdrawal time (minutes)	18	≥6
Complication rate	1 in 1100	1 in 1000

McClellan et al. Expanding access to colorectal cancer screenings: Benchmarking quality indicators in a primary care colonoscopy program. *Journal of the American Board of Family Medicine* 2015; 28:689-692.

Breast and Cervical Services

PUBLIC HEALTH
TEXAS A&M UNIVERSITY

Breast Health Services:

- Mammograms
- Clinical breast exams
- Advanced diagnostics, when warranted, including ultrasounds and breast biopsies

Cervical Health Services:

- HPV vaccinations
- Pap tests
- Advanced diagnostics, when warranted, including colposcopies and loop electrosurgical excision procedures (LEEPs)

Results: WH Clinical Services (3/2014 – 8/2017)

PUBLIC HEALTH
TEXAS A&M UNIVERSITY

- Clinical Breast Exams: 373
- Mammograms: 993
- Breast Ultrasounds: 203
- Breast Biopsies: 43
- Pap Tests: 474
- Colposcopies: 215
- LEEPS: 49

Total Services = 2,350
Number of DX'd Breast Cancers = 18
Number of Cervical Cancer Precursors = 141
Number DX'd Cervical Cancers = 2

Results: WH Education & Training (3/2014 – 5/2017)

PUBLIC HEALTH
TEXAS A&M UNIVERSITY

- 161,721 lay persons reached indirectly*
- 5,177 women educated or navigated directly
- 40,754 professionals reached indirectly**
- 908 students and professionals received training

**Examples of indirect reach to lay persons include TV interviews, radio, newspaper, social media, brochures left at site, PSAs.*

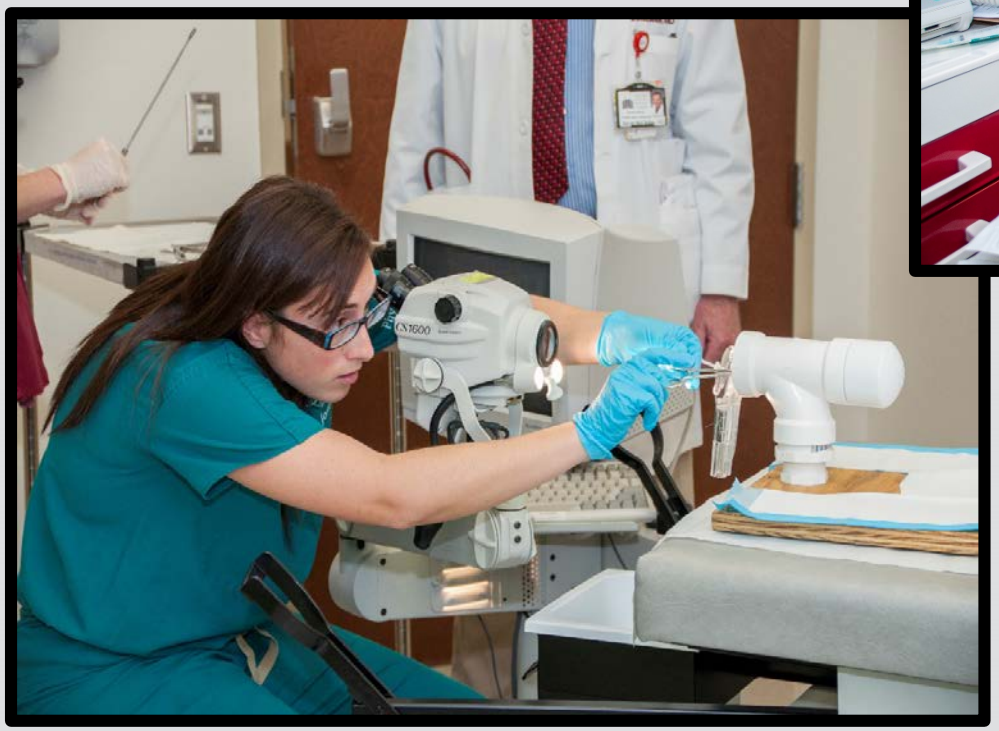
***Examples of indirect reach to professionals include conferences, e-newsletters to partners, and publications.*

Interprofessional Training

PUBLIC HEALTH
TEXAS A&M UNIVERSITY

Texas A&M Health Science Center

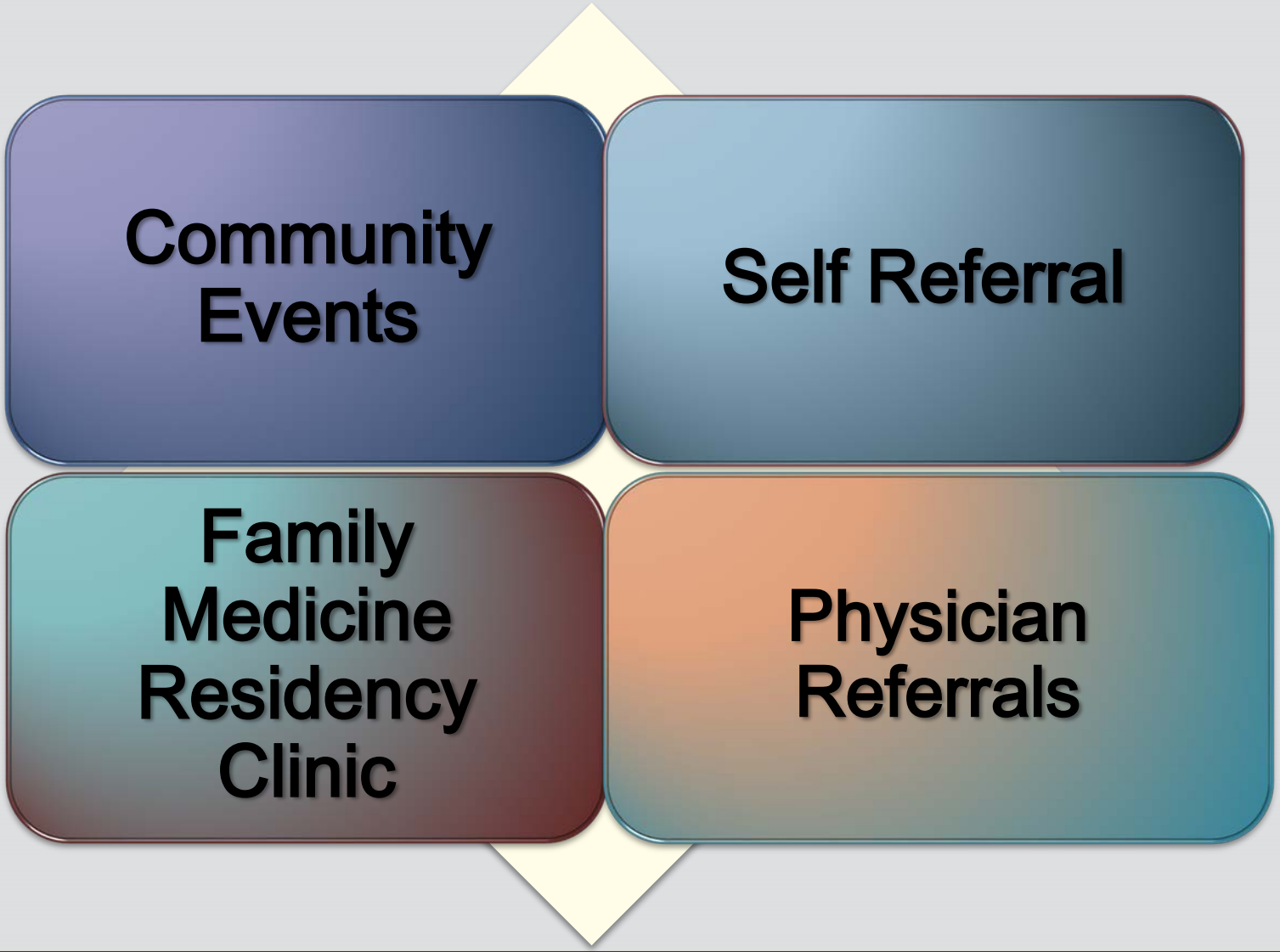
Clinical Learning Resource Center



Family medicine residents, nurse practitioner trainees, public health students, and community health workers trained collaboratively in the simulation laboratory.

Sources of Referrals

PUBLIC HEALTH
TEXAS A&M UNIVERSITY



CHW Integration

PUBLIC HEALTH
TEXAS A&M UNIVERSITY

- Community Health Workers (CHWs) also known as *promotoras* provide culturally appropriate, bilingual education and navigation
- Studies show that integration of CHWs into cancer screening programs can increase:
  - Cancer knowledge
  - Screening rates
  - Screening guidelines adherence
  - Referrals
  - Volume of services performed

CHWs with SuperColon™

PUBLIC HEALTH
TEXAS A&M UNIVERSITY

ACTION Project Overview

PUBLIC HEALTH
TEXAS A&M UNIVERSITY

- **ACTION:** Access to Cancer Training, Information, Outreach and Navigation
- **Project Dates:** 2015-2017
- **Purpose:** Engage CHWs and partner organizations to deliver more effective cancer education, training, and navigation.
- **Foundations**: Resources and expertise developed from four prior CPRIT projects

ACTION Grant Service Area

PUBLIC HEALTH
TEXAS A&M UNIVERSITY

Northeast

- Cherokee, Gregg, Henderson, Rusk, Smith, Upshur, Van Zandt, and Wood Counties

Extended Brazos Valley

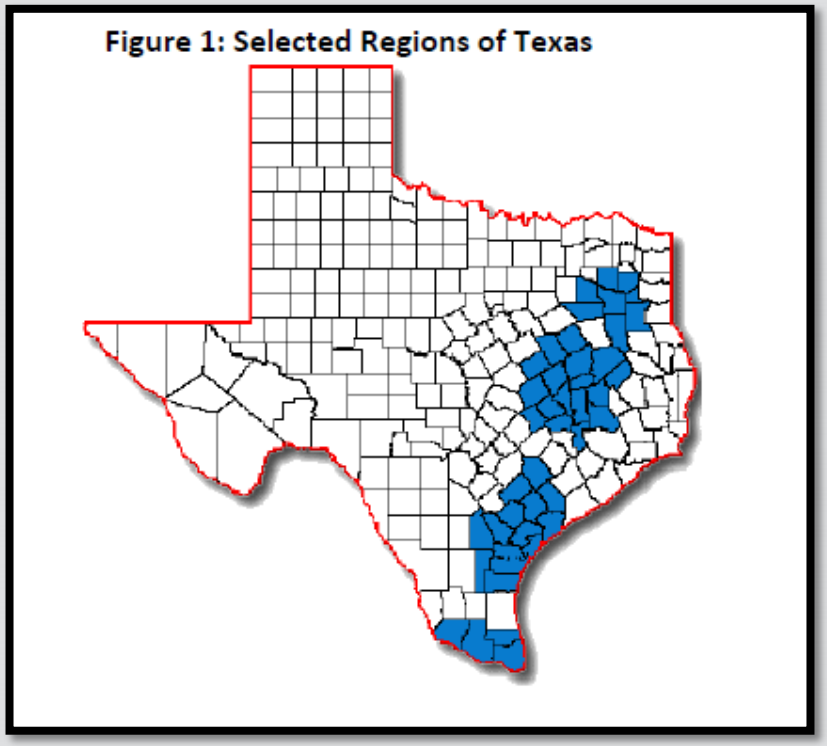
- Brazos, Burleson, Robertson, Grimes, Leon, Madison, Washington, Milam, Waller, Lee, Montgomery, Walker, Trinity, Houston, Freestone, Limestone, and Falls Counties

Coastal Bend

- Kleberg, Nueces, Jim Wells, San Patricio, Refugio, Beeville, Live Oak, Bee, Goliad, Victoria, Jackson, Lavaca, Dewitt, Calhoun, and Aransas Counties

Lower Rio Grande Valley

- Cameron, Willacy, Hidalgo, and Starr Counties



ACTION Team Expertise

- Delivering state-certified CHW training
- Engaging bilingual, bicultural CHWs and instructors
- Engaging rural and medically-underserved communities in research and practice

Curriculum Developed

PUBLIC HEALTH
TEXAS A&M UNIVERSITY

- 41 CEU hours developed for CHWs
- Available in both English and Spanish
- Available free online, or through group in-person training
- DSHS-approved to maintain Texas state CHW certification

Colorectal Cancer

- Prevention & Detection
- Treatment
- Survivorship

(12 total hours)

Cervical Cancer

- Prevention & Detection
- Treatment
- Survivorship

(12 total hours)

Breast Cancer

- Prevention& Detection
- Treatment
- Survivorship

(12 total hours)

Cancer Navigation (5 total hours)

Curriculum Development

PUBLIC HEALTH
TEXAS A&M UNIVERSITY

CEUs for CHW Instructors:

- 5.0 hour training available in-person or via webinar
- "Training CHW Instructors to Deliver the NCHWTC Cancer Education & Navigation Curriculum"

Training Outcomes

PUBLIC HEALTH
TEXAS A&M UNIVERSITY

- Online:
  - **746** CHWs completed self-paced CEU modules
- In-Person:
  - **45** CHW instructors completed 'Train the Trainer" CEU module taught by ACTION instructors
  - **341** CHWs attended in-person training workshops taught or co-taught by ACTION instructors
    - Austin, Bryan, Corpus Christi, Harlingen, Houston, Laredo, Rio Grande City, Tyler

Partnerships

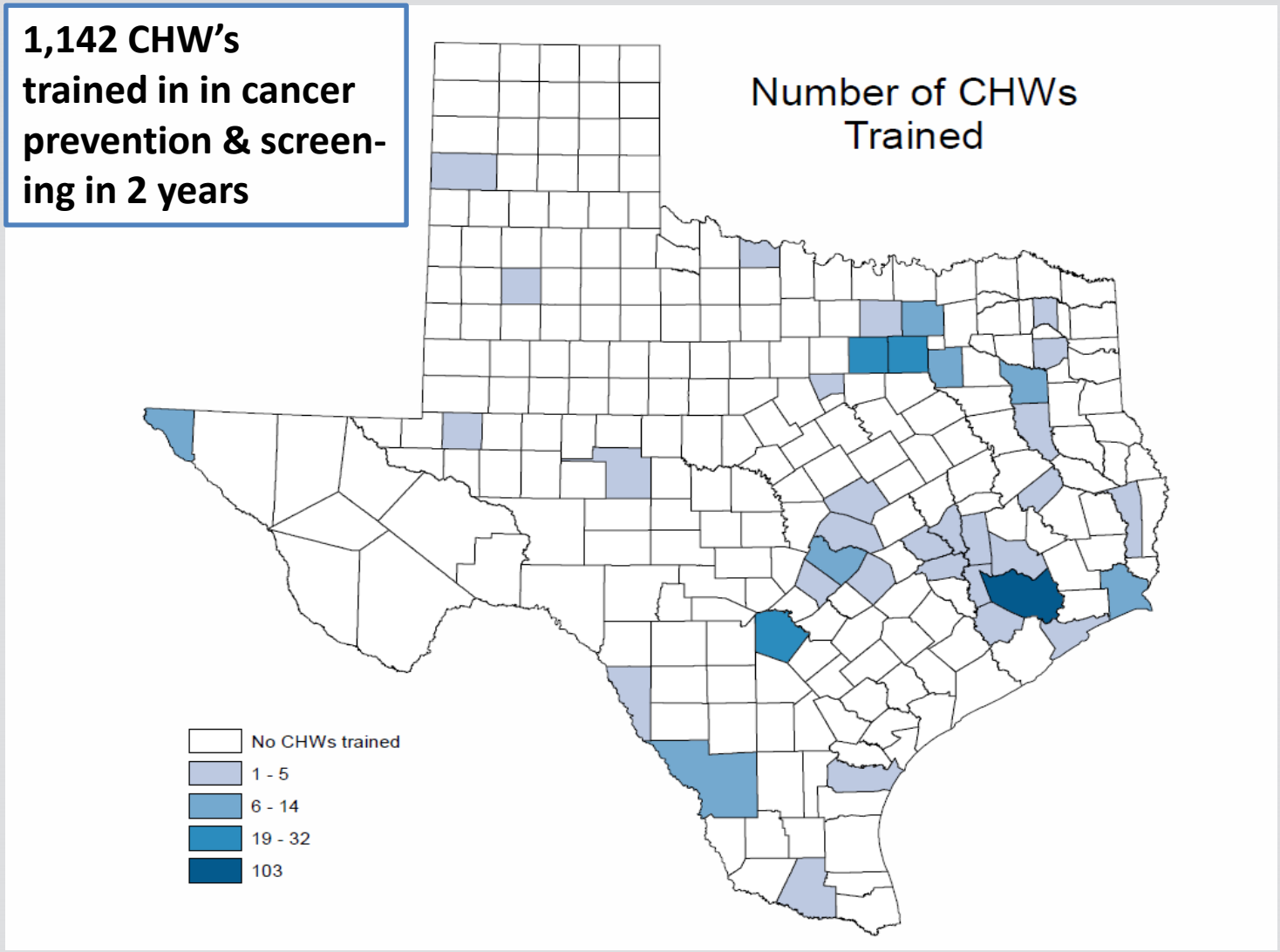
PUBLIC HEALTH
TEXAS A&M UNIVERSITY

- An affiliation model was developed to disseminate CHW training modules to other CHW instructors.
- Allows instructors not employed by Texas A&M to deliver ACTION CHW CEUs.
- Technical assistance is offered to partnering organizations.

CPRIT-A&M benefits for Texans

PUBLIC HEALTH
TEXAS A&M UNIVERSITY

1,142 CHW's trained in in cancer prevention & screening in 2 years



CPRIT-A&M Benefits for Advance Nursing in Texas

PUBLIC HEALTH
TEXAS A&M UNIVERSITY

- 20 MSN-FNP Students Received Training
- 50 Prelicensure (BSN) Students Trained
- Six (6) Faculty Trained
- 86 Women received *well-woman* exams
- 60% of A&M FNP graduates secured positions in rural healthcare, shortage areas in medically underserved areas of Texas.

CPRIT-A&M Medical Training Accomplishments

PUBLIC HEALTH
TEXAS A&M UNIVERSITY

- 73 Family Medicine Residents have been trained in colonoscopy procedures

- 58 Family Medicine Residents have been trained in breast and cervical cancer screening, education and prevention, including LEEPS, breast biopsies and colposcopies

- Residents work alongside Family Nurse Practitioners, Nursing Students, Public Health Students and CHW's.

Lessons Learned

PUBLIC HEALTH
TEXAS A&M UNIVERSITY

- Build on past project successes and experiences
- Engage our academic, medical, clinical, and population health community partners, “win-win”.
- Partner with faith-based and educational community partners, (e.g., Back to School Events)
- Engage multicultural, bilingual CHWs to deliver culturally competent, medically accurate cancer information;
- Look for Clinical Trials partners and expand reach of our successful programs.

Sustainability

PUBLIC HEALTH
TEXAS A&M UNIVERSITY

- Publishing our clinical model for Residency and FNP based training.
- Online & live presence for CHW Cancer Prevention & Education Training
- Downloadable educational materials and toolkits
- Affiliation model expands the reach of cancer education and navigation training for CHWs
- Find long-term funding partners for safety-net needy patients who are uninsured.
- Work with legislature to expand Scope of Practice

Contact us!

PUBLIC HEALTH
TEXAS A&M UNIVERSITY

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CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	AGENDA ITEM 7, CHIEF EXECUTIVE OFFICER REPORT
DATE:	NOVEMBER 22, 2017

As of this writing the Chief Executive Officer Report for the November 29, 2017, Oversight Committee (OC) meeting will consist of the following items:

- Personnel update, including introduction of new staff
- FY 2018 Grant Award Funds Available (attached)
- Preparation for the January 17, 2018, Special Meeting (memo attached)

Other topics may be added as warranted.

In addition, for your reference copies of the CPRIT Activities Updates for September and October provided to you previously are included at the end of the tab. These reports are done in months in which the OC does not meet.

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CPRIT has awarded **1,189** grants totaling **$1.881 billion**
- 189 prevention awards totaling $195.1 million
- 1000 academic research and product development research awards totaling $1.686 billion

Of the $1.686 billion in academic research and product development awards,
- 29.7% of the funding ($500.8 million) supports clinical research projects
- 26.2% of the funding ($441.2 million) supports translational research projects
- 25.9% of funding ($436.1 million) supports recruitment awards
- 14.7% of the funding ($248.0 million) supports discovery stage research projects
- 3.5% of funding ($59.9 million) supports training programs.

CPRIT has 10 open Requests for Applications (RFAs)
- 3 Research Recruitment
- 3 Academic Research
- 4 Prevention

FY 2018 GRANT AWARD FUNDS AVAILABLE

General Obligation Bond Proceeds

	Prevention	Academic / Product Development Research	1% Grant Funding Buffer	Operating Budget	Total Appropriations
Available Appropriated Funds	$ 28,022,956	$ 255,239,310		$ 16,737,734	$ 300,000,000
Appropriations Transfer to DSHS		$ (2,969,554)		$ 2,969,554	
Adjusted Appropriations	$ 28,022,956	$ 252,269,756		$ 19,707,288	$ 300,000,000
Total Available for All Grants			$ 280,292,712		
1% of Total Available Grant Funding			$ 2,802,927		
Adjusted Grant Award Funding	28,022,956	$ 249,466,829			$ 277,489,785

	Prevention Grants	Academic Research Grants	PD Research Grants			
Total Available for Grant Awards (Total GO Bond Proceeds Less Operating Budget)	$ 28,022,956	$ 189,202,317	$ 63,067,439			$ 280,292,712
Total Available for Grant Awards Incorporating 1% Grant Funding Buffer	$ 28,022,956	$ 187,100,122	$ 62,366,707			$ 277,489,785
Announced Grant Awards						
	$ -	$ -	$ -			
Announced Grant Award Subtotal	$ -	$ -	$ -	$ -		$ -
Grant Award Adjustments						
		$ -				$ -
Revised Grant Award Subtotal	$ -	$ -	$ -			$ -
Available Funds	$ 28,022,956	$ 187,100,122	$ 62,366,707			$ 277,489,785
Pending Grants-PIC Recommendations						
Prevention Dissemination Award	$ (294,804)					
AR Recruitment Awards (3)		$ (10,000,000)				
AR Core Facility Supplement (RP170691)		$ (943,570)				
Pending Award Subtotal	$ (294,804)	$ (10,943,570)	$ -			$ (11,238,374)
Total Potential Grant Funding Committed	$ (294,804)	$ (10,943,570)	$ -			$ (11,238,374)
1% Grant Funding Buffer	$ -	$ 2,102,195	$ 700,732			$ 2,802,927
Potential Available Funds as of Nov. 30, 2017	$ 27,728,152	$ 176,156,552	$ 62,366,707			$ 266,251,411

Operating Budget Detail		
Indirect Administration	$	3,030,652
Grant Review & Award Operations	$	13,707,082
Subtotal, CPRIT Operating Costs	$	16,737,734
Cancer Registry Operating Cost Transfer	$	2,969,554
Total, Operating Costs		19,707,288

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE ROBERTS
SUBJECT:	PLANNING FOR THE JANUARY 17, 2018, SPECIAL OVERSIGHT COMMITTEE MEETING
DATE:	NOVEMBER 22, 2017

Summary

This report summarizes preparations and expectations for the special meeting of the Oversight Committee (OC) on January 17, 2018. No action is required by the OC at this time.

Discussion

The goals for the special meeting are:

- A decision on the FY 2019 OC Program Priorities;
- A decision on draft funding estimates for fiscal years 2020-23 including amounts to include in CPRIT's *Request for Legislative Appropriations for the 2020-21 Biennium*;
- To inform the OC of the implications on priorities and operations of reduced funding for fiscal years 2020-22; and
- Consensus on process and timeline for priority setting process moving forward.

These topics have been discussed at previous OC meetings and the program subcommittees in advance of this November 29 OC meeting. As discussed in the subcommittee meetings, staff would like to schedule special subcommittee meetings in early January to review material and assure freshness of the information in OC member's minds at the time of the January 17 meeting. During December these additional meetings will be arranged through subcommittee members.

Staff is working with Presiding Officer Montgomery on materials for the special meeting to be made available to you prior to the subcommittee meetings.

Materials related to the annual funding projects will be the same or similar to what you have seen to date. Materials related to the Program Priorities will be distributed from the three program chiefs. The current (same as the proposed Program Priorities for FY 2018) are behind the Tab related to Agenda Item 13 in this meeting book. Please review these Priorities over the weeks ahead for ideas you'd like considered in modifying and adopting the FY 2019 Priorities.

CPRIT MANAGEMENT DASHBOARD
FISCAL YEAR 2017

	SEPT	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	CUMULATIVE (ANNUAL)	CUMULATIVE (TO DATE)
ACCOUNTABILITY														
Announced Grant Awards	12		48			14			10			61	145	
New Grant Contracts Signed	9	15	6	4	21	11	10	20	5	3	1	4	109	
New Grant Contracts In Negotiation			41			15			13			10	79	
Grant Reimbursements Processed (#)	147	182	186	289	216	217	237	181	100	268	164	114	2,301	
Grant Reimbursements Processed ($)	$ 16,840,484	$ 13,844,271	$ 15,610,663	$ 25,547,229	$ 24,395,194	$ 35,405,089	$ 22,446,293	$ 17,441,664	$ 10,746,189	$ 23,995,193	$ 16,305,485	$ 23,948,821	$ 246,526,576	
Revenue Sharing Payments Received	$ 4,000	$ -	$ 11,862	$ -	$ -	$ 21,339	$ -	$ 5,728	$ 12,889	$ 18,126	$ -	$ 25,069	$ 99,013	$ 3,234,216
Total Value of Grants Contracted ($)	$ 30,061,230	$ 29,635,362	$18,107,181	$ 2,866,290	$ 35,989,029	$ 19,487,212	$ 21,237,864	$ 47,311,317	$ 7,564,206	$ 9,494,530	$ 2,000,000	$ 30,946,716	$ 254,700,937	
Grants Awarded (#)/ Applications Rec'd (#)	12%	12%	13%	13%	13%	13%	13%	13%	13%	12%	12%	13%		
Debt Issued ($)/Funding Awarded ($)	64%	67%	64%	64%	67%	73%	73%	73%	72%	72%	72%	69%		
Grantee Compliance Trainings/Monitoring Visits	0	4	3	0	0	4	4	5	3	2	7	0	32	
Awards with Delinquent Reimbursement Submission (FSR)			1			0			11			0		
Awards with Delinquent Matching Funds Verification			0			0			0			1		
Awards with Delinquent Progress Report Submission			2			0			7			1		
IA Agency Operational Recommendations Implemented	0	0	0	0	0	0	0	0	0	8	8	8	24	
IA Agency Operational Recommendations In Progress	8	8	8	8	8	8	8	8	8	0	0	0		
Open RFAs	11	3	5	10	10	10	13	8	8	13	8	8		
Prevention Applications Received	36	0	0	0	0	0	40	0	0	0	0	0	76	716
Product Development Applications Received	19	0	0	0	0	20	0	0	0	0	0	19	58	402
Research Applications Received	2	2	3	3	169	7	12	12	0	532	0	3	745	6,013
Help Desk Calls/Emails	230	247	167	110	254	254	163	195	331	214	219	208	2,592	
MISSION														
ACADEMIC RESEARCH PROGRAM														
Number of Research Grants Awarded (Annual)			46			6			10			52	114	
Recruited Scientists Announced														216
Recruited Scientists Accepted														149
Recruited Scientists Contracted														135
Published Articles on CPRIT-Funded Projects (#)													1,998	
Jobs Created & Maintained (#)													2,801	
Trainees in CPRIT-Funded Training Programs (#)														
Open Clinical Trials (#)														90
Number of Patents Resulting from Research													19	

CPRIT MANAGEMENT DASHBOARD
FISCAL YEAR 2017

	SEPT	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	CUMULATIVE (ANNUAL)	CUMULATIVE (TO DATE)
Number of Patent Applications													100	
Number of Investigational New Drugs													42	
PRODUCT DEVELOPMENT RESEARCH PROGRAM														
Number of Product Development Grant Awarded (Annual)			2			0			0			1	3	
Life Science Companies Recruited (in TX)														9
Published Articles on CPRIT-Funded Projects													49	
Number of Jobs Created & Maintained														515
Open Clinical Trials (#)														15
Number of Patents Resulting from Research													8	
Number of Patent Applications													37	
Number of Investigational New Drugs													10	
PREVENTION PROGRAM														
Number of Prevention Grant Awarded (Annual)			0			9			0			8	17	
People Served by CPRIT-Funded Prevention and Control Activities			181,686			211,700			217,524			231,301	842,211	
People Served through CPRIT-Funded Education and Training			89,885			107,761			95,298			127,024	419,968	
People Served through CPRIT-Funded Clinical Services			91,801			103,939			122,226			104,277	422,243	
TRANSPARENCY														
Total Website Hits (Sessions)	5,975	5,618	7,019	5,137	8,089	7,798	6,805	5,577	7,072	6,612	5,202	8,466	79,370	
Total Unique Visitors to Website (Users)	4,485	4,009	4,768	3,608	5,563	5,673	4,978	3,848	4,692	4,653	3,883	6,162	56,322	

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	CPRIT ACTIVITIES UPDATE – SEPTEMBER 2017
DATE:	SEPTEMBER 29, 2017

Topics in this memo include the appointment of Dr. Mahendra Patel to the Oversight Committee, recent milestones in our fight against cancer, a staffing summary, CPRIT outreach efforts, CPRIT's biennial conference preparations, and updates from Compliance, Programs, and Operations.

