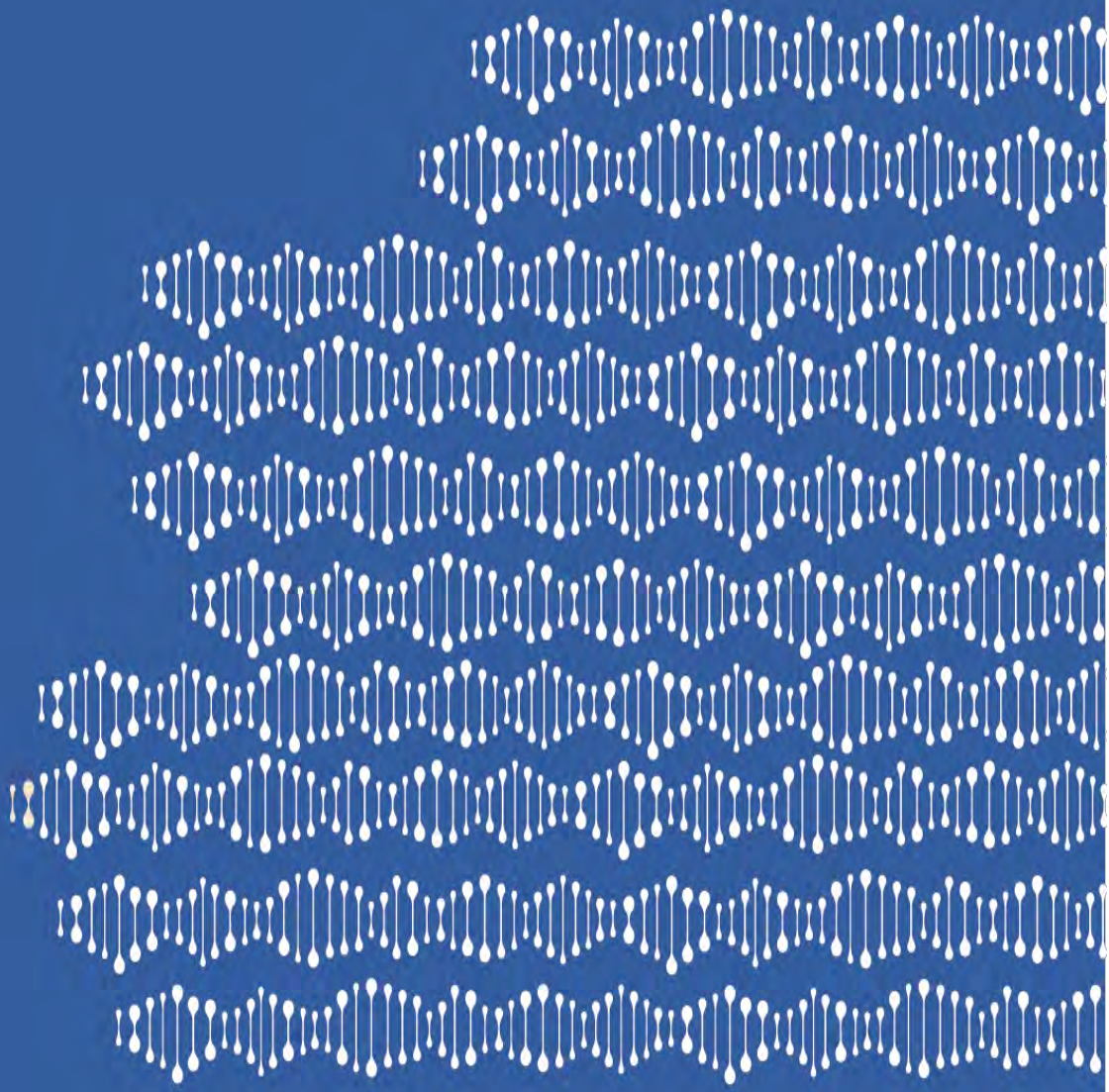
CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

Oversight Committee Meeting

November 16, 2016



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

Oversight Committee Meeting Agenda

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

November 16, 2016
10:00 a.m.

The Oversight Committee may discuss or take action regarding any item on this agenda, and as authorized by the Texas Open Meetings Act, Texas Government Code Section 551.001 et seq., may meet in closed session concerning any purpose permitted by the Act. Anyone wishing to offer public comments must notify the Chief Executive Officer in writing prior to the start of the meeting. The Committee may limit the time a member of the public may speak.

1. Call to Order
2. Roll Call/Excused Absences
3. Adoption of Minutes from the August 17, 2016 and September 14, 2016 meetings **TAB 1**
4. Public Comment
5. Grantee Presentation **TAB 2**
6. Chief Executive Officer Report **TAB 3**
7. Chief Scientific Officer Report and Grant Award Recommendations **TAB 4**
8. Chief Product Development Officer Report and Grant Award Recommendations **TAB 5**
9. Chief Prevention and Communications Officer Report **TAB 6**
10. Scientific Research and Prevention Program Committee Appointments **TAB 7**
11. FY 2017 Program Priorities **TAB 8**
12. Internal Auditor Report **TAB 9**
    - FY 2016 Internal Audit Annual Report
13. Amendments to 25 T.A.C. Chapters 701 – 703 **TAB 10**
    - Final Order Approving Amendments to Chapters 701 – 703
    - Proposed Amendments to Chapter 703 and Authorization to Publish in *Texas Register*
14. Plan for Management of Royalty/Equity Portfolio **TAB 11**
15. Contract Approvals **TAB 12**
    - CSRA Inc. Contract Amendment
    - Outside Legal Services
16. Chief Operating Officer Report **TAB 13**
17. Chief Compliance Officer Report **TAB 14**
18. Subcommittee Business
19. Compliance Investigation Pursuant to Health & Safety Code § 102.2631
20. Consultation with General Counsel
21. Future Meeting Dates and Agenda Items
22. Adjourn

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

Summary Overview of the November 16, 2016, Oversight Committee Meeting

This summary provides an overview of major agenda items and background on key issues for Committee consideration at the November 16, 2016, Oversight Committee meeting.

CEO Report
Wayne Roberts will present the CEO's report and address issues including a personnel update, the 2017 Oversight Committee Program Priorities, action items from the August 17th and September 14th Oversight Committee meetings, and report on FY 2017 grant award funds available.

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 award recommendations for Individual Investigator Research Awards, Investigator Research Awards for Computational Biology, Investigator Research Awards for Cancer in Children and Adolescents, Investigator Research Awards for Prevention and Early Detection, Research Training Awards, Early Translational Research Awards, Recruitment of Established Investigators, and First-Time, Tenure-Track Faculty recruitment grants.

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

Chief Product Development Officer Report and Grant Award Recommendations
Mr. Mike Lang will provide an update on the Product Development Program and present the Program Integration Committee's award recommendations for Texas Company Product Development Awards.

Information related to the Product Development grant applications recommended for funding will not be publicly disclosed until the Oversight Committee meeting. The information is available to board members through a secure electronic portal.

Chief Prevention and Communications Officer
Dr. Becky Garcia will give a report regarding the Prevention Program activities as well as an update on the agency's communications activities.

Scientific Research and Prevention Programs Committee Appointments
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 appointment is final. Biographical sketches for the appointees are included in the board packet. Additionally, the

Product Development Review Council has added a new member who is a current peer reviewer already approved by the Oversight Committee.

FY2017 Program Priorities
Health and Safety Code Chapter 102 requires CPRIT's Oversight Committee to establish program priorities on an annual basis. Chairs of the programmatic subcommittees will present their respective program priorities. The Oversight Committee will vote on final program priorities for FY 2017.

Internal Auditor Report
Weaver and Tidwell, CPRIT's internal auditor, will present the 2016 internal audit report.

Amendments to 25 TAC Chapters 701-703
Ms. Doyle will present the final order approving amendments to Chapters 701-703 that the Oversight Committee provisionally approved at the August meeting. If approved, the amendments will become effective in December.

Ms. Doyle will also present two proposed changes to the agency's administrative rules. Texas Health and Safety Code § 102.108 authorizes the Oversight Committee to implement rules to administer CPRIT's statute. These rule changes will be brought back to the Oversight Committee for final approval in February after the public has an opportunity to comment on the proposed rule changes.

Contract Approvals
Ms. McConnell will present a recommendation for the approval of the following contracts:

- CSRA Inc. Contract Amendment
- Outside Legal Services contracts to assist the agency in intellectual property review of product development applications that reach the due diligence stage.

Chief Operating Officer Report
Heidi McConnell will discuss the operating budget, performance measures, and debt issuance history for the fourth quarter of FY 2016.

Chief Compliance Officer Report
Vince Burgess will report on the status of required grantee reports, financial status report reviews, annual grantee certifications, desk reviews and site visits as well as grantee training and technical assistance. He will also discuss a summary of compliance program activities that took place in FY 2016.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

Oversight Committee Meeting
August 17, 2016

1. Call to Order

A quorum being present, Presiding Officer Geren called the Oversight Committee to order at 9:59 a.m.

2. Roll Call/Excused Absences

Committee Members Present:
Angelos Angelou
Pete Geren
Ned Holmes
Will Montgomery
Amy Mitchell
Cynthia Mulrow, M.D.
Bill Rice, M.D.
Craig Rosenfeld, M.D.

Committee Members Absent:
Donald (Dee) Margo

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

3. Adoption of Minutes from the May 18, 2016 and May 19, 2016 Meetings (Tab 1)

MOTION:
On a motion made by Mr. Montgomery and seconded by Ms. Mitchell, the Oversight Committee unanimously voted to approve the minutes of the Oversight Committee meetings held on May 18, 2016, and May 19, 2016.

4. Public Comment

Presiding Officer Geren introduced Mr. Cam Scott, Senior Director of Texas Government Relations for the American Cancer Society Cancer Action Network for public comment. Mr. Scott noted that his agency does not request or receive funds from CPRIT, but sees CPRIT as a partner in the fight against cancer. He introduced the Texas Cancer Partnership, which is a new collaboration of organizations in Texas with the shared goal of ending cancer. In addition to the Cancer Action Network, other founding members of the Texas

Cancer Partnership include the American Lung Association, Susan G. Komen Austin, Leukemia and Lymphoma Society, Livestrong Foundation, and Texas Healthcare and Bioscience Institute.

Mr. Scott testified that the Texas Cancer Partnership recognizes that one of the most significant catalysts for progress against cancer is the decision that Texas lawmakers and Texas voters made in 2007 to invest $3 billion in cancer research and prevention. With the creation of CPRIT, the state has become a global leader in the effort to eliminate cancer.

He invited interested organizations to collaborate with or become a supporter of this important work and noted that the partnership has created a website at www.TexasCancerPartnership.org. Mr. Scott closed by commending the voluntary service of the Oversight Committee members and recognized the importance of the members' role in safeguarding the integrity and the efficacy of CPRIT on behalf of Texas taxpayers.

Presiding Officer Geren thanked Mr. Scott for his comments and introduced Ari Kahn, Ph.D., Human Translational Genomics Coordinator at the Texas Advanced Computing Center for The University of Texas at Austin. Dr. Kahn commented about CPRIT's process for tracking and aggregating the data collected by our grantees. Dr. Khan stated that determining how all the projects correlate and work together will have a large impact on a cure for cancer. Presiding Officer Geren and Mr. Roberts discussed the programs priorities and various ways CPRIT gathers information from grantees and assess impact. Presiding Officer Geren thanked Mr. Kahn for his comments.

5. Chief Executive Officer Report (Tab 2)

Wayne Roberts, Chief Executive Officer, provided an update on several CPRIT activities.

- Personnel Update: Mr. Roberts introduced new employees Dr. Patty Moore, Program Manager for Academic Research; Ralph Azeez, Grant Accountant; and Jodi Garza, Grant Compliance Specialist. The Communications Specialist position closed August 12, 2016.

- 2017 Oversight Committee Program Priorities: Mr. Roberts explained that major drafting of the priorities took place two years ago. CPRIT has two new chiefs with new ideas, so he encouraged the Oversight Committee subcommittees to take a fresh look at CPRIT Program Priorities.

- Special Oversight Committee Meeting on September 14, 2016: Mr. Roberts expects that several grant recommendations for recruits and core facilities extensions will be presented for approval at the September 14th meeting. There also may be several contracts and contract extensions for the Oversight Committee's consideration.

- New Event Starting In September – Mr. Roberts has invited Thomas Yankeelov, Ph.D., a CPRIT-funded Established Investigator recruit to The University of Texas at Austin in the Department of Biomedical Engineering, to make a short presentation on his work.

CPRIT will plan for one or two grantees to give short presentations on their work at future Oversight Committee meetings.

- American Cancer Society Cancer Action Network Events: Mr. Roberts reported that CPRIT staff have attended events in Houston and Austin put on by the ACS Cancer Action Network, and plan to attend the Dallas event on August 30, 2016. The events have hosted excellent presentations by Senator Kirk Watson, Representative Kyle Kacal, Representative Sarah Davis and others on the impact of CPRIT awards.

- The Quarterly Report on Grant Funding Available shows $258,000 will be left for this year's allocation if the recommendations presented today are approved.

6. Chief Scientific Officer Report and Grant Award Recommendations (Tab 3)

Academic Research Activities Update

Dr. Jim Willson, Chief Scientific Officer, reports that Academic Research funding in FY 2016 to date is $198,549,131, not including August awards. Dr. Willson provided an overview of the FY 2016 Academic Research awards, beginning with the recruitment awards. Fifty-six recruitment nominations were received through May 2016 for three 2016 recruitment RFAs: Established Investigators, Rising Stars, and First-Time, Tenure Track Faculty Members. During the fourth quarter of FY 2016, 15 more Recruitment Awards were received and are currently under review. Some recruitment applications are on today's agenda for consideration. The remaining recruitment awards received during the last quarter of the fiscal year will be recommended in FY 2017 because sufficient funds are not available to support all recommended recruitment awards in FY 2016. If recommended by the Scientific Review Council, the award recommendations will be considered at a special Oversight Committee meeting on September 14, 2016.

Dr. Willson reported that CPRIT released six Requests for Applications (RFAs) in February 2016 resulting in 479 applications submitted for review cycle 17.1. The Program Integration Committee's recommendations for funding will be considered at the November 2016 Oversight Committee meeting.

Dr. Willson also noted for the record that at the May 2016 Oversight Committee meeting, High Impact/High Risk Award RP160834 "Integrated-Cavity-Enhanced Pre-Screening for Lung Cancer," was awarded to Dr. John Bevan at Texas A&M University. Dr. Bevan passed away prior to executing the grant contract. CPRIT has approved the institution's request that the Co-Principal Investigator, Dr. Vladislav Yakovlev, replace Dr. Bevan as Principal Investigator for this award.

Academic Research Proposed Awards

Moving on to the award recommendations, Dr. Willson indicated that there are two Core Facility Support Awards totaling $10,598,728, six Multi-Investigator Research Awards totaling $27,702,887, and five First-Time/Tenure Track Faculty Member Awards, each

award for up to $2,000,000 over four years, which are presented for the Oversight Committee's consideration. He noted that the Program Integration Committee deferred two Core Facilities Services Awards and five Multi-Investigator Awards recommendations in May. On August 2, 2016, the Program Integration Committee considered the deferred awards and recommended all seven applications for Oversight Committee approval.

Dr. Willson reported that 10 of the 12 awards for consideration today address specific priorities identified by the CPRIT Oversight Committee. The Program Integration Committee recommends funding each of the Multi-Investigator Research Awards at 80 percent due to concerns about sufficient funds being available for all the awards.

In response to a question about childhood cancer data collection, Dr. Willson responded that childhood cancers are a rare event. Cases are treated at dedicated children's hospitals throughout Texas that are participating in this resource with the Texas Children's Hospital and Baylor College of Medicine. A patient's parents must agree to participation.

In reference to RP160844, *Center for Innovative Drug Discovery: Enhancement of a Shared Cancer Resource*, Dr. Willson was asked what provisions had been made for sharing information. Dr. Willson stated that assembling the information and resources will be overseen by an executive committee formed by the center to judge which investigators have access to the resource based on scientific merit and interest. Dr. Willson also noted that CPRIT requires that all published material from research grants supported by CPRIT funds be entered into the National Library of Medicine's PubMed Central no later than 12 months after the official date of publication for dissemination. Publications that are submitted to the library have to provide access to the actual data sets.

In reference to RP160771, The Adolescent and Childhood Cancer Epidemiology and Susceptibility Service, Dr. Willson was asked what "gene environment interaction" meant. He explained it was the influence environmental factors have on genes—meaning that "inherited" diseases can be modified by environmental conditions in either a protective, neutral, or harmful way. In other words, gene environment interaction is defined as "a different effect of an environmental exposure on disease risk in persons with different genotypes". This effort is to try to obtain this information at the time of diagnosis of a childhood cancer.

Compliance Certification (all awards)

Mr. Vince Burgess, Chief Compliance Officer, presented his certification of the review process for the all proposed grant awards being recommended to the Oversight Committee at this meeting. He stated he had reviewed the compliance pedigrees for the grant applications submitted to CPRIT for the following grant mechanisms:

- Recruitment of First-Time, Tenure-Track Faculty Members Awards
- Core Facility Support Awards
- Multi-Investigator Research Awards

- Competitive Continuation/Expansion – Evidence-Based Cancer Prevention Services
- Evidence-Based Cancer Prevention Services
- Evidence-Based Cancer Prevention Services – Colorectal Cancer Prevention Coalition
- Evidence-Based Cancer Prevention Services – See, Test, and Treat® Program
- Dissemination of CPRIT-Funded Cancer Control Interventions
- Cancer Prevention Promotion and Navigation to Clinical Services

Mr. Burgess stated he was satisfied that the application review process resulting in the grant awards recommended by the Program Integration Committee followed applicable laws and agency administrative rules and certified for the Oversight Committee's consideration the academic research and prevention award recommendations being presented at this meeting.

Mr. Burgess further noted that the deferred Core Facility Support Awards and Multi-Investigator Research Awards applications were previously certified in May 2016 when applications were first considered by the Program Integration Committee on May 3, 2016. The Program Integration Committee voted in May to defer the seven applications to a later meeting.

Conflict of Interest Notification

Presiding Officer Geren noted for the record that no Oversight Committee members reported conflict of interest with any of the applications being considered for awards at this meeting.

Academic Research Grant Award Recommendations

This list includes applications already approved by the Oversight Committee on May 18, 2016, as well as the seven previously deferred applications that are recommended by the PIC for the August 17, 2016, meeting. The previously deferred applications recommended by the PIC on August 2, 2016, are highlighted in blue and are updated to reflect budget amount changes as approved by the PIC.

App ID	Mechanism	Organization/ Company	Application Title	Budget
RP160805	CFSA	Baylor College of Medicine	Preclinical Candidate Discovery Core	$5,999,997
RP160813	HIHR	Acelerox	Nanoparticle Prophylaxis for Protection from Chemotherapy Ototoxicity	$195,665
RP160795	HIHR	Baylor College of Medicine	A "Pap smear" for ovarian cancer	$200,000
RP160657	CFSA	The University of Texas at Austin	Targeted Therapeutic Drug Discovery & Development Program	$4,982,636

App ID	Mechanism	Organization/ Company	Application Title	Budget
RP160776	HIHR	The University of Texas at Austin	Rapid Molecular Diagnosis of Lung Cancer Biopsies by Ambient Ionization Mass Spectrometry	$200,000
RP160884	HIHR	Baylor College of Medicine	RNA processing stress: a new therapeutic entry point in triple-negative breast cancer	$200,000
RP160847	HIHR	Texas A&M Engineering Experiment Station	A Body Coil for MR Imaging and Spectroscopy of Cancer at 7 Tesla	$200,000
RP160732	CFSA	The University of Texas Health Science Center at San Antonio	UTHSCSA Cancer Genome Sequencing and Computation Core	$3,680,756
RP160652	MIRA	The University of Texas M. D. Anderson Cancer Center	Defining and Defeating Mechanistic Subtypes of KRAS-mutant Lung Cancers	$5,981,040
RP160668*	MIRA	The University of Texas M. D. Anderson Cancer Center	Pathogenesis and Early Progression of Lung Cancer	$4,606,275
RP160834	HIHR	Texas A&M University	Integrated-cavity-enhanced pre-screening for lung cancer	$200,000
RP160842	HIHR	Texas A&M University System Health Science Center	Novel roles for NIK in high-grade glioma: regulation of mitochondrial dynamics to control cell migration and invasion	$200,000
RP160716	CFSA	The University of Texas Health Science Center at San Antonio	Texas Pediatric Patient Derived Xenograft Facility	$5,079,843
RP160713	HIHR	The University of Texas Southwestern Medical Center	Amino Acid Sensing: Directing Cell Growth through mTORC1	$198,983
RP160693	MIRA	The University of Texas M. D. Anderson Cancer Center	Acute Myeloid Leukemia in the Immunosuppressed Microenvironment	$6,000,000

App ID	Mechanism	Organization/ Company	Application Title	Budget
RP160739	HIHR	The University of Texas M. D. Anderson Cancer Center	Targeting Histone Acetylation Readers in MLL- translocated Leukemias	$200,000
RP160661**	MIRA	The University of Texas Southwestern Medical Center	Towards Carbon Beam Stereotactic Body Radiation Therapy (C-SBRT) for Higher Risk Early Stage Lung Cancer	$4,103,894
RP160667***	MIRA	The University of Texas M. D. Anderson Cancer Center	DNA-Protein Crosslink Repair Pathways and Cancer Therapy	$5,101,316
RP160822	HIHR	Texas AgriLife Research	Exploring Geminivirus-encoded suppressor of histone methyltransferases as an anti-cancer drug	$199,958
RP160866	HIHR	The University of Texas at Dallas	Renal Clearable Nanodelivery System for Triple Negative Breast Cancer Therapy	$200,000
RP160710	MIRA	The University of Texas M. D. Anderson Cancer Center	A Randomized Clinical Trial Platform with Translational Studies to Overcome Resistance in Triple Negative Breast Cancer	$5,997,677
RP160806	HIHR	Texas Tech University	Development of high throughput technology to identify drugs for muscle wasting during cancer	$199,995
RP160674	MIRA	The University of Texas Medical Branch at Galveston	Comparative Effectiveness Research on Cancer in Texas (CERCIT) 2.0	$6,000,000
RP160827	HIHR	Texas A&M University System Health Science Center	A platform technology for the isolation of anti- cancer monoclonal antibodies from chickens	$200,000
RP160775	HIHR	The University of Texas Health Science Center at Houston	Becoming fatter to survive: cancer cells increase lipid storage to counter metabolic stress	$200,000