Speaker Straus Appoints Mahendra C. Patel, M.D., to the Oversight Committee

House Speaker Joe Straus announced the appointment of Dr. Mahendra Patel of San Antonio to the Oversight Committee on September 15. Dr. Patel will fill the vacancy left by Dr. Cynthia Mulrow's resignation. He is a pediatric hematologist-oncologist. Dr. Patel has an extensive record of leadership in the San Antonio medical community, including his time as the Medical Board Chair at Methodist Healthcare System and as the Chief of Staff at Methodist Children's Hospital. While at the National Cancer Institute in Bethesda, Maryland, Dr. Patel was instrumental in developing the division of pediatric neuro-oncology as a principal investigator on numerous phase one/two clinical trials researching brain tumors in pediatric patients. His term will expire January 2021.

Upcoming Oversight Committee Meetings

The Oversight Committee will meet November 29, 2017, at 10:00 a.m. in Room E1.012 of the Texas Capitol Extension.

The Oversight Committee will have a special meeting on January 17, 2018. The tentative agenda includes discussion and possible action on FY 2019 and future program priorities, requests for applications driven by the program priorities, funding estimates for 2020-23, and the legislative appropriations request for the 2020-21 fiscal biennium. The meeting will be in Suite 6-127 of the Travis Building (CPRIT offices), 1701 North Congress Avenue, Austin, Texas, 78701. We have not yet set the time for the meeting to start.

Recent Milestones in the Fight Against Cancer

- CPRIT passed the two-thirds mark in our grant making authority with the awards approved at the August Oversight Committee meeting. We project that by the end of FY 2023, CPRIT prevention and research awards will total $2.804 billion. To date CPRIT has awarded $1.881

billion in grants, leaving a balance of $923 million to award through August 31, 2022, the last day the statute authorizes CPRIT to approve new grant awards.

- **All three UT System National Cancer Institute Designated Cancer Centers have new Directors.**

  Ruben A. Mesa, M.D., began August 1 as the director of The University of Texas Health Science Center at San Antonio (UTHSC-San Antonio) Cancer Center. Dr. Mesa had been professor of medicine and chair of the Division of Hematology & Medical Oncology at the Mayo Clinic in Arizona. Dr. Mesa is an expert on the management of myeloproliferative neoplasms, a group of bone marrow disorders that often lead to leukemia.

  Carlos Arteaga, M.D., began September 1 as the director of The University of Texas Southwestern Medical Center (UT Southwestern) Harold C. Simmons Comprehensive Cancer Center. Dr. Arteaga previously served as director for the Center for Cancer Targeted Therapies and breast cancer research programs and associate director for translational and clinical research at Vanderbilt University. He is a renowned authority on breast cancer and has developed many of today's standard therapies.

  Peter Pisters, M.D., is the new President of The University of Texas MD Anderson Cancer Center. His appointment became official in September. Dr. Pisters is a cancer surgeon and hospital administrator who has been President and Chief Executive Officer of the University Health Network in Toronto, Canada. Dr. Pisters returns to MD Anderson where he was a cancer surgeon and developed the Center's regional care centers.

- The Dell Medical School at The University of Texas at Austin (UT-Austin) has established a Department of Oncology. The new department, the medical school's ninth, is chaired by CPRIT Scholar Gail Eckhardt, M.D., who joined Dell Medical in September 2016 as the inaugural executive director of the LIVESTRONG Cancer Institute and the school's associate dean of cancer programs.

- NIH designated Baylor College of Medicine (BCM) as one of three NIH Proteogenomic Translational Research Centers**.** The Center will develop biomarkers in the context of clinical trials using an integration of proteomics and genomics to understand drug response and resistance to therapies. CPRIT Scholar Matthew Ellis, M.D. leads the Center and it will focus on breast cancer. The CPRIT-supported proteomic core facility at BCM provides the technical infrastructure for this important NIH award.

- NIH also designated BCM as a NIH Proteogenomic Data Analysis Center. The Center is led by CPRIT Scholar, Bing Zhang, Ph.D., and will use advanced computational methods to integrate and analyze different data types (genomics, transcriptomics, and proteomics, imaging and clinical data) to improve the understanding of the genome-proteome relationship and the interplay/regulation of signaling pathways involved in cancer.

- According to a report in *Nature,* UT Southwestern ranks fifth in the world in the number of published research articles cited as significant sources in third-party patent applications. This

new measurement is a way to evaluate an institution's impact and influence on industrial innovation, i.e., how a scientific discovery leads to, or plays a part in, the development and commercialization of new products and services.

- Congratulations to CPRIT Scholar James Allison, Ph.D., of MD Anderson who is the co-recipient of the Balzan Foundation award with Robert Schreiber of the Washington University School of Medicine. The Balzan recognized them for their work on antibody treatments (immune checkpoint inhibitors) that has increased the survival of patients with metastatic melanoma.

- Congratulations to MD Anderson on continuing as the top-ranked cancer hospital in the United States, according to 2017 rankings from *U.S. News & World Report*.

- CPRIT grantee Dr. Ralph DeBeradinis of UT Southwestern was selected by the National Cancer Institute to receive its prestigious Outstanding Investigator Award. The award includes annual funding of $600,000 for seven years to support Dr. DeBerardinis' continuing research into changes in cellular metabolism that occur in cancer. Dr. DeBerardinis' research focuses on cellular metabolism and how altered metabolic states stimulate the development or progression of cancer.

- The University of Texas System Board of Regents recognized CPRIT grantee Dr. Mien-Chie Hung with the Regents' Outstanding Teaching Award, which honors exceptional instruction in the university classroom. Dr. Hung is a professor and chair of the department of molecular and cellular oncology at UT MD Anderson Cancer Center. He also teaches at the MD Anderson Cancer Center UTHealth Graduate School of Biomedical Sciences and has served as major advisor to more students than any other faculty member in the history of the school. A former student said, "Dr. Hung's love for teaching sets him apart from others. He passes on patience, love and knowledge of science to the younger generation of students."

- Dr. Jane Bolin, a CPRIT grantee at the Texas A&M University System Health Science Center, was invited to present the Texas Cancer Screening, Training, Education and Prevention Program (C-STEP) in an August 30, 2017, Centers for Disease Control (CDC)-sponsored webinar entitled "Rural Cancer: Data Disparities and Determination – Insights from the CDC MMWR Rural Health Series." Two hundred and eighteen professionals from across the nation attended. Dr. Bolin was asked most of the follow-up questions and acknowledged CPRIT positively multiple times.

- Dr. Abbey Berenson, a multiple CPRIT grantee at The University of Texas Medical Branch at Galveston, was recently cited in *U.S. News & World Report* about her study on HPV vaccine effectiveness. "It appears that enough women have gotten the HPV vaccine to create 'herd immunity' that will provide some protection to females who go unvaccinated…we are now seeing a reduction in infections among women who have not received the vaccine." The journal *Obstetrics & Gynecology* published the study results in its September 7, 2017, edition.

- A new study published in *Nature* led by CPRIT Scholar Sean Morrison Ph.D., Children's Medical Center Research Institute at UT Southwestern, found that blood forming stem cells in mice take up unusually high levels of vitamin C (ascorbate) compared to other cells. When levels of ascorbate in the mice were depleted, the risk of leukemia increased. Further studies found that blood stem cells use ascorbate to modify DNA and thereby regulate which genes turn on and turn off. So when stem cells don't receive enough vitamin C, DNA can become damaged in a way that alters cell function and increases the risk of leukemia. It has been known that people with lower levels of vitamin C are at increased cancer risk and this research provides part of the explanation.

- A team of CPRIT supported researchers from The University of Texas at San Antonio, UT Southwestern and The University of Texas at Dallas discovered a "first-in-class" drug that can prevent breast cancer growth when traditional therapies stop working. Many breast cancers require estrogen to grow and these cancers can be effectively treated with a hormone therapy, such as tamoxifen, that works by preventing estrogen from binding to its receptor, a necessary step for cancer cells to multiply. But the estrogen receptor can mutate and change its shape over time so that tamoxifen no longer fits neatly with the receptor and no longer prevents the breast cancer growth. The new drug works by blocking other molecules – proteins called co-factors – that also must attach to the estrogen receptor for cancer cells to grow in response to estrogen. So far, it has been tested in mice and in cancer cells removed from patients and works well in both, and there have been no signs of toxicity in the tests. The team hopes to get a clinical trial under way in about a year. This research is an example of the magic that results when complementary expertise combines to solve a problem. The lead investigators include Ganesh Raj, M.D., a cancer surgeon at UT Southwestern, and CPRIT grantees Ratna Vadlamudi, Ph.D., a cancer biologist at UT-San Antonio, and Jung-Mo Ahn, Ph.D., a chemist at UT-Dallas.

- A team of scientists, surgeons, and engineers at UT Austin, BCM, and MD Anderson reported in *Science Translational Medicine* on the development of a new handheld device that rapidly and accurately identifies cancerous tissue during surgery, delivering results in about 10 seconds – more than 150 times as fast as existing technology. The "MassSpec Pen" is an innovation that gives surgeons precise diagnostic information about what tissue to cut or preserve as they perform surgery, helping to improve treatment and reduce the chances of cancer recurrence. This innovation was developed by Livia Schiavinato Eberlin, Ph.D., Assistant Professor, Department of Chemistry, UT-Austin, who is the recipient of CPRIT High Impact High Risk and Early Translational Research Awards to adopt mass spectrometry to clinical tissues using a technique called ambient ionization. This allows direct analysis of the molecular profile of a solid tissue without fixation or other processing steps and provides immediate molecular diagnosis. The team plans to conduct a clinical trial to evaluate the impact of the "MassSpec Pen" on care of patients undergoing surgery for breast cancer.

- BCM's Maria Jibaja-Weiss' CPRIT-funded project "Improving Breast Cancer Screening and Follow-up of Medically Underserved Harris County Residents" has successfully integrated culturally- and linguistically-appropriate breast cancer education into the clinic flow at all Harris Health System ambulatory care centers while increasing the proportion of women

screened by over 65 percent. In addition, the wait time for a diagnostic referral went from an average of 121 days to as little as one day through the Breast Screening Clinic established by the project.

- Because of the work of Dr. Lei-Shih Chen on the CPRIT project, "Cancer Genomics training program for a competent Texas health education workforce," Texas is the first state to provide cancer genomics training for health educators. This project led to a significant increase in Texans' cancer genomic literacy, the collection and use of family history, and the ability to access and discuss needs with genetic specialists for further cancer genetic evaluation and testing.

- Immatics U.S., Inc. initiated enrollment of patients into a Phase I clinical trial of its first adoptive cellular therapy (ACT) IMA101. The company is developing a personalized immunotherapy for the treatment of multiple solid tumors, including ovarian, gastric, esophageal, head and neck squamous cell carcinoma, and non-small cell lung cancers. This novel therapy "reprograms" patient's immune cells to attack cancer cells. The single-center trial of IMA101 is now enrolling patients at MD Anderson Cancer Center. This study will include up to 20 patients with relapsed and/or refractory solid cancers for which no established treatment is available. Immatics U.S. located in Houston after receiving a CPRIT product development grant in February 2015. The company credited "a critical mass of leading immunotherapy experts and the unique clinical infrastructure available in Houston," for its decision to locate in the city "to build a sustainable, world-class cancer immunotherapy company in Texas [that will] translate the value of novel cancer targets into better and longer lives for cancer patients."

- Curtana Pharmaceuticals announced that the Food and Drug Administration (FDA) granted orphan drug designation to the company's lead drug for the treatment of glioblastoma in adults and in children. Glioblastomas are incurable brain cancers. Median survival is less than 15 months and the five-year survival rate is less than 10 percent. Curtana's novel drug selectively spares normal cells and significantly reduces cancer cell migration into normal brain tissue in animal models. This has significantly prolonged survival in animal models of brain cancer. The company recently completed a pre-investigational new drug (IND) meeting with the FDA to discuss clinical trial design and plans to file an IND application in the first half of 2018. Orphan drug designation is important because it accelerates FDA review. Curtana received a CPRIT product development research grant in August 2014 to fund this work.

- Medicenna Therapeutics reported it has safely treated the first 10 patients in its Phase IIb recurrent glioblastoma clinical trial. The lack of adverse safety reports through 10 patients is an encouraging milestone. The company will continue to enroll patients through 2017 at five new clinical sites. Medicenna has completed three clinical trials in 72 patients, including 66 adults with recurrent glioblastoma, demonstrated compelling efficacy and obtained Fast-Track and Orphan Drug status from FDA. According to Medicenna, unlike most other cancer therapies, the company's novel therapies have the potential to purge both the tumor and the immunosuppressive tumor microenvironment, offering a unique treatment paradigm for a large majority of cancer patients. The company will present at the 2017 Congress of

Neurological Surgeons Annual Meeting regarding an interim safety and tolerability evaluation of convection enhanced delivery of its targeted immunotherapy in the Phase IIb clinical study. Medicenna received a product development research grant award in February 2015.

- Molecular Templates, Inc. completed its merger with Threshold Pharmaceuticals and announced the close of a $40 million fundraising series. The combined company, headquartered in Austin, publicly trades on Nasdaq (MTEM). Molecular Templates also closed a separate $20 million equity investment from Takeda Pharmaceutical Company associated with a collaboration and licensing agreement. The funding will further development of the company's lead drug candidate, MT-3724. MT-3724 is in a Phase I clinical trial for heavily pre-treated non-Hodgkin's lymphoma patients at the Memorial Sloan-Kettering Cancer Center, the MD Anderson Cancer Center, and the University of Arizona. The company is preparing to start enrolling an expansion arm of the Phase I study focused on relapsed and refractory diffuse large lymphoma patients. Molecular Templates is also developing MT-4019 as a preclinical drug candidate targeting a protein expressed on the surface of myeloma cells. Molecular Templates received product development research grants in 2011 and in 2016 to fund development of MT-3724 and MT-4019.

- Pelican Therapeutics will locate their laboratory headquarters in San Antonio following the award of a $200,000 economic development grant by the San Antonio City Council. The new lab will develop the clinical version of the company's novel T cell co-stimulator therapy. Pelican's lead compound is a monoclonal antibody that stimulates the immune system to kill cancer cells. The opening of Pelican's headquarters in San Antonio is expected to provide high-wage jobs to support bioscience research and a Phase I clinical trial for its cancer immunotherapy agent. Separately the company announced that they entered into a manufacturing agreement with KBI biopharma for production of antibodies for clinical trials and commercial sale. Pelican received a CPRIT product development research grant in May 2016.

- Fierce Biotech named Aravive Biologics to its list of "Fierce 15" companies for 2017. The industry trade association's list recognizes "the best science combined with the best and brightest management teams, and…a genuine chance of being the Next Big Thing." The company's leading candidate, Aravive-S6, blocks the activation of a cancer signaling pathway by serving as a decoy that prevents the binding of a protein to the AXL receptor on the surface of tumor cells. The AXL receptor acts as a "survival switch," a key driver of invasiveness and metastasis, and a regulator of resistance to chemo drugs. The therapy targets acute myeloid lymphoma and certain solid tumor indications including ovarian, pancreatic, and breast cancer. Aravive relocated from California to Texas because of a CPRIT product development grant awarded in November 2015.

Personnel

As of September 29, 2017, CPRIT has filled 31 of its 35 authorized full-time equivalent positions. The hiring freeze imposed by Governor Abbott at all state agencies and institutions of

higher education expired August 31, 2017. This allowed CPRIT to begin the hiring again to fill vacancies and new positions authorized by the 85th Legislature.

- Rosemary French has accepted the position of Program Manager for Product Development and will start October 16. She replaces Cathy Allen, who is retiring.

- Bob Lansdowne, Debra McHenry, and Joan Thomas started September 1 as Grant Accountants.

- The Compliance Program Manager position is posted. In addition, we expect to have the two open Grant Compliance Specialist positions filled by early October.

- Executive Assistant Adriane Natal retired this month. A temporary contract employee will take her place while we post the position and hire a permanent employee.

CPRIT Outreach

- On August 15 I briefed Texas Secretary of State Rolando Pablos on CPRIT's cancer research scholar recruitment efforts and how this complements Governor Abbott's University Research Initiative to recruit high level scholars to Texas institutions of higher education. I have invited Secretary Pablos to provide a welcoming address to attendees of our November biennial conference.

- Several members of CPRIT staff met with representatives of the Texas Cancer Partnership on September 5 to discuss results of the 85th Texas Legislature and the Partnership's plans for the ensuing interim and the 86th Texas Legislature. The Texas Cancer Partnership is a coalition of cancer research and prevention advocates working together to support CPRIT.

- I attended events sponsored by the Congressional Caucus on Childhood Cancer in Washington, D.C. on September 14 and 15. Congressman Michael McCaul, R-Austin is the co-chair of the Caucus. I invited Rep. McCaul to address our November biennial conference on his efforts to increase federal support for research and treatment of childhood cancers. Rep. McCaul and a group of bipartisan lawmakers introduced the RACE (Research to Accelerate Cures and Equity) for Children Act, which empowers the FDA to require that adult cancer drugs be tested for safety and effectiveness in children. President Trump signed the legislation on August 18. Rep. McCaul also was part of the effort to reauthorize the Creating Hope Act of 2011, which provides incentives for pharmaceutical companies to create new treatments for pediatric cancer patients. Rep. McCaul reintroduced the Childhood Cancer Survivorship Treatment, Access and Research (STAR) Act earlier this year to improve efforts to identify and track childhood cancer incidences and support opportunities to expand research of therapeutics for children diagnosed with cancer.

- On September 15 Kristen Doyle provided an update on CPRIT's activities and the recent legislative session to the Texas Medical Association's Committee on Cancer.

- I provided a CPRIT legislative update to the membership of the Texas Healthcare & Bioscience Institute (THBI) on September 21 and discussed current agency initiatives and pertinent metrics related to our fight against cancer. THBI is the major healthcare and bioscience professional organization in Texas with many high-profile industry members.

- Mike Lang, Becky Garcia, and Spence Miller-Payne attended the San Antonio City Council meeting on September 21 when the City Council voted to approve an ordinance authorizing a $200,000 economic development grant for CPRIT grantee Pelican Therapeutics to locate its headquarters in the city. In his remarks to the council, the Director of Economic Development recognized the role of CPRIT in attracting Pelican to Texas.

- Over the weekend of September 22-23, I attended the annual Tribfest sponsored by the *Texas Tribune*. This important confab brings together over 1,000 local, state and federal policy decision makers in a variety of venues to discuss significant current events. You may recall that last year Dr. James Willson, Chief Scientific Officer, participated on a panel related to state cancer activities along with State Representative Sarah Davis and Lance Armstrong. This year Oversight Committee member Mayor Dee Margo was on a panel on big-city economics.

- I discussed outcomes of the 85th Texas Legislature and CPRIT interim activities with staff of Speaker Straus on September 26.

Compliance Program Update

Submission Status of Required Grant Recipient Reports

CPRIT's grant management system (CGMS) produces a summary of delinquent reports each week; this is the primary source used by CPRIT's compliance staff to follow up with grantees. CPRIT typically has 570+ grants that are either active or wrapping up grant activities and receives an average of 570 grantee reports each month.

As of September 25, 2017, 12 required reports from six entities have not been filed by the set due date; six (50%) are Academic Research grants, three (25%) are Product Development Research grants, and three (25%) are Prevention grants. In most cases, CPRIT does not disburse grant funds until the grantee files the required report(s). In some instances, grantee institutions may be ineligible to receive a future award if the grantee does not submit the required reports. CPRIT's grant compliance specialists and grant accountants continue to review and process incoming reports and reach out to grantees to resolve filing issues.

FSR Reviews

CPRIT's Grant Compliance Specialists performed 199 second-level reviews of grantee Financial Status Reports (FSRs) during the months of August and September. Fourteen FSRs (7%) required resubmission due to insufficient or inaccurate documentation submitted by the grantee. 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.

Desk Reviews

CPRIT staff performed 32 desk reviews in August and September. Grant Compliance Specialists perform desk-based financial monitoring/reviews during the course of grant awards to verify that grantees expend funds in compliance with specific grant requirements and guidelines. Desk reviews may target an organization's internal controls, current and past fiscal audits, and timeliness of required grantee report submission. Grant Compliance Specialists are working with 17 grantees to remediate desk review findings.

On-Site Reviews

Grant Compliance Specialists are working with nine grantees to remediate on-site review findings. On-site reviews typically include an examination of a 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.

Annual Compliance Attestation (Self-Certification)

Grantees must submit an annual self-certification demonstrating compliance with statutory and administrative grant requirements, CPRIT's policies and procedures, the grant contract, and the Uniform Grant Management Standards (UGMS). This opportunity to self-report, in the form of a checklist, provides a baseline of grantee compliance and allows Grant Compliance Specialists to work proactively with grantees towards full compliance prior to a desk review or on-site review. Compliance staff is working with one grantee to remediate deficiencies identified in its attestation.

Single Audit Tracking

As part of ongoing monitoring efforts, grant compliance specialists track the submission of grantees' independent audit reports and the resolution of issues identified in these reports. 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 findings must be compiled in an independent audit report and submitted to CPRIT within 30 days of receipt, but no later than 270 days after the grantee's fiscal year.

Grant Compliance Specialists are working with seven grantees to remediate audit findings. Grantees are given 30 days from the receipt of the audit to submit supporting documentation to demonstrate remediation efforts. There are currently no grantees with a delinquent audit or Corrective Action Plan. 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 additional time by the due date of the required audit and CPRIT's CEO approved the request.

Training & Support

A grantee training webinar is scheduled for October 11, 2017. The training will cover grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. This will be the third training offered this year in support of the annual compliance training requirement which states that the Authorized Signing Official (ASO) and at least one other employee from each grantee organization must attend an annual compliance training by November 1 of each year.

Academic Research Program Update

FY18 Cycle 1 (18.1) RFAs Update

Table 1 displays the number of applications submitted for Cycle 18.1 by RFA mechanism. These applications are currently under review by the Scientific Review Council. Dr. Willson will present the award recommendations to the Program Integration Committee and the Oversight Committee in February 2018.

Table 1: FY18.1 IIRA Application Submissions by Mechanism

Fiscal Year RFA Cycle	IIRA Submitted	IIRACCA Submitted	IIRACT Submitted	IIRACB Submitted	IIRAP Submitted	Total Submissions
18.1	**356**	**39**	**54**	**43**	**40**	**532**

IIRA: Individual Investigator Research Awards
IIRACCA: Individual Investigator Research Awards for Cancer in Children and Adolescents
IIRACB: Individual Investigator Research Awards for Computational Biology
IIRACT: Individual Investigator Research Awards for Clinical Translation
IIRAP: Individual Investigator Research Awards for Prevention and Early Detection

Recruitment Summary Data

Table 2 displays the number of recruitment applications submitted for Cycles 18.1 and 18.2, which were reviewed by the Scientific Review Council (SRC) on September 14, 2017. SRC recommended grant applications will be presented to the Program Integration Committee and the Oversight Committee for approval at the November 29, 2017 Oversight Committee meeting.

Table 2: Summary of Recruitment Application Submissions Cycles 18.1 & 18.2

Cycles 18.1-18.2	# Applications Submitted
Recruitment Established Investigators	2
Recruitment Rising Stars	0
Recruitment of First-Time Tenure Track Faculty Members	4
Total	**6**

FY18 Cycle 2 Request for Academic Research Applications

Following approval by the Oversight Committee on August 16, 2017, CPRIT announced and posted three Requests for Applications (RFAs) on August 25, 2017. CPRIT will begin receiving applications October 18, 2017, through January 31, 2018. Applications will be reviewed in May 2018 and SRC recommended applications will be presented to the Program Integration Committee and the Oversight Committee for approval in August 2018. The three RFAs are:

- **Core Facility Support Awards (CFSA)**
  Supports the development or improvement of core facilities that will provide valuable services to support and enhance scientifically meritorious cancer research projects. CPRIT is particularly interested in supporting core facilities that provide enabling services to cancer investigators from multiple Texas institutions. Applications responding to this RFA that address one of the program priorities for academic research adopted by CPRIT's Oversight Committee are particularly encouraged.
  Award: Up to $3,000,000 (total costs) for the first 2 years and up to $1,000,000 (total costs) for each subsequent year; Maximum duration: 5 years

- **High-Impact/High Risk Research Awards (HIHR)**
  Provides short-term funding 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. Applications responding to this RFA that address one of the program priorities for academic research adopted by CPRIT's Oversight Committee are particularly encouraged.
  Award: Up to $200,000 (total costs); Maximum duration: 2 years.

- **Multi-Investigator Research Awards (MIRA)**
  This Multi-Investigator Research Award (MIRA) mechanism is intended to support highly integrated programs of collaborative and cross-disciplinary research among multiple Texas investigators. Applications responding to this RFA that address one of the program priorities for academic research adopted by CPRIT's Oversight Committee are particularly encouraged.
  Award: Up to $6,000,000 (total costs); Maximum duration: 4 years.

Product Development Research Program Update

FY 2018 Cycle 1 Product Development Research Applications

CPRIT received 18 applications by the August 10, 2017 deadline. The peer review panels met September 25 and 26 to evaluate the applications and determine the applicants moving to the next step of the review process, in person presentations to the review panels. Four companies will be invited to present their applications in Houston October 23-26, 2017. Mr. Lang will present the companies recommended for grant awards to the Program Integration Committee and the Oversight Committee in February 2018.

Catalyzing Commercialization

Mr. Lang and the Dr. Willson have developed strategies to bridge between the current academic and product development programs. They propose modifying CPRIT's existing Early

Translational Research Applications to include more focus on clinical and commercial objectives and insure support is available for this work. A proposed Seed Award program will provide startup funding to new company spinouts from Texas research institutions. CPRIT has scheduled a planning meeting in October with the chairs of the Academic Research and Product Development Research Subcommittees to review draft proposals for requests for applications.

Prevention Program Update

FY 2018 Cycle 1 Prevention RFAs

The Prevention Program released three RFAs for the first cycle of FY 2018 on June 8. CPRIT extended the original application date, September 14, to September 21 due to the impact of hurricane Harvey on many applicants. Peer review panels will meet December 11-14, 2017. The Oversight Committee will consider the recommendations at the February 2018 meeting. The RFAs released June 8 included:

- **Evidence-Based Cancer Prevention Services**
  Seeks to fund projects that will deliver evidence-based cancer prevention and control clinical services. Priority is 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 $1.5 million; Maximum duration of 36 months.

- **Tobacco Control and Lung Cancer Screening**
  Seeks to fund programs on tobacco prevention and cessation, as well as screening for early detection of lung cancer. Through 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. It 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 $1.5 million; Maximum duration of 36 months.

- **Dissemination of CPRIT-Funded Cancer Control Interventions (DI)**
  Seeks to fund projects to facilitate the dissemination and implementation of successful CPRIT-funded, evidence-based cancer prevention and control interventions across Texas. A proposed project should develop one or more "products" based on the results of the CPRIT-funded intervention. The project should also identify and assist others to prepare to implement the intervention and/or prepare for grant funding.
  Award: Maximum of $300,000; Maximum duration of 24 months.

- **Reposting of Dissemination (DI) RFA**
  To speed up the review and approval of applications to the Dissemination RFA, we revised this mechanism's submission and review process. The RFA is now open continuously and reviewed by the Prevention Review Council (PRC) quarterly. Recommendations of meritorious applications, if any, will be forwarded to the Oversight Committee for consideration at quarterly meetings. Applications received by October 3, 2017, will be reviewed by the PRC and brought to the OC at the November 29, 2017, meeting.

FY 2018 Cycle 2 Prevention RFAs

The RFAs for the second cycle of FY 2018 (18.2) are being reviewed and edited. RFAs will be posted in October with applications due in March 2018, peer review in May 2018 and consideration by the Oversight Committee in August 2018. The 18.2 RFAs include: Evidence-Based Cancer Prevention Services (EBP), Tobacco Control and Lung Cancer Screening (TCL), and Dissemination of CPRIT-Funded Cancer Control Interventions (DI). In addition, the Prevention Program is releasing a new RFA this cycle:

- **Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations**
  Seeks to support the coordination and expansion of evidence-based services to prevent cancer in underserved populations that do not have adequate access to cancer prevention interventions and health care and bring together networks of public health and community partners to implement programs tailored to 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. In either case, the expansion must include delivery of services to nonmetropolitan and medically underserved counties in the state. Award: Maximum of $3 million; Maximum duration of 36 months.

Other activities

Quarterly progress reports were due on September 15, 2017, and CPRIT will report the prevention program performance measures to the Legislative Budget Board by October 13.

Dr. Garcia is on the Advisory Council of the Texas Health Improvement Network (THIN). THIN addresses the state's urgent health care challenges and improving the health care system in Texas. THIN has proposed five interim charges for consideration by the Lieutenant Governor and Speaker. One of these is to "Identify and study barriers and opportunities to improving health and health care in rural Texas."

Communications

- Cancer Awareness Month Activities
  September is Childhood Cancer Awareness Month. CPRIT released a series of blogs on our website about work conducted by grantees across the state. The posts focus on efforts to fight childhood cancer by individual investigators, a MIRA grant, and UT Southwestern's kidney cancer SPORE. CPRIT also released a video showcasing Dr. Peter Houghton of UTHSC-San Antonio.

  October is National Liver Cancer Awareness Month. Work has begun on a video feature on the CPRIT funded Texas Hepatocellular Carcinoma Consortium (TxHCCC), a liver cancer research project involving four institutions: BCM, MD Anderson, UT Southwestern and UTHSC-San Antonio. Spencer Miller-Payne and Chris Cutrone

interviewed Dr. Hashem El-Serag from MD Anderson and Dr. Jorge Morrero from UT Southwestern. CPRIT will use the footage on our social media channels and as a pitch to the news media.

The Communications team recorded interviews with the Moncrief Cancer Institute staff in Fort Worth on September 5 for a future video that CPRIT will share online during National Cancer Prevention Month in February.