App ID	Mechanism	Organization/ Company	Application Title	Budget
RP160771****	CFSA	Baylor College of Medicine	The Adolescent and Childhood Cancer Epidemiology and Susceptibility Service (ACCESS) for Texas	$6,000,000
RP160844*****	CFSA	The University of Texas at San Antonio	Center for Innovative Drug Discovery: Enhancement of a Shared Cancer Resource for South Texas	$4,598,728
RP160841	HIHR	The University of Texas Health Science Center at San Antonio	Targeting EWS-FLI-1 for degradation	$200,000
RP160765	HIHR	Texas A&M University System Health Science Center	An unlikely therapeutic target for malignant bone disease: Dkk-1 activates a stress resistance mechanism in bone tumor cells	$200,000
RP160852	HIHR	Texas State University - San Marcos	Chemo-preventive Approach to Cancer Exploiting a Presumptive Link between Genomic Instability and Structural Stability of non-B DNA Sequences	$200,000
RP160770	HIHR	The University of Texas at Dallas	Optical opening of blood-brain barrier for brain tumor drug delivery by plasmonic nanobubbles	$200,000
RP160819	HIHR	Texas AgriLife Research	Quantitative mapping of intracellular protein- protein interactomes in healthy and cancerous cells	$198,753
RP160704	HIHR	The University of Texas at Austin	High affinity therapeutic mimotope antibodies to the oncogenic Epidermal Growth Factor Receptor	$200,000
RP160763	HIHR	The University of Texas Health Science Center at Houston	Targeting multiple myeloma stem cell niche	$200,000

CFSA = Core Facilities Support Awards
HIHR = High-Impact/High-Risk Research Awards

MIRA = Multi-Investigator Research Awards

* RP160668 - The peer review panel recommended the deletion of Project 4 from the MIRA application. As a result, the funds dedicated to that project were removed from the budget for a revised total of $5,757,844. The final score was based on revised scope with the deletion of Project 4.

** RP160661 - The peer review panel recommended the deletion of Project 3 and Project 4 from the MIRA application. As a result, the funds dedicated to those projects were removed from the budget for a revised total of $5,129,867. The final score was based on revised scope with the deletion of Projects 3 and 4.

*** RP160667 - The peer review panel recommended changes to the MIRA application by modifying Project 2 by deleting Aim 3 and reducing the budget by the amount dedicated to that project. Additionally, the panel recommended reducing the budget for Core 1 by 25%. Finally, the panel recommended reducing Core 2 by $20,000. These changes resulted in a revised budget totaling of $6,376,645.

**** RP160771 - The peer review panel recommended the overall budget be reduced to the allowable $6,000,000 for entire funding period. One required reduction is $500,000 ($100,000/year) for pilot projects that were not substantiated. Other reductions can be made based on budget negotiations with CPRIT.

***** RP160844 - The peer review panel recommended reducing the personnel budget by 1/3 ($507,155), removing $150,000 for pilot projects, and $100,000 for a software suite. The revised budget total is $4,598,728. The final score was based on these budget reductions.

Academic Research Recruitment Grant Award Recommendations

App ID	Mech.	Candidate	Organization/Company	Budget Requested
RR160078	RFT	Mazur, Pawel	The University of Texas M.D. Anderson Cancer Center	$2,000,000
RR160075	RFT	Zang, Cheng-Zhong	The University of Texas Southwestern Medical Center	$2,000,000
RR160067	RFT	Kapoor, Prabodh	The University of Texas Health Center at Tyler	$2,000,000
RR160070	RFT	Chaumeil, Myriam	The University of Texas Southwestern Medical Center	$2,000,000
RR160066	RFT	Nielsen, Alec	Rice University	$2,000,000

RFT = Recruitment of First-Time, Tenure-Track Faculty Members
REI = Recruitment of Established Investigators
RRS = Recruitment of Rising Stars

MOTION:
On a motion made by Mr. Montgomery and seconded by Mr. Holmes, the Oversight Committee unanimously voted to approve the Program Integration Committee's recommendations for the Core Facility Support awards, Multi-Investigator Research awards, and First-Time, Tenure Track recruitment awards.

MOTION:
On a motion made by Mr. Montgomery and seconded by Ms. Mitchell, 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.

7. Prevention and Communications Officer Report and Grant Award Recommendations (Tab 4)

Prevention Program Activities Update

Dr. Rebecca Garcia, Chief Prevention and Communications Officer, presented the Prevention Program update. She reports that 44 applications were received for FY 2016 Cycle 2; 14 applications are presented for approval today for grant awards. Applications for FY 2017 Cycle 1 are due August 30 and will be presented to the Oversight Committee for consideration in February 2017. Dr. Garcia indicated that the project to list the grants in each of the 254 counties is complete and staff is working on ways to format and display the data. She reported that a complete redesign of the grantee quarterly reports is underway. The revised report will be tested with a few grantees during August, prior to its release.

An Oversight Committee member asked about providing the prevention metrics by legislative district. Mr. Roberts responded that HIPAA privacy regulations prevent CPRIT from accessing data by street address that would be needed in order for CPRIT or the Texas Legislative Council to compile the desired report.

Prevention Program Proposed Grant Awards

Dr. Garcia presented the Prevention Program grant awards totaling $13,690,454 for Oversight Committee approval. These include:

- 7 Evidence-Based Cancer Prevention Services grants totaling $9,046,499
- 1 Colorectal Cancer Prevention Coalition grant totaling $2,100,000
- 1 Competitive Continuation/Expansion for Evidence-Based Cancer Prevention Services grant totaling $1,496,111
- 1 Cancer Prevention Promotion and Navigation to Clinical Services grant totaling $399,954
- 2 Dissemination of CPRIT-Funded Cancer Control Interventions grants totaling $599,766
- 2 Evidence-Based Cancer Prevention Services – See, Test & Treat® Program grants totaling $48,124

Dr. Garcia reported that all of the recommended grants fulfill at least one Prevention Program priority and several fulfill more than one priority.

Presiding Officer Geren noted that the Prevention Program's Dissemination grants are an impactful way of sharing effective programs with all parts of the state.

An Oversight Committee member asked if it would be possible to estimate the number of cancers prevented due to the Prevention Program grants, then translate that into lives saved and dollars saved in proportion to the investments made. Dr. Garcia responded that it may be difficult to determine how much of the decline in mortality rates could be attributed to CPRIT's efforts with the data we currently collect. Staff will look into options. Additional data collection and statistical analysis would likely require contracted expertise.

Compliance Certification

Presiding Officer Geren noted that Mr. Burgess had previously provided the compliance certification for all of the award recommendations for the Academic Research and Prevention programs and reported no compliance issues.

Conflict of Interest Notification

Presiding Officer Geren stated for the record that no Oversight Committee members reported a conflict of interest with any of the applications presented for awards.

Prevention Grant Award Recommendations

App ID	Mech.	Applicant Name	Organization	Total Funding Requested
PP160081	DI	Reitzel, Lorraine R	University of Houston	$299,981
PP160116	STT	McKernan, Stephen	Lone Star Community Health Center, Inc. dba Lone Star Family Health	$23,602
PP160079	EBP	Jibaja-Weiss, Maria L	Baylor College of Medicine	$1,161,015
PP160093	DI	Layeequr Rahman, Rakhshanda	Texas Tech University Health Sciences Center	$299,785
PP160058	CCE	Berenson, Abbey B	The University of Texas Medical Branch at Galveston	$1,496,111
PP160075	EBP	Singal, Amit	The University of Texas Southwestern Medical Center	$1,499,826
PP160110	PN	Ross, Theodora S	The University of Texas Southwestern Medical Center	$399,954

PP160080	EBP	Morales-Campos, Daisy Y	The University of Texas Health Science Center at San Antonio	$1,302,955
PP160122	EBP	Rustveld, Luis	Baylor College of Medicine	$1,477,698
PP160105	STT	Coffey, Donna M	Houston Methodist	$24,522
PP160121	EBP	Trivedi, Madhukar H	The University of Texas Southwestern Medical Center	$1,365,226
PP160097	EBP	Rodriguez, Ana M	The University of Texas Medical Branch at Galveston	$747,727
PP160089	EBP	Mittal, Sahil	Baylor College of Medicine	$1,492,052
PP160103	CRC	Ross, Theodora S	The University of Texas Southwestern Medical Center	$2,100,000

PN = Cancer Prevention and Navigation to Clinical Services
CCE = Competitive Continuation/Expansion – Evidence-Based Cancer Prevention Services
DI = Dissemination of CPRIT-Funded Cancer Control Interventions
EBP = Evidence-Based Cancer Prevention Programs
SST – Evidence-Based Cancer Prevention Services – See, Test & Treat® Program
CRC = Colorectal Cancer Coalition

MOTION:
On a motion made by Mr. Holmes and seconded by Mr. Montgomery, the Oversight Committee unanimously voted to approve the Program Integration Committee's recommendations on 14 Prevention grant awards.

MOTION:
On a motion made by Mr. Montgomery and seconded by Ms. Mitchell, 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.

8. Chief Product Development Officer Report (Tab 5)

Product Development Activities Update

Mike Lang, Chief Product Development Officer, reported that of the 32 applications submitted for Review Cycle 16.2, thirteen were recommended for the in person Peer Review meeting on May 10-12, 2016. Following the in-person presentations, seven applications were recommended for due diligence review, which will be completed in October 2016. Award recommendations from this cycle will be presented to the Oversight Committee for consideration at the November meeting. Mr. Lang also reported that 19 applications have been received for Review Cycle 17.1. Recommendations from the 17.1 cycle are expected to be presented to the Oversight Committee for consideration at the February 2017 meeting.

Mr. Lang indicated that some clarifying, non-substantive changes to the program priorities have been made as part of the annual review of program priorities.

The honoraria policy is also updated annually and is an item for consideration on today's Oversight Committee agenda. Mr. Lang discussed a change to provide a mechanism to pay reviewers with appropriate expertise for their time reviewing the business plans submitted by Early Translational Research Award (ETRA) grantees.

Mr. Lang reported that a targeted Request for Applications (RFA) focusing on diagnostics is under consideration. When combined with outreach to diagnostic firms and revenue sharing terms tailored to the diagnostic industry, a targeted RFA should increase the number of diagnostic applications for CPRIT awards. CPRIT's Product Development Advisory Committee will be asked to provide input on developing this targeted RFA.

Dr. Rice noted that this targeted RFA has been discussed in the Product Development Research Subcommittee and the subcommittee supports this approach.

An Oversight Committee member asked if molecular testing services in Texas are provided by the universities or if there are private labs in Texas providing these services. Mr. Lang responded that about 800 small start-up companies provide most of these services across the country. Each has a particular molecular test. Tissue samples are sent to these labs for testing, with reports sent to the prescribing physician. Two of these molecular diagnostics companies are CPRIT awardees located in Texas.

In response to a question by an Oversight Committee member, Ms. Doyle explained that input from Oversight Committee members, particularly through the subcommittees, informs the RFAs that are issued by CPRIT. However, the Oversight Committee is not called upon to vote to approve the issuance of new RFAs. Each programmatic subcommittee ensures that the programs are carrying out their program priorities.

Presiding Officer Geren announced that due to time constraints on the Internal Auditor, Mr. Lang's report would be interrupted now to allow the Internal Auditor to present her report.