- *Innovations in Cancer Prevention and Research V* Conference
  CPRIT will hold its biannual Innovations in Cancer Prevention and Research conference in Austin November 13-14, 2017. Conference registration is currently at 200. We expect registrations to increase when CPRIT notifies those who submitted abstracts of their acceptance. Due to Hurricane Harvey, the submission deadline for abstracts was extended to September 17; CPRIT received 419 abstracts by the deadline.

  We released a series of video interviews with the CPRIT Program Officers throughout September via email and social media to promote the conference. Two videos announce the Childhood Cancer and Immunotherapy sessions, one promotes the Prevention sessions and one highlights the Product Development Research sessions.

- Bob Sechler, a business reporter for the *Austin American Statesman*, interviewed me on September 19 for an article that appeared on the front page, above the fold of Sunday's September 24 print and online editions. The article consisted of an update on CPRIT activities and speculation on CPRIT's future post-2023.

Operations and Finance Update

- Heidi McConnell sent a request to the Texas Public Finance Authority (TPFA) on September 21 to issue $68.2 million in General Obligation Commercial Paper Notes on CPRIT's behalf. This is the first tranche of bond funding planned for FY 2018. TPFA will transfer the proceeds to CPRIT's account in the treasury by September 29.

- CPRIT's financials component of the state's Centralized Accounting and Payroll/Personnel System (CAPPS) became active September 1. The CAPPS financials integrates accounts payable, general ledger/commitment control, purchasing, and asset management and automates transactions among those modules. This transition culminates months of work by CPRIT's accounting team.

Upcoming Subcommittee Meetings

Listed below are upcoming November Oversight Committee subcommittee meetings.

Subcommittee	Date & Time
Board Governance	November 3 at 10:00 a.m.
Audit	November 7 at 10:00 a.m.
Prevention	November 8 at 10:00 a.m.
Academic Research	November 9 at 10:00 a.m.
Product Development	November 10 at 10:00 a.m.
Nominations	November 11 at 10:30 a.m.

CPRIT will send an agenda, call-in information, and supporting material to the subcommittees one week prior to the meeting date.

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CPRIT has awarded **1,189** grants totaling **$1.881 billion**

- 189 prevention awards totaling $195.1 million
- 1000 academic research and product development research awards totaling $1.686 billion

Of the $1.686 billion in academic research and product development awards,

- 29.7% of the funding ($500.8 million) supports clinical research projects
- 26.2% of the funding ($441.2 million) supports translational research projects
- 25.9% of funding ($436.1 million) supports recruitment awards
- 14.7% of the funding ($248.0 million) supports discovery stage research projects
- 3.5% of funding ($59.9 million) supports training programs.

CPRIT has 3 open Requests for Applications (RFAs)

- 3 Research Recruitment

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	CPRIT ACTIVITIES UPDATE – OCTOBER 2017
DATE:	OCTOBER 31, 2017

Topics in this memo include the appointment of Dr. David Cummings to the Oversight Committee, upcoming Oversight Committee meeting preparation, recent milestones in our fight against cancer, a staffing summary, CPRIT outreach efforts, updates from Compliance, Programs, and Operations, and CPRIT's biennial conference preparations.

Governor Abbott Appoints David A. Cummings, MD, to the Oversight Committee

Governor Abbott appointed David Cummings, M.D. to the Oversight Committee for a term set to expire on January 31, 2023. Dr. Cummings of San Angelo is a cancer physician at the Shannon Clinic and board certified in Medical Oncology by the American Board of Internal Medicine. He is a member and past president of the Concho Valley County Medical Society and a member of the American Society of Clinical Oncology and the Texas Medical Association. He is a former member of the American College of Physicians and the American Medical Association. Dr. Cummings received a Bachelor of Arts in business and pre-medicine from Baylor University and Doctor of Medicine from Texas Tech University Health Sciences Center and School of Medicine. Dr. Cummings replaces Dr. Bill Rice, whose term expired.

Upcoming Oversight Committee Meetings

The Oversight Committee will meet November 29, 2017, at 10:00 a.m. in Room E1.012 of the Texas Capitol Extension. CPRIT will post the final agenda for the Oversight Committee meeting by November 21, 2017; a tentative agenda is attached. Three members have notified me that they will be unable to attend the meeting. **If you have not already done so, please notify me as soon as possible if you are not able to attend the November meeting or have travel arrangements that will cause you to leave the meeting early.**

You will receive an email from CPRIT by November 3 with a link and password to access the Program Integration Committee's recommendations via the grant award portal. The portal has supporting documentation regarding each project proposed for an award, including the application, CEO affidavit, summary statement, and grant pedigree. A summary of the award slate will also be available through the portal. Please allow some time to complete the individual conflict of interest checks and review the supporting material.

Oversight Committee members should receive an electronic copy of the agenda packet by November 22. Hard copies of the agenda packet will be available at the meeting.

The Oversight Committee will have a special meeting on January 17, 2018. The tentative agenda includes discussion and possible action on FY 2019 and future program priorities, requests for applications implementing the program priorities, funding estimates for 2020-23, and the legislative appropriations request for the 2020-21 fiscal biennium. The meeting will be in Suite 6-127 of the Travis Building (CPRIT offices), 1701 North Congress Avenue, Austin, Texas, 78701. The time has not been set.

Recent Milestones in the Fight Against Cancer

The University of Texas MD Anderson Cancer Center has been selected for a leading role in a new federal initiative to advance treatments using the body's immune system to fight cancer. As part of a $215 million public-private partnership announced by the National Institutes of Health, MD Anderson will receive funding to help identify and test chemical signatures in the body that will predict which patients will benefit from immunotherapy approaches pioneered by CPRIT Scholar James Allison. The partnership is the first initiative announced under the Trump Administration involving the national Cancer Moonshot. Under the initiative, MD Anderson will get $11 million over five years to conduct tumor analysis and immune monitoring in immunotherapy clinical trials conducted by multi-institutional networks. The analysis and monitoring attempts to identify biomarkers that could guide future treatment.

A multi-institutional team led by CPRIT scholar Erez Lieberman Aiden (assistant professor of genetics at Baylor College of Medicine and a senior scientist at Rice University's Center for Theoretical Biological Physics) has created the first high-resolution 4-D map of genome folding, which tracks an entire human genome as it folds over time. The report, which could lead to new ways of understanding genetic diseases, appears as the cover article of the October issue of the journal *Cell* (171:305-320, 2017). This work is important to understanding how the gene is regulated. If stretched out from end-to-end, the DNA in each cell would be over six feet long. But the DNA must fold to fit inside the cell's nucleus, which is less than a thousandth of an inch wide. This folding is not merely a way of packing a long DNA strand into a tiny space—the folding pattern is different for each organ. This compact folding leads the genome to bend back upon itself, so that two pieces that lie far apart along the DNA molecule — like a gene and its regulatory element — can come within close proximity. Having a better understanding of where these loops occur in different cell types may lead to a better understanding of gene regulation. Earlier this year Aiden received a $3.3 million award from the National Institutes of Health to establish one of eight new mapping centers for NIH's Encyclopedia of DNA Elements Project.

CPRIT supported research reported in the journal *Neoplasia* found that individuals with certain types of bacteria in their gut may be more likely to respond well to cancer immunotherapy. CPRIT grantee Dr. Andrew Koh, associate professor of Pediatrics and Microbiology, The University of Texas Southwestern Medical Center, analyzed the gut bacteria of 39 melanoma patients who were treated with immunotherapies and found a strong association between a good response and the presence of a particular type of bacteria. This research suggests there are certain beneficial bacteria needed to optimize the effectiveness of checkpoint inhibitors. These bacteria

somehow prime an individual's immune system to facilitate its attack on cancer cells. While these observations do not establish a firm causal connection between gut microbes and immunotherapy efficacy, they may lead to a probiotic cocktail that could be given along with immunotherapy to enhance the chance of response.

A UT Southwestern team has made a potentially paradigm shifting discovery in the stimulation of cancer cell growth. A century-old observation known as the Warburg Effect indicates that cancer is fueled exclusively by glucose (sugar) with lactate produced as a waste product. In contrast the Southwestern team reports in the journal *Cell* that lactate is not only a waste product but is a fuel source consumed by growing lung cancer cells. This finding represents a major shift in how researchers view cancer metabolism and opens a new avenue of study for therapies and imaging techniques for lung cancer. This research was supported in part by a CPRIT Investigator Initiated Research Award to Dr. Ralph DeBerardinis and is important because understanding the lactate pathway could help to find therapeutic targets for lung cancer. Lactate uptake could also have predictive value when used as an imaging tracer. An important factor in these new discoveries is the collaboration between scientists and the clinical team. Working closely with medical personnel in Radiology, Pathology, Pharmacy, Anesthesiology, and the surgical team, researchers analyzed the metabolism of tumors during surgeries to remove tumors. This approach provides important insights that may not occur in laboratory-based experiments.

Congratulations to Carrie L. Byington, MD, dean of the Texas A&M College of Medicine, senior vice president of the Texas A&M University Health Science Center and vice chancellor for health services at the Texas A&M University System, who has been elected to the National Academy of Medicine. Dr. Byington represents Texas A&M System as a member of CPRIT's University Advisory Committee.

Pelican Therapeutics entered a service agreement with Selexis, a pharmaceutical development services firm specializing in cell therapies. Pelican and Selexis will collaborate to advance PTX-35, Pelican's lead product candidate, into clinical development. PTX-35 stimulates the action of Memory CD8+ cytotoxic T-cells, a class of T-cell responsible that kills tumor cells. PTX-35 is intended to be used in combination with other immunotherapies to extend the duration of their tumor killing activity. Pelican will use Selexis' proprietary technology to develop research cell banks that express the drugs Pelican is developing. CPRIT awarded the company a product development grant in May 2016.

Immatics U.S. Inc. enrolled initial patients in a Phase I trial at MD Anderson of IMA201. This investigational immunotherapy uses Immatics' proprietary ACTengine® technology to genetically engineer a patient's own T-cells to activate these cells to attack solid tumors. The study will include up to 16 patients with relapsed and/or refractory squamous non-small cell lung cancer or head and neck squamous cell carcinoma, for which no standard of care therapy is available. Phase 1 clinical trials are typically intended to provide initial human safety and efficacy data. The primary objective of this study is to determine safety and tolerability of IMA201 in the target patient population. Secondary objectives include assessing anti-tumor activity and time-dependent clinical outcomes. Immatics also announced the completion of its Series E financing, raising $58 million to support ongoing clinical studies and further develop its pipeline of novel cancer immunotherapies. CPRIT awarded the company a product development grant in February 2015.

Aravive Biologics, Inc. was honored as the 2017 "Innovator of the Year" by YTEXAS, at their 4th Annual YTEXAS ReLO Awards on September 29, 2017. YTEXAS is an organization that accelerates CEO connectivity and corporate presence for companies that are newly relocated to Texas. The ReLO Awards honor the 'Featured 50' notable corporate relocations from the previous 5 years. Aravive was selected in recognition of the potential offered by its novel cancer therapy. The company, formerly known as Ruga Corporation, is developing therapies to treat malignancies while sparing normal healthy cells. Its lead program focuses on the GAS6/AXL pathway to treat both acute myeloid leukemia (AML) and a variety of solid tumors. CPRIT awarded Aravive a product development grant in November 2015.

A CPRIT award to The Rose in Houston increased the availability and access to preventive breast cancer screening in ten rural communities using mobile mammography vans and community partnerships. The short-term impact is that many women who otherwise would not have received a screening mammogram did. The long-term impact is that women in these rural areas have been educated about the importance of breast health and early detection and have found a healthcare resource in their community through the partnerships.

A CPRIT prevention grant to Texas Tech University Health Sciences Center at El Paso developed a culturally sensitive, bilingual breast cancer screening, education and navigation program that recruited nearly 2,000 women and achieved an 86 percent diagnostic completion rate. In addition, 11 cancers were identified and all women were successfully navigated into treatment through program protocols and case management.

Personnel

CPRIT has 35 authorized full-time equivalent (FTE) positions, of which 32 are filled as of October 31, 2017. With the hires described below, we have filled the positions for additional compliance program staff approved by the 85th Texas Legislature, giving us a total of 8 compliance staff.

- Stephen Nance accepted the position of Program Manager for Compliance and will start November 1.
- Rashonda Thomas, Grant Accountant was promoted to the vacant Grant Compliance Specialist position, effective November 1.
- Melanie Jamison joined the agency on October 16 as a Grant Compliance Specialist.

Additional staff changes include:

- Mary Gerdes, my Executive Assistant retired on October 20, 2017.
- We are screening applications submitted for three vacant position postings, Grant Accountant, Executive Assistant, and Operations Specialist, and will begin interviews soon.
- Two temporary contractors have been retained to support and augment the Information Technology team.

CPRIT Outreach

- I attended the Fall Meeting of the National Association of State Budget Officers meeting October 6-7 in Alexandria, Virginia. Numerous topics concerning federal and state health care issues and financing were discussed along with updates on the federal budget and national economy.

- Kristen Doyle, General Counsel and Deputy Executive Officer, was an invited participant at the ASPET/ADDC Academic Drug Discovery Colloquium's conference *Fueling Innovation: Public Programs Driving Drug Discovery* at the NIH Campus in Bethesda, Maryland, on October 12 – 13.

- On October 12 the *Texas Tribune* interviewed me on implementation of CPRIT's statutory changes in 2013 and the 2013 State Auditor's management audit as well as future plans for the agency. The reporter indicated the article will be published as a Q&A, although no date has been set.

- Ramona Magid, Senior Program Manager for Prevention attended the quarterly Cancer Alliance of Texas meeting on October 19. She is the CPRIT representative on the executive committee of the alliance.

- Dr. Garcia attended a meeting October 23 of the Texas Health Improvement Network (THIN), which is charged with addressing the state's urgent health care challenges and improving the health care system in Texas.

- I discussed CPRIT's peer review and contracting process with a peer review representative of the Oak Ridge Associated Universities (ORAU). This 121-member university consortium partners with Oak Ridge National Laboratory to conduct scientific collaborations and peer review analysis. ORAU also manages the Oak Ridge Institute for Science and Education for the U.S. Department of Energy.

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As of October 23, 2017, seven entities have not filed 21 required reports by their due date; 20 (95%) are Academic Research grants and one (5%) is a Product Development Research grant. Approximately half of these delinquent reports are the result of the aftermath of Hurricane Harvey. CPRIT's grant accountants and grant compliance specialists continue to 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 report(s). In some instances,

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Grant Compliance Specialists are working with two grantees to remediate audit findings. CPRIT gives grantees 30 days from the receipt of the audit to submit supporting documentation to demonstrate remediation efforts. Currently, there are two grantees with a delinquent audit. Grantees are unable to receive reimbursements or advances if they are delinquent in filing the required audit and corrective action plan, unless the grantee requested additional time by the due date of the required audit and CPRIT's CEO approves the request.

Desk Reviews

Grant Compliance Specialists perform desk-based financial monitoring/reviews during the course of grant awards to verify that grantees expend funds in compliance with specific grant requirements and guidelines. Desk reviews may target an organization's internal controls, current and past fiscal audits, and timeliness of required grantee report submission. Grant Compliance Specialists are working with eight grantees to remediate desk review findings.

On-Site Reviews

Grant Compliance Specialists are working with four grantees to remediate on-site review findings. On-site reviews typically include an examination of 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.

Training & Support

CPRIT's compliance staff conducted a grantee training webinar on October 11, 2017, with approximately 90 grantee staff in attendance. The training 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 offered this year in support of 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 November 1 of each year. As of this most recent training webinar, all active grantees have met the training requirement for this year.

Academic Research Program Update

Fiscal Year 2018 Cycle 1 (18.1)

FY 2018 Academic Research Cycle 1 (18.1) applications are currently under review. Table 1 Provides information about the applications received for the five Requests for Applications (RFAs) that closed June 8, 2017. Of the 504 applications, 166 or 32.9 percent advanced to full scientific reviews convened over October 16-24, 2017. The Scientific Review Council (SRC) will review the 18.1 peer review panel recommendations on November 16, 2017, and finalize award recommendations to present to CPRIT. Dr. Willson will present The Scientific Review Council and Program Integration Committee recommendations at the February 21, 2017, Oversight Committee meeting.

Table 1: FY 2018.1 Total Number of Submissions by Mechanism & Percent Reviewed

Mechanism	Applications	Full Review	% Full Review
Individual Investigator Research Awards (IIRA)	332	106	31.9%
Individual Investigator Research Awards for Cancer in Children and Adolescents (IIRACCA)	37	15	40.5%
Individual Investigator Research Awards for Computational Biology (IIRACB)	43	11	25.6%
Individual Investigator Research Awards for Clinical Translation (IIRACT)	53	20	37.7%
Individual Investigator Research Awards for Prevention and Early Detection (IIRAP)	39	14	35.9%
Total	**504**	**166**	**32.9%**

FY 2018 Cycle 2 Request for Academic Research Applications

Following approval by the Oversight Committee on August 16, 2017, CPRIT released three RFAs on October 18, 2017, with a closing date of January 31, 2018. CPRIT will review applications in May 2018 and SRC recommended applications will be presented to the Program Integration Committee on July 31, 2018, and to the Oversight Committee on August 15, 2018. The three RFAs are:

- **Core Facility Support Awards (CFSA)**
  Support the development or improvement of core facilities to provide valuable services to support and enhance scientifically meritorious cancer research projects. CPRIT is interested in supporting core facilities that provide enabling services to cancer investigators from multiple Texas institutions. Applications responding to this RFA that address one of the program priorities for academic research adopted by the OC are encouraged.
  Award: Up to $3,000,000 (total costs) for the first 2 years and up to $1,000,000 (total costs) for each subsequent year; Maximum duration: 5 years

- **High-Impact/High Risk Research Awards (HIHR)**
  Provide short-term funding to explore the feasibility of high-risk projects that, if successful, could contribute major new insights into the etiology, diagnosis, treatment, or prevention of cancers. Applications responding to this RFA that address one of the program priorities for academic research adopted by the OC are encouraged.
  Award: Up to $200,000 (total costs); Maximum duration: 2 years.

- **Multi-Investigator Research Awards (MIRA)**
  Provide support for highly integrated programs of collaborative and cross-disciplinary research among multiple Texas investigators. Applications that address one of the program priorities for academic research adopted by the OC are encouraged.
  Award: Up to $6,000,000 (total costs); Maximum duration: 4 years.

Product Development Research Program Update

FY 2018 Cycle 1 Product Development Research Applications

CPRIT accepted 18 product development applications were submitted by the August 10, 2017, deadline. CPRIT convened the peer review screening meeting September 25 and 26. At the conclusion of the screening meetings, peer reviewers selected four companies to make an in-person presentation at the peer review panel meeting in Houston on October 25. Following the in-person presentations, the peer review panels decided that two of the four presenting firms should proceed to due diligence review. Following review of the due diligence reports in January. The Product Development Review Council recommendations will be presented to the Oversight Committee in February for approval.

Prevention Program Update

FY 2018 Cycle 1 Prevention RFAs
CPRIT released three OC approved RFAs for the first cycle of FY 2018 on June 8. CPRIT extended the original application date, September 14, to September 21 to provide applicants affected by Hurricane Harvey more time to submit. Peer review panels will meet December 11-14 in Dallas. The Oversight Committee will consider the Program Integration Committee's recommendations at the February 2018 meeting. The released FY 2018 Cycle 1 RFAs include:

- **Evidence-Based Cancer Prevention Services**
  Seeks to fund projects that deliver evidence-based cancer prevention and control clinical services. Priority given to projects that address OC program priorities and serve areas of the state not well addressed by current CPRIT funded projects.
  Award: Maximum of $1.5 million; Maximum duration of 36 months.

- **Tobacco Control and Lung Cancer Screening**
  Seeks to fund programs on tobacco prevention and cessation, as well as screening for early detection of lung cancer. Through this RFA CPRIT seeks 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 $1.5 million; Maximum duration of 36 months.

- **Dissemination of CPRIT-Funded Cancer Control Interventions (DI)**
  Seeks to fund projects that facilitate the dissemination and implementation of successful CPRIT-funded, evidence-based cancer prevention and control interventions across Texas. Proposals should be in a position to develop one or more "products" based on the results of the CPRIT-funded intervention. Project should also identify and assist others to prepare to implement the intervention and/or prepare for grant funding.
  Award: Maximum of $300,000; Maximum duration of 24 months.

The Prevention Program has revised the submission and review process for the Dissemination RFA to expedite review and approval of applications. It will now be open continuously and reviewed by the Prevention Review Council (PRC) quarterly. Recommendations, if any, will be forwarded to the Oversight Committee for consideration at quarterly meetings. The PRC reviewed the current cycle of dissemination applications. Dr. Garcia will present the PRC's recommendation at the Oversight Committee meeting on November 29.

FY 2018 Cycle 2 Prevention RFAs

CPRIT posted the RFAs for the second cycle of FY 2018 (18.2) on October 27. Applications are due in March, peer review in May, and consideration by the Oversight Committee in August 2018. The 18.2 RFAs include Evidence-Based Cancer Prevention Services, Tobacco Control and Lung Cancer Screening, and Dissemination of CPRIT-Funded Cancer Control Interventions (see descriptions for these RFAs above). In addition, CPRIT released the following new RFA:

- **Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations**
  Seeks to support the coordination and expansion of evidence based services to prevent cancer in underserved populations that do not have adequate access to cancer prevention interventions and health care thereby 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. Expansion must include delivery of services to nonmetropolitan and medically underserved counties in the state.
Award: Maximum of $3 million; Maximum duration of 36 months.

Communications Update

Cancer Awareness Month Activities

October was Liver Cancer Awareness Month. Communications created a video on the Texas Hepatocellular Carcinoma Consortium (THCCC) and worked with the four institutions in the consortium - Baylor College of Medicine, MD Anderson, UT Southwestern and UTHSC-San Antonio to get media placement. To date, coverage has occurred in El Paso and the Rio Grande Valley. All stories featured an interview with THCCC administrative investigator Dr. Hashem El-Serag of BCM. In addition, Oversight Committee member Mayor Margo was interviewed by an El Paso television station. The video of Dr. El-Serag discussing liver cancer and the THCCC was distributed through social media. Another video for social media featuring Dr. Jorge Morrero of UTSW discussing liver cancer is being produced.

Plans are being made to coordinate social media promotion and a possible op-ed with the University of Houston on The Great American Smoke-Out on November 16.

Innovations in Cancer Prevention and Research V Conference

As of October 30, registration for the biennial conference in Austin November 13-14, 2017 is 613. More than 420 abstracts will be presented at the conference during the two-day poster session. CPRIT will interview numerous speakers and grantees during the conference for future videos and media relation events in the upcoming year. Plans include using Facebook Live to stream potions of the general session presentations. In addition, roving cameras will interview attendees and capture conference activities.

Operations and Finance Update

CPRIT's independent financial audit started this month with an entrance meeting between CPRIT staff and the McConnell & Jones audit team on October 4. McConnell & Jones will complete the audit by the end of November. The Audit Subcommittee will hold a special meeting on December 4 to review the results of the audit report with the audit team.

Upcoming Subcommittee Meetings

Listed below are upcoming November Oversight Committee subcommittee meetings.

Subcommittee	Date & Time
Board Governance	November 2 at 10:00 a.m.
Audit	November 6 at 10:00 a.m.
Prevention	November 7 at 10:00 a.m.
Academic Research	November 8 at 10:00 a.m.
Product Development	November 9 at 10:00 a.m.
Nominations	November 10 at 10:30 a.m.

CPRIT will send an agenda, call-in information, and supporting material to the subcommittees one week prior to the meeting date.

*****

CPRIT has awarded **1,189** grants totaling **$1.881 billion**

- 189 prevention awards totaling $195.1 million
- 1000 academic research and product development research awards totaling $1.686 billion

Of the $1.686 billion in academic research and product development awards,

- 29.7% of the funding ($500.8 million) supports clinical research projects
- 26.2% of the funding ($441.2 million) supports translational research projects
- 25.9% of funding ($436.1 million) supports recruitment awards
- 14.7% of the funding ($248.0 million) supports discovery stage research projects
- 3.5% of funding ($59.9 million) supports training programs.

CPRIT has 7 open Requests for Applications (RFAs)

- 3 Research Recruitment
- 3 Academic Research
- 4 Prevention

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	VINCE BURGESS, CHIEF COMPLIANCE OFFICER
SUBJECT:	COMPLIANCE PROGRAM UPDATE
DATE:	NOVEMBER 3, 2017

The Chief Compliance Officer is responsible for apprising the Oversight Committee and the Chief Executive Officer of the 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's grant management system (CGMS) produces a summary of delinquent reports each week; this is the primary source used by CPRIT's compliance staff to follow up with grantees. CPRIT typically has 570+ grants that are either active or wrapping up grant activities and receives an average of 570 grantee reports each month.

As of November 1, 2017, 28 required reports from 15 entities had not been filed by the set due date; 25 (89%) are Academic Research grants and three (11%) were Product Development Research grants. Approximately half of these delinquent reports are the result of the aftermath of Hurricane Harvey. CPRIT's grant accountants and grant compliance specialists continue to 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 report(s). In some instances, grantee institutions may be ineligible to receive a future award if the grantee does not submit the required reports.

FSR Reviews

CPRIT's Grant Compliance Specialists performed 167 second-level reviews of grantee Financial Status Reports (FSRs) during the month of October. Twenty-three FSRs (14%) required

resubmission due to insufficient or inaccurate documentation submitted by the grantee. 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 Tracking

As part of ongoing monitoring efforts, grant compliance specialists track the submission of grantees' independent audit reports and the resolution of issues identified in these reports. 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 findings must be compiled in an independent audit report and submitted to CPRIT within 30 days of receipt, but no later than 270 days after the grantee's fiscal year.

Grant Compliance Specialists are working with two grantees to remediate audit findings. Grantees are given 30 days from the receipt of the audit to submit supporting documentation to demonstrate remediation efforts. Currently, there are two grantees with a delinquent audit. Grantees are unable to receive reimbursements or advances if they are delinquent in filing the required audit and corrective action plan, unless the grantee requested additional time by the due date of the required audit and CPRIT's CEO approved the request.

Desk Reviews

Grant Compliance Specialists perform desk-based financial monitoring/reviews during the course of grant awards to verify that grantees expend funds in compliance with specific grant requirements and guidelines. Desk reviews may target an organization's internal controls, current and past fiscal audits, and timeliness of required grantee report submission. Grant Compliance Specialists are working with eight grantees to remediate desk review findings.

On-Site Reviews

Grant Compliance Specialists are working with four grantees to remediate on-site review findings. On-site reviews typically include an examination of 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.

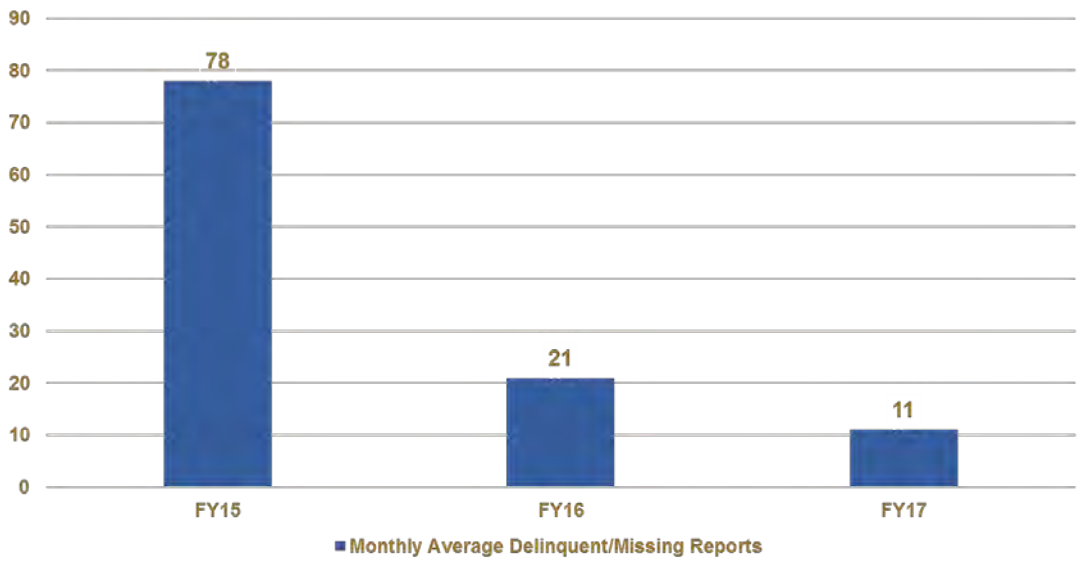
Training & Support

A grantee training webinar was conducted on October 11, 2017 with approximately 90 grantee staff in attendance. The training 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 offered this year in support of the annual compliance training requirement which states that the Authorized Signing Official (ASO) and at least one other employee from each grantee organization must attend an annual compliance training by November 1 of each year. As of this most recent training webinar, all active grantees have met the training requirement for this year.

FY17 Compliance Program Activities Summary

During FY17, the Compliance Program continued to refine and strengthen existing compliance functions that support the integrity and transparency of CPRIT's agency processes. Some of the highlights from FY17 are:

- **Grant Recipient Report Monitoring** – The number of delinquent reports in FY17 continued to decline from previous years, with an average of 11 reports per month. The average number of delinquent reports for the past three fiscal years are represented in the chart below.



- **Compliance Monitoring Reviews** (Desk and On-site) – The Compliance team performed over 276 compliance reviews (249 desk reviews, 27 on-site reviews) during FY17. This represents approximately 50% active grant coverage.

- **Training and Education** – In FY17, CPRIT staff conducted three grantee training webinars, four new grantee trainings, and three trainings for new Authorized Signing Officials (ASOs). Over 400 grantee staff attended these training opportunities provided to our active grantees.
- **Second-level Reviews of Financial Status Reports (FSR's)** – The Compliance team performed a second-level review of over 2,200 FSR's.
- **Single Audit Reviews** – The Compliance team reviewed over 42 audit reports and actively worked with 12 grantees to remediate audit findings.
- **Annual Compliance Attestation** – The Compliance team further refined the annual compliance attestation process, reviewed 59 attestations submitted by grantees, and collaboratively worked with four grantees to remediate deficiencies.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	JAMES WILLSON, MD., CHIEF SCIENTIFIC OFFICER
SUBJECT:	ACADEMIC RESEARCH PROGRAM UPDATE
DATE:	NOVEMBER 29, 2017

FY17 Academic Research Program Review

1. Academic Research Program Priorities in FY17

The fiscal year 2017 program priorities for academic research adopted by the Oversight Committee include funding projects that address:

- Recruitment of outstanding cancer research to Texas
- Investment in core facilities
- A broad range of innovative, investigator-initiated academic research projects
- Prevention and early detection
- Computational biology and analytic methods
- Childhood cancers
- Population disparities and cancers of importance in Texas (lung, liver, cervix cancers)

CPRIT utilized a variety of grant award mechanisms (Requests for Applications) to achieve the priorities established for the academic research program:

- *Recruitment Awards* support recruitment of cancer researchers at all levels to academic institutions in Texas.
- *Research Training Awards* provide support for training programs at Texas academic institutions.
- *Core Facilities Support Awards* facilitate the development or improvement of core facilities that will provide valuable services to support and enhance scientifically meritorious cancer research projects.
- *Individual Investigator Research Awards (IIRA)* seek new fundamental knowledge about cancer and cancer development as well as the development of state-of-the-art technologies, and tools. Targeted IIRAs solicit proposals for novel research in childhood and adolescent cancers, computational biology, and prevention and early detection.
- *High-Impact/High Risk Research Awards* provide short-term funding 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.
- *Multi-Investigator Research Awards* stimulate collaboration and bring together researchers and clinicians to work on a common problem in cancer.

- *Early Translational Research Awards* support investigator initiated projects that "bridge the gap" between promising new discoveries achieved in the research laboratory and commercial development for a therapeutic, device, or diagnostic assay.

2. Academic Research Program Review and Awards in FY17

CPRIT academic research award applications undergo rigorous scientific reviews conducted by seven independent peer review panels. The peer review panels are composed of prominent cancer researchers, and are selected from outside of Texas for their distinguished expertise. They are charged to assess research proposals based on scientific merit and potential impact on cancer. Each of the seven panels is chaired by an eminent cancer researcher; together, these chairs make up the Scientific Review Council, chaired by Richard Kolodner, Ph.D., a member of the National Academy of Sciences and Distinguished Professor in the departments of Medicine and Cellular and Molecular Medicine at the University of California, San Diego School of Medicine and head of Ludwig Institute for Cancer Research in San Diego.

In 2017 CPRIT supported the recruitment of 35 cancer researchers to Texas academic institutions with awards totaling $99,100,000, as displayed in Table 1.

Table 1: FY17 CPRIT Recruitment Awards

Funding Mechanism	Applications Submitted	Applications Awarded	Funding	Success Rate
Established Investigators Award	17	7	$41,100,000	41%
Rising Stars	11	1	$4,000,000	9%
First –Time Tenure Track Faculty Members	55	27	$54,000,000	49%
Total	**83**	**35**	**$99,100,000**	**33%**

CPRIT awarded 83 grants totaling $111,290,000. These awards fund a broad range of innovative, investigator-initiated projects through 41 Individual Investigator Research Awards, 19 High-Impact, High-Risk grants, and 7 Early Translational Research Awards as displayed in Table 2. Seven new and 4 renewed Core Facilities Support Awards and renewal of 5 Research Training Awards enhance Texas' cancer research capacity and life sciences infrastructure.

Table 2: FY117 Academic Research Awards

Funding Mechanism	Applications Received	Applications Awarded	Total Funding	Success Rate
Core Facilities Support Awards	30	11	$46,560,000	37%
Early Translational Research Awards	54	7	$6,720,000	13%
High Impact/High Risk	143	19	$3,800,000	13%
Individual Investigator Research Awards (IIRA)	292	26	$22,280,000	9%
IIRA Cancer in Children and Adolescents	45	7	$8,040,000	16%
IIRA Computational Biology	44	3	$2,630,000	7%
IIRA Prevention and Early Detection	35	5	$5,820,000	14%
Research Training Awards	9	5	$15,440,000	56%
Total	**652**	**83**	**$111,290,000**	**21%**

Table 3 illustrates the targeted priorities as addressed by the Academic Research Program grants awarded in FY17.

Table 3: FY17 Data by Academic Research Program Priorities*

CPRIT Priorities Addressed	# Grants	Award Amount
Recruitment of outstanding cancer researchers to Texas	35	$99,100,000
Investment in core facilities	11	$46,560,000
A broad range of innovative, investigator-initiated academic research projects	41	$38,770,000
Prevention and early detection	14	$21,260,046
Computational biology and analytic methods	14	$39,983,177
Childhood cancers	22	$46,478,271
Population disparities and cancers of importance in Texas (lung, liver, cervix cancers)	21	$40,896,125

Some grants address more than one priority

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: CPRIT OVERSIGHT COMMITTEE

FROM: JIM WILLSON, MD, CHIEF SCIENTIFIC OFFICER

SUBJECT: ACADEMIC RESEARCH AWARD FUNDING MODIFICATION RECOMMENDATION

DATE: NOVEMBER 1, 2017

Summary and Recommendation

The Academic Research Program requests funding for Award RP170691 be increased by $943,570 to $4,766,430 to accurately reflect the reduction in budget that was recommended by the Scientific Review Council on July 13, 2017. RP170691was approved by the Oversight Committee on August 16, 2017.

Discussion

The Scientific Review Council (SRC) and Program Integration Committee recommended seven Core Facilities Support Awards totaling $30,502,278 with subsequent approval by the Oversight Committee on August 16, 2017. For one of these awards (RP170691) the SRC recommended the following budget reductions: recommended that all costs associated with the "Egg PDX and Advanced in vivo Models Unit" be eliminated from the budget. The award amount approved by the Oversight Committee on August 16, 2017 reflected the budget reduction.

When calculating the revised award amount, CPRIT did not adjust the budget to include costs for the entire award period. The Academic Research Program is requesting the funding for Award RP170691 be increased by $943,570 to $4,766,430 to correct this omission. The revised amount reflects the SRC recommendations and does not exceed the amount requested in the original application.

Core Facilities Support Award Recommendation

ID	Score	Title	PI	Organization	Current Award	Recommended Award	Priorities
RP170691	2.2	Patient-Derived Xenograft and Advanced in Vivo	Lewis, Michael	Baylor College of Medicine	$3,822,860	$4,766,430	Childhood Cancers

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CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: REBECCA GARCIA, PHD, CHIEF PREVENTION AND COMMUNICATIONS OFFICER

SUBJECT: PREVENTION PROGRAM UPDATE

DATE: NOVEMBER 29, 2017

FY 2018 Dissemination of CPRIT-Funded Cancer Control Interventions (DI) Applications

This RFA is continuously open; the Oversight Committee considers recommendations from this mechanism (if any) at quarterly meetings. The 18.2 cycle closes on December 5, 2017.

Four applications were received by October 3; the Prevention Review Council (PRC) reviewed these DI applications on October 24 and the Program Integration Committee (PIC) met on October 31. Dr. Garcia will present the PIC's recommendation at the Oversight Committee meeting on November 29.

FY 2018 Cycle 1 Prevention Applications

CPRIT released three RFAs for the first cycle of FY 2018 in June. Thirty-four applications requesting $46,348,666 were received by the deadline. Peer review panels will meet December 11-14 in Dallas to conduct their review. The PRC meets January 12 and the Oversight Committee will consider the PIC's recommendations at the February 2018 meeting.

Mechanism	Number Received	Total $ Requested
Evidence-based Cancer Prevention Services	28	$38,438,664
Tobacco Control and Lung Cancer Screening	6	$7,910,002
TOTAL	**34**	**$46,348,666**

FY 2018 Cycle 2 Prevention RFAs

CPRIT posted the RFAs for the second cycle of FY 2018 (18.2) on October 27. Applications are due in February, peer review in May, and consideration by the Oversight Committee in August 2018. The 18.2 RFAs include:

- **Evidence-Based Cancer Prevention Services**
  Seeks to fund projects that deliver evidence-based cancer prevention and control clinical services. Priority given to projects that address OC program priorities and serve areas of the state not well addressed by current CPRIT funded projects.
  Award: Maximum of $1.5 million; Maximum duration of 36 months.

- **Tobacco Control and Lung Cancer Screening**
  Seeks to fund programs on tobacco prevention and cessation, as well as screening for early detection of lung cancer. Through this RFA CPRIT seeks 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 $1.5 million; Maximum duration of 36 months.

- **Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations -- *NEW***
  Seeks to support the coordination and expansion of evidence based services to prevent cancer in underserved populations that do not have adequate access to cancer prevention interventions and health care thereby 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. Expansion must include delivery of services to nonmetropolitan and medically underserved counties in the state.
  Award: Maximum of $3 million; Maximum duration of 36 months.

- **Dissemination of CPRIT-Funded Cancer Control Interventions (DI)**
  Seeks to fund projects that facilitate the dissemination and implementation of successful CPRIT-funded, evidence-based cancer prevention and control interventions across Texas. Proposals should be in a position to develop one or more "products" based on the results of the CPRIT-funded intervention. Project should also identify and assist others to prepare to implement the intervention and/or prepare for grant funding.
  Award: Maximum of $300,000; Maximum duration of 24 months.

Other Activities

- Ramona Magid, Senior Program Manager for Prevention attended the quarterly Cancer Alliance of Texas meeting on October 19. She is the CPRIT representative on the executive committee of the alliance.

- Dr. Garcia attended a meeting October 23 of the Texas Health Improvement Network (THIN), which is charged with addressing the state's urgent health care challenges and improving the health care system in Texas.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	REBECCA GARCIA PHD, CHIEF PREVENTION AND COMMUNICATIONS OFFICER
SUBJECT:	COMMUNICATIONS UPDATE
DATE:	NOVEMBER 17, 2017

The following is an overview of the agency's communication activities through November 15, 2017.

Earned Media

The communications team conducted media outreach to secure positive coverage for CPRIT, including a print article in the Houston Chronicle on August 17 on the recruitment of a new CPRIT scholar, an agency overview article in the Austin American-Statesman on September 23, a Q&A with Wayne Roberts in the Texas Tribune on November 2 and a feature story on KXAN (NBC Austin) about CPRIT's Innovation Conference which was syndicated through NBC and Telemundo channels across the state.

Per our communications plan, our team leveraged an opportunity during October's Liver Cancer Awareness Month to tell the story of the Texas Hepatocellular Carcinoma Consortium (THCCC). The communications team developed a video about THCCC featuring Baylor College of Medicine's Dr. Hashem El-Serag. The team also created a video which featured UT Southwestern lead investigator Dr. Jorge Marrero. Following distribution to broadcast outlets, this effort prompted coverage in the Rio Grande Valley and El Paso.

During the Innovations V conference, the communications team also conducted media relations efforts resulting in 12 stories in Austin and across the state, including one in Spanish language format from Univision Austin. The stories were carried in the markets of Abilene, Amarillo, Brownsville, El Paso, Lubbock, Midland-Odessa, San Angelo, Texarkana, Waco and Wichita Falls.

Grant Awards Announcement: Following the Oversight Committee's approval of grant awards at its August 16 meeting, CPRIT distributed a press release to local, regional and national outlets announcing 60 grants through its Scholars program.

Coverage: (July 22, 2017 – November 15, 2017)

- 26 articles featured CPRIT
- 52 additional articles mentioned CPRIT (stories primarily focused on work of

grantees)

Coverage Highlights: (see clipped articles following report)

- August 17, 2017, *Houston Chronicle*, Newest State Cancer Grants Lure Back Former Houston Research Star
- August 18, 2017, *D Healthcare,* UT Southwestern Names New Cancer Center Director
- August 23, 2017, *El Paso Herald-Post,* TTUHSC El Paso Awarded $3.7 Million Colorectal Cancer Prevention Grant
- September 15, 2017, *San Antonio Business Journal,* Biotech CEO, San Antonio Talent and Affordability Lured Company Headquarters
- September 20, 2017, *Dallas Morning News*, $22 Million in Grants Brings New Talent to a North Texas Cancer Center
- September 23, 2017, *Austin American-Statesman*, 10 Years in, State's Cancer Fund Faces an Uncertain Future
- November 2, 2017, *The Texas Tribune*, Texas Cancer Institute CEO: Research and Prevention Need State Support
- November 14, 2017, *KXAN NBC Austin*, CPRIT enters 10th Year of Working with Cancer Research

Innovations in Cancer Prevention and Research V Conference

A final report will be produced when attendee evaluations are tallied, and revenue and expense are finalized. Registration for the biennial conference in Austin was 836. This number includes CPRIT staff and Oversight Committee members. More than 420 abstracts were presented at the conference during the two-day poster session.

In addition, CPRIT conducted on-camera interviews with 10 speakers and grantees over the course of the conference for future videos and media relations efforts in 2018. The communications team developed real-time video content from the conference for all of CPRIT's social media channels including Facebook, Twitter and YouTube. Over 4,700 impressions during the conference period were made on Twitter.

Communications Activities

- The Great American Smoke-Out was promoted via social media on November 16. To read more, visit: https://www.cancer.org/healthy/stay-away-from-tobacco/great-american-smokeout.html.
- Shrikanth Gadad, PhD was interviewed during Innovations V conference in preparation for media relations ahead of a January press conference announcing his CPRIT recruitment grant to Texas Tech Health Sciences Center at El Paso.
- Media outreach is planned to generate earn media for National Cervical Health Awareness Month (January) and National Cancer Prevention Month (February). We will be working with CPRIT's institutional partners in select media markets, and using interviews of grantees conducted during Innovations V conference. Short videos for

social media will also be created and distributed on CPRIT social media outlets, including a feature on the Moncrief Cancer Institute in February.

Social media:

Facebook (last 28 days):

- Reach: 1,862
- Engagement: 297
- Most popular post: Ten Year Anniversary of CPRIT: On this day ten years ago, the Cancer Prevention and Research Institute of Texas became a reality. The vote on November 6, 2007, marked when Texas, like it has done so many times, stepped forward to lead on an important issue impacting many people.

Twitter

- 9,400 impressions over entire month
- Top tweet: 10 years ago today Texans voted to make CPRIT a reality. Texans Conquer Cancer! https://cprit.us/2hMjyI2
- 4,700 impressions over conference period
- Top conference tweet: Watch @bcmhouston Dr. Heslop discuss the CPRIT Innovations V conference: https://cprit.us/2zE9HgY #CPRIT2017

HOUSTON CHRONICLE

August 17, 2017 By **Todd Ackerman**

Newest state cancer grants lure back former Houston research star

The Cancer Prevention & Research Institute of Texas Wednesday awarded more than $100 million in grant money, including a $6 million package to lure back Christopher Amos, a former Houston researcher who discovered a gene that makes some people more likely to get hooked on cigarettes and more prone to develop lung cancer.

A pre-eminent scientist who discovered a gene that makes people more likely to get hooked on cigarettes and develop lung cancer is returning to Houston with the help of a major grant from the scholar recruitment program of Texas' cancer agency.

Christopher Amos, formerly at MD Anderson Cancer Center and currently at Dartmouth College, will join Baylor College of Medicine this fall as head of its Institute for Clinical and Translational Research. He v.ri.ll also develop a program that seeks to identify people at risk of developing cancer based on their genetic make-up and other factors.

"It'll be like being a kid in a candy store," Amos said about the coming return. "I still have a lot of friends in Houston, from MD Anderson to the UT School of Public Health."

Dr. Melissa Bondy, associate director of Baylor's Dan L. Duncan Comprehensive Cancer Center, called Amos a "big-time recruit" for Baylor. Currently the interim director of Dartmouth's orris Cotton Cancer Center, Amos worked at MD Anderson for 19 years before leaving five years ago to become head of Dartmouth's Center for Genomic Medicine.

Amos' recruitment package was one of the biggest grants awarded this week by the Cancer Prevention and Research Institute of Texas, the state agency tasked with awarding $3 billion for cancer research. The agency awarded 60 grants totaling $102 million.

Amos was awarded one of two $6 million "established investigator" grants. The other would bring Dr. Carlos Arteaga, an expert on targeted therapy and breast cancer, from Vanderbilt to UT Southwestern. In addition, 12 first-time tenure-track researchers each were awarded $2 million packages to come to Texas.

In all, the 14 recruits would get $36 million, the latest outlay under CPRIT's scholar recruitment program, which has allowed Texas to raid other top institutions for powerhouse scientists, "rising stars" and promising first-time faculty.

Among those first-time faculty members receiving the latest grants are scientists from laboratories at Harvard University, Stanford University, Johns Hopkins University, the California Institute of Technology, the Salk Institute for Biological Sciences, Dana Farber Cancer Center and Memorial Sloan Kettering Cancer Center.

Eight years after the agency was launched, CPRIT has so far paid out $436 million for 135 cancer researchers under the program, eight of them members of the National Academy of Sciences, the nation's most distinguished organization of scientists.

The war chest has helped Texas build a reputation as a hotbed of cancer research rather than just the home of MD Anderson, considered the world's No. 1 cancer center. The University of Texas Southwestern Medical Center in Dallas, in particular, has used CPRIT grants to elevate its cancer center's reputation.

The recruits have brought into Texas roughly $227 million in peer-reviewed grant money from national funding sources.

The program's most famous recruit is James Allison, the Lasker Award-winning scientist who discovered a natural brake on the immune system, then developed a drug to release the body's defenses to attack the patient's tumor, the new paradigm of cancer treatment. In 2012, he was recruited to MD Anderson from Memorial Sloan Kettering with a $10 million recruitment grant.

But the program has lured other big names too: Sean Morrison to UT Southwestern; Dr. Matthew Ellis to Baylor; Frank McKean to the University of Houston; Dr. Gail Eckhardt to UT Austin; and KC. Nicolaou to Rice University.

Amos is another well-known figure, mostly due to his 2008 discovery at MD Anderson identifying the inherited gene variations that raise smokers' chance of getting lung cancer by as much as 80 percent compared to tobacco users without the genes. The research also found those with the variants are more likely to become addicted to nicotine.

"It's a kind of a double-whammy gene," Bondy said at the time. Amos is expected to start at Baylor sometime this fall.

The discovery marked the first time researchers had found a common genetic variant that influences the risk of getting cancer.

The largest grant awarded by CPRIT this week was a $9 million package to ViraCyte LLC, a Texas Medical Center company spun out of Baylor immunotherapy research. The award will fund the company's efforts to improve outcomes of stem cell transplants using immune cells manipulated to target viruses that can cause cancer.

All told, CPRIT has now awarded 1,189 grants totaling more than $1.89 billion, nearly two-thirds of the $3 billion assault on cancer Texas voters overwhelmingly approved in 2007 and the agency began giving out in 2009. The agency has until 2023 to award the rest of the money.

You can read a full round-up of the grants here.

http://www.houstonchronicle.com/local/prognosis/article/Newest-state-cancer-grants-lure-former-Houston-11824855.php

D CEO HEALTHCARE
The Business of Healthcare in North Texas

08/18/2017 | by Olivia Nguyen

UT Southwestern Names New Cancer Center Director

Dr. Carlos L. Arteaga (Courtesy of: UT Southwestern)

UT Southwestern has named Dr. Carlos Arteaga as its new director for the Harold C. Simmons Comprehensive Cancer Center. Arteaga replaces Dr. James Wilson, who left in 2016 to become chief scientific officer at the Cancer Prevention and Research Institute of Texas. Arteaga begins September 1.

In his new role, Arteaga will oversee the center's 275-person staff of doctors, nurses, scientists, and other medical professionals within 30 departments ranging from basic science to clinical care. Additionally, he will manage more than 12 major cancer programs at the center, which provide "innovative treatments for complex care."

Arteaga previously served as director for the Center for Cancer Targeted Therapies and breast cancer research programs and associate director for translational and clinical research at Vanderbilt University. He was also a professor of oncology and cancer biology at the university, where he's been since 1989.

Dr. Gregory Fitz, executive VP for academic affairs and provost and dean of UT Southwestern, said in a statement: "Arteaga brings a wealth of experience to this leadership role that will help further integrate UT Southwestern's advances in multidisciplinary cancer care and clinical/translational investigation across departmental boundaries. Such integration is fundamental to our commitment to our patients to advance the treatment and prevention of cancer through innovative therapies, leading-edge clinical trials, and the latest technology."

Arteaga earned his M.D. from the University of Guayaquil in Guayaquil, Ecuador. He trained in internal medicine and medical oncology at Emory University in Atlanta and the University of Texas Health Sciences Center in San Antonio.

http://healthcare.dmagazine.com/2017/08/18/ut-southwestern-names-new-cancer-center-director/

EL PASO HERALD-POST

TTUHSC EL PASO AWARDED $3.7 MILLION COLORECTAL CANCER PREVENTION GRANT

Navkiran Shokar, M.D., M.P.H., M.A., has received $3.7 million from the Cancer Prevention and Research Institute of Texas (CPRIT) to reduce the impact of colorectal cancer in West Texas.

Doctors recommend adults ages 50 and older get tested for colon cancer, but many West Texans are not following these guidelines. Only 54 percent of qualifying El Pasoans get tested for the cancer, compared to 69 percent of the rest of the U.S. Rural West Texas counties fare far worse, with screening rates falling as low as 28 percent.

"In West Texas, colorectal cancer cases and mortality rates are significant," Dr. Shokar explained. "The lack of knowledge about the importance of colorectal cancer screening, coupled with a lack of access to screening services, has created a barrier to health care in our region."

RELATED ARTICLES

WFAA/KHOU LIVE STREAM: FLOODING IN HOUSTON + Texas Tribune Coverage

August 28, 2017

City Activates Emergency Operations Center, 'Potential' for 1500 Houston Evacuees

August 27, 2017

Dr. Shokar will use the grant to expand the reach of the Southwest Coalition for Colorectal Cancer Screening (SuCCCeS), a collaboration among public, private, non-profit, and for-profit health service providers led by Texas Tech University Health Sciences Center El Paso (TTUHSC El Paso). SuCCCeS' goal is to increase the number of El Pasoans who are getting screened for colon cancer.

UTEP Invites Community to Minerpalooza 2017

August 27, 2017

The new CPRIT funds will help SuCCCeS expand its service area to an additional 25 West Texas counties, encompassing an area with a combined population of nearly 2.9 million residents.

These counties, which stretch from Big Bend Country to the Panhandle Plains, have high rates of poverty, low educational attainment, low rates of health care coverage, are predominantly Hispanic, and are critically medically underserved. In fact, several of the target counties do not have a single physician.

Dr. Shokar and the coalition will begin the effort by integrating services into health care organizations in El Paso, as well as within clinics in the over 40,000-square-mile region. The team will offer free colorectal cancer screening services to eligible men and women; in-person and video colon cancer prevention education that is bilingual; and navigation to timely treatment for participants who have been diagnosed with cancer.

SuCCCeS will also train health care providers to promote colon cancer screening, to reduce patient barriers to screening, and to enhance potential resources for their patients, such as insurance coverage options for colonoscopies.

Dr. Shokar's ultimate goal is not only to have more adults screened, but also to educate West Texans of all ethnic backgrounds about the importance of regular screening for early diagnosis — when colon cancer is most curable.

Over the course of the three-year grant, SuCCCeS is expected to provide 11,100 screening and diagnostic tests, 16,000 educational services, and 600 professional education services.

Dr. Shokar already has a strong history of leading successful cancer prevention programs. This is her sixth award from CPRIT as a principal investigator. Thus far, her grants have brought $15 million to the El Paso community for cancer prevention and early detection services and research.

SuCCCeS coalition members include nine hospitals, 26 clinics, and 150 community partners.

https://elpasoheraldpost.com/ttuhsc-el-paso-awarded-3-7-million-colorectal-cancer-prevention-grant/

Biotech CEO: San Antonio talent and affordability lured company headquarters

SAN ANTONIO BUSINESS JOURNAL

San Antonio can close the deal to land Pelican Therapeutics' new headquarters and lab in a matter of days, provided the City Council approves a municipal incentive package to support the move.

If that vote goes as expected, Pelican's presence could lead to more biotech wins and more critical mass for San Antonio's still somewhat undiscovered bioscience industry.

Pelican Therapeutics CEO Dr. Rahul Jasuja said the biotech company was sold on San... more

FILE PHOTO

Pelican Therapeutics – a subsidiary of Durham, North Carolina-based Heat Biologics, a publicly traded company – has already secured approval for $15 million in grant funding from the Cancer Prevention & Research Institute of Texas. Now, its leadership is waiting on the City Council's approval of a local grant of up to $200,000 to help the company establish its presence here.

In return for the city incentives, Pelican has committed to create nearly two dozen high-paying jobs over the next five years and to invest nearly $2 million in improvements to develop its San Antonio operations at 8122 Datapoint Drive, which is near the South Texas Medical Center.

Michele Boggs, senior vice president of business development for the San Antonio Economic Development Foundation, said BioMed SA President Ann Stevens began working with Pelican's leadership as far back as 2012. That recruiting effort ultimately led to EDF officials engaging in talks with the company about the move.

"We had several meetings with them," Boggs said. "This is a world-class company."

Dr. Rahul Jasuja, CEO of Pelican Therapeutics, said the company was considering multiple Texas cities and that a couple of key factors set San Antonio apart. One was the availability of research talent working in cancer research, including Cancer Insight founder Dr. George Peoples and his team.

"That was a major driving factor," Jasuja said in an exclusive interview. "There was an opportunity to work hand in hand with his group, for close collaboration with our scientists and his team."

San Antonio has also proven to be a more economical option.

"San Antonio may lack some visibility compared to Houston and Austin in terms of biotech business. But we found that, for fledgling and emerging companies, there was great value when looking for lab space in San Antonio – in close proximity to the medical center," Jasuja said. "Some of the other cities were far more costly."

DALLASNEWS
by The Dallas Morning News

$22 million in grants brings new talent to a North Texas cancer center

Sabriya Rice, Business of Health Care Reporter

The UT Southwestern Simmons Cancer Center has received $22 million in grant money to recruit tenured faculty and new investigators focused on various types of cancers.

The money is part of more than $34 million awarded to the center in August by the Cancer Prevention and Research Institute of Texas, which has financially supported oncology research and prevention programs at institutions across the state for about a decade.

The Harold C. Simmons Cancer Center is one of two institutions in Texas — and 49 in the country — to be designated a comprehensive cancer center by the National Cancer Institute, meaning the institution must offer a range of lab, clinical and population-based research.

Funding from Texas' CPRIT program was integral in helping to recruit him from the Vanderbilt- Ingram Cancer Center in Tennessee, according to UT Southwestern.

Faculty and researchers newly recruited to UT Southwestern as part of the August CPRIT awards are expected to begin by 2018. They come to North Texas from notable institutions like the Dana-Farber Cancer Institute, Memorial Sloan Kettering Cancer Center and Johns Hopkins School of Medicine.

They will use the grant money to support salaries for postdoctoral fellows, graduate medical students and laboratory staff, as well as for supplies, and equipment.

Funding will also be used to support research on tumor suppression, melanoma, triple-negative breast cancer and other initiatives.

The projects being funded locally "hold great potential" for improving cancer treatment, Dr. Daniel Podolsky, UT Southwestern's president, said in a news release.

The recent grant awards bring the total that the North Texas center has received since 2009 to more than $270 million. The full list of awards is available on the CPRIT website.

The Simmons cancer center employs 275 people, including doctors, nurses and researchers. Its new director as of Sept. 1, Dr. Carlos Arteaga, is an internationally recognized breast cancer expert who aims to expand the clinical trials available to local cancer patients.

my Statesman
from Austin American-Statesman

10 years in, state's cancer fund faces an uncertain future

BUSINESS By Bob Sechler - American-Statesman Staff

Lance Armstrong and the "Survivor One" bus stopped by Highland Park Baptist Church in Austin in 2007 during his campaign for Proposition 15, which created the Cancer Prevention and Research Institute of Texas.

Posted: 12:00 a.m. Saturday, September 23, 2017

Highlights

- Cancer Prevention and Research Institute of Texas has 5 years left in its current mission.
- Questions arise about whether CPRIT will seek more taxpayer money to continue its work beyond that time.

As it nears the 10th anniversary of its creation by Texas voters, a variety of metrics can be used to gauge the impact of the state agency charged with fighting cancer.

For instance, the Cancer Prevention and Research Institute of Texas — commonly known as CPRIT — has recruited 135 researchers to the state, helped put in motion 108 clinical drug trials and can boast of funding 29 newly minted oncology companies.

But two numbers are starting to loom particularly large for CPRIT: $1 billion and five years.

That's the amount of taxpayer money CPRIT has left from its original $3 billion authorization to dole out in grants for cancer research, prevention and product development in the state — and how much longer it has to do it. CPRIT hit the two-thirds mark in its spending last month.

The fate of CPRIT, widely considered the nation's second-largest source of funding for cancer research behind the federal government, is unclear once either its money or time runs out. Some state lawmakers already are laying groundwork to oppose what they view as the likelihood of an eventual push by CPRIT backers for additional taxpayer support so it can continue its mission.

CPRIT Chief Executive Wayne Roberts said the agency is "totally focused on how to spend the last $1 billion" and isn't engaged in any such planning.

"If the Legislature wants CPRIT to be continued (beyond then), they will find a way to fund it at a level they deem to be appropriate," Roberts said.

CPRIT was authorized by voters in 2007 to issue $3 billion in taxpayer-backed bonds — in increments of up to $300 million per year — to pay "for research in Texas to find the causes of and cures for cancer." The vote came after an emotional campaign that featured famed cyclist and cancer survivor Lance Armstrong traveling across the state in a bus dubbed "Survivor One" to advocate for it.