Agenda Item 13 taken out of order - Internal Auditor Report (Tab 10)

Ms. Alyssa Martin, Internal Auditor, presented information on the status of the following 2016 Internal Audits:

- Commodity and Service Contracts
- Revenue
- Cash Management
- Information Technology Services Follow-up
- Grants Management

Ms. Martin briefly explained the table titled Schedule of Audits, Status, and Findings Summary, compiled at the request of an Oversight Committee member to provide an

overview of all internal audits performed, their findings, and the status of those findings being closed or open.

Presiding Officer Geren stated there were two audit reports included with the Oversight Committee meeting materials supported by a recommendation from the Audit Subcommittee for the Committee's approval:

- Follow-Up Procedures Report Over Prior Year Grant Management Findings; and,
- Internal Audit Report Over Commodity and Service Contracts.

MOTION:
On a motion made by Mr. Angelou and seconded by Mr. Montgomery, the Oversight Committee unanimously voted to approve the Internal Audit Follow-up Procedures Report over Prior Year Grant Management Findings.

MOTION:
On a motion made by Mr. Montgomery and seconded by Dr. Rice, the Oversight Committee unanimously voted to approve the Internal Audit Report over Commodity and Services Contracts.

At 12:28 p.m., Presiding Officer Geren called a 20-minutes recess of the Oversight Committee. Business resumed at 12:50 p.m.

Agenda Item 8 Continued: Chief Product Development Officer Report (Tab 5)

Presiding Officer Geren asked Mr. Lang to continue his presentation.

Mr. Lang reported on the implementation of the no repeat award policy discussed at the May 2016 Oversight Committee meeting. The product development RFAs have been amended to notify applicants that only companies that have not previously received an award are eligible to be considered for a CPRIT award. The purpose is to maximize the number of new novel technologies under development and the number of new startup companies in Texas.

An Oversight Committee member noted that the Product Development Research Subcommittee has discussed the issue and questioned whether establishing a no-repeat award policy may be in conflict with another CPRIT policy to promote the best science.

Another Oversight Committee member stated that he agrees with the no-repeat policy because once a company is relocated to Texas, it should be able to get follow-on funding and it is a better economic development policy to get as many companies to Texas as possible.

Mr. Roberts noted that a final decision on the "no-repeat awards" policy has not been made. He explained that before the no-repeat policy is finalized, it would be appropriate to get input from the Product Development Advisory Committee to help decide if the policy should be permanently implemented.

Mr. Lang reported that he had met with several Texas academic institutions to evaluate interest in collaborating to increase academic commercialization. Such a program would provide resources to Texas research institutions not specifically tied to a single investigator. This could bridge the gap between our Academic Research and Product Development Research Programs. Mr. Lang indicated that he plans to solicit the input of CPRIT's Product Development Advisory Committee and the University Advisory Committee on how best to structure this potential new award mechanism.

An Oversight Committee member questioned whether this was necessary because academic institutions already have technology transfer offices with facilities and large budgets to provide these services. It was the member's view that how an academic commercialization program is funded is a choice the academic institution makes.

Following up on that point, another Oversight Committee member questioned whether CPRIT could add value because these are sophisticated institutions with large budgets. In some cases, business schools associated with the institutions can provide additional expertise in monetizing assets generated by the institutions. This is particularly true for institutions that emphasize entrepreneurship in their undergraduate and graduate programs. The Oversight Committee member asserted that if the institution believes it could make money by putting more resources into that aspect of their operations, the Boards of Regents or the Trustees would allocate resources to do so.

Another Oversight Committee member stated that the technology transfer offices may not have the necessary expertise in bioscience and other areas where it is not easy to form initial companies.

Mr. Lang introduced the topic of monitoring the royalty and equity returns generated by CPRIT's grant awards. CPRIT investments have generated asset holdings with potentially significant monetary value. Most CPRIT investments have royalty-based return. In addition, CPRIT holds equity in three firms. A monitoring process will be required to ensure compliance now that some of the CPRIT awardees are progressing towards revenue generation.

Currently, CPRIT does not have the resources or personnel to implement a long-term monitoring system or to actively manage equity assets. The Texas Treasury Safekeeping Trust Company, which is part of the Comptroller's Office, provides these services for other assets owned by the state. Staff is exploring having the Safekeeping Trust Company monitor and manage assets generated by CPRIT's revenue sharing terms. If the Safekeeping Trust Company is not able to assist CPRIT, a contract with a third party for these services may be needed.

An Oversight Committee member asked about follow-on funding. Mr. Lang explained that the information in the Follow-on Funding Summary was prepared in response to questions raised at the Product Development Research Subcommittee. The "contract amount" column is the amount of the company's CPRIT contract. For some of the projects, all grant funds have been paid out, but that is not true for many on-going projects. Information in the

"Follow-on Funding" column is the funds that these companies have raised from other sources subsequent to the CPRIT award. Mr. Lang explained that the follow-on funding information demonstrates the success our awardees are having at raising capital from other sources after receiving a CPRIT award.

There were no further questions or comments for Mr. Lang.

9. Scientific Research and Prevention Program Committee Appointments (Tab 6)

Mr. Roberts presented the appointments to the Scientific Research, Prevention, and Product Development Peer Review Committees. The presentation included 4 appointments to the Product Development Peer Review panels, one appointment to the Prevention Peer Review panels, and 12 appointments to the Academic Research Peer Review panels.

An Oversight Committee member questioned whether CPRIT would pay for international travel for a proposed reviewer living outside of the country. After confirming with CPRIT's grant review contractor, Mr. Roberts reported that the appointee in question resides in California.

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

10. FY 2107 Honoraria Policy (Tab 7)

Mr. Roberts presented the FY 2017 honoraria policy for the Oversight Committee's consideration. He explained that CPRIT's enabling legislation requires CPRIT's Chief Executive Officer, in consultation with the Oversight Committee, to adopt a policy regarding honoraria paid by CPRIT for peer review services. The FY 2017 honoraria policy has been revised to reflect the additional time spent by Prevention and Academic Research panel members related to peer review activities.

MOTION:
On a motion made by Dr. Rosenfeld and seconded by Ms. Mitchell, the Oversight Committee unanimously voted to approve the FY 2017 Honoraria Policy.

11. Health & Safety Code Section 102.1062 Waiver (Tab 8)

Mr. Roberts presented his request for Oversight Committee approval of conflict of interest waivers for FY 2017 for Donald Brandy, Dr. Rebecca Garcia, Dr. John Hellerstedt, Amy Mitchell, and Will Montgomery. Information on each waiver request is in the board meeting materials.

MOTION:

On a motion made by Mr. Angelou and seconded by Dr. Rice, the Oversight Committee unanimously voted to approve the proposed Health & Safety Code Section 102.1062 waivers for Donald Brandy, Dr. Rebecca Garcia, Dr. John Hellerstedt, Amy Mitchell, and Will Montgomery.

12. Proposed Amendments to 25 T.A.C. Chapters 701-703 (Tab 9)

Kristen Doyle, Deputy Executive Office and General Counsel, presented changes to CPRIT's administrative rules for Oversight Committee approval for publication in the *Texas Register*. Most of the changes are non-substantive or clarifying. The specific changes for each section are delineated in a table in the committee meeting materials. She stated that proposed changes, including any revisions suggested during the public comment period, will be brought to the Oversight Committee in November for final approval.

Presiding Officer Geren noted that the substantive changes were discussed in detail and recommended for publication by the Board Governance Subcommittee.

MOTION:
On a motion made by Dr. Mulrow and seconded by Mr. Holmes, the Oversight Committee unanimously voted to approve the publication of the proposed changes to Texas Administrative Code 701-703 in the *Texas Register*.

14. Chief Operating Officer Report (Tab 11)

Chief Operating Officer Heidi McConnell presented a report on the following items:

- FY 2016, 3rd Quarter Operating Budget
- FY 2016, 3rd Quarter Performance Measures
- Debt Issuance History
- FY 2018-19 Legislative Appropriations Request

Ms. McConnell noted that with the addition of $865,235 in revenue sharing payments in July, the cumulative total in revenue sharing payments is now over $3 million.

In response to an Oversight Committee member question, Ms. McConnell stated that the quarterly report itself was not audited, but the expenditures reported are audited regularly through internal audits. In addition, the agency's financial transactions are reconciled after the end of each fiscal year with the State Comptroller's books and published in the Comprehensive Annual Financial Report (CAFR) for the state. CPRIT's transactions reported in the CAFR are also audited annually in the financial audit.

15. Contract Approvals (Tab 12)

Ms. McConnell presented four FY 2017 service contract renewals for Oversight Committee approval:

- Due Diligence Services with ICON Clinical Research for $309,000
- Economic Assessment of the Cost of Cancer in Texas with The Perryman Group for $150,000
- Outside Legal Services with Yudell Isidore for $200,000
- Strategic Communication Program Services with Hahn Public Communications for $149,975

In response to an Oversight Committee member question, Ms. McConnell explained that the outside legal counsel performs intellectual property due diligence review of product development grant applications.

MOTION:
On a motion made by Mr. Montgomery and seconded by Ms. Mitchell, the Oversight Committee unanimously voted to approve contracts with ICON Clinical Research, The Perryman Group, Yudell Isidore, and Hahn Public Communications.

16. Subcommittee Business (Tab 13)

Diversity Subcommittee Chair, Dr. Mulrow, presented the Diversity Subcommittee report recommending that the value and necessity of collecting gender, ethnicity, racial and other population metrics be evaluated by the Academic Research, Product Development Research, and Prevention Oversight Committee subcommittees for inclusion in an agency-wide diversity data collection policy developed by the staff based on subcommittee evaluations.

Mr. Roberts explained that this issue has been discussed by each of the programmatic subcommittees. An Oversight Committee member has recommended that the information be encapsulated in an annual report. Mr. Roberts said, with the Oversight Committee approval, the information will be included in CPRIT's existing annual report due each January with the first report appearing in January 2018, which would give each subcommittee a year to identify the data requirement needs.

Mr. Holmes reported that the Board Governance Subcommittee discussed this change and agreed that making the change will strengthen CPRIT's efforts at diversity.

To implement this recommendation, Ms. Doyle recommended adopting proposed amendments to the Prevention, Product Development, Scientific Research, and Audit Subcommittee charters. She explained that the charter amendments were made by moving the language from the Diversity Subcommittee charter into each program subcommittee charter.

MOTION:
On a motion made by Mr. Montgomery and seconded by Mr. Angelou, the Oversight Committee unanimously voted to approve the proposed reassignment of Diversity Subcommittee responsibilities to the Scientific Research, Product Development, Prevention, and Audit subcommittees.

MOTION:
On a motion made by Mr. Angelou and seconded by Ms. Mitchell, the Oversight Committee unanimously voted to approve the proposed amendments to the charters of the Scientific Research, Product Development, Prevention, and Audit subcommittees.

17. Chief Compliance Officer Report (Tab 14)

Mr. Vince Burgess, Chief Compliance Officer, reported that delinquent reports are still on a downward trend and are anticipated to stay below five percent of the over 570 reports due every month. Reviews performed by the Compliance Program staff are a result of CPRIT's annual grant risk assessment process. Grants that are assessed a priority one receive an on-site review. Grants assessed a priority two or three usually receive a desk review.