Cures for various forms of cancer remain elusive a decade after that vote. But progress in devising treatments has been made, and professionals in the health sciences sector say CPRIT rightfully deserves credit for helping fuel the gains and for seeding a growing biomedical industry in Texas.

“To the companies that get CPRIT funding, it is incredibly important,” said Tom Luby, who heads the Texas branch of Johnson & Johnson’s incubator program for startups, known as JLABS, located in the Texas Medical Center in Houston. “There is a high degree of failure (for small oncology companies with unproven treatments), so raising money from traditional sources can be very challenging.”

To date, an estimated 72 percent of CPRIT’s grants have gone to fund research, 18 percent have gone to early stage companies to help get promising drug research off the ground, and 10 percent have gone for cancer prevention programs around the state. According to CPRIT, the funding has triggered $1.37 billion in follow-on investing by venture capital firms, resulted in slightly more than 79,000 direct and indirect Texas jobs and has generated dozens of clinical trials that have enrolled a total of 9,782 patients and helped Texans more easily access state-of-the-art treatments.

Luby, who worked in Boston with Johnson & Johnson prior to coming to Texas, also credits CPRIT with making the state internationally known in health sciences circles, saying CPRIT “put Texas on the map as a place to think about doing oncology drug development.”

Still, CPRIT’s reputation hasn’t always been sterling.

Bouncing back from scandal

A high-profile scandal involving the alleged mishandling of $56 million in grants engulfed the agency in 2012. CPRIT's top three executives at the time resigned, and one was indicted — although he eventually was acquitted after contending he'd been made a scapegoat amid the ensuing political storm.

State lawmakers nearly shuttered CPRIT in the wake of the scandal, prohibiting it from issuing grants through much of 2013. The moratorium was lifted after CPRIT's management structure was overhauled to include more rigorous oversight.

Roberts, who was brought on board to help stabilize CPRIT shortly after the scandal broke and has steered it since then, said the agency has moved past it and has become known for "rigorous peer review" and an "insistence upon maintaining the integrity of our processes."

State lawmakers appear to agree. They voted during the regular legislative session this year for a bill that, among other things, prolonged CPRIT's mandate an extra two years by pushing its so-called "sunset" date — a term for the top-to-bottom review that state agencies periodically undergo to determine if they should continue to exist — out to 2023, from 2021. CPRIT can't issue grants in the final year before its sunset date.

The move to prolong the life of CPRIT under its existing funding authorization won broad support as something of a feel-good vote that enabled lawmakers to demonstrate support for the fight against cancer. But another proposal, sponsored by state Sen. Charles Schwertner, R-Georgetown, came close to winning approval as well, and it signaled that some might not be inclined to give the agency another extension if it's accompanied by a request for more taxpayer money.

Schwertner's bill, which won approval in the Senate but failed to make it onto the House floor, would have required CPRIT to develop a plan to become self-sufficient once its existing taxpayer money runs out.

"I don't think anyone can argue against or oppose the goal of curing cancer," Schwertner said. But "whether (paying for research into it) is an essential function of state government, I think is a legitimate question to raise at this time."

Schwertner, who chairs the Senate's Health and Human Services Committee, said he expects CPRIT supporters will eventually push for more state money to extend the agency beyond its new sunset date, although there haven't been any formal proposals to do so yet. He said he opposes such a move.

"It doesn't rise to a constitutional responsibility (of the state's), and it certainly doesn't rise to the highest priority, in my opinion," he said, given numerous other demands on the state budget.

'Exactly what they bargained for'

Schwertner's prediction that an effort eventually will be made to provide CPRIT with additional taxpayer money appears well-founded.

State Sen. Jane Nelson, who chairs the powerful Senate Finance Committee, voted in favor of his bill this year but has been a longtime advocate for state funding to fight cancer, and she recently told the American-Statesman that she "would certainly support allocating resources to help prevent and eradicate" it given "the human and financial toll this disease takes." She added that the potential amount is uncertain and will be dependent on many factors.

“We hoped — but never assumed — that royalties and other income would be available to help sustain the institute,” said Nelson, R-Flower Mound, who played a major role in creating CPRIT.

Under Schwertner’s bill, CPRIT would have been required to devise a plan by Dec. 1 next year “to become financially self-sufficient and to continue operations without state funds other than patent royalties and license revenues” from the research and companies it previously has funded once its existing money runs out.

Roberts, however, said CPRIT wasn’t set up to do that.

“If the Legislature had instructed us to design a self-sufficiency portfolio back in 2007, the ratio (among CPRIT’s categories of grants) would be completely flipped,” he said. “In fact, there probably would be no grants for prevention and basic research,” and all the money would go for product development in later-stage companies with a higher likelihood of paying off financially.

The agency’s grants for research and product development contain royalty components for the state, but it has received a total of only about $3.2 million in such payments so far. The figure should grow significantly in coming years, Roberts said, but the amount is uncertain and could be far in the future.

He said his goal in the time remaining before CPRIT’s new sunset date arrives “is to make sure that we are worthy of a discussion (that the agency) be continued” long term.

“I think we are doing exactly what the citizens of Texas intended” when they voted to fund CPRIT a decade ago, Roberts said. “At the end of the day, when we do ride off into the sunset, the Legislature and the citizens of Texas will say they got exactly what they bargained for.”

If CPRIT eventually is abolished, however, executives in the health sciences sector say the void will be felt.

"From our point of view, (CPRIT) has been tremendously important," said Ken Moseley, senior vice president at Bellicum Pharmaceuticals in Houston, which received $5.7 million from CPRIT in 2011 and about $17 million last year. Bellicum, which has gone from a handful of employees in 2011 to more than 120, is developing cellular immunotherapies for hematological cancers and solid tumors, as well other diseases.

Without CPRIT, Moseley said, "I honestly don't know where the money would have come from (in 2011) to develop our drug and start the clinical trials in so many sites."

THE TEXAS TRIBUNE

Texas cancer institute CEO: Research and prevention need state support

> Wayne Roberts, CEO of the Cancer Prevention and Research Institute of Texas, said the institute has played a critical role in researching and preventing cancer and needs state funding to continue.

BY MATTHEW CHOI NOV. 2, 2017 12 AM

Ten years ago this month, Texas voters overwhelmingly supported creating the Cancer Prevention and Research Institute of Texas. The idea was to make Texas a leader in fighting cancer by giving $3 billion in grants across the state for research and prevention. But in 2012, allegations arose that millions of taxpayer dollars were distributed in grants without the proper peer review, miring the institute, known as CPRIT, in scandal.

Current CEO Wayne Roberts joined the institute in 2013 to help it recover from the scandal, following lengthy recommendations from the state auditor to restructure the organization's oversight.

Designed to last 15 years on $3 billion of state bond funding, CPRIT has just under $1 billion and five years left for future grants. Some in the Legislature now question the state's role in financing the institute in the future. Sen. Charles Schwertner, R-Georgetown, introduced an unsuccessful bill this year aimed at weaning the institute off of state funding.

But in a conversation with The Texas Tribune, Roberts questioned the sustainability of the organization if state funding is not renewed.

Editor's note: This interview has been edited for length and clarity.

The Texas Tribune: When you joined the institute, what did you do to prevent another scandal from happening?

Roberts: It's important to put what happened into perspective. Three out of 498 awards at that time, or six-tenths of 1 percent, had issues.

I worked very closely with the Legislature to make sure that they got the information they needed to strengthen our statutes. Prior to the very first legislative meeting in 2013, the agency began implementing the auditor's January recommendations. And we implemented all of them, both the legislative changes to strengthen our statutes and the state auditor's recommendations, probably in record time.

Today I am required to certify, under oath, that every step in the grant-making process has been followed before a grant can be acted upon by our board. The certifications are posted to our website so that everyone can see my attestation that the process was followed.

I had a mantra that I had developed that I still use today: We will adhere to the process; we will document that adherence; and we will do so with maximum transparency. And I do believe that the agency has fulfilled all three of those aspects of the mantra.

TT: What would you say have been CPRIT's biggest accomplishments so far?

Roberts: An excellent proxy measure at this point in time as to how well we're doing are the number of clinical trials that CPRIT has funded through its grantees. To date, we have about 108 clinical trials with nearly 9,800 patients. These are patients that are being treated with pharmaceuticals whose development has been funded by CPRIT. There are 9,800 people that have hope today, where they would not have had hope yesterday.

Another metric would have to come from our prevention program. Our prevention program has touched all 254 counties. We've provided some 3.9 million services, including educational and training activities, to practitioners, and also screenings. There are 12,000 people who as a result of CPRIT's grants now are aware that they have a cancer or a likelihood of getting cancer, which they can act on proactively. Whether we have saved those individuals' lives, I won't venture. But if you ask them, I think they will probably say that we have.

In product development, the new life science companies we have created or brought to Texas would be another benchmark of success. To date, we have either brought or created 29 companies to the state of Texas from around the world. We have to date funded those 29 companies with $330 million. That investment has brought a hard $1.37 billion in follow-on private sector funding to the state of Texas.

TT: Sen. Schwertner introduced an unsuccessful bill during this year's legislative session for CPRIT to plan for eventual self sufficiency when its $3 billion in state funding runs out. Do you think CPRIT has a future as a financially self-sufficient organization?

Roberts: Self-sufficiency is not contemplated in our enabling legislation or the constitution. Had it been, our portfolio would be significantly different from what it is today. We would have funded more later-stage drug and product development to compete with private venture funding. Instead we have tended to focus on very early stage, proof of concept, very first stage clinical trials.

At the end of 2023, if the Legislature wants to continue CPRIT, it will be up to them to find a way to fund it. My experience after 40 years of working with the Legislature is that if they want something done, they'll figure out how to fund it.

If CPRIT is not continued, then we will ride off into the sunset, knowing that we've been part of a fantastic historical undertaking. No other state has ever funded cancer research to this level. We're doing exactly what the citizens of Texas bargained for when they approved the creation of CPRIT and dedicated $3 billion to fight cancer here.

TT: Why is it important for CPRIT to continue?

Roberts: I still get asked on occasion, "When are you going to discover a cure for cancer?" Cancer is constantly changing; that's its nature. Today, in many respects, science has made cancer a manageable disease, but a cure is not likely going to come from an individual breakthrough. It's going to come from an ecosystem of researchers and healthcare professionals collaborating and pushing the boundaries of medicine. CPRIT has brought incredible momentum to this ecosystem that will benefit not only Texans but every human on this planet.

Finally, prevention is a cure for cancer. Don't smoke, wear sunscreen and get a colonoscopy.

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CPRIT enters 10th year of working with cancer research

By Steffi Lee
Published: November 14, 2017, 7:00 pm | Updated: November 14, 2017, 7:45 pm

Related Coverage

Affidavit: CPRIT probe didn't target Gov. Rick Perry

Davis questions Abbott's role during CPRIT turmoil

AUSTIN (KXAN) – Hundreds of cancer research experts were in Austin the last two days sharing ideas on treatment and prevention, as well as supporting an agency they say will help Texas become a healthier state.

The Cancer Prevention and Research Institute of Texas (CPRIT) held the Innovations V Conference, bringing together the latest research happening in the state. Dr. Harpreet Singh, CEO of Immatics US Inc., was one of the presenters during the conference.

Immatics Biotechnologies GmbH is a Germany-based company that started working in Texas two years ago, through a partnership with the University of Texas MD Anderson Cancer Center. Singh said what brought Immatics to continue its research in Texas was largely due to a nearly $20 million CPRIT grant and the partnership with MD Anderson.

They launched Immatics US, Inc., which is a company dedicated to finding adoptive cellular therapies (ACT) for the treatment of a range of tumor types. Cancer immunotherapy is using the immune system to recognize and destroy cancer cells.

Singh said while it works in certain blood and skin cancers like melanoma, there are many types of cancers where cancer immunotherapy doesn't work yet. "Cancers like lung cancer, ovarian cancer, breast cancer, head and neck cancer, pancreatic cancer – the options that cancer patients have today are still very limited," Singh said.

Immunotherapy is something that requires a lot of experience and safety management in the process, Singh said.

"If you think of immunotherapy being the hammer, what we deliver are the nails," Singh said. "You need the right nails on the cancer cells so that you can apply the hammer. MD Anderson brings in the hammer, we bring in the nails."

Cam Scott, senior director of government relations in Texas for the American Cancer Society, said the type of work Singh's doing is critical for cancer treatment research. Right now, Immatics has two clinical trials approved by the FDA.

"We have a lot of clinical trials happening here that are the result of CPRIT-funded research," Scott said.

Mike Lang, CPRIT's chief product development officer, said immunotherapy can provide dramatic impact, but typically "have impact only on specific patient populations."

"Cancer is a highly heterogeneous disease, i.e. it's a collection of hundreds of similar diseases," he said in a statement. "Immunotherapies are typically highly effective on particular cancer subtypes."

Dr. Navkiran Shokar, a professor and vice chair for research at Texas Tech University Health Sciences Center – El Paso, said the impact of CPRIT can be felt by families right now. Shokar cites a cervical cancer program and a breast cancer screening program in her community, all stemming from CPRIT.

"We're really able to make big, meaningful differences in people's lives," Shokar said. "That's the other thing about CPRIT that's really beneficial to the community in that it does fund services, which many other kind of grants don't do."

Dr. Lorraine Reitzel is an associate professor at the University of Houston and a grantee of CPRIT funding. She has two grants and it's being used to work with healthcare agencies across Texas to create a tobacco-free workplace program.

"It includes all kinds of education, clinical training, tobacco-free workplace policies, community outreach," she said. "The idea is we work with agencies where the consumers and even the employees tend to use tobacco at particularly high rates. We know that if we can implement comprehensive tobacco-free workplace programs, we can increase tobacco quit rates."

CPRIT Oversight

Voters approved the creation of CPRIT a decade ago, but some lawmakers remain firm that the agency needs to be self-sufficient when state funding runs out.

State Senator Charles Schwertner, R-Georgetown, filed legislation the last two sessions to require CPRIT to have a plan in place when that happens. Schwertner said in an emailed statement the organization should've thought about the issue of sustainability from the start of its existence.

"In general, I don't support continued state financial assistance when voters approved a certain dollar amount over a certain amount of time," he said. "It's not fiscally responsible and it's not a good use of taxpayer dollars."

CPRIT was the focus of a financial probe in 2012, with state leaders putting a hold on grants due to allegations of corruption. Lawmakers eventually restored CPRIT's budget after passing provisions to restructure the agency's grant processes, improving oversight and preventing conflicts of interest.

According to CPRIT's website, the agency has funded 1,189 awards for cancer research, product development and prevention. The total amount awarded so far is $1.8 billion. Recipients include academic institutions, non-profit organizations and private companies across the state.

CPRIT's sunset review date is in 2023, which is when lawmakers will have to act on this voter-approved agency. Singh hopes there will be continued support for the cancer research community, so clinical trials can be worked on and doctors will have resources to help patients.

"Not just clinical responses, but durable clinical responses that really extend the lives of cancer patients in a meaningful fashion," he said.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	CPRIT OVERSIGHT COMMITTEE MEMBERS
FROM:	MICHAEL LANG, CHIEF PRODUCT DEVELOPMENT OFFICER
SUBJECT:	PRODUCT DEVELOPMENT PROGRAM REPORT
DATE:	NOVEMBER 29, 2017

FY 2018 Product Development Program Priorities

Product Development program for FY 2018 are discussed under agenda item 13. CPRIT staff recommends maintaining these priorities unchanged from those adopted for FY 2017. The Oversight Subcommittee on Product Development concurred with this recommendation on November 9.

FY 2017 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
- Stimulation 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**

FY 2018 RFAs

CPRIT has two Product Development Research Award mechanisms; Texas Company Product Development Research Awards and Company Relocation Product Development Research Awards. They are identical in every way except Texas location. Texas companies assert they are currently meeting the Texas location criteria while relocation companies assert the will meet the criteria post award. The application and review process for both awards are handled concurrently.

Highlights of both award mechanisms include:

- Invested in preclinical research and early clinical research necessary to demonstrate initial clinical safety and efficacy (typically phase 1, phase 2A);
- All cancer-related sectors are eligible: therapeutics, diagnostics, devices, and tools;
- Recipient companies must currently be or commit to be Texas based;
- 50% Matching: recipient companies are required to raise $1.00 in matching funds for every $2.00 contributed by CPRIT;

- Applicants may request up to $20 million in CPRIT funds;
- Funding is released in tranches and tied to the achievement of contract specified milestones; and
- All award contracts include a revenue-sharing agreement.

CPRIT staff recommends maintaining these programs unchanged for 2018. The Product Development subcommittee concurred with this recommendation.

Product Development Research FY 2018 Award Cycle 1 Update

Eighteen applications were submitted and accepted. Screening teleconferences were held September 25-26 where four were selected to present at peer review. These four presented at the Peer Review Panel meetings October 25 where two firms were selected to progress to due diligence. The total funding request of the two companies is $39.7 million.

Due diligence has commenced, and the results are scheduled to be reviewed by the Product Development Advisory Council (PDRC) on January 16, 2018. Applications recommended by PDRC and Program Integration Committee will be presented to the Oversight Committee in February for approval.

FY 2018 Cycle 2 Product Development Research Applications

The 18.2 RFA is being edited for a planned December 22 opening to accept applications. Applications that complete the review process will be presented to the OC in August 2018.

FY 2018-2022 RFA Budget and Timeline

CPRIT has been conducting two review cycles annually. Recommendations from these award cycles are brought to the OC for approval at the February and August OC meetings. We anticipate this will support 4 to 5 investments annually averaging $15 million each.

An example of how annual funding projections could play out follows:

- FY 2018 -2 Cycles: $76 million allocated for up to five companies awarded approximately $15 million each.
- FY 2019-2 Cycles: $76 million allocated for up to five companies awarded approximately $15 million each.
- FY 2020-2 Cycles: $46 million allocated for up to three companies awarded approximately $15 million each.
- FY 2021-1 Cycle: $38 million allocated for up to two companies awarded approximately $15 million each.
- FY 2022-1 Cycle: $16 million allocated for one company award.

The proposed RFA budget and timeline for FY 2018-2022 was presented to the Product Development Oversight Subcommittee at the November 9, 2017, meeting for consideration.

A budget scenario in which the funds allocated for FY 2022 are accelerated to 2021 was provided to the Product Development Subcommittee for future consideration. The objective is maximizing cost effectiveness as CPRIT's budget tapers off in these years.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	CAMERON ECKEL, STAFF ATTORNEY
SUBJECT:	APPOINTMENTS TO THE SCIENTIFIC RESEARCH AND PREVENTION PROGRAMS COMMITTEE
DATE:	NOVEMBER 16, 2017

Summary and Recommendation

The Chief Executive Officer has appointed three experts to the CPRIT's Scientific Research and Prevention Programs Committee. CPRIT's statute requires the appointments be approved by the Oversight Committee. The Nominations Subcommittee discussed the appointments at its meeting on November 10, 2017, and recommends that the Oversight Committee vote to approve the appointments.

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 an important 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 Nominations Subcommittee considered the pending peer reviewer appointments and recommends Oversight Committee approval.

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

Nominations to Product Development Research peer review panels:

- Chitra Edwin, Ph.D., RAC.
- Helen Maslocka
- Daniel L. Mooradian, Ph.D.

CHITRA EDWIN, Ph.D., RAC.

SUMMARY

Extensive experience in the regulatory affairs, and compliance of drugs, *in vitro* diagnostics (IVD), and medical devices in infectious diseases, oncology, and cardiology. Successfully established technical teams. Leadership in the management of multidisciplinary teams. Effective liaison with multinational collaborators. Prepared regulatory compliant documents, regulatory submissions, and managed document control. Influential business development, organizational and negotiating skills. Invited speaker at major Regulatory conferences. Entrepreneur and Co-founder of non-profit organizations on science, and international business.

PROFESSIONAL EXPERIENCE

SPOTLIGHT INNOVATION, INC. 2016 - Present
Senior Vice President of Regulatory Affairs & Compliance

Responsible for the regulatory affairs, regulatory strategy, compliance operations, FDA, and regulatory agencies interactions, quality systems (QA/QC) for rare, emerging, neglected diseases applicable for Orphan Drug, and Fast Track designations. Involved in the safety assessment, labeling, advertising, promotion and regulatory compliance of homeopathic OTC therapeutic products.

UNIVERSITY OF CINCINNATI, Cincinnati, OH 2008 - Present
(*Public Educational Institution; 5,000- 10,000; 42,000 enrollment***)**
Director; Capstone Project; Master's in Drug Development Program 2008 - 2015
Adjunct Associate Professor, Pharmaceutical Sciences; College of Pharmacy, University of Cincinnati

- Lecturer on pre-clinical testing guidelines, regulatory verification, validation, and compliance (GLP, cGMP).
- Directed the Capstone Project, Master's in Drug Development Program focused on didactic scientific, regulatory and business aspects of new drug development.
- Mentored graduate students. Responsible for project management, and communication oversight between faculty and students to ensured successful program completion.

BIOTECHNOLOGY CONSULTING SOLUTIONS, Ltd, Cincinnati, OH. 2006 - 2016
President & Founder

Functioned as a Subject Matter Expert (SME) providing consulting advice to Fortune Global 500 corporations, mid-sized manufacturing companies, Contract Research Organizations (CROs), healthcare consulting companies, biotech start-ups, academic institutions, and state funded bioscience organizations.

Selected Projects:

- Developed the regulatory strategy and product development plans for an automated, high-throughput infectious disease medical diagnostic (PMA) with innovative molecular based technology. The Japanese client executed the decision to proceed with the development plan.
- Developed the regulatory strategy for a novel regenerative stem cell project.
- Led the technology transfer of an innovative oncology medical device from Europe to the US. Prepared the regulatory strategy including technology assessment, and plan for a PMA approval. Led a national search of GLP compliant CROs, conducted due diligence, and finalized a CRO to perform animal testing. Designed the experimental protocols for non-clinical safety testing.
- Consulted for a European manufacturer on the regulatory strategy for a combination product comprising a drug delivery medical device (510k) for the treatment of acute otitis media in pediatric patients.
- Lead the effort on a "proof of concept" study for an oncology medical device prototype.
- Enforced EMEA and FDA compliance (ICH, USP); cGMP/ GLP

OPUS INSTITUTIONAL REVIEW BOARD, Ltd, Atlanta, GA. 2010– 2015
(*Private; 10 – 20 staff and Board members***)**
Scientific Biopharmaceutical Board Member

- Board participant on formal review of clinical protocols to ensure FDA and DHHS compliance. Studies included products with oncology applications e.g. radiographic markers for soft tissue, and for brachytherapy radiation treatment
- Trained on IRB GCP, NIH certification requisites for AAHRPP accreditation.

CLEVELAND HEARTLAB, Inc., Cleveland, OH 2013 – 2015
(*Private; 100 – 120 employees*)
Vice-President, Regulatory and Quality Affairs

Responsibilities included the project management leadership of development, regulatory strategy, labeling, promotional materials and compliance leading to the FDA 510(k) submission, and to CE Mark approval of the Universal CardioMPO™ IVD ($10 million market value). Management of the QA Program.

Achievements:

- Orchestrated and managed the entire lifecycle of the Universal CardioMPO™ by demonstrating feasibility of a basic R&D prototype, leading to a regulatory submission. Initiated the project single-handedly then established a Project Team in the US, and Japan.
- Built and directed a handpicked Virtual Project Team of Subject Matter Experts (including former FDA officials).
- Selected and conducted due diligence of IRBs, suppliers/ vendors e.g. clinical samples etc. Negotiated pricing and arranged all NDAs, and contractual agreements.
- Prepared project budget forecasts, and responsible for capital expenditures.
- Established project timelines and goals. Typically, met timelines.
- Successfully directed the design control process, verification/ validation testing and clinical study design, manufacturing and QC performed by a global Japanese CRO.
- Developed the CE Technical File, and secured CE Mark approval for the Universal CardioMPO™.
- Established commercialization in EU through an Authorized Representative.
- Led all FDA (CDRH) direct interactions, and the preparation of the 510(k) submission (eCopy).
- Managed the cGMP QA Program, Risk Management (ISO14971) and instituted polices to ensure compliance with US and EU agencies.
- Directed handpicked QA consultants, followed by hiring a full-time QA Manager.
- Managed and arranged internal audits, and supplier audits.
- An initial mock internal audit of the program generated 44 major non-conformances when I took over the program. In a year, the next annual audit had no non-conformances.
- Initiated, selected a Notified Body and achieved ISO 13485:2003 CMDCAS certification.
- Functioned as the Regulatory and Quality Management Representative. Led Design Review, Management Review meetings, and QA employee trainings.
- Responsible for FDA Establishment Registration, deviations, CAPAS, OOS.
- Responsible for the implementation of the Documentation System, document control of SOPs; Validation and Clinical Study Protocols and Reports. Created many SOPs and Validation protocols.
- Enforced FDA, EU MDD and PMDA regulatory compliance (CLSI, ICH).
- Promoted from Director to Vice President.

CINCINNATI CHILDREN'S HOSPITAL MEDICAL CENTER (CCHMC), Cincinnati, OH. 2004 - 2005
(*Not-for-profit; 5,000-10,000***)**
Field Services Associate Professor; University of Cincinnati College of Medicine
Responsibilities included the scientific and regulatory oversight of a Clinical Research Testing Laboratory providing contract clinical trial support for infectious diseases vaccines. Facilitated business development activities.

Achievements:

- Arranged numerous on-site visits of potential clients interested in clinical testing services.Procured and negotiated a Procter & Gamble Beauty Care validation contract. Functioned as the PI for the project involving the microbial surveillance of human test samples using molecular diagnostic technology.
- Actively involved in the scientific, technical and regulatory oversight of the laboratory testing program in support of clinical trials for vaccines.
- Participated in regulatory project teams, audits, on-site and off-site sponsor (Merck, GSK) visits.
- Trained laboratory personnel on Biosafety Level 2 (BL2) compliance, GLP compliance.
- Initiated and obtained CLIA registration, and filed for CAP accreditation.

MASSBIOLOGICS (MASSACHUSETTS BIOLOGIC LABORATORIES), Jamaica Plain, MA 2001- 2003
University of Massachusetts Medical School
(*Not-for-profit; FDA-licensed Manufacturer; 201 - 500)*
Senior Manager
Management of the GLP compliant bioanalytical core testing facility which supported Discovery/ R&D, process development, manufacturing, QA/QC, and clinical serology for pre-IND, IND, and BLA products (vaccines for human use).

Achievements:

- Directed and executed the preclinical assay development strategies for the bio-analytical testing of human use therapeutic biologics (infectious disease vaccines). A menu of standardized, validated assays/ IVDs (many RUO) was designed and customized for the evaluation of specific biomarker targets.
- Upgraded, and equipped the GLP laboratory for current compliance. Enforced on-going compliance.
- Hired staff, and established a bioanalytical technical team of 10 reports.
- Involved in the technology transfer efforts of an infectious disease vaccine prototype from a biopharmaceutical company (MedImmune) for cGMP manufacturing.

BIOTRANSPLANT, Inc. (ELIGIX, Inc), Medford, MA 1999 - 2001
(*Public; 30 - 100***)**
Senior Scientist
Managed the safety testing, verification and validation of two oncology medical devices used for the *ex vivo* treatment of human stem cell and bone marrow transplants. Prepared protocols and results reports used in the Technical File.

Achievements:
Two medical devices, the Eligix HDM CD8-DLI and BCell-SC Cell Separation Systems have CE Mark approval (distributed by Gambro BCT, Europe).

NOVARTIS (CHIRON CORPORATION), Walpole, MA 1993 - 1998
(*Public; 1,000 – 6,000***)**
Staff Scientist / Project Leader – Product Development
Led the development of a HIV diagnostic assay (IVD; PMA) from concept to manufacturing transfer. The ADVIA Centaur® HIV1/O/2 assay performed with the automated ADVIA Centaur® System is FDA approved (PMA; Siemens Healthcare Global). Product development of infectious disease assays (Rubella, CMV) which have obtained 510(k) clearances.

Achievements:

- Led the team through R&D, design control, verification, validation and pre-IDE.
- Established a GLP, BL2 compliant laboratory and initiated discovery of a HIV diagnostic assay.
- Demonstrated R&D feasibility of the HIV IVD for continued development and eventual commercialization. Arranged biosafety and OSHA training for the employees on handling HIV.
- Promoted to Staff Scientist and Project Leader. Developed a team of 10 reports, and 30 team members located in Walpole, MA, Oberlin, OH, and Emeryville, CA.

EDUCATION & CREDENTIALS:

Ph.D., University of Minnesota, St. Paul, MN.
Medical Microbiology/ Immunology

R.A.C., Regulatory Affairs Professional Society board certification

POST-DOCTORAL TRAINING

HARVARD MEDICAL SCHOOL, Boston, MA
Department of Medicine; Division of Infectious Diseases

DANA FARBER CANCER INSTITUTE, Boston, MA
Instructor in Medicine

BRIGHAM AND WOMEN'S HOSPITAL, Boston, MA
Research Fellow in Medicine; promoted to Instructor in Medicine

ADDENDUM

PROFESSIONAL MEMBERSHIPS

Sigma Xi, MIT Enterprise Forum, Regulatory Affairs Professional Society, Foreign Policy Leadership Council, BioOhio, Kindervelt
Sigma Delta Epsilon, Graduate Women in Science: Chair and Committee member – Omega Chapter
Co-Founder & President – Alpha Omega Chapter (Massachusetts)
India-US Business Network: Co-founder.

WEBINARS AND TRAININGS CONDUCTED (2010 – present):

FDAnews, Regulatory Affairs Professional Society (RAPS), Elsevier Business Intelligence etc.:

- Auditing the QC Microbiology Laboratory for FDA compliance.
- Immunogenicity to biologics: processes, impact on efficacy and safety, and management strategy.
- CGMP: Strategies for implementation and compliance for Phase 1 IND and Biologic products.
- Writing and maintaining quality Standard Operating Procedures (SOPs) to guarantee FDA compliance.
- Combination Products: current regulations, challenges and strategies to surmount them.
- Opening a CLIA (Clinical Laboratory Improvement Amendments) Laboratory? Understanding the requirements, regulations and important considerations.
- Good Laboratory Practice (GLP) for Non-Clinical Laboratory Studies - Application and Compliance to Ensure Safety of Biologic Therapeutics and Medical Devices (2-day In-person Training)

GLOBAL CONFERENCE COMMITTEE MEMBER:

- Xavier University/ FDA MedCon Medical Devices Conference, 2011
- Xavier University/ FDA Pharmaceutical Global Outsourcing Conference, 2012
- OMICS Group: International Summit on GMP & GCP: USA, Europe, Japan, Asia Pacific, 2012
- OMICS Group: 3rd International Conference on Pharmaceutical Regulatory Affairs, 2013

RECENT INVITED SPEAKING/ PANEL MEMBER ENGAGEMENTS (2014 – 2017):

- "Regulatory Strategy: Where should you start?" Regulatory Strategy Forum for Biologics; Regulatory Convergence 2014, RAPS, September 27, 2014, Austin, TX.
- "Obtaining Buy-In for Regulatory Strategy" Regulatory Strategy Forum for Biologics; Regulatory Convergence 2014, RAPS, September 28, 2014, Austin, TX
- "CLIA & 510(k) Separate vs. Parallel Review Paths for Diagnostic Assays: Pros vs. Cons" 5th Annual Clinical Diagnostics & Regulatory Approvals Conference; Q1 Productions, October 27, 2014, Alexandria, VA.
- "Fast Track Designation for Medical Devices". Regulatory Filing Strategies Summit; ExL Pharma, February 23, 2015, Philadelphia, PA.
- "Review of FDA Guidance on Administrative Procedures for CLIA Categorization", 6th Semi-Annual Clinical Diagnostics & Regulatory Approvals Conference; Q1 Productions, May 4, 2015, San Diego, CA
- "Regulatory Strategy Forum for Medical Devices" Regulatory Convergence 2015, RAPS, October 24, 2015, Baltimore, MD.
- Speaker: "Current State: In vitro diagnostic device studies using leftover human specimens." Regulatory Convergence 2016, RAPS, September 20, 2016, San Jose, CA.
- Speaker: "Current State: In vitro diagnostic device studies using leftover human specimens." Regulatory Convergence 2017, RAPS, September 12, 2017, Washington, DC.
- "2nd Strategic Partnerships for Drug Repurposing Forum"; ExL Events, October 26, 2017, Boston, MA.

HELEN MASLOCKA

PROFILE

Results driven executive with broad experience in new technologies/products and building businesses. CEO, general manager, business development and marketing executive skilled at driving revenue, raising capital (venture and IPO), corporate partnering, licensing, corporate communications, investor relations, acquisition and launch strategies for healthcare IT, medical device, biopharmaceutical, , and healthcare services companies. Expertise in a wide range of consulting projects.

- Innovator.
- Maximize profitability and employ total quality management.
- Effective in a variety of corporate cultures, from services to start-ups to Fortune 500 companies.
- Attract, mentor and motivate first-rate talent.
- Champion team-based, can-do culture; respected as a persuasive consensus builder talented at creating successful transactions and integrating organizations and teams.
- Served on presidential healthcare policy committee.
- Four medical device patents.

PROFESSIONAL EXPERIENCE

INDEPENDENT CONSULTANT **2007 to present**
Interim CEO, business development executive consultant working within the full breadth of life sciences including but not limited to medical devices, molecular diagnostics, tools, services, information technology (recently IT storage issues as it relates to large database development and search especially), biotechnology, greentech, and project on sustainability.

DEWEY, DEVLIN AND KING, Investment Bank, New York and California
Venture Partner **2006 to present**
Evaluate and execute financing on healthcare companies either through venture capital, private equity, hedge funds, reverse mergers, or m &a. Consult on business development strategy.

MEDCOOL, INC., Wellesley, MA **2002 – 2006**
President and CEO
Cardioneuro biomedical device company developing non-invasive therapy for ischemic conditions.

- Raised $4.4 million Series A and B rounds; investors included Boston Scientific.
- Led all-star team, completing sketch to product in ten months from financing.
- Completed successful human feasibility study completed in 20 cardiac arrest patients.
- Developed successful first commercial prototype.
- Negotiated clinical trial plan with FDA and reimbursement strategy.
- Created top scientific and business Advisory Boards (e.g., Fred Frank, Lehman Bros.).
- Executed on corporate valuation curve; overcame challenge of prior company failures in space.

BRANDEIS UNIVERSITY, Waltham, MA **2002**
Three-month special assignment
Technology licensing/business development evaluation and recommendations to Science Committee and Board of Trustees, on request of Provost and Science Committee.

CARDIOFOCUS, INC., Norton, MA **1998 – 2001**
President and CEO
Biomedical device turnaround – biotechnology and photonic-based medical device combination.

- Developed business and strategic vision—refocused, renamed, and turned around company—now focused on photonics based catheter development use in cardiovascular markets.
- Executed very difficult turnaround communications program to reposition company.
- Positioned company for acquisition by Guidant and other cardiovascular companies.
- Raised $12 million in new venture financing from top tier firms; full P&L responsibility.
- Licensed non-core intellectual property and created licensing agreements with customers.
- Moved company to new ISO certified 13,000 square foot headquarters.
- FDA approval on first product. Negotiated reimbursement strategy.

MEDCONTRAX, Portsmouth, NH **1997 – 1998**
B2B Internet ASP-model software company, sold to a strategic buyer with very favorable shareholder returns.
President and CEO

- Achieved "proof of concept" prototype developed supply chain software product.
- Established 16 company Advisory Board including Merck, SmithKline, Abbott, McKesson.

LEUKOSITE, INC., Cambridge, MA **1996 – 1997**
Biotechnology company developing drugs to treat cancer and autoimmune diseases.
Vice President for Corporate Development – Consultant

- Instrumental in creating and consummating joint venture with Ilex Oncology for development of CAMPATH-1H, a Phase II/III potential $150 million drug that made IPO possible.
- Orchestrated and drove strategic planning effort and business plan.
- Oversaw development of comprehensive investor and corporate communications.
- Raised $7 million in private placement pre-IPO and member of $100 million IPO team.

SERAGEN, INC., Hopkinton, MA **1992 – 1996**
Biotechnology company sold to Ligand Pharmaceuticals, Inc.
Vice President, Corporate Development, Investor Relations and Corporate Communications

- Directed dermatology business development activities for lead product in $125 million deal with Lilly.
- Created international IR/PR program including crisis management, SEC compliance, insider trading, and general communication strategy and tactics, increasing market capitalization 2x.
- Identified merger/acquisition opportunities.
- Raised $10 million in private placement. First PIPE without investment banker.
- Key team member raising $60 million in an IPO and follow-on offerings.

SUMMIT TECHNOLOGY, INC., Waltham, MA **1987 – 1991**
A high growth $300 million medical device company.
Director of Business Development and Marketing, Investor Relations

- Launched Lasik procedure internationally.
- Created and led marketing programs domestically and internationally to $40 million in sales.
- Drove and managed the exercise of two sets of warrants resulting in $10 million in capital.
- Managed $17 million European private placement.

SUMMIT TECHNOLOGY continued

- Created award winning international investor and public relations program resulting market capitalization from $20 million to over $1.5 billion.

MCKESSON CORPORATION, General Medical Division, Worcester, MA **1984 – 1987**
District Manager (joined firm as ops mgr., sales rep; multiple promotions). Grew sales 4x to $100 million.

MASSACHUSETTS GENERAL HOSPITAL, Boston, MA **1981 – 1984**
Manager of Clinical Administration. Precedent-setting fiscal accountability for 30% of inpatient beds.

Diversity of healthcare experience extends to undergraduate and graduate positions with the Harvard Community Health Plan, large physician practice management, Massachusetts Department of Public Health – Statistics, and Travelers Insurance company.

EDUCATION

Graduate Degree in Management, Harvard University, Cambridge, MA
BA, Psychology with Biology, Boston College, Chestnut Hill, MA
Advanced coursework in biochemistry and molecular biology

PROFESSIONAL AND CIVIC INVOLVEMENT

Memberships, AdvaMed, Mass. Medical Device Association, Biotechnology Industry Organization (served on Government Relations and Bioethics committees), Licensing Executives Society, Commonwealth Institute; Boston Club, and TEC (International Organization of CEO's).

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Advisory Board, **University of Oregon Health Sciences**, 2004-Present
Advisory Board Member, **Jennifer Diamond Cancer Foundation**, 2005- Present – personally obtained large grants from top five pharmaceutical companies
Kerry Healthcare Policy Committee, Executive Committee Advisory Board member

OP ED

Ms. Maslocka's opinions on health care policy, regulation, the state of the industry have been quoted in the *Wall Street Journal, New York Times, Boston Business Journal, San Francisco Chronicle, and Boston Globe.*

Daniel L. Mooradian, Ph.D.

St. Paul, MN

EXECUTIVE SUMMARY

Successful Scientist, Educator, Entrepreneur and Medical Device Executive with a unique combination of technical expertise and business knowledge gained as a result of 17+ years of experience in the global Medical Device marketplace.

Unique combination of academic/corporate R&D experience with a record of leadership in both the private and public sector. Independent and internationally recognized researcher in biomaterials, surface modification, tissue engineering. ***A committed Educator*** with teaching and curriculum development experience and a keen understanding of the skills necessary for students to compete effectively in a global medical device/biotechnology industry. ***A committed advocate for Academic/Industry partnership*** with a record of innovative Industry Outreach throughout my academic/Industry career. ***Successful inventor and entrepreneur*** who has successfully commercialized polymeric and tissue-based implantables, medical instrumentation/surgical tools/diagnostics, and combination devices. ***A seasoned leader of medical device product development*** with the ability to support and motivate teams to deliver on time and within budget. Thorough understanding of the Regulatory environment in which medical device develop takes place with experience in the US, Europe and China. Substantial experience in ***Business development***, Mergers & Acquisitions, technology assessment, ***intellectual property protection*** and ***technology transfer*** in both the biotechnology and medical device fields. Exceptional communications skills in both technical and corporate settings. ***Frequent speaker at medical and professional conferences*** on a variety of medical and business topics. Equally comfortable speaking to clinicians, scientists, engineers, investors, Boards, etc. ***Strong academic credentials*** in Experimental Pathology. Author of 25+ peer-reviewed publications, 5 book chapters, 45+ abstracts and inventor on 8 issued US patents and a number of international patents and patent applications in the medical device field.

CHRONOLOGY

The University of Minnesota November 2013 - Present
Technological Leadership Institute
Honeywell/James J. Renier Endowed Chair in Technology Management
Director of Graduate studies – MS in Medical Device Innovation

Successfully launched this innovative program in May 2014 with only five month lead-time. This involved recruited 6 teaching faculty, leading curriculum development and recruited a cohort of 18 students. The program has grown steadily in size and recognition over the past three years. We now have 54 Graduates of the program working in the medical device industry world-wide. The MS-MDI program is an important addition to TLI's portfolio of Master of Science programs aimed at developing leaders in technology-intensive industries. Given the importance of the medical device industry to Minnesota's economy and to maintaining Minnesota's competitiveness nationally and globally, this program reflects a strategic partnership between the University and its public/private partners. We are currently recruiting students for our fourth cohort to begin in May 2018.

I have also led effort to establishing a partnership with the Costa Rican Economic Development agency (CINDE) and the faculty and leadership at the Technologica de Costa Rica (TEC) to incorporate key elements of our curriculum into their MS in Medical Device Engineering. I hold an adjunct teaching appointment at TEC, and teach a course in Medical Industry Dynamics on an annual basis in San Jose, CR.

PI on NSF i-Corp grant to fund customer discovery by a student-led start-up with a novel treatment for dry eye (2017-2018).

The Simpatico Group LLC November 2012 - Present
Founder & President

The Simpatico Group is a consulting firm providing Scientific/technical, business and regulatory consulting services to clients related to the development and commercialization of medical devices with emphasis on compliance with quality systems and design control procedures, protection of intellectual property. Provide expert witness services supporting product liability and patent litigation in areas of expertise.

Innova Medical Design LLC November 2012 – Present
Chief Scientific Officer

Innova Medical Design is a Twin Cities-based early-stage Medical Device company focusing on the development of novel devices to treat needle pain which remains a challenge to patient compliance in chronic conditions such as diabetes and hospital procedures that include IV set-up, blood draw or injection. Currently involved in fund-raising in the US and European Union.

Axonia Medical, Inc. August 2014 – September 2016
Member of the Board of Directors

Axonia Medical was an early-stage medical device company that is developing disruptive technologies for the treatment of peripheral nerve injury. Based on technology from the University of Pennsylvania invented by Dr. Doug Smith, the company is applying the principles of "stretch growth" to the in vitro growth of human axons for surgical implantation to repair long nerve defects that are otherwise beyond the scope of current surgical repair.

Synovis Life Technologies, Inc. December 2008 - October 2012
Vice President of Research & Development

Managed a group of 16 scientists and engineers responsible for Research and Development in support of the company's Surgical, Microsurgical, Orthopedic and Wound Care businesses. Managed the company's IP portfolio, developed a scientific foundation for the clinical use of the Company's products, managed the planning and execution of the Company's product development pipeline leading to timely commercialization of innovative products across Synovis business units.

- Created an integrated Life Science/Engineering/Project Management organization organization aligned around a set of clearly defined product development objectives.
- Developed and launched products such as Veritas® Collagen matrix, Peri-Strips Dry® with Veritas®; Circular PSD with Veritas® and the Flow COUPLER® that have generated more than $140M in revenue for Synovis Life Technologies, Inc. and constituted a large part of the company's offerings.

- Key member of an executive Management team that traveled to Beijing, China and successfully sought licensure of Neurotube® peripheral nerve conduit with an SFDA review panel. The Neurotube® is the first peripheral nerve conduit approved for sale in China.
- Inventor on a number of key patents in the Synovis Portfolio (see patents listed below)
- Member of the due diligence team responsible for the acquisition of Pegasus Biologics in 2010.
- Member of the due diligence team leading up to the acquisition of Synovis by Baxter International in 2012.
- Member of the Baxter Integration Core Team post-acquisition (February 2012 - October 2013)

Boston Scientific Corporation
Director of the Research and Technology Center
Cardiac Rhythm Management/Neuromodulation 2007-2008

P&L responsibility for a staff of 35 including scientist, veterinarians and technicians in BSC's State-of-the-art GLP preclinical research facility with an annual operating budget of $5M US. with direct-line reporting to the VP of Preclinical Sciences within the Clinical Department of Boston Scientific and the VP of New Technology within the R&D organization of Guidant post-acquisition

- Managed all aspects of operations of this 50,000 square-foot facility in the northern suburbs of St. Paul
- Expanded services to include the global BSC businesses including Cardiovascular, Neurovascular and neuromodulation businesses in addition to the facilities core support for cardiac rhythm management division
- Integrated anatomic/microscopic pathology into on-site services to facilitate model and study development and execution
- Established veterinary interventional cardiology core on-site to improve the efficiency, standardization and quality of preclinical Drug-eluting Stent studies carried out internally in support of regulatory submissions

Director of Preclinical Sciences May 2006 – December 2007
Interventional Cardiology/Peripheral Interventions

Responsible for developing and implementing preclinical research strategy in support of worldwide product approvals for the BSC Interventional Cardiology, Peripheral Interventions and Vascular Surgery businesses. Led multiple preclinical programs, and collaborated with a variety of internal and external stakeholders to accomplish business goals. Managed the expenditure of approximately ~$10M annually. Facilitated the establishment of systems to ensure compliance with governmental regulations related to preclinical research in support of domestic and international regulatory submission.

- Provided effective local leadership to a preclinical team of ~20 scientists in Maple Grove while reporting to VP of Preclinical Sciences in Natick, MA.
- Member of the Peripheral Interventions Management Team - ensured functional alignment with business unit objectives.
- Developed a successful strategy to address issues related to stent fracture with regulatory agencies - effectively reducing the testing/reporting requirements associated with post-market surveillance.
- Successfully supported regulatory submissions of DES platforms in the US, Canada, Europe and Japan.

Queststar Medical, Inc.
Vice President of Research & Development 2005 - 2006

Management of Research & Development/Product Development of start-up company's pipeline of point-of-care and home-based diagnostics.

- Completed development of a low-cost, reliable blood glucose monitoring system (BGMS) for the international markets, a second generation BGMS which offers significantly reduced sample volume (1 μL) and test time (5 sec) while offering a very competitive cost per test strip that was abandoned for business reasons during clinical testing.
- Demonstrated Feasibility of a revolutionary optical fiber-based BGMS in collaboration with NASA with sub-milliliter blood volumes, very rapid test times (< 2 sec) and test strip costs that were to be well below those of available devices. The core optical fiber technology was also being used to develop POC diagnostics for cardiac care (i.e., early markers of platelet activation such as p-selectin, sCD40L).

Synovis Life Technologies, Inc.
Director of Research & Development 2003-2004

Responsible for R&D in the Surgical Products Division managing a group of 3 scientists and 4 engineers with an annual budget of ~ $2.5M.

- Established company's first "Stage-Gate" product development process to improve product selection, execution and on-time launch.
- Led team responsible for redesign of the Peristrips Dry with Veritas delivery system, significantly reduced failures in the field and delivering sustained revenue growth of this $25M+ product-line.

Principal Scientist 2001-2002

Recruited by the VP of R&D to rebuild and refocus R&D after the departure of two senior (PhD level) staff members. Subsequently recruited key members of our senior staff, worked to restore department morale, and to create a greater sense of responsibility and accountability amongst R&D staff. Also established strong relationships of cooperation and trust with key functions (Quality, Regulatory, Sales/Marketing, Operations) necessary for success in product development.

Knowledge Frontiers, LLC 1997-1999
Co-founder & Member
Co-founder of this start-up consulting firm that specialized in Technology Assessment and Scientific Due Diligence for the Medical Device and Biotechnology Industries.

ACADEMIC APPOINTMENTS

University of Minnesota School of Medicine
Assistant Professor – Founding Faculty Member 1997-2000
Department of Biomedical Engineering

- Carried out independent research in Cardiovascular Tissue Engineering and Local Drug Delivery to Treat Restenosis.
- Founding member of the Drug Delivery Center in the College of Pharmacy.
- Principal architect of the Department's "Basic Sciences" curriculum. Organized and taught "Biology for Biomedical Engineers" and

"Pathobiology of Medical Devices to undergraduates and Graduate students in BME.

Founder & Director of the Blood & Biocompatibility Research Laboratory
University of Minnesota Medical School 1997-2000

- The Blood and Biocompatibility Research Laboratory (BBRL) was a GLP compliant contract research facility in the University of Minnesota's School of Medicine that conducted state-of-the-art research on the compatibility of biomedical devices with blood & tissue and provided a portfolio of standardized methods for the biological characterization of biomaterials and medical devices in support of both University and Industry R&D. Clients included a variety of established medical device companies as well as start-ups.

Co-Director for Industry Interactions
Biomedical Engineering Institute - University of Minnesota 1996-1999

Responsible for developing and coordinating outreach activities that improved opportunities for industry funded research and technology transfer in the Biomedical Engineering Institute. Worked closely with select faculty, staff and Foundation staff to raise $10M endowment for the Institute.

Assistant Professor 1993-1997
Department of Laboratory Medicine & Pathology

- Developed independent research program in cardiovascular injury and repair (Total funding ~ $2.5M)
- Founding member of the University's Biomedical Engineering Center
- Awarded one of four McKnight Land Grant Professorships granted to promising U of MN faculty each year (1994).

Research Associate
Department of Laboratory Medicine & Pathology 1991-1992
Research focus: *Identification of bioactive domains in large proteins of the extracellular matrix: Use of synthetic peptide analogs to modulate healing and repair in vivo.*

American Heart Association - Post-Doctoral Fellow 1988-1990
Department of Laboratory Medicine & Pathology
Research Focus: *Growth Factor interactions with Extracellular matrix components: Regulation of vascular function.*

EDUCATION

Ph.D. in Experimental Pathology, Wayne State University Medical School
Detroit, MI 1987
Thesis: *Growth Regulation in Rouse Sarcoma virus transformed Cerebrovascular endothelial cells*

B.S. in Natural Sciences with Minor in Armenian History
University of Michigan – Dearborn
Dearborn, MI 1982

HONORS AND AWARDS

Honeywell/James J. Renier Endowed Chair in Technology Management – 2013-present; McKnight Land-Grant Professorship, University of Minnesota – 1994; American Heart Association Fellow – 1989-1990.

PROFESSIONAL ACTIVITIES

Committees and Boards

Nanotechnology Advisory member and Chair – Dakota County Technical College (2010-present); Co-Chair of the "Global Clinical Trials Outsourcing Conference" in 2014, 2015 and 2016 (Arena International); Board of Directors – Axonia Medical, Inc. (2014-2016); Frost & Sullivan R&D Thought Leader (2010-2012); Frost & Sullivan R&D Program Advisory Board Member (2011-2012); Member of the University of Minnesota – Technology Transfer Assessment Committee (2005 – 2006); Co-Chair of Medical Alley R&D Special Interest Group (2003-2005); Scientific Advisory board, Comedicus Incorporated (1997-2004); Scientific Advisory Board, Enduratec Systems, Inc. (1999-2004). Microtechnology Laboratory Advisory Committee (1998-2000); Institutional Animal Care and Use Committee (1998-2000); Minnesota Project Innovation Small Business Innovative Research (SBIR) Advisory Committee, (1998-2000).

PUBLICATIONS & PATENTS

Peer-reviewed papers:

1. K.C. Palmer, D.L. Mooradian and C.A. Diglio. Enhancement of differentiated type II cell function in the A549 cell line by mitomycin C. Patrol. Immunopathol. Res. 6:221-233 (1987).
2. D.L. Mooradian, R.C. Lucas, J.A. Weatherbee, and L.T. Furcht. Transforming growth factor-β1 binds to immobilized fibronectin. J. Cell. Biochem. 41(4):189-200 (1989)
3. D.L. Mooradian and C.A. Diglio. Effects of epidermal growth factor and transforming growth factor-β1 on rat heart endothelial cell anchorage-dependent and -independent growth. Exp. Cell Res. 186:122-129 (1990).
4. D.L. Mooradian, A.F. Purchio and L.T. Furcht. Differential effects of transforming growth factor-β1 on the growth of poorly and highly metastatic murine melanoma cells. Cancer Research. 50(2):273-277 (1990).
5. Ulman, D.L. Mooradian, L.T. Furcht, and S. Luikart. Effects of TGF-β1 on proteoglycan production in bone marrow cultures in vitro. Exp. Hematol. 18:1121-1125 (1990).
6. D.L. Mooradian and C.A. Diglio. Production of a transforming growth factor-beta-like growth factor by RSV-transformed rat cerebrovascular endothelial cells. Tumor Biology. 12(3):171-183 (1991).
7. D.L. Mooradian, J.B. McCarthy, K.V. Komanduri, and L.T. Furcht. Effects of transforming growth factor-β1 on human adenocarcinoma cell adhesion, motility and invasion in vitro. J. Natl. Cancer Inst. 84(7):523-527 (1992).
8. D.L. Mooradian, P. Trescony, K. Keeny, and L.T. Furcht. Effect of glow discharge surface modification of plasma TFE vascular graft material on fibronectin and laminin retention and endothelial cell adhesion. J. Surgical Research. 53(1):74-81 (1992).
9. D.L. Mooradian, J.B. McCarthy, D.J. Cameron, A.P.N. Skubitz, and L.T. Furcht. Rabbit corneal epithelial cells adhere to two distinct heparin-binding synthetic peptides from fibronectin. Journal of Investigative Ophthalmology and Visual Science. 33(11):3034-3040 (1992).
10. D.L. Mooradian, J.B. McCarthy, D.J. Cameron, and L.T. Furcht. Characterization of FN-C/H-V, a novel synthetic peptide from fibronectin that promotes rabbit corneal epithelial cell adhesion, spreading, and motility. Journal of Investigative Ophthalmology and Visual Science. 34(1):153-164 (1993).

11. Fasseen, D.L. Mooradian, R. Dickenson, P. Leturneau, T Oegema and J.B. McCarthy. Cell surface CD44-related chondroitin sulfate proteoglycan is required for transforming growth factor-β-stimulated mouse melanoma cell motility and invasive behavior on type I collagen. Journal of Cell Science. 105:501-511 (1993).
12. T. Eastlund, W. Low and D.L. Mooradian. Isolation and culture of human osteoblast progenitors from human fetal calvarium. Transplantation Proceedings Transplantation Proceedings. 26(6):4000-1 (1994).
13. D.L. Mooradian, C. A. Diglio, B. Lester and B. Fernandes. Angiopeptin (BIM23014c) inhibits vascular smooth muscle cell migration in vitro via a G-protein-dependent, adenylyl cyclase-dependent inhibition of cAMP accumulation. Journal of Cardiovascular Pharmacology. 25:611-618 (1995).
14. D.L Mooradian, Tom Hutsell and Larry Keefer. NO-Donor molecules: Effect of release rate on smooth muscle cell growth inhibition in vitro. Journal of Cardiovascular Pharmacology. 25:674-678 (1995).
15. J.C. Huebsch, J.B. McCarthy, C.A. Diglio and D.L. Mooradian. Endothelial cell interactions with synthetic peptides from the carboxyl-terminal heparin-binding domains of fibronectin. Circulation Research. 77(1):43-53 (1995).
16. R.T. Tranquillo, T.S. Griton, B.A. Bromberek, T.G. Triebes, D.L. Mooradian. Magnetically-Oriented Tissue-Equivalent Tubes: Applications to a circumferentially-oriented media-equivalent. Biomaterials. 17:349-357 (1996).
17. J.C. Huebsch, T.G. Triebes, G.B. Fields, D.L. Mooradian. Surfaces modified with a photoreactive peptide from the carboxyl-terminal heparin-binding domains of fibronectin (FN-C/H-V) support endothelial cell adhesion and spreading. J. Biomech. Mater. Res. 32:555-567 (1996).
18. D.J. Smith, D. Chakravarthy, S. Pulfer, M.L. Simmons, J.A. Grabie, M.L. Cirto, J.E. Saavedra, K.M. Davies, T.C. Hutsell, D.L. Mooradian, S.R. Hanson, and L.K. Keefer. Nitric Oxide-Releasing Polymers Containing the [NO(O)NO]-Group. J. Med. Chem. 39(5):1148-1156 (1996).
19. A.S. Kohler, P.J. Parks, D.L. Mooradian, G.H.R. Rao, and L.T. Furcht. Platelet adhesion to novel phospholipid materials: Modified phosphotidylcholine covalently immobilized to silica, polypropylene and PTFE materials. J. Biomed. Mater. Res. 32(2):237-242 (1996).
20. T. Chandy, D.L. Mooradian, and G.H.R. Rao: Platelet adhesion and spreading on protein coated surfaces: Variations in behavior in washed cells, PRP and whole blood. Journal of Biomaterials Applications. 13(1):46-65 (1998).

21. T. Chandy, D.L. Mooradian, and G.H.R. Rao: Chitosan/polyethylene glycol-alginate microsapsules for oral delivery of hirudin. J. of Applied Polymer Science. 70:2143-2153 (1998).
22. T. Chandy, D.L. Mooradian, and G.H.R. Rao: Evaluation of modified alginate-chitosan-polyethylene glycol microcapsules for cell encapsulation. Artif. Organs. 23(10): 894-903 (1999).
23. Ogle and D.L Mooradian. The role of integrins in the smooth muscle cell-mediated compaction and strengthening of a tissue engineered blood vessel. Tissue Engineering. 5(4):387-401 (1999).
24. T. Pakalns, K.L. Haverstick, G.B. Fields, J.B. McCarthy, D.L. Mooradian and M. Tirrell. Cellular recognition of synthetic peptide amphiphiles in self-assembled monolayer films. Biomaterials. 20:2265-2279 (1999).
25. J.E. Saavedra, D.L. Mooradian, M. H. Schoenfish, K. A. Mowery, M. L. Citro, K. M. Davies, M. E. Meyerhoff, and L.K. Keefer. Conversion of polysaccharides to nitric oxide-releasing form: Dual mechanism anticoagulant activity of diazeniumdiolated heparin. Bioorg Med Chem Lett. 10(8):751-3 (200).
26. B.A. Weisenberg, and D.L. Mooradian. Hemocompatibility of materials used in micro-electromechanical systems: platelet adhesion and morphology in vitro. J Biomed Mater Res. 60(2):283-91 (2002).
27. B.M. Ogle and D.L. Mooradian. Manipulation of remodeling pathways to enhance the mechanical properties of a tissue engineered blood vessel. J Biomech Eng. 124(6):724-33 (2002).
28. Spector D, Perry Z, Konobeck T, Mooradian D, and S. Shikora. Comparison of hemostatic properties between collagen and synthetic buttress materials used in staple line reinforcement in a swine splenic hemorrhage model. Surg Endosc. 2011 Apr;25(4):1148-52. Epub 2010 Sep 11
29. Mooradian DL, Konobeck T, Kuester W and M. Bravo. Innovative Sutureless Microvascular Anastomtic Device with Embedded Doppler Monitor. Journal of Medical Devices. 8(2):020918. 2014

Books/Book chapters:

1. B. Ogle, P. Gairola, J. Balik and D.L. Mooradian: Tissue Engineering: A New Discipline at the Interface between Basic Science, Medicine and Engineering. The Journal of Minnesota Academy of Science. 63(2):29-41 (1998).