- Desk Reviews: CPRIT has performed approximately 250 desk reviews this fiscal year, 39 in the past quarter. The data show that of the desk review audits this year, about 54 percent had at least one finding, but grantees have quickly remediated most of those findings. Currently staff is working with just two grantees to remediate findings.
- On-site Reviews: Six reviews were performed this past quarter and staff is working with two grantees to remediate findings. Findings from on-site reviews are typically seen with new product development grants and usually result from incomplete procedures for purchasing, contract monitoring, and debarment checks.
- Single Audit Tracking: There are currently 10 grantees with outstanding audit findings.
- Training and Support: CPRIT staff conducted a grantee training webinar in June 2016 with approximately 140 grantee staff in attendance. Also, CPRIT compliance staff has been invited to present two grantee trainings onsite in August and one more is scheduled at UT Southwestern Medical Center, which will be available for all North Texas grantees. As a result of grantee trainings in March and June, staff developed a Frequently Asked Questions document and posted it on CPRIT's website as a resource for grantees. Additionally, three compliance and ethics training sessions for CPRIT staff were conducted in June 2016.

18. FY 2017 Program Priorities Process (Tab 15)

Dr. Garcia stated this report is informational. It represents the process staff is proposing and the timeline for updating and approving the 2017 Program Priorities. The Oversight Committee will vote on the 2017 priorities in November 2016.

19. Compliance Investigation Pursuant to Health & Safety Code § 102.2631
20. Consultation with General Counsel

Presiding Officer Geren stated there were no business to discuss for standing Item 19 and Item 20.

21. Future Meeting Dates and Agenda Items

Presiding Officer Geren announced the next Oversight Committee meeting is a special meeting scheduled for September 14, 2016, at 10:00 a.m., location to be determined. He then noted the proposed schedule of 2017 quarterly meetings and subcommittee meetings, for approval by the Oversight Committee.

MOTION:
On a motion made by Mr. Montgomery and seconded by Mr. Angelou, the Oversight Committee unanimously voted to approve the proposed schedule of Oversight Committee meetings and subcommittee meetings for FY 2017.

22. Adjourn

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

Meeting adjourned at 2:18 p.m.

_____ _____

Signature Date

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

Oversight Committee Meeting
September 14, 2016

1. Call to Order

A quorum being present, Presiding Officer Geren called the Oversight Committee to order at 10:02 a.m.

2. Roll Call/Excused Absences

Committee Members Present:
Angelos Angelou
Pete Geren
Donald (Dee) Margo
Amy Mitchell
Bill Rice, M.D.
Craig Rosenfeld, M.D.

Committee Members Absent:
Ned Holmes
Will Montgomery
Cynthia Mulrow, M.D.

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

3. Public Comment

Presiding Officer Geren noted there are no requests for public comment.

4. Grantee Presentation (Tab 1)

Presiding Officer Geren announced that CPRIT Grantee Dr. Thomas Yankeelov was unable to attend this meeting and his presentation will be rescheduled for the November 2016 Oversight Committee meeting.

5. Chief Executive Officer Report (Tab 2)

Wayne Roberts, Chief Executive Officer, presented his report. He noted that the position of Communications Specialist is expected to be filled shortly. Mr. Roberts reported that on

September 24, 2016, Dr. James Willson, Chief Scientific Officer, will participate in a discussion on cancer research, along with Lance Armstrong, cancer survivor and former professional cyclist; Dr. Ronald DePinho, President of The University of Texas M.D. Anderson Cancer Center, and State Representative Sarah Davis who sits on the Texas House Public Health Committee. New York Times Magazine Editor-in-Chief Jake Silverstein will moderate the keynote panel, which is part of the 2016 TribFest Conference. Mr. Roberts also noted that several CPRIT research and prevention staff will travel to Texas A&M University on October 5, 2016, to discuss grant opportunities for the system components.

Mr. Roberts recounted that the American Cancer Society Cancer Action Network held their third meeting on August 30, 2016, in Dallas. Presiding Officer Geren, Oversight Committee members Dr. Rice and Dr. Rosenfeld, Dr. Willson, and Mr. Roberts attended on behalf of CPRIT. The Bridge Breast Network made a presentation at the meeting, along with several of their clients. There were many positive comments about CPRIT's role in cancer research and prevention in Texas. Mr. Roberts thanked Mr. Cam Scott of the American Cancer Society Cancer Action Network for organizing the events.

Mr. Roberts indicated there are sufficient FY 2017 funds available for all awards being presented today.

6. Chief Scientific Officer Report and Grant Award Recommendations (Tab 3)

Academic Research Proposed Awards

Dr. James Willson, Chief Scientific Officer, presented 14 projects totaling $50,062,539 for approval. The grant recommendations are grouped together in four slates corresponding to the grant mechanisms released in Cycle 17.1 and Recruitment Award Nominations FY16.10, 16.11 and 16.12.

Dr. Willson reported that the recommendations represent:

- 4 Core Facilities Support Awards – Competitive Renewals totaling $16,062,539.
- 3 Recruitment of Established Investigators totaling $18,000,000.
- 1 Recruitment of Rising Stars totaling $4,000,000.
- 6 Recruitment of First Time -Tenure Track Faculty Members totaling $12,000,000.

The program priorities addressed by the grant recommendations being presented are:

- 1 addresses Prevention and Early Detection.
- 1 addresses Cancers of Importance to Texas – Lung Cancer.
- 2 address Computational Biology and Analytic Methods.
- 14 address Enhance Texas' Research Capacity and Life Science Infrastructure.

The four Core Facilities Support Awards (CFSA) - Competitive Renewal recommendations being presented were reviewed with the 16.2 CFSA review cycle. However, Dr. Willson reported that the Review Council did not make its final decisions on the Competitive Renewal recommendations until after August 31. The Review Council's action on the ten

Recruitment Awards presented today took place after the start of FY 2017 to assure sufficient funds were available to support all recommended research grants in FY 2016.

An Oversight Committee member noted that the core facilities resources are used across several facilities and asked if this was specifically encouraged by CPRIT or if sharing occurred naturally due to the nature of the facilities. Dr. Willson stated that when the applications are reviewed, one measure used is whether the impact of the facility is across multiple Texas facilities.

In reference to the renewal of awards to program already in existence, an Oversight Committee member asked if the facilities' business plans include become self-supporting and if the facilities cease to exist when CPRIT funding ceases. Dr. Willson responded that these facilities are not self-sustaining in that the infrastructure, the investment in technology and the continuing education for investigators is changing every year so that the core facilities must continually invest in upgrading technology. If CPRIT funding ceased, these core facilities' activities would be truncated.

Noting that three of the new recruits recommended for awards today are going to The University of Texas at Austin, an Oversight Committee member asked if there was a conscious effort to bring investigators to the new medical school. Dr. Willson responded that many institutions in Texas, including the Dell Medical School at The University of Texas at Austin, are using the CPRIT recruitment awards to build centers of expertise in cancer research. Another Oversight Committee member remarked that CPRIT's review process does not favor any particular institution, though The University of Texas at Austin has recently come forward with very competitive candidates. Mr. Roberts noted that not all the recruits to The University of Texas at Austin hold appointments with the medical school.

Academic Research Grant Award Recommendations

App ID	Mechanism	Organization/ Company	Application Title	Budget
RP170005	CFSA-CR	Dean Edwards	Baylor College of Medicine	$5,000,000
RP170003	CFSA-CR	Richard Leff	Texas Tech University Health Sciences Center	$2,499,900
RP170002	CFSA-CR	Jianjun Shen	The University of Texas M.D. Anderson Cancer Center	$5,000,000
RP170006	CFSA-CR	Jung Woo	Scott & White Healthcare	$3,562,639

CFSA-CR: Core Facilities Support Awards - Competitive Renewal

Academic Research Recruitment Grant Award Recommendations

App ID	Mech.	Candidate	Organization/Company	Budget Requested
RR160077	REI	Michael Clarke	The University of Texas M.D. Anderson Cancer Center	$6,000,000
RR160082	RFTFM	Bai Xiao-chen	The University of Texas Southwestern Medical Center	$2,000,000
RR160088	RFTFM	David Taylor	The University of Texas at Austin	$2,000,000
RR160080	RFTFM	Esra Akbay	The University of Texas Southwestern Medical Center	$2,000,000
RR160096	RFTFM	Xin Ye	The University of Texas M.D. Anderson Cancer Center	$2,000,000
RR160083	RFTFM	Li Wenbo	The University of Texas HSC at Houston	$2,000,000
RR160089	RRS	Robert Jeng	The University of Texas M.D. Anderson Cancer Center	$4,000,000
RR160097	RFTFM	Han Xu	The University of Texas M.D. Anderson Cancer Center	$2,000,000
RR160101	REI	Guo-Min Li	The University of Texas Southwestern Medical Center	$6,000,000
RR160093	REI	Gail Eckhardt	The University of Texas at Austin	$6,000,000

REI: Recruitment of Established Investigators
RRS: Recruitment of Rising Stars
RFTFM: Recruitment of First-Time Tenure Track Faculty Members

Compliance Certification

Mr. Vince Burgess, Chief Compliance Officer, presented his certification of the review process for the proposed grant awards being recommended to the Oversight Committee at this meeting. He stated he had reviewed the compliance pedigrees for the grant applications submitted to CPRIT for the:

- Core Facility Support Awards – Competitive Renewal
- Recruitment of Established Investigators
- Recruitment of Rising Stars
- Recruitment of First-Time, Tenure-Track Faculty Members Awards

Mr. Burgess affirmed he was satisfied that the application review process that resulted in the above mechanisms recommended by the Program Integration Committee followed applicable

laws and agency administrative rules and certified the academic research award recommendations for the Oversight Committee's consideration.

Conflict of Interest Notification

Presiding Officer Geren noted for the record that Mr. Angelou reported a conflict of interest with the two The University of Texas at Austin applications recommended for awards. The Oversight Committee agreed to take up the award recommendations together in one vote, with the exception of the award recommendations for The University of Texas at Austin, so that Mr. Angelou could vote on the recommendations without conflicts.

MOTION:

On a motion made by Dr. Rice and seconded by Mr. Margo, the Oversight Committee unanimously voted to approve the Program Integration Committee's recommendations for a Recruitment of Established Investigator award, and First-Time, Tenure Track recruitment awards to The University of Texas at Austin.

Presiding Officer Geren noted for the record that Mr. Angelou did not vote on these recommendations.

MOTION:

On a motion made by Dr. Rosenfeld and seconded by Mr. Margo, the Oversight Committee unanimously voted to approve the Program Integration Committee's recommendations for the Core Facilities - Competitive Renewal awards and the remaining Recruitment of Established Investigator, Rising Star and First-Time, Tenure Track recruitment awards.

MOTION:

On a motion made by Dr. Rice and seconded by Mr. Margo, 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.

7. FY 2017 Program Priorities

Mr. Roberts announced there was no information to present at this time.

8. Internal Auditor Program Report and FY 2016 Internal Audit Reports (Tab 4)

Ms. Alyssa Martin, Internal Auditor, presented information on the status of several 2016 Internal Audits. She reported that the Internal Audit Report over Revenue was completed with an overall report rating of "strong". The August 15, 2016, report was included with the Oversight Committee meeting materials. Ms. Martin indicated that the Internal Audit Report over Cash Management was completed with an overall report rating of "strong". The August 26, 2016, report was included with the Oversight Committee meeting materials.
Ms. Martin also presented recommended revisions to the FY 2017 and FY 2018 Internal Audit Plan originally developed as part of the comprehensive three-year audit plan from

2016 through 2018. The revisions are recommended based on the risk assessment update conducted with CPRIT executive management in mid-August and the information the audit team has gained about CPRIT's operations as it conducted several audits during 2016. The changes include replacing the non-grant expenditures audit with an evaluation of the pre-award grant management process originally scheduled for 2018 because the non-grant expenditures were already evaluated in 2015 with a strong overall rating. In 2018, the pre-award grant management process would be replaced with an evaluation of CPRIT's state reporting. Based on the strong ratings from revenue and cash management audits and the coverage of those audits, the Legislative Appropriations Request and the commercial paper funding audits scheduled for 2018 would be replaced with a communications audit.