2. J.B. McCarthy, A.P.N. Skubitz, J. Iida, D.L. Mooradian, M.S. Wilke, and L.T. Furcht. Tumor cell adhesive mechanisms and their relationship to metastasis. Seminars in CANCER RESEARCH, Saunders Scientific Publications, Vol. 2, pp 155-167, 1991.
3. S. Hansen, T.C. Hutsell, L.K. Keefer, D.L. Mooradian, D.J. Smith. NO Donors: A Continuing Opportunity in Drug Design. Advances in Pharmacology. 34:383-398, 1996
4. D. Mooradian (Ed.) Extracellular Matrix-derived Implants in Clinical Medicine. Woodhead Publishing Series in Biomaterials. 2016 Elsevier Ltd.
5. D. Mooradian. Allografts and xenografts in soft tissue repair: current use and future trends. Chapter 4, pg 41-62 in Extracellular Matrix-derived Implants in Clinical Medicine. Woodhead Publishing Series in Biomaterials. Elsevier Ltd. 2016.

Abstracts:

1. K.C. Palmer, D.L. Mooradian, and C.A. Diglio. Cell line A549: Enhancement of differentiated type II cell function using mitomycin C. J. Cell Biol. 101(5)pt.2:489a (1986).
2. D.L. Mooradian and C. A. Diglio. Modulation of beta-TGF-like activity in the RCE-T1 cell line. Federation Proceedings. 46(3):676a (1987).
3. D.L. Mooradian, G.J. Spencer, J.B. McCarthy, and L.T. Furcht. Transforming growth factor-β 1 (TGF-β1) promotes metastatic cell invasion in vitro. J. Cell Biol. 107(6, Pt.3):597a (1988).
4. D.L. Mooradian, J.B. McCarthy, G.J. Spencer, A.F. Purchio, and L.T. Furcht. Differential effects of transforming growth factor-β1 on metastatic cell growth and invasion in vitro. Cancer and Metastasis Reviews. 8(3):102a (1989).
5. L.T. Furcht, A.P.N. Skubitz, A. Charonis, E. Tsilibary, J.B. McCarthy, and D.L. Mooradian. Molecular control of metastatic tumor cell adhesion and migration. Cancer and Metastasis Reviews. 8(2):174 (1989).
6. D.L. Mooradian, P. Trescony, K. Keeny, and L.T. Furcht. Binding and retention of fibronectin and laminin by Plasma TFE™ vascular graft material. 4th University of Minnesota Research Poster Session, Radisson University, Minneapolis, MN. May 4, 1990.

7. D.L. Mooradian, J. B. McCarthy, K.V., Komanduri, and L.T. Furcht. Effects of transforming growth factor-β on human adenocarcinoma cell adhesion, motility, and invasion in vitro. J. Cell Biol. 111(5:part 2), 85a (1990).
8. D.J. Cameron, D.L. Mooradian, and L.T. Furcht. Rabbit corneal epithelial cell adhesion to proteolytic fragments and synthetic peptides of fibronectin. J. Invest. Ophthalmol. and Vis. Sci. 32(4):1072 (1991).
9. D.L. Mooradian, P. Trescony, K. Kenny, and L.T. Furcht. Binding and retention of fibronectin and laminin by Plasma TFE™ vascular graft material. Transactions of the Society for Biomaterials. 14:85 (1991).
10. D.L. Mooradian, D.J. Cameron, and L.T. Furcht. Identification of a novel adhesion- and motility-promoting sequence from the heparin-binding domain of plasma fibronectin. J. Invest. Ophthalmol. and Vis. Sci. 33(4):1276 (1992).
11. L.T. Furcht, D.K. Olivero, A.P.N. Skubitz, J.B. McCarthy, M.S. Wilke, and D.L. Mooradian. A synthetic peptide approach to understanding the molecular basis of cell adhesion: Implications in cell/biomaterial interactions. Surfaces in Biomaterials Symposium. Minneapolis, MN. October, 1992.
12. D.L. Mooradian and Joseph Huebsch. Peptide/biomaterial hybrids as substrates for endothelial cell adhesion, spreading, motility and proliferation. Biomedical Interfacial Engineering Annual Program Review, September, 1992.
13. B. Fernandes, B. Lester, and D.L. Mooradian. Inhibition of smooth muscle cell migration by the somatostatin analog, angiopeptin: A possible mechanism of angiopeptin-mediated inhibition of intimal hyperplasia. Biomedical Engineering Society Annual Poster Session. Minneapolis, MN. June 1993.
14. J.C. Huebsch and D.L. Mooradian. Peptide/Biomaterial hybrids as substrates for endothelial cell attachment, spreading and migration. Biomedical Engineering Society Annual Poster session. Minneapolis, MN. June 1993.
15. L. Kidder, T. Eastlund, and D.L. Mooradian. Isolation and culture of human osteoblast progenitors from human fetal calvarium. American Association of Tissue Banks. Boston, MA. October 22-25, 1993.
16. L.S. Kidder, D.T. Eastlund, and D.L. Mooradian. Isolation and culture of osteoblast progenitors from human cadaveric bone marrow: Demonstration of in vitro bone-like nodule formation. American Association of Tissue Banks. Boston, MA. October 22-25, 1993.
17. E.J. Fogt and D.L. Mooradian. Investigation of Methods of Analysis of Antithrombin III Interactions with Heparinized Surfaces. University of Minnesota, CIE Fall Review, Minneapolis, MN. September 1993.

18. B. Fernandes, B. Lester, and D.L. Mooradian. Inhibition of vascular smooth muscle cell migration by the somatostatin analog, Angiopeptin: Possible role in angiopeptin-mediated inhibition of intimal hyperplasia. University of Minnesota, CIE Fall Review, Minneapolis, MN. September 1993.
19. T. Eastlund, W. Low, and D. L. Mooradian. Isolation and culture of human osteoblast progenitors from human fetal calvarium. Cell Transplantation. 3:238 (1994).
20. B. Fernandes, B. Lester, C. Diglio, and D.L. Mooradian. Inhibition of vascular smooth muscle cell migration by the somatostatin analogue, angiopeptin. The FASEB Journal. 8(4): A319 (1994).
21. D.L. Mooradian, T. Hutsell, and L. Keefer. Inhibition of human aortic smooth muscle cell proliferation by nitric oxide-releasing compounds. The FASEB Journal. 8(4): A538 1994.
22. S. Hanson, T. Hutsell, L. Keefer, D. L. Mooradian, and D. Smith. Nitric Oxide-donors: A continuing opportunity in drug design. Conference on the Biochemistry and Molecular Biology of Nitric Oxide, Los Angeles, CA (1994).
23. D.L. Mooradian, T. Hutsell, and L. Keefer. Novel Nitric oxide-releasing compounds inhibit vascular smooth muscle cell proliferation in vitro. Cell of Molecular Biology Training Grant Spring Symposium, Just say NO. Minneapolis, MN. May 21, 1994.
24. R.T. Tranquillo, T.S. Gerton, G. Triebes, D.L. Mooradian. Characterization of an oriented bioartificial artery. Biomedical Engineering Society Annual Meeting, Tempe, Arizona. October 1994.
25. T. Eastlund, W.C. Low, D.L. Mooradian. Isolation and culture of osteoblast progenitors from human fetal calvarium. 3rd European Conference on Tissue Banking and Clinical Application of Grafts. Vienna, Austria. October 4-7, 1994.
26. A.S. Kohler, D.L. Mooradian, P.J. Parks, G. Rao, L.T. Furcht. Grafting of modified phospholipids to glass: Evaluation of platelet interaction and analysis of surface morphology. Transactions of the Society for Biomaterials (1995).
27. E.J. Fogt, L. Cahalan, B.R. Lester, C.M. Brinkman, D.L. Mooradian. Development of a radioisotopic μwell assay for the study of antithrombin-III binding to heparinized biomaterials. Transactions of the Society for Biomaterials (1995).
28. T.S. Girton, G. Triebes, D.L. Mooradian, R.T. Tranquillo. Characterization of a magnetically-oriented bioartificial arterial media. ASAIO Cardiovascular Science and Technology Conference. Washington, DC., December 1994.

29. R.T. Tranquillo, T.S. Girton, B.A. Bromberek, G. Triebes, D.L. Mooradian. Magnetically-oriented tissue-equivalent tubes: Application to a circumferentially-oriented media-equivalent. American Society of Mechanical Engineers: Bioengineering Conference, Beaver Creek, Colorado 1995.
30. T.S. Girton, D.M. Knapp, D.L. Mooradian, R.T. Tranquillo. Determining the relative contributions of cells and collagen to isotropic and oriented tissue-equivalents. American Society of Mechanical Engineers: Bioengineering Conference, Beaver Creek, Colorado, 1995.
31. R.T. Tranquillo, T.S. Girton, B.A. Bromberek, T.G. Triebes and D.L. Mooradian. Magnetically-oriented tissue-equivalent tubes: Applications to a circumferentially-oriented media-equivalent. 2nd International Conference on Cell Engineering, 1995.
32. A.S. Kohler, D.L. Mooradian, P. Parks, G. Rao, L.T. Furcht. Grafting of modified phospholipids to glass: Evaluation of platelet interaction and analysis of surface morphology. Surfaces in Biomaterials Meeting, Minneapolis, MN, 1995.
33. L.K. Keefer, S.R. Hanson, D.L. Mooradian, D.J. Smith, S. Kaul, T. C. Hutsell. Localized nitric oxide (NO) delivery as an approach to preventing thrombosis and restenosis. IBC 2nd Annual Restenosis Conference, Washington, DC. October 1995.
34. T. Chandy, D.L. Mooradian and G.H.R. Rao. Pericardial Calcification: Changes due to PEG grafting and antiplatelet therapy. Interfacing Biomaterial Science and Tissue Engineering, University of Minnesota, September 1997.
35. P. Gairola, T.Chandy, G.H.R. Rao, and D.L. Mooradian. Influence of Fluid Shear and Blood Components on Platelet Attachment to Surfaces Coated with an OVA-Conjugate of FN-C/H-V. Interfacing Biomaterial Science and Tissue Engineering, University of Minnesota, September 1997.
36. B. M. Ogle, and D.L. Mooradian. Role of Integrins in the Spontaneous Compaction of a Collagenous Bioartificial Artery. Interfacing Biomaterial Science and Tissue Engineering, University of Minnesota, September 1997.
37. B. M. Ogle, and D.L. Mooradian. The Role of Integrins in Regulating Smooth Muscle Cell-Medicated Compaction of a Bioartificial Media. Society for Biomaterials Annual Meeting (San Diego, CA), April 1998.
38. T. Pakalns, K. Haverstick, J.B. McCarthy, D.L. Mooradian and M. Tirrell. Cellular Recognition of Synthetic Peptide Amphiphiles in Supported Bioartificial Membranes. ACS National Meeting, Boston, MA. August 1998.

39. T. Palkalns, K.. Haverstick, J.B. McCarthy, D.L. Mooradian, and M. Tirrell. Cellular Recognition of Synthetic Peptide Amphiphiles in Supported Bioartificial Membranes. AIChE Annual Meeting, Miami Beach, FL., November 1998.

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42. L. Durhman, C. Zimmerman, and D.L. Mooradian. Development of a One-Compartment Pharmacokinetic Model for the Delivery of NO-donor Compounds via Polymeric Systems. Society for Biomaterials, Providence, Rhode Island, April 1999.

43. B. Ogle and D.L. Mooradian. Ascorbic Acid and Retinoic Acid Influence the Mechanical Compliance of a Tissue-Engineered Blood Vessel. Sixth World Biomaterials Congress, Kamuela, Hawaii. May 1999.

44. B.N. Oray, A. Lambert, R. Wonsetler and D.L. Mooradian. Physical and Biochemical Characterization of a Novel Non-Crosslinked, Propylene Oxide-Treated Acellular Collagen Matrix: Comparison with Solvent Extracted and Freeze-Dried Cadaveric Fascia Lata. Society for Urology and Engineering Annual Meeting, Orlando, FL, May 2002.

45. D.L. Mooradian, A. Lambert, R. Wonsetler, and B.N. Oray. Residual DNA in Biological Sling Materials: A Comparison between PO-Treated Bovine Pericardium, Processed Human Dermis, and Solvent Extracted and Freeze-Dried Cadaveric Fascia Lata. Society for Urology and Engineering Annual Meeting, Orlando, FL, May 2002.

46. B.N. Oray, A. Lambert, R. Wonsetler and D.L. Mooradian. Physical and Biochemical Characterization of a Novel Non-Crosslinked, Propylene Oxide-Treated Acellular Collagen Matrix: Comparison with Solvent Extracted and Freeze-Dried Cadaveric Fascia Lata. South Central Section – American Urology Association Annual Meeting, Colorado Springs, Colorado, October 2002.

47. D.L. Mooradian, A. Lambert, R. Wonsetler, and B.N. Oray. Residual DNA in Biological Sling Materials: A Comparison between PO-Treated Bovine Pericardium, Processed Human Dermis, and Solvent Extracted and Freeze-Dried

Cadaveric Fascia Lata. South Central Section – American Urology Association Annual Meeting, Colorado Springs, Colorado, October 2002.

Patents (Eight of 20+ patents and applications world-wide):

1. US Pat. No. 5,711,959 “Biocompatible Materials”
2. US Pat. No. 5,853,744 “Solid-Phase Method for Attaching a Biomolecule to a Substrate Surface with a Photo-reactive Crosslinking agent”
3. US Pat. No. 6,057,137 “Tissue-Equivalent Rods Containing Aligned Collagen Fibrils and Schwann cells”
4. US Pat. No. 6,194,182 “Magnetically Oriented Tissue-Equivalent and Biopolymer Tubes”
5. US Pat. No. 7,128,748 “Circular Stapler Buttress Combination”
6. US Pat. No. 7,144,588 “Method of Preventing Surgical Adhesions”
7. US Pat. No. 7,192,400 “Device and Method for Vascular Monitoring“
8. US Pat. No. 7,776,060 “Circular Stapler Buttress Combination”

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	FY 2018 PROGRAM PRIORITIES ADOPTION
DATE:	NOVEMBER 22, 2017

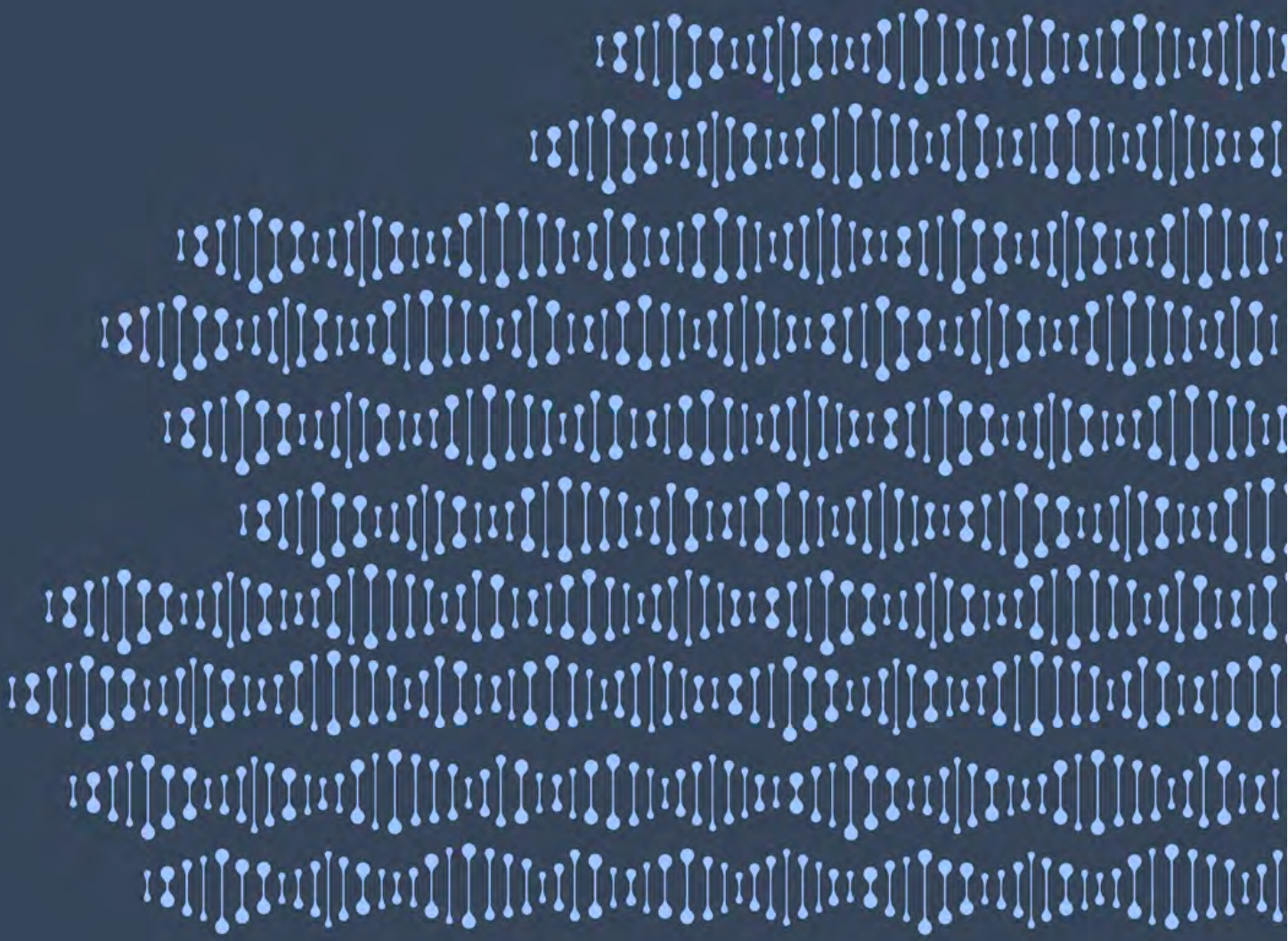
The Oversight Committee (OC) previously approved plans for the release of FY 2018 Requests for Proposals (RFAs). Those RFAs reflected the priorities proposed for 2018 and no changes to the program priorities were noted. However, to comply with state law FY 2018 Program Priorities must be formally adopted.

The discussion and adoption of priorities for FY 2019 will occur in January. FY 2019 is the last year of full funding. The discussions of priorities for FY 2019 and beyond will be informed by annual projections of funds available for grants through 2022 (the last year in which CPRIT can make new grant awards). Declining funds available for grants each year will affect the number and types of RFAs for each program. This will begin the discussion of how CPRIT's award programs are phased down as we approach the Sunset Year of 2023.

The proposed FY 2018 Program Priorities behind this memo are identical to those approved for FY 2017. I recommend reapproval of the FY 2017 Program Priorities for FY 2018. I further recommend that we prepare for the FY 2019 Program Priorities as outlined in the CEO report under Agenda Item 7.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Program Priorities 2018



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ABOUT CPRIT PROGRAM PRIORITIES PROJECT

CPRIT is governed by Health and Safety Code: Chapter 102. Legislation from the 83rd Texas Legislature modified that code to include enhancements to CPRIT's governance and operations. One of the specific enhancements requires CPRIT's Oversight Committee to establish program priorities on an annual basis. The priorities are intended to provide transparency in how the Oversight Committee directs the orientation of the agency's funding portfolio between and within its three programs as well as guide CPRIT staff and Review Councils 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 priorities are to be reviewed and adjusted annually as circumstances change and new information is found concerning cancer-related advances in prevention, academic research and product development research.

CPRIT Purpose

Health and 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

Health and 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 approved the 2015 program priorities in November 2014 after a six-month process that included subcommittee meetings and public input. The program priorities were subsequently incorporated into the requests for applications released by each program. The Oversight Committee reaffirmed the program priorities for 2017 in November 2016. In the fall of 2017 the Oversight Committee Subcommittees worked with the Program officers and respective Advisory Committees to review and update the program priorities for 2018.

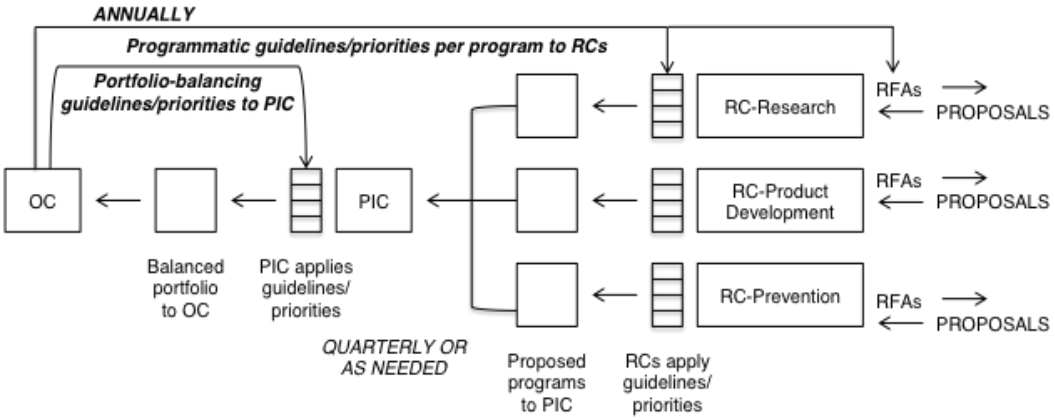
SCOPE OF PROGRAM PRIORITIES PROJECT

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 set out to establish 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 as a result of recruiting researchers, training health care/science professionals, attracting companies and supporting investigator startups.

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 Requests for Applications (RFAs) and evaluation of applications to those RFAs.

CPRIT's three programs are currently guided by established key principles essential to executing CPRIT's purpose. The main principle underlying all three programs is that they will continue to ensure only applications with scientific merit will move forward in CPRIT's peer review grant process. In addition, the programs have established principles that are unique to each program. The new program priorities will 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 information 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 particular emphasis on population disparities and cancers of significance in Texas (e.g. lung, liver, and cervical cancers).

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
- Targeting underfunded areas
- 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 • Prevention and early detection • Computational biology and analytic methods • Childhood cancers • Population disparities and cancers of importance in Texas

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:

- Are evidence based – offering effective prevention interventions based on the existing body of knowledge about and evidence for cancer prevention.
- Deliver primary, secondary, or tertiary (includes survivorship) prevention interventions – providing 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.

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

- Potential for impact
- Geographic distribution
- Cancer type
- 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.

Data on cancer incidence, mortality and disparities (geographic, ethnic, etc.) are reviewed 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

Product Development Research

Background:

The Product Development Research Program funds private companies to develop products that benefit cancer patients. Developing novel cancer treatments results from a series of research and development activities.

1. Basic research provides understanding of biological principles, the causal factors of disease, the natural history of disease progression and how disease may be cured or ameliorated. Basic research is typically conducted in a university setting funded primarily by government grants.
2. Applied research involves inquiry involving the practical application of science. In CPRIT's context it demonstrates methods to diagnose or treat disease. Scientists typically conduct applied research in a university setting using government and/or private funds. Promising technologies may be patented and licensed to private companies for continued development or spun out from the university in nascent companies for development.
3. The process of product development converts a one-time phenomenon to a safe and reliable product usable in a clinical setting.
4. Clinical research confirms the safety and efficacy on the target patient population.
5. Regulatory approval is required prior to commercial use. Product development, clinical research and regulatory approval are historically undertaken by startup companies funded by private investors and, in recent years, by the public sector to promote economic development.

As a product moves through this process, risks are reduced at each step. Earlier stage programs have higher risk and are the least likely to attract private capital. CPRIT typically invests in early stage companies where private capital is hardest to obtain. CPRIT uses subject matter expert peer reviewers to identify the most promising projects. CPRIT's investment in early stage companies increases the number of cancer therapies in development in Texas thereby stimulating the Texas life sciences ecosystem.

CPRIT uses its limited resources to maximize clinical benefits including curing disease, slowing progression, earlier detection, mitigating side effects, and/or reducing cost of care. More scientifically and commercially attractive product development opportunities exist than CPRIT can fund. Therefore, to invest strategically the Product Development Research focuses on the following:

Novel Projects

1. Novel ideas that offer therapeutic or diagnostic benefits not currently available; i.e., disruptive technologies.
2. Projects addressing large or challenging unmet medical needs.
3. Projects based on sound scientific research, with strong management and compelling business plans that will be attractive to private investment.
4. Early stage projects when private capital is most difficult to obtain.

Grow the Ecosystem

1. Catalyze the Texas life sciences ecosystem by supporting new company startups in Texas or attracting promising companies to Texas.
2. Identify 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.
3. Support commercialization of technologies developed at Texas institutions.

Established Principles:

- Support commercial development of novel products that address unmet cancer diagnosis and treatment needs.
- Stimulate the Texas life sciences ecosystem by funding in spaces that lacks private investment (the technology "Valley of Death" subsequent to research grants but before private investment).
- Invest in projects based on sound scientific research with strong management and sound business plans that will attract future private investment.

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 could have an impact and distinguish it from other funding sources provides a basis for focusing resources and guiding decisions when resources are limited. 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, attempts to control cancer by chemotherapy, radiation, and even targeted therapy have been thwarted by the ability of cancer cells to develop resistance to these treatment modalities. Detecting cancer early in its development is a more desirable approach to cancer control. In spite of 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 would create the evidence base for new approaches to prevention and early detection, product development research would provide new methods, diagnostics, imaging or devices for early cancer detection, and the prevention program would implement interventions to put these new approaches into practice once a solid evidence base of effectiveness exists. Strategies would 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. Research and development are needed between the stages of discovery science, traditionally funded by grants from federal sources and foundations, and late term development and commercialization of drugs, devices, diagnostic tests, and biologicals traditionally funded by private sector industries. Data indicate that such 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 new 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 in which pre- and post-doctoral fellows are educated 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 can take time, jobs and economic activity are generated throughout the process. 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

Below is a table illustrating how each of CPRIT's three programs could 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 new 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 new 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.

Cancer Research and Prevention Institute of Texas
2018 Interanl Audit Plan
October 2017

Audit Area	Risk Rating	Summary Procedures	Audit Focus	Timing
2018 Planned New Internal Audits				
Post Award Grant Monitoring	High	Internal Audit will include an evaluation of risks and internal controls in place related to CPRIT's Grant Contracting and Post-Award Grant Monitoring practices. Activities to be evaluated will include Fund Availabiltiy, Certifications, Contract Terms, Grant Contract Execution, Grantee Monitoring, Sub-Recipient Monitoring, Grantee Reporting, and Scientific Review.	Internal Audit	December 4 - 15, 2017
Grant Contracting	Moderate			
State Reporting	High	Internal Audit will include an evaluation of risks and internal controls in place related to CPRIT's State Reporting practices. Activities to be evaluated will include Annual Reporting, Research/Analytical Supporting, Texas Caner Plan, State Reporting, Public Information Act Requests, and Ad Hoc Reporting.	Internal Audit	May 14 - 25, 2018
Information Technology Services	High	Internal Audit will include an evaluation of risks and internal controls in place related to CPRIT's Information Technology Services practicies. Activities to be evaluated will include Network Operations, Help Desk, Change Management, Website Maintenance and Monitoring Third Party Providers.	Internal Audit	February 12 - 23, 2018
Communications	Moderate	Internal Audit will include an evaluation of risks and internal controls in place related to CPRIT's Communications practices. Activities to be evaluated will include Website Content Compliance, Newsletter/Listserv, Granteee Communications, Achievement Report, Media Relations, and Publicly Available Information.	Internal Audit	March 12 - 23, 2018
2018 Planned Internal Audit Follow-up				
Procurment and P-Cards	High	Internal Audit will perform follow-up procedures on the 9 open findings from the 2017 Internal Audit to ensure corrective action has been taken.	Follow-up	April 9 - 13, 2018
Pre-Award Grant Management	High	Internal Audit will perform follow-up procedures on the 3 open findings from the 2017 Internal Audit to ensure corrective action has been taken.	Follow-up	March 26 - 28, 2018
Training	Moderate	Internal Audit will perform follow-up procedures on the 2 open findings from the 2017 Internal Audit to ensure corrective action has been taken.	Follow-up	January 8 - 12, 2018
Internal Agency Compliance	Moderate	Internal Audit will perform follow-up procedures on the 1 open findings from the 2017 Internal Audit to ensure corrective action has been taken.	Follow-up	January 8 - 12, 2018
Information Security	High	Internal Audit will perform follow-up procedures on the 7 open findings from the 2017 Internal Audit to ensure corrective action has been taken.	Follow-up	January 15 - 19, 2018
2018 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 to the Audit Committee of internal audit activities.	Policy Compliance	Ongoing

10-1

Cancer Prevention and Research Institute of Texas
Internal Audit of Post-Award Grant Management and Grant Contracting
Internal Audit Risk Coverage
October 2017

Scope: The audit will focus on CPRIT's Post-Award Grant Management and Grant Contracting processes. We will evalaute the following sub-processes:

- Contract Execution
- Contract Compliance
- Financial Reporting
- Grantee Reporting
- Compliance Monitoring
- Contract Extension
- Contract Closeout
- Grant Funding Closeout

Monitored Risks

Post-Award Grant Management and Grant Contracting		
Process Area	**Risks Monitored**	
Contract Execution	1	Award commitments/contracts are appropriately authorized by the Oversight Committee
	2	Use of standard contract templates are appropriate and approved
	3	Deviations to standard and required contract terms are appropriate and approved
	4	Contracts clearly define compliance requirements and include State requirements
	5	Contract renewals are validated via the RFA process
	6	Required certifications are reviewed and approved prior to contract execution
	7	Contract amendments and revisions are appropriately reviewed and approved
Contract Compliance	8	State grant laws and regulations are met
	9	Arrangements allowing self-dealing or kickback payments are not in place
	10	Conflicts of interest by the grantee have been identified and reported
	11	Contract records are adequately documented and retained
Financial Reporting	12	Reimbursement requests are reviewed and approved
	13	Costs charged to CPRIT grants are monitored by CPRIT personnel
	14	Grant distributions are approved prior to disbursement
	15	Periodic grant financial monitoring procedures regarding budgets, coding, and fixed assets are performed
	16	Use of matching funds is reviewed and validated for completeness and accuracy
	17	Financial reports and audits from grantees are reviewed and potential irregularities and exceptions are investigated
Grantee Reporting	18	Reports submitted by grantees to CPRIT are monitored for completeness, accuracy and timeliness
	19	Programmatic/scientific assessments of progress reports are conducted with results accepted
	20	Reports are reviewed for compliance with contract terms
	21	Cost analysis of program progress is performed on grantee reported results
Compliance Monitoring	22	Grantees receive onboarding and periodic compliance and management training
	23	Costs charged to CPRIT grants are monitored by CPRIT personnel
	24	Use of matching funds is reviewed and validated for completeness and accuracy
	25	Grantee policies and procedures are reviewed by CPRIT
	26	Grantee accounting systems are reviewed for sufficiency by CPRIT
	27	Grantee segregation of duties is assessed
	28	Grantee procurement practices are reviewed to ensure appropriate use of CPRIT funds
	29	Grantees have appropriate controls and monitoring of inventory purchased with grant funds
	30	Agreements with subcontractors include all CPRIT contractual requirements and administrative regulations
	31	Grantees have procedures in place to monitor subcontractors for compliance
	32	Corrective action follow-up performed for grantees and sub-contractors with deficiencies
Contract Extension	33	Grantee financial and programmatic performance is evaluated prior to extensions
	34	Extensions are reviewed and approved
Contract Closeout	35	Services and fund expenditures are verified prior to closeout
	36	All open requests for reimbursement are validated and reconciled
	37	Grant and grantee documents are archived and retained
	38	Final grantee progress report evaluations are performed
Grant Funding Closeout	39	Final progress reports are verified prior to contract close-out
	40	Grant funds are reconciled by funding source prior to close-out
	41	Close-out final payments are approved

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: KRISTEN PAULING DOYLE, GENERAL COUNSEL
CAMERON L. ECKEL, STAFF ATTORNEY CHAPTER 703

SUBJECT: RULE CHANGE PROPOSED FOR FINAL ADOPTION

DATE: NOVEMBER 16, 2017

Summary and Recommendation

The Board Governance Subcommittee recommends that the Oversight Committee adopt the proposed administrative rule change to § 703.13 as originally considered at the August 2017 meeting. A proposed amendment to § 703.26 was also considered during the August meeting, but CPRIT recommends that rule change be modified based on public comments received and republished. Once the Oversight Committee approves the final order adopting the rule change, CPRIT will submit the amendment to the Secretary of State and the change will be considered final and effective 20 days later.