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 the Information Security audit. The following staff were asked to join the Oversight Committee in the closed session: Alyssa Martin (Internal Auditor), Daniel Graves (Internal Auditor), Heidi McConnell, Kristen Doyle, and Wayne Roberts.

Presiding Officer Geren convened in closed session at 11:18 a.m.

Presiding Officer Geren reconvened the open meeting at 12:07 p.m.

MOTION:
On a motion made by Mr. Margo and seconded by Dr. Rice, the Oversight Committee unanimously voted to approve the Internal Audit Reports for Revenue, Cash Management, and Information Security.

MOTION:
On a motion made by Dr. Rice and seconded by Dr. Rosenfeld, the Oversight Committee unanimously voted to approve the FY 2017 Internal Audit Plan.

9. Contract Approvals (Tab 5)

Ms. Heidi McConnell, Chief Operations Officer, presented a contract with Weaver and Tidwell, LLP, in an amount not to exceed $236,250, for implementation of the approved 2017 Internal Audit Plan. CPRIT awarded the initial contract to Weaver and Tidwell, LLP, in FY 2016 following the completion of the competitive Request for Proposal procurement that year. CPRIT would be exercising the first renewal option for services in FY 2017.

Dr. Rebecca Garcia, Chief Prevention and Communications Officer, presented a conference venue contract with the Austin Renaissance Hotel for an estimated $230,000. The contract includes $170,000 in estimated food and beverage costs, which will be offset by conference registration fees. It also includes $60,000 in audiovisual costs, which are estimated costs and will be finalized as the schedule and needs of the program are determined.

MOTION:

On a motion made by Dr. Rosenfeld and seconded by Ms. Mitchell, the Oversight Committee unanimously voted to approve contracts with Weaver and Tidwell, LLP, and the Austin Renaissance Hotel.

10. Subcommittee Business
11. Compliance Investigation Pursuant to Health & Safety Code § 102.2631
12. Consultation with General Counsel

Presiding Officer Geren stated there was no business to discuss for standing items 10, 11, and 12.

13. Future Meeting Dates and Agenda Items

Presiding Officer Geren announced the next regular Oversight Committee meeting is scheduled for November 16, 2016, at 10:00 a.m.

14. Adjourn

MOTION:

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

Meeting adjourned at 12:12 p.m.

_____ _____

Signature Date

The University of Texas at Austin
Biomedical Engineering

Thomas Yankeelov

Professor

W.A. "Tex" Moncrief, Jr., Simulation-Based Engineering and Sciences Professorship II – Computational Oncology

Research Areas:

Biomedical Imaging and Instrumentation

Computational Biomedical Engineering

Research Focus

Computational biology, advanced in vivo imaging, mathematical modeling.

Research Interests

The overall goal of Dr. Thomas Yankeelov's clinical research is to improve patient care by employing advanced imaging methods for the early identification, assessment, and prediction of tumors' response to therapy. He develops tumor forecasting methods by integrating advanced imaging technologies with patient-specific data and builds predictive, multi-scale biophysical models of tumor growth with the purpose of optimizing therapies for the individual cancer patient.

https://www.bme.utexas.edu/about-us/faculty-directory/yankeelov

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	AGENDA ITEM 6, CHIEF EXECUTIVE OFFICER REPORT
DATE:	NOVEMBER 4, 2016

As of this writing the Chief Executive Officer Report for the November 16, 2016, Oversight Committee (OC) meeting will consist of the following items:

- Personnel update, including introduction of new staff
- Action Items from the August 17 and September 14, 2016, OC Meetings (see following attachment)
- Report on "FY 2017 Grant Award Funds Available" (see following attachment)

In addition, for your reference, copies of the CPRIT Activities Update for October provided to you previously is included at the end of this tab. This is a report provided to you in months in which the OC does not meet.

Other topics may be added as warranted.

*****

CPRIT has awarded **1,070** grants totaling **$1.676 billion**

- 172 prevention awards totaling $169.1 million
- 898 academic research and product development research awards totaling $1.507 billion

Of the $1.507 billion in academic research and product development awards,

- 29.2% of the funding ($440.0 million) supports clinical research projects
- 27.3% of the funding ($410.7 million) supports translational research projects
- 25.6% of funding ($385.0 million) supports recruitment awards
- 15.0% of the funding ($226.5 million) supports discovery stage research projects
- 2.9% of funding ($44.4 million) supports training programs.

CPRIT has 5 open Requests for Applications (RFAs)

- 3 Research Recruitment
- 2 Academic Research

Action Items from August 17, 2016, Oversight Committee Meeting

Develop a model to show number of cancers CPRIT has prevented, lives saved, and savings based on each of the prevention activities, e.g., HPV vaccinations. (Dr. Rosenfeld)

Dr. Garcia requested the data below from Texas Cancer Registry in May 2016. The data indicate mortality rate decline and estimated deaths averted comparing 2008 to 2013(the most recent date that data are available). Decline in mortality rates are attributed to many factors including better prevention, early detection and improved cancer therapies. We would need to explore the feasibility of identifying CPRIT's specific contribution to these metrics with the data that we currently collect. Additional data collection and statistical analysis would require contracted expertise.

Data Request #16264 -- % change and averted deat

Age adjusted mortality rate decline:	2008 rate	2013 rate	% change 2008 to 2013	Approx. # of deaths averted
All malignant cancers	169.9	156.8	-13.1%	3,306
Lung and bronchus	46.2	38.7	-7.5%	1,916
Female breast cancer	21.8	20.1	-1.7%	234
Cervical cancer	2.9	2.7	-0.2%	22
Colorectal cancer	16	14.5	-1.5%	343

Rates are per 100,000 and age-adjusted to the 2000 US Std Population (19 age groups - Census P25-1130) standard.

Prepared by the Texas Department of State Health Services, Cancer Epidemiology and Surveillance Branch, Texas Cancer Registry. Data Request # 16264 5/13/2016.

Cost Savings estimate from Perryman report:

Every $1 spent through CPRIT or screening/prevention leads to $22 in treatment cost savings, preserved productivity, and other economic benefits through earlier detection of cancers.

Specify statewide prevention activities by CPRIT and other public and nongovernmental organizations. (Dr. Rice)

We know of no comprehensive list of organizations providing prevention services in the state. We are aware of some existing reports, e.g., one CPRIT grantee developed a 2015 report on colorectal cancer prevention activities in Texas and DSHS is preparing a strategic plan on HPV that will have some data specific to HPV in Texas. We will talk to DSHS to identify any other reports they may have or have planned. These types of reports

typically require conducting surveys and environmental scans to try and collect information on activities throughout the state.

Provide prevention metrics by legislator district. (Dr. Rice)

This has been requested and addressed previously. Metrics by legislator districts aren't available because: 1) legislative districts change about every 10 years making them a poor source for linear data analysis by academics and others, and 2) HIPAA privacy regulations prevent CPRIT from accessing data by street address that would be needed in order for us or the Texas Legislative Council to compile the desired report. Currently the Prevention program can report by county the projects that propose to deliver services to that county. The grantee quarterly reports are being revised to report on the number of services delivered and people served by county. County metrics are a reasonable proxy. How to present the formidable amount of data in a useful manner is being investigated.

If a cancer is detected in the prevention program do we (or can we) steer the client to an appropriate clinical trial funded in either the Academic or Product Development Research Programs? (Dr. Mulrow)

No. Prevention grantees are required to steer clients with identified issues to health care providers. CPRIT does not provide health care. It is the responsibility of the health care provider to determine if existing protocols exists and who provides them. If no known protocol exists then the provider has access to a federal list of active clinical trials. CPRIT sponsored clinical trials would be in this federal repository.

CPRIT should proactively contact promising company developments and get them to apply either for a company relocation grant or a new company grant. (Dr. Rosenfeld)

Staff is unsure how to implement this suggestion. We are unaware of any publicly available list of "promising new companies". We can discuss cold-calling companies referred to in articles collected for us through our media services. This may be time-consuming with uncertain results. Staff has attended national conferences, e.g., BIO, and spoken at RESI (Redefining Early Stage Investments) and J Labs meetings, all of which have provided one-on-one networking opportunities that have resulted in applications. Staff proactively promotes all three programs to encourage applications and always seeks appropriate venues to publicize our funding opportunities.

CPRIT should attend more national conferences to promote product development. (Dr. Rosenfeld)

As noted above, staff has attended conferences and will continue to do so. However, the best promotional opportunities appear to be when invited to speak or sit on panels. I encourage all of the chiefs to identify meaningful networking opportunities, including national conferences. However, due to the often staggering cost of registration this must be done strategically to make efficient use of people, time and money. For instance, I wanted to attend or send a representative to a TED conference targeted to programs such as ours. However, the registration in excess of $10,000 plus travel to and lodging at the venue was, in my opinion, unacceptable for public sector entities. Professional gatherings are usually less costly but still not for the faint of heart.

Action Items from September 14, 2016, Special Oversight Committee Meeting

What other OC priorities are being addressed by core facility awards beyond improving life science research infrastructure? The chart underrepresents priorities that may be addressed through projects using the core facility. (Mr. Geren)

Currently the annual progress reports for core facilities do not identify how research conducted through the core facility ties to OC priorities. We will modify the annual reports to report on how they were used relative to OC priorities. It is important to note that "Enhance Texas' Research Capacity and Life Science Infrastructure" is a specific OC priority. No prioritization of priorities has occurred. However, the 2016 Program Priorities state "…it is critically important to add to the life sciences infrastructure in …Texas" to extend "CPRIT's impact …for years beyond the lifetime of the program." This includes recruitment and core facilities. Perhaps a better job of addressing the issue of how large projects like core facilities benefit the health of Texans by facilitating research in addition to that funded by CPRIT should occur. This entire subject will be discussed with the OC Subcommittee on Academic Research.

How many NCI or NIH funded research projects use the core facilities provided by CPRIT? (Mr. Geren)

This is similar to another metric sought by CPRIT for follow-on non-CPRIT funding to researchers after CPRIT grants expire. We are investigating how to get these data through the annual reports and post-grant inquiries. However, report modifications can result in additional costs for CSRA which will have to be negotiated and approved by the OC and Legislative Budget Board. Post-grant information may have to be solicited through specialized service contracts.

We get follow-on funding for product development research grants; can we get them for academic research and prevention? (Mr. Geren)

See the preceding response. We capture product development research follow-on funding by contacting our product development grantees quarterly. The number of product development grantees is significantly smaller than the number of academic research and prevention grantees. CPRIT is not staffed sufficiently to conduct similar quarterly surveys for academic research and prevention so a new specialized service contract may have to be established to provide these data. Doing so will be considered. However, follow-on funding for closed First-Time, Tenure Track Faculty Member recruitment grants has been determined and will be reported for other recruitment categories. Without doubt, such metrics are extremely valuable.