Discussion

State law requires an agency to set policy using a rulemaking process, which includes an opportunity for public comment on proposed rules and rule changes before the agency formally adopts the policy.

The Oversight Committee approved publication of proposed rule amendments §§ 703.13 and 703.26 at the August meeting. CPRIT published the proposed rules in the *Texas Register* and made the rules available on the agency's website. CPRIT received two comments from the public related to the proposed change to unallowable costs in § 703.26(e). Both parties indicated that the description of the proposed unallowable expense may be overly broad. Based on the comments, CPRIT recommends that the Oversight Committee not adopt the proposed change to § 703.26 as published on September 1st. No comments were received regarding § 703.13.

The Board Governance Subcommittee met on November 2nd to review the final order with CPRIT's General Counsel. The Subcommittee recommends the Oversight Committee approve the final order adopting the proposed rule change.

Next Steps

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

TITLE 25. HEALTH SERVICES

PART 11. CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CHAPTER 703. Grants for Cancer Prevention and Research

The Cancer Prevention and Research Institute of Texas ("CPRIT" or "the Institute") adopts the amendment to § 703.13. The proposed change clarifies that a grant recipient must maintain grant records and allow inspection of grant records for a period of three years. The proposed amendment was published in the September 1, 2017, issue of the *Texas Register* (42 TexReg 4453).

Reasoned Justification

The proposed change to § 703.13(a) clarifies that a grant recipient must maintain records related to a grant project for a period of three years following the date of the last disbursement of grant funds made by the Institute or the date when all reports are submitted to and approved by the Institute, whichever is later. Currently, the Institute's administrative rules are silent on the grant recipient's record retention obligations and the rule provides needed guidance for grant recipients. Section 703.13 is further amended to require a grant recipient to allow inspection of grant records for a period of three years following the date of the last disbursement of grant funds made by the Institute or the date when all reports are submitted to and approved by the Institute, whichever is later. Currently, the audit period is up to three years following the end of the grant recipient's fiscal year during which the grant contract was terminated. This proposed change will provide uniformity between the inspection period and the proposed term for grant recipient's records retention obligations.

Summary of Public Comments and Staff Recommendation

CPRIT received no public comments regarding the proposed amendment to § 703.13.

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

Certification

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

To be filed with the Office of Secretary of State on December 1, 2017.

703.13 Audits and Investigations

(a) Upon request and with reasonable notice, an entity receiving Grant Award funds directly under the Grant Contract or indirectly through a subcontract under the Grant Contract shall allow, or shall cause the entity that is maintaining such items to allow the Institute, or auditors or

investigators working on behalf of the Institute, including the State Auditor and/or the Comptroller of Public Accounts for the State of Texas, to review, inspect, audit, copy or abstract its records pertaining to the specific Grant Contract during the term of the Grant Contract and for the three year period following the date the last disbursement of funds is made by the Institute or all reports required pursuant to the Grant Contract are submitted and approved, whichever date it later.

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

(2) The Grant Recipient may maintain its records in either electronic or paper format.

(b) Notwithstanding the foregoing, the Grant Recipient shall submit a single audit determination form within 60 days of the anniversary date of the Grant Contract effective date. The Grant Recipient shall report whether the Grant Recipient has expended $750,000 or more in state awards during the Grant Recipient's fiscal year. If the Grant Recipient has expended $750,000 or more in state awards in its fiscal year, the Grant Recipient shall obtain either an annual single independent audit, a program specific independent audit, or an agreed upon procedures engagement as defined by the American Institute of Certified Public Accountants and pursuant to guidance provided in subsection (e).

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

(2) The audit must be submitted to the Institute within 30 days of receipt by the Grant Recipient but no later than 270 days following the close of the Grant Recipient's fiscal year and shall include a corrective action plan that addresses any weaknesses, deficiencies, wrongdoings, or other concerns raised by the audit report and a summary of the action taken by the Grant Recipient to address the concerns, if any, raised by the audit report.

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

(B) The Grant Recipient's request for additional time must be submitted on or before the due date of the required audit and corrective action plan. For purposes of this rule, the "due date of the required audit" is no later than the 270th day following the close of the Grant Recipient's fiscal year.

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

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

during the pendency of the delinquency unless the Institute's approval declines to permit reimbursements or advances of Grant Award funds until the delinquency is addressed.

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

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

(1) The option to perform an agreed upon procedures engagement is intended for a non-profit or for-profit Grant Recipient that is not subject to Generally Accepted Government Audit Standards (also known as the Yellow Book) published by the U.S. Government Accountability Office.

(2) The agreed upon procedures engagement will be conducted in accordance with attestation standards established by the American Institute of Certified Public Accountants.

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

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

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

(A) Processes and controls;

(B) The Grant Contract;

(C) Indirect Costs;

(D) Matching Funds, if appropriate;

(E) Grant Award expenditures (payroll and non-payroll related transactions);

(F) Equipment;

(G) Revenue Sharing and Program Income;

(H) Reporting; and

(I) Grant Award closeout.

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

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

To:	**OVERSIGHT COMMITTEE MEMBERS**
From:	**KRISTEN PAULING DOYLE, GENERAL COUNSEL** **CAMERON L. ECKEL, STAFF ATTORNEY**
Subject:	**CHAPTERS 701 AND 703 PROPOSED RULE CHANGES**
Date:	**NOVEMBER 16, 2017**

Summary and Recommendation

The Board Governance Subcommittee recommends that the Oversight Committee approve the proposed administrative rule changes. The proposed changes affect Texas Administrative Code Chapters 701 and 703. After approval, CPRIT will publish the proposed changes in the *Texas Register* for public comment.

Discussion

CPRIT's administrative rules set policy guiding CPRIT's grant review and grant contracting processes. State law requires agencies to use a rulemaking process, which includes an opportunity for the public to comment on proposed rules and rule changes before the agency adopts the final policy.

The Board Governance subcommittee met on November 2nd to discuss the proposed rule changes with legal staff.

- The first proposed change is new rule § 701.37 requiring grant recipients to follow the requirements of the State of Texas travel policy administered by the Texas Comptroller of Public Accounts for travel expenses CPRIT reimburses grantees with grant award funds. The new rule also describes the appropriate documentation that must be submitted to support travel expense reimbursement requests and provides guidance regarding special requirements for international travel expenses to be reimbursed with CPRIT grant funds.
- The second proposed change, to § 703.26, prohibits payment by a grantee to a subcontractor if the subcontractor employs an individual who is a relative of key personnel employed by the grantee and working on the same grant project. The expense is unallowable if grant funds are used to pay any portion of the relative's salary or the relative is responsible for submitting on behalf of the subcontractor expenses to be paid by the grantee. A grantee may request that the Institute's Chief Executive Officer allow an exception to allow payment to a subcontractor that employs a relative. If the Chief

Executive Officer grants an exception, he must notify the Oversight Committee in writing. If a grant recipient has stricter internal policies concerning this issue, then this proposed amendment will not supersede those policies. The purpose of this proposed rule change is to reduce potential conflicts of interest between a grant recipient and a subcontractor.

The subcommittee voted to recommend approval and publication of the two rule changes to the Oversight Committee.

Next Steps

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

TITLE 25. HEALTH SERVICES

PART 11. CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CHAPTER 701. Policies and Procedures

The Cancer Prevention and Research Institute of Texas (Institute) proposes a new rule § 701.37. The proposed new rule outlines travel policy requirements for grant recipients.

Background and Justification

The proposed new rule § 701.37 requires grant recipients to follow the requirements of the State of Texas travel policy administered by the Texas Comptroller of Public Accounts for travel expenses to be reimbursed with CPRIT grant award funds. The new rule also describes the appropriate documentation that must be submitted to support travel expense reimbursement requests and provides guidance regarding special requirements for international travel expenses to be reimbursed with CPRIT grant funds.

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 changes are 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 new rule is in effect the public benefit anticipated due to enforcing the rule will be the clarification of what the Institute considers appropriate travel expenses reimbursed with grant funds and the required supporting documentation.

Small Business and Micro-Business Impact Analysis

Ms. Doyle has determined that the rule change will not affect small businesses or micro businesses.

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 sections will be in effect:

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

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

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

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

(5) the proposed rule will create a new rule;

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

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

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

Submit written comments on the proposed new rule 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 15, 2018. The Institute asks parties filing comments to indicate whether they support the proposed rule revision and, if a change is requested, to provide specific text proposed to be included in the rule. Comments may be submitted electronically to kdoyle@cprit.texas.gov. Comments may be submitted by facsimile transmission to 512/475-2563.

Statutory Authority

The Institute proposes this new rule 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 this rule.

Rule § 701.37 Grant Recipient Travel Policy

(a) Travel costs for Grant Recipients are allowable based on the State of Texas travel policy, administered by the Texas Comptroller of Public Accounts, provided that costs are deemed by the Institute to be reasonable and necessary. The Institute will not reimburse a Grant Recipient for travel expenses in an amount that exceeds the standards in the State of Texas travel policy.

(b) Grant Recipients must provide adequate supporting documentation when requesting reimbursement for travel expenses on a Financial Status Report pursuant to § 703.24.

(1) A separate travel expense report should be submitted for each trip taken.

(2) Meal costs may be charged on an actual cost basis or on a per diem, provided that one method is used uniformly on an entire trip.

(3) Lodging expenses must be supported with either a receipt or, if a receipt is unavailable, the canceled check or credit card slip used to pay the lodging expense, the credit card billing on which the lodging charges appear, or a copy of the check, slip or billing.

(4) Mileage must be supported with a detailed record of actual point-to-point mileage with odometer readings or copies of mapping website mileage. Mileage should not be rounded to the nearest decimal point.

(5) Transportation expenses must be supported with a receipt or itinerary, if neither is available then a Grant recipient should provide the canceled check or credit card slip used to pay for the transportation, the credit card billing on which the transportation charges appear or a copy of the receipt, check, slip or billing.

(6) Rental of motor vehicles must be supported by a receipt and/or rental contract.

(7) Incidental expenses must be supported by an itemization of the expenses incurred.

(c) International travel must either be part of the Grant Recipient's approved budget in the Grant Contract or the Grant Recipient must receive prior approval from CPRIT for the international travel if the international travel is added to the budget subsequently.

(1) International travel costs may be reimbursed according to the United States Department of State rates, if the costs are deemed by CPRIT to be reasonable and necessary.

(2) Grant Recipients should submit requests for reimbursement in United States dollar amounts. If the original cost is in a foreign currency, the Grant Recipient must convert the cost to a dollar amount and provide documentation of the exchange rate used for the conversion.

(d) Nothing herein prohibits a Grant Recipient from a having more restrictive internal travel policy requirements.

TITLE 25. HEALTH SERVICES

PART 11. CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CHAPTER 703. Grants for Cancer Prevention and Research

The Cancer Prevention and Research Institute of Texas (Institute) proposes an amendment to § 703.26. The proposed change expands the list of unallowable costs to include payments by a grant recipient to a subcontractor that employs a relative of the grant recipient's key personnel working on the same project.

Background and Justification

The proposed change to § 703.26(e) prohibits payment by a grant recipient to a subcontractor if the subcontractor employs an individual who is a relative, as defined by Texas Administrative Code § 701.3(57), of key personnel employed by the grant recipient and working on the same grant project. The expense is unallowable if the grant recipient uses grant funds to pay the subcontractor for any portion of the relative's salary or the relative is responsible for submitting on behalf of the subcontractor expenses for payment by the grant recipient. The grant recipient may request that the Institute's Chief Executive Officer allow an exception to allow payment to a subcontractor that employs a relative. If the Chief Executive Officer grants an exception, he must notify the Oversight Committee in writing. If a grant recipient has stricter internal policies concerning this issue then this proposed amendment will not supersede those policies. The purpose of this proposed rule change is to reduce potential conflicts of interest between a grant recipient and a subcontractor.

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 the clarification of what the Institute will consider unallowable expenses and the reduction of potential conflicts of interest in the payment of grant funds.

Small Business and Micro-Business Impact Analysis

Ms. Doyle has determined that the rule change will not affect small businesses or on micro businesses.

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 section 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 rules;

(6) the proposed rule change will expand existing rules;

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

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

Submit written comments on the proposed rule change to Ms. Kristen Pauling Doyle, General Counsel, Cancer Prevention and Research Institute of Texas, P. O. Box 12097, Austin, Texas 78711, no later than January 15, 2018. The Institute asks parties filing comments to indicate whether they support the rule revision proposed by the Institute and, if a change is requested, to provide specific text proposed to be included in the rule. Comments may be submitted electronically to kdoyle@cprit.texas.gov. Comments may be submitted 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. Kristen Pauling Doyle, the Institute's General Counsel, 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.

(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 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 the Grant Recipient or an individual.

(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:

(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.

(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.

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

(f) The Institute is responsible for making the final determination regarding whether an expense shall be considered an Allowable Cost.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

To:	**OVERSIGHT COMMITTEE MEMBERS**
From:	**HEIDI MCCONNELL, CHIEF OPERATING OFFICER**
Subject:	**CHIEF OPERATING OFFICER REPORT**
Date:	**NOVEMBER 15, 2017**

CPRIT Financial Overview for FY 2017, Quarter 4

FY 2017, Quarter 4 Operating Budget

CPRIT expended or obligated approximately $2.5 million in Indirect Administration during the year and approximately $12.9 million in Grant Review and Award Operations, which is about 92% of the overall administrative budget for the fiscal year. Invoices for goods and services provided during FY 2017 continue to come in after the fiscal year ends, so there will be additional expenditures recognized against the agency's FY 2017 budget. In addition, we notified the Legislative Budget Board and the Governor's Office at the end of August that the agency is carrying forward $731,882 in unexpended balances into FY 2018 for information technology software, hardware, and related support services as well as for five agency service contracts.

During the fourth quarter, the agency received $56,821 in revenue sharing payments. Of this amount $18,126 was deposited into General Revenue Fund 0001 in June for general use by the state. The remaining amount of $38,695 was deposited into the new Cancer Prevention and Research Interest and Sinking Fund 5168 created in July 2017. H.B. 3849, passed during the 2017 legislative session and signed by the Governor in June, allowed the Comptroller of Public Accounts to create this account in the state treasury. Total revenue sharing payments received in FY 2017 were $99,013.

FY 2017, Quarter 4 Performance Measure Report

CPRIT reported on its five key performance measures—two quarterly and three annual—to the Legislative Budget Board. CPRIT met or exceeded performance on four out of five measures. It did not meet performance on the product development measure for company relocations to Texas because no company grant recipients relocated to Texas during the fourth quarter or at any point during the year.

Debt Issuance History

CPRIT has not requested any additional debt issuances since February 2017 when TPFA issued $269 million of general obligation bonds on CPRIT's behalf. This was the total amount of funding that CPRIT required for operating expenses and grant award obligations for the year.

State Financial and Procurement Reports

I and my staff have completed or are completing the following reports due in November and December to various state oversight agencies:

1) Annual Financial Report for the Year Ended August 31, 2017, due November 20th – submitted November 15, 2017
2) Audited Financial Statements for the Year Ending August 31, 2017, due December 20th – McConnell & Jones LLP is finalizing the audit report and a special Audit Subcommittee meeting is scheduled December 4, 2017, for the audit team to present the final report
3) FY 2018 Operating Budget due December 1st – in progress
4) Historically Underutilized Business (HUB) Biennial Report for 2018-19 due December 1st – in progress
5) FY 2018 State Agency Procurement Plan due December 1st – in progress

Cancer Prevention and Research Institute of Texas
Quarterly Financial Report
As of August 31, 2017

Indirect Administration (B.1.1.)

		2017 Appropriated	2017 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
1001	Salaries and Wages	$ 1,432,617	$ 1,347,500		$ 1,271,245	76,255	94%	$ 1,271,245	$ 76,255
1002	Other Personnel Costs	52,785	67,785		57,197	10,588	84%	57,197	10,588
2001	Professional Fees and Services	807,317	877,434		817,894	59,540	93%	817,894	59,540
2003	Consumable Supplies	27,584	27,584		13,634	13,950	49%	13,634	13,950
2004	Utilities	58,577	43,577		15,897	27,680	36%	15,897	27,680
2005	Travel	45,000	45,000		28,959	16,041	64%	28,959	16,041
2006	Rent-Building	-	18,408		18,408	0	0%	18,408	0
2007	Rent-Machine and Other	32,172	34,207		28,106	6,101	82%	28,106	6,101
2009	Other Operating Expenses	574,600	569,157		296,652	272,505	52%	296,652	272,505
	Subtotal - Indirect Administration (B.1.1.)	**$ 3,030,652**	**$ 3,030,652**	**1.02%**	**$ 2,547,992**	**$ 482,660**	**84%**	**$ 2,547,992**	**$ 482,660**

Grant Review and Award Operations (A.1.3.)

		2017 Appropriated	2017 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
1001	Salaries and Wages	$ 2,730,580	2,939,141		$ 2,939,141	$ 0	100%	$ 2,939,141	$ 0
1002	Other Personnel Costs	3,856	125,950		125,950	0	0%	125,950	0
2001	Professional Fees and Services	10,809,493	10,360,839		9,734,509	626,330	94%	9,734,509	626,330
2003	Consumable Supplies	-	-		-	-	0%	-	-
2004	Utilities		15,000		12,026	2,974	80%	12,026	2,974
2005	Travel	65,000	65,000		51,075	13,925	79%	51,075	13,925
2009	Other Operating Expenses	201,297	304,296		85,656	218,640	28%	85,656	218,640
	Conference		20,481		-	20,481	0%	-	20,481
	Subtotal - Grant Operations (A.1.3.)	**$ 13,810,226**	**$ 13,830,707**	**4.66%**	**$ 12,948,356**	**$ 882,351**	**94%**	**$ 12,948,356**	**$ 882,351**

Grants

		2017 Appropriated	2017 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
4000	Grants - Prevention (A.1.2)	$ 28,334,312	$ 28,334,312		$ 12,024,696	$ 16,309,616	42%	$ 12,024,696	$ 16,309,616
4000	Grants - Research (A.1.1.)	251,780,562	$ 251,780,562		163,069,773	$ 88,710,789	65%	163,069,773	88,710,789
	Subtotal - Grants	**$ 280,114,874**	**$ 280,114,874**	**94.32%**	**$ 175,094,469**	**$ 105,020,405**	**63%**	**$ 175,094,469**	**$ 105,020,405**
	Grand Totals	**$ 296,955,752**	**$ 296,976,233**	**100.00%**	**$ 190,590,817**	**$ 106,385,416**	**64%**	**$ 190,590,817**	**$ 106,385,416**

Cancer Prevention and Research Institute of Texas

Cancer Prevention and Research Institute Fund Account - 5136

As of August 31, 2017

	08/01/2017-08/31/2017	AY 17 Year to Date as of 08/31/2017
Beginning Balance : 08/01/2017		**$ 600,506**
Increases:		
(1)	$ -	$ -
(2)	-	
Total Increases	**$ -**	**$ 600,506.00**
Reductions:		
Expenditures - Appropriated	$ -	$ -
	$ -	$ -
	$ -	$ -
Total Reductions	**$ -**	**$ -**
Ending Balance, 08/31/2017		**$ 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, 2017

	08/01/2017-08/31/2017	AY 17 Year to Date as of 08/31/2017
Beginning Balance : 08/01/2017		**$ -**
Increases:		
(1) License Plate Revenue Received	$ 1,052.29	$ 10,970.40
Total Increases	**$ 1,052.29**	**$ 10,970.40**
Reductions:		
Expenditures - Appropriated	$ (420.00)	$ (8,021.94)
	-	-
	-	-
Total Reductions	**$ (420.00)**	**$ (8,021.94)**
Ending Balance, 08/31/2017		**$ 2,948.46**

Note:

Cancer Prevention and Research Institute of Texas

Appropriated Receipts - 666

As of August 31, 2017

		08/01/2017-08/31/2017	AY 17 Year to Date as of 08/31/2017
Beginning Balance : 08/01/2017			**$ 96,416.49**
Increases:			
(1)	Product Development Application Fees Received	$ 13,000.00	$ 33,000.00
(2)	Appropriated Receipts applied to payments	$ -	$ -
(3)	Conference Registration Fees	$ 57,492.62	$ 57,495.62
(4)	Conference Registration Fees-Credit Card	$ 1,169.42	$ 1,169.42
Total Increases		**$ 71,662.04**	**$ 91,665.04**
Reductions:			
	Conference Expenditures - Appropriated	$ -	$ -
	Credit Card Fees Expended	$ (585.85)	$ (585.85)
	Legal Services Expenses (Application Fees)	$ -	$ (41,000.00)
Total Reductions		**$ (585.85)**	**$ (41,585.85)**
Ending Balance, 08/31/2017			**$ 146,495.68**

Begin balance is $76,000 for application fees and $20,416.49 for conference fees

Cancer Prevention and Research Institute of Texas

General Revenue Fund Account - 0001

As of August 31, 2017

		08/01/2017-08/31/2017	AY 17 Year to Date as of 08/31/2017
Beginning Balance : 08/01/2017			**$ -**
Increases:			
(1)	Revenue Sharing / Royalties	$ -	$ 60,318.27
Total Increases		**$ -**	**$ 60,318.27**
Reductions:			
	Expenditures - Appropriated	$ -	$ -
	Sweep Account	$ -	$ (60,318.27)
		$ -	$ -
Total Reductions		**$ -**	**$ (60,318.27)**
Ending Balance, 08/31/2017			**$ -**

Note:

Cancer Prevention and Research Institute of Texas

Sinking Fund Account - 5168

As of August 31, 2017

		08/01/2017-08/31/2017	AY 17 Year to Date as of 08/31/2017
Beginning Balance : 08/01/2017			**$ -**
Increases:			
(1)	Revenue Sharing / Royalties	$ 38,695.04	$ 38,695.04
Total Increases		**$ 38,695.04**	**$ 38,695.04**
Reductions:			
	Expenditures - Appropriated	$ -	$ -
		$ -	
		$ -	$ -
Total Reductions		**$ -**	**$ -**
Ending Balance, 08/31/2017			**$ 38,695.04**

Note:

Cancer Prevention and Research Institute of Texas

FY 2017, 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	800,000	175,441	206,098	207,730	222,796	812,065	101.51%
Number of Entities Relocating to TX for Cancer Research Related Projects	2.00	0.00	0.00	0.00	0.00	0.00	0.00%
Annual Age-adjusted Cancer Mortality Rate	152.5	N/A	N/A	N/A	N/A	149.6	98.10%
Number of Published Articles on CPRIT-Funded Research Projects	450	N/A	N/A	N/A	N/A	2,047	454.89%
Number of New Jobs Created and Maintained	315	N/A	N/A	N/A	N/A	3,229	1025.08%

Variance Explanations

Number of Entities Relocating to TX for Cancer Research Related Projects
This output is dependent on the number of companies applying for CPRIT Company Relocation Awards that can successfully advance through CPRIT's rigorous review and evaluation process, receive an award and actually relocate operations to Texas.
Number of Published Articles on CPRIT- Funded Research Projects
CPRIT's grant portfolio has grown resulting in a larger number of published articles reported by grantees than projected.
Number of New Jobs Created and Maintained
CPRIT's grant portfolio has grown resulting in a larger number of jobs created and maintained reported by grantees than projected.

Item 17

Subcommittee Business

Oversight Committee Assignments

Proposed November 29, 2017

FY 2018 – FY 2019 Subcommittees

FY 2018 - 2019	Audit	Brd Gov	Nom	Prev	Aca Res	Prod Dev	Contract
Angelou			X			X	
Margo	X		X	X		X	
Mitchell		X		X			X
Montgomery	X	X			X		X
Patel		X		X	X		
Rice	X	X			X	X	
Rosenfeld			X			X	X

X = Chair

X = Interim Chair

X = Interim member

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	KRISTEN DOYLE, DEPUTY EXECUTIVE OFFICER AND GENERAL COUNSEL
SUBJECT:	TEXAS OPEN MEETINGS ACT AND PUBLIC INFORMATION ACT UPDATES
DATE:	NOVEMBER 17, 2017

Summary

Texas Administrative Code § 702.21 requires that Oversight Committee members receive training on the Public Information Act (PIA) and the Texas Open Meetings Act (TOMA) after each regular session of the legislature. This memo summarizes changes made to the PIA and TOMA during the 85th Legislative Session. I have attached a comprehensive overview of the TOMA, originally provided to Oversight Committee members in August 2014 and updated in February 2016. A review of this memo and the attachment fulfills the required training. CPRIT legal staff and Oversight Committee members may meet in closed session for legal advice and counsel on these issues. If you have specific questions or need more information, please contact me directly at 512/305-8486.

Changes to the Open Meetings Act

- **SB 1440 (Campbell/Larson) –** The change amends the definition of "meeting," clarifying that a quorum of members of a governmental body attending a candidate forum, appearance, or debate is not a meeting subject to TOMA. Without this clarification, elected officials, particularly in small towns, were avoiding candidate events where a quorum of other members elected to the same governmental body would be present.
- **SB 564 (Campbell/Capriglione) –** The change clarifies an exception to TOMA that allows the governing body to meet in closed session regarding information technology security practices.
- **HB 3047 (Dale/Schwertner) –** The change resolves an issue about governing board members participating by videoconference. TOMA considers a member participating in a meeting by videoconference absent from the meeting when the governing body loses video or audio connection with the member. The meeting may continue only if the governing body has a quorum without the disconnected member.

Changes to the Public Information Act

- **SB 79 (Nelson/Capriglione)** – Allows governmental bodies to direct a requestor to the agency's website if the requested information already exists online.
- **HB 3107 (Ashby/Nichols)** – Makes a number of changes to the PIA, including establishing a 60-day window for a requestor to review the information after the agency has provided the information for inspection; clarifying that multiple requests submitted by the same requestor on the same day count as one request for purposes of calculating costs; allowing agencies to establish reasonable monthly and yearly limits on the amount of time agency personnel spends on responding to specific requestor; and permitting a complaint to be filed with the Attorney General's office if the county or district attorney has failed to act on the complaint within 90 days.
- **SB 533 (Nelson/Geren)** – Requires state agencies to redact confidential information from contracts posted publicly.
- **SB 705 (Birdwell/Price)** – Allows the governor's office to redact an applicant's personal information (home address, home telephone number, social security number, and family member information) included on the application for a gubernatorial appointment.

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Texas Open Meetings Act – An Overview

Texas Government Code Chapter 551, commonly 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."

When Does the Act Apply to Communications Between Members?

Generally, 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.

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

Yes. 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.[10]

  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 because one of the requirements of participation by telephone is that convening a quorum in one location is difficult or impossible.

  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. A member or employee of the governmental body may participate remotely by video conference if the agency broadcasts the video and audio feed live at the meeting when a quorum of the members is present in one location.[11] The statute requires a quorum of the governing board, including the presiding officer, to be physically present at one location open to the public.

[10] Tex. Govt. Code Ann. §§ 551.121 - .126.
[11] Tex. Govt. Code Ann. 551.127

Texas law allows a member of the public to testify at a meeting from a remote location by video conference.

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."[12]

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

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

requirements. Criminal violations include knowing participation in a walking quorum or an unauthorized closed meeting.