FY 2017 GRANT AWARD FUNDS AVAILABLE

General Obligation Bond Proceeds

	Prevention	Academic / PD Research	Prevention Percentage Based on Available Award Appropriations	Operating Budget	Total Appropriations
Available Appropriated Funds	**$ 28,319,312**	**$ 254,879,810**		**$ 16,800,878**	**$ 300,000,000**
Unexpended Bond Proceeds Carry Forward		**$ -**			**$ -**
Unexpended Balance Carry Forward		**$ -**			
Approved Adjustment to Operating Costs		**$ -**		**$ -**	
Appropriations Transfer to DSHS		**$ (2,969,554)**		**$ 2,969,554**	
Adjusted Appropriations	**$ 28,319,312**	**$ 251,910,256**		**$ 19,770,432**	**$ 300,000,000**
Total Available for All Grants			**$ 280,229,568**		
Calculated 10% for Prevention Grants of Total Available Grant Funding			**$ 28,022,957**		
Adjustment for 10% Prevention Grants Limit	**(296,355)**	**$ 296,355**			
Adjustment to Address Avg Prevention Historical Limit	**(1,851,835)**	**$ 1,851,835**			
Revised Adjusted Appropriations	**26,171,122**	**$ 254,058,446**		**$ 19,770,432**	**$ 300,000,000**

	Prevention Grants	Academic Research Grants	PD Research Grants		
Total Available for Grant Awards (Total GO Bond Proceeds Less Operating Budget)	**$ 26,171,122**	**$ 190,543,834**	**$ 63,514,612**		**$ 280,229,568**
Announced Grant Awards					
9/14/16 AR Core Facilities Awards		$ 16,062,539	$ -		
9/14/16 AR Recruitment Awards		$ 34,000,000	$ -		
Announced Grant Award Subtotal	**$ -**	**$ 50,062,539**	**$ -**	$ -	**$ 50,062,539**
Pending Grants-PIC Recommendations					
11/16/16 PDR Awards-2 companies			$ 32,146,716		
11/16/16 AR Awards-Translational Research		$ 3,974,486			
11/16/16 AR Awards-IIRA		$ 17,892,210			
AR Awards-Childhood and Adolescent Cancers		$ 8,035,738			
11/16/16 AR Awards-Computational Biology		$ 2,634,668			
16 AR Awards-Prevention and Early Detection		$ 5,819,500			
11/16/16 AR Awards-Research Training		$ 14,866,638			
11/16/16 AR Recruitment Awards		$ 8,000,000			
Pending Award Subtotal	**$ -**	**$ 61,223,240**	**$ 32,146,716**		**$ 61,223,240**
otal Potential Grant Funding Committed	**$ -**	**$ 111,285,779**			**$ 111,285,779**
Available Funds as of Nov. 17, 2016	**$ 26,171,122**	**$ 79,258,055**	**$ 31,367,896**		**$ 168,943,789**
PIC Deferred AR Grant Applications		**$ 10,033,103**			

Operating Budget Detail	
Indirect Administration	$ 3,030,652
Grant Review & Award Operations	$ 13,770,226
Subtotal, CPRIT Operating Costs	$ 16,800,878
Cancer Registry Operating Cost Transfer	$ 2,969,554
Total, Operating Costs	19,770,432

FY 2017 GRANT AWARD FUNDS AVAILABLE

General Obligation Bond Proceeds

	Prevention	Academic / PD Research	Prevention Percentage Based on Available Award Appropriations	Operating Budget	Total Appropriations
Available Appropriated Funds	**$ 28,319,312**	**$ 254,879,810**		**$ 16,800,878**	**$ 300,000,000**
Unexpended Bond Proceeds Carry Forward		**$ -**			**$ -**
Unexpended Balance Carry Forward		**$ -**			
Approved Adjustment to Operating Costs		**$ -**		**$ -**	
Appropriations Transfer to DSHS		**$ (2,969,554)**		**$ 2,969,554**	
Adjusted Appropriations	**$ 28,319,312**	**$ 251,910,256**		**$ 19,770,432**	**$ 300,000,000**
Total Available for All Grants			**$ 280,229,568**		
Calculated 10% for Prevention Grants of Total Available Grant Funding			**$ 28,022,957**		
Adjustment for 10% Prevention Grants Limit	**(296,355)**	**$ 296,355**			
Adjustment to Address Avg Prevention Historical Limit	**(1,851,835)**	**$ 1,851,835**			
Revised Adjusted Appropriations	**26,171,122**	**$ 254,058,446**		**$ 19,770,432**	**$ 300,000,000**

	Prevention Grants	Academic Research Grants	PD Research Grants		
Total Available for Grant Awards (Total GO Bond Proceeds Less Operating Budget)	**$ 26,171,122**	**$ 190,543,834**	**$ 63,514,612**		**$ 280,229,568**
Announced Grant Awards					
9/14/16 AR Core Facilities Awards		$ 16,062,539	$ -		
9/14/16 AR Recruitment Awards		$ 34,000,000	$ -		
Announced Grant Award Subtotal	**$ -**	**$ 50,062,539**	**$ -**	$ -	**$ 50,062,539**
Pending Grants-PIC Recommendations					
11/16/16 PDR Awards-2 companies			$ 35,089,415		
11/16/16 AR Awards-Translational Research		$ 3,974,486			
11/16/16 AR Awards-IIRA		$ 17,892,210			
AR Awards-Childhood and Adolescent Cancers		$ 8,035,738			
11/16/16 AR Awards-Computational Biology		$ 2,634,668			
16 AR Awards-Prevention and Early Detection		$ 5,819,500			
11/16/16 AR Awards-Research Training		$ 14,866,638			
11/16/16 AR Recruitment Awards		$ 8,000,000			
Pending Award Subtotal	**$ -**	**$ 61,223,240**	**$ 35,089,415**		**$ 61,223,240**
otal Potential Grant Funding Committed	**$ -**	**$ 111,285,779**			**$ 111,285,779**
Available Funds as of Nov. 17, 2016	**$ 26,171,122**	**$ 79,258,055**	**$ 28,425,197**		**$ 168,943,789**
PIC Deferred AR Grant Applications		**$ 10,033,103**			

Operating Budget Detail	
Indirect Administration	$ 3,030,652
Grant Review & Award Operations	$ 13,770,226
Subtotal, CPRIT Operating Costs	$ 16,800,878
Cancer Registry Operating Cost Transfer	$ 2,969,554
Total, Operating Costs	19,770,432

CPRIT MANAGEMENT DASHBOARD
FISCAL YEAR 2016

	SEPT	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	CUMULATIVE (ANNUAL)	CUMULATIVE (TO DATE)
ACCOUNTABILITY														
Announced Grant Awards	5		77			6			36			26	150	
New Grant Contracts Signed	8	0	1	4	25	31	10	5	4	0	22	7	117	
New Grant Contracts In Negotiation			43			24			27			26	120	
Grant Reimbursements Processed	31	7	266	208	529	245	294	129	96	311	139	72	2,327	
Grant Reimbursements Processed	$ 2,897,094	$ 23,414,469	$ 19,906,130	$ 21,102,375	$ 41,408,221	$ 19,447,324	$ 23,751,614	$ 12,000,762	$ 8,771,030	$ 26,088,909	$ 13,760,393	$ 15,661,467	$ 228,209,788	
Revenue Sharing Payments	$ -	$ 10,117	$ 4,959	$ -	$ 21,122	$ -	$ -	$ 9,358	$ 5,745	$ -	$ 865,236	$ 5,150	$ 921,686	$ 3,135,203
Total Value of Grants Contracted	$ 49,662,860	$ -	$2,000,000	$ 9,202,957	$ 42,908,491	$ 40,857,638	$ 14,512,920	$ 6,058,940	$ 9,645,064	$ -	$ 51,572,468	$ 15,678,823	$ 242,100,161	
Grants Awarded (#)/ Applications Rec'd (#)	12%	11%	13%	13%	13%	13%	12%	12%	12%	12%	12%	12%		
Debt Issued ($)/Funding Awarded	62%	62%	58%	58%	62%	61%	61%	61%	64%	64%	64%	66%		
Grantee Compliance Trainings/Monitoring Visits	3	2	2	0	3	0	3	0	1	5	6	5	30	
Awards with Delinquent Reimbursement Submission (FSR)			5			3			0			1		
Awards with Delinquent Matching Funds Verification			10			3			0			1		
Awards with Delinquent Progress Report Submission			4			3			1			3		
IA Agency Operational Recommendations Implemented	0	6	6	6	6	6	6	6	9	9	9	9		
IA Agency Operational Recommendations In Progress	13	7	7	7	7	7	7	7	2	2	2	2		
Open RFAs	17	14	9	9	11	11	15	9	8	10	10	11		
Prevention Applications Received	0	0	0	0	0	0	44	0	0	0	0	36	80	640
Product Development Applications Received	25	0	0	0	0	32	0	0	0	0	0	19	76	344
Research Applications Received	4	212	2	6	5	5	9	13	488	8	1	2	755	5,268
Help Desk Calls/Emails	193	289	231	159	143	323	191	300	422	198	189	315	2,953	
MISSION														
RESEARCH PROGRAM														
Number of Research Grants Awarded (Annual)			55			8			33			12	108	
Recruited Scientists Announced														159
Recruited Scientists Accepted														119
Recruited Scientists Contracted														110
Published Articles on CPRIT-Funded Projects (#)													1,257	
Jobs Created & Maintained (#)													3,306	
Trainees in CPRIT-Funded Training Programs (#)														
Open Clinical Trials (#)														53
Number of Patents Resulting from Research													14	
Number of Patent Applications													56	

CPRIT MANAGEMENT DASHBOARD
FISCAL YEAR 2016

	SEPT	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	CUMULATIVE (ANNUAL)	CUMULATIVE (TO DATE)
Number of Investigational New Drugs													33	
PRODUCT DEVELOPMENT PROGRAM														
Number of Product Development Grant Awarded (Annual)			1			0			2			0	3	
Life Science Companies Recruited (in TX)													2	9
Published Articles on CPRIT-Funded Projects													24	
Number of Jobs Created & Maintained													529	
Open Clinical Trials (#)														7
Number of Patents Resulting from Research													0	
Number of Patent Applications													6	
Number of Investigational New Drugs													4	
PREVENTION PROGRAM														
Number of Prevention Grant Awarded (Annual)			12			0			0			14	26	
People Served by CPRIT-Funded Prevention and Control Activities			120,112			130,335			158,329			173,387	582,163	
People Served through CPRIT-Funded Education and Training			58,126			55,377			72,564			79,087	265,154	
People Served through CPRIT-Funded Clinical Services			61,986			74,958			85,765			94,300	317,009	
TRANSPARENCY														
Total Website Hits (Sessions)	8,560	7,901	8,581	4,617	5,993	7,458	7,031	7,001	9,533	5,819	6,848	7,884	87,226	
Total Unique Visitors to Website (Users)	5,778	5,472	5,679	3,376	4,435	5,251	4,916	4,789	6,171	4,332	5,134	5,722	61,055	

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	CPRIT ACTIVITIES UPDATE – OCTOBER 2016
DATE:	OCTOBER 31, 2016

Topics in the memo include recent milestones in our fight against cancer; preparation for the November Oversight Committee meeting; CPRIT staffing; legislative and related briefings; Compliance, Program, and Operations updates and staff presentations and meetings.

Preparation for the November Oversight Committee Meeting

The Oversight Committee will meet November 16 at 10:00 a.m. in the Capitol Extension E1.012. The final agenda for the Oversight Committee meeting will be posted by November 8, 2016; a tentative agenda is attached.

You will receive an email from CPRIT by November 2 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. There will be a large number of recommended awards, please allow 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 COB November 9. Hard copies of the agenda packet will be available at the meeting.

Recent Milestones in the Fight Against Cancer

CPRIT Grantees in the news:

- CPRIT grantees, Malcolm Brenner M.D., Ph.D. and Cheryl Walker, Ph.D., were named to the National Academy of Medicine. This is considered one of the highest honors in the fields of health and medicine and recognizes individuals who have demonstrated outstanding professional achievement and commitment to service. Dr. Brenner, Professor of Pediatrics and Molecular and Human Genetics at Baylor College of Medicine (BCM), is director of the Center for Cell and Gene Therapy, and responsible for stem cell transplant programs at Texas Children's Hospital and Methodist Hospital. His CPRIT supported research developed genetically modified T cells that can safely and effectively target cancer tumors. Dr. Walker, a molecular biologist recently relocated from Texas A&M to Baylor to develop the Center

for Precision Environmental Health, where she is researching environmental causes of cancer.

- The Academy of Medicine, Engineering and Science of Texas (TAMEST) selected Joshua Mendell, M.D., Ph.D., CPRIT Scholar and Professor of Molecular Biology at UT Southwestern Medical Center and a Howard Hughes Medical Institute Investigator, as the recipient of the 2016 Edith and Peter O'Donnell Award in Medicine. Dr. Mendell, recruited from Johns Hopkins in 2011 as a CPRIT Rising Star recruit, researches the role of noncoding RNAs.

- Ralph DeBerardinis, M.D., Ph.D., a CPRIT grantee at UT Southwestern was chosen as a Howard Hughes Medical Institute Faculty Scholar. The program awards grants of $600,000 to $1.8 million over five years to early-career scientists with potential to make unique contributions to their field. Distinguished scientists evaluated 1,400 applications and selected 84 Faculty Scholars based on prior research, current investigations, and future potential for bold, innovative investigations.

- Margaret Spitz, M.B.,B.Ch., M.P.H., professor in the Dan L Duncan Comprehensive Cancer Center at Baylor College of Medicine (BCM), has been appointed by President Obama as a member of the National Cancer Advisory Board. An expert in molecular epidemiology, Ms. Spitz has a long-standing interest in genetic susceptibility to lung cancer, with an emphasis on variation among individuals in susceptibility to tobacco carcinogenesis. She is the principal investigator of the recently funded CPRIT Post-Graduate Training Program in Integrative Cancer Epidemiology at BCM.

- Gail Tomlinson, M.D., Ph.D., Director, Pediatric Hematology-Oncology at The University of Texas Health Science Center at San Antonio received a $250,000 Hyundai Scholar Award to develop novel strategies for treating childhood liver tumors. This award is a direct follow-up of her CPRIT research detailing the genomic description of childhood liver tumors.

Notable CPRIT supported research and prevention accomplishments:

- CPRIT grantee, Jennifer Wargo, M.D., associate professor of Genomic Medicine and Surgical Oncology, MD Anderson reported in the journal *Cancer Discovery* that immune response measured in tumor biopsies taken during the course of early treatment with an immune check-point inhibitor predicts which melanoma patients will benefit. Analysis of biopsies before treatment did not indicate who would respond; however, in treatment, there were significant differences in the immune system biomarkers between responders and non-responders. Her findings provide insight on how to guide treatment with this exciting new class of immune therapies.

- Rice University bioengineer, Junghae Suh, Ph.D., was awarded a $1.8 million grant by the National Cancer Institute (NCI) to research the use of viral gene therapy to fight ovarian cancer. The grant will fund collaborative research with Dr. Anil Sood, an ovarian-cancer specialist at MD Anderson Cancer Center, to adapt otherwise-harmless adeno-associated viruses to recognize ovarian-cancer tumors and deliver therapeutic genes to diseased cells. The team won a CPRIT High impact/High risk award that provided part of the funding

needed to show that their concept works and to convince the NCI to fund the further development of the gene therapy. Also of note, Dr. Suh recently won the Outstanding New Investigator Award from the American Society of Gene and Cell Therapy in recognition of her contributions to the field.

- Matthew Ellis, M.D., a CPRIT Established Investigator and professor and director of the Lester and Sue Smith Breast Center at Baylor College of Medicine, and collaborators from Baylor College of Medicine, Washington University School of Medicine, MD Anderson Cancer Center and the Mayo Clinic, reported in *Nature Communications* on the complexity of the genetic makeup of an individual patient's breast cancer and the promise of more effective treatments by matching them with genetic mutations in the cancer.

- CPRIT grantees Jim Brugarolas, M.D., Ph.D., James Amatruda, M.D., Ph.D, Ralph DeBerardinis, M.D., Ph.D., and Joshua Mendell, M.D., Ph.D., received $11 million in funding from NCI to support kidney cancer research at UT Southwestern Medical Center's Harold C. Simmons Comprehensive Cancer Center. Kidney cancer currently has no method of early detection and is challenging to treat. CPRIT support established the foundation for the program's early detection and treatment research that will now advance with funding from the NCI SPORE. This research is important to Texans as the incidence of kidney cancer in Texas is rising and is significantly higher than the national rates.

- Investigators from the Harold C. Simmons Comprehensive Cancer Center reported in the journal *Nature* results of a pre-clinical study in mice transplanted with kidney cancer from over 20 patients and showed that a HIF-2 inhibitor under development by Peloton Therapeutics Inc. controlled cancer in half of the tumors. UT Southwestern oncologists reported at the 2016 annual meeting of the American Society of Clinical Oncology that the HIF-2 inhibitor is well tolerated in patients and had activity even in heavily pretreated patients.

- A CPRIT funded team from Rice University and the University of North Texas collaborated with Israeli researchers to discovered a way to fight the overexpression of a protein, NAF-1, that is associated with the proliferation of breast cancer using pioglitazone, a drug now used to treat type 2 diabetes. Their findings reported in the *Proceedings of the National Academy of Sciences* could bring a new weapon to the battle against breast, prostate, gastric, cervical, liver and laryngeal cancers.

- CPRIT Scholar, Daniel Siegwart, Ph.D., at the UT Southwestern Simmons Comprehensive Cancer Center successfully developed a nanoparticle delivery method that can transport a drug into lung cancer cells without going inside normal lung cells. The findings appeared in the *Proceedings of the National Academy of Sciences* and are important because these nanoparticles provide an alternative for selective drug delivery to tumor cells that may improve efficacy and reduce adverse side effects of cancer therapies.

- In research funded in part by a CPRIT MIRA award to investigators at UT Southwestern have found a chink in a so-called "undruggable" lung cancer's armor – and identified an existing drug that might provide treatment. The study, published in *Nature*, describes how the

drug Selinexor killed lung cancer cells and shrank tumors in mice when used against cancers driven by the aggressive and difficult-to-treat KRAS cancer gene. Selinexor is already in clinical trials for treatment of other types of cancer, primarily leukemia and lymphoma but also gynecological, brain, prostate, and head and neck cancers. These findings have led to development a clinical trial of Selinexor in lung cancer.

- UT Southwestern Medical Center researchers developed an MRI-based method to track the state and progression of a common type of brain cancer. This new method is a much more rapid way of assessing therapy – allowing the physician to know to stop treatments that aren't working or continue treatments that are. This research was supported by CPRIT grants and reported in the *Journal of Clinical Oncology*.

- Peloton Therapeutics Inc. recently announced that it has raised $52.4 million in venture capital, which it plans to use to support clinical trials on its novel kidney cancer treatment. Peloton was founded six years ago by biochemists and molecular geneticists from the UT Southwestern Medical Center. In 2010, it was awarded a CPRIT grant and in 2011 completed $18 million in Series A financing rounds. Peloton manufactures a molecular therapy that targets a protein called hypoxia-inducible factor (HIF)-2alpha. People with mutations of the protein have a higher propensity for developing renal cell carcinoma, in which malignant cells form inside the tubules of the kidney.

- Cell Medica, a CPRIT-funded cellular immunotherapy company, announced a new collaboration with University College of London (UCL) to license and develop new T-cell therapies developed by UCL.

- DNAtrix, a CPRIT-supported clinical stage biotechnology company developing virus-driven immunotherapies for cancer, announced the award of a $2 million grant from the FDA's Office of Orphan Products Development to support its Phase 2 clinical trial for patients with recurrent glioblastoma. This FDA grant program supports the development of medicines for rare diseases or conditions where no current therapy exists. About 100 applications are received per year from which roughly 10 are selected for funding following rigorous scientific review.

- MIRNA announced it is closing its ongoing Phase 1 clinical study after significant adverse events were noted in treated patients. They are analyzing the adverse events to identify causes and will report to the FDA.

- ESSA received FDA approval for an Investigational New Drug application to conduct clinical studies of a new prostate cancer drug.

- The team behind CPRIT prevention project *Get FIT to Stay Fit – Stepping Up to Fight Colorectal Cancer in the Panhandle* was recognized at the 2016 Texans Caring for Texans ceremony in Canyon, Texas for the efforts made across the Panhandle to combat colorectal cancer. The Texas Tech University Health Sciences Center project led by Dr. Misra, Dr. Mishra, and Michelle Marsh strives to break down the barriers that their population faces with access to health screenings.

- Dr. Maria Jibaja-Weiss of Baylor College of Medicine met with Ms. Anabella Aspiras, Director of Patient Engagement, Cancer Moonshot Task Force for VP Joe Biden during her visit to Houston. Ms. Aspiras was interested in the activities of the Community Network of Cancer Prevention (CNCP), which was established with CPRIT grant funds. This CPRIT funded prevention project provides cancer prevention services and resources, for which funding is almost non-existent. Ms. Aspiras conducted a site visit of the CNCP activities and was impressed by the commitment to improve health disparities in Houston.

- Elena Marina, Community Health Worker, met State Senator José Menéndez at the Edgewood Independent School District Back to School Health Fair to discuss the CPRIT funded project GRACIAS Texas: Genetic Risk Assessment for Cancer in All South Texas. Dr. Gail Tomlinson at The University of Texas Health Science Center at San Antonio leads the project. Senator Menéndez expressed interest in the program and later provided a letter of appreciation and a Certificate of Congratulations for their work.

Personnel Changes and Job Openings

CPRIT has 32 authorized full-time equivalent (FTE) positions, of which 31 are filled as of November 1, 2016.

- Chris Cutrone started October 3 as Senior Communications Specialist.

- Mark McCollum, Grant Compliance Specialist, resigned to take a position with the City of Austin effective September 30. The position is posted through November 3.

Legislative Briefings and CPRIT Outreach

- On August 2 Chief Scientific Officer Dr. Jim Willson led a panel of national experts on "Accelerating More Research and The Role of Patients" at the American Cancer Society Cancer Action Network's National Cancer Moonshot Roundtable on Overcoming Barriers to Progress in Cancer Research.

- On August 22 Dr. Willson and I visited Texas Tech University and Texas Tech University Health Sciences Center to learn about their cancer research and to promote interest in CPRIT grant opportunities. Meetings were held with numerous administrators and faculty of the two institutions.

- Chief Prevention Officer Dr. Becky Garcia presented at the August 31 Texas Alliance for Colorectal Cancer Testing meeting in Houston. The Alliance is a statewide coalition of organizations that are providing colorectal cancer screening. The majority of members are CPRIT grantees.

- On September 14 I formally presented CPRIT's request for legislative appropriations in the statutorily required public hearing to staff of the Governor's Office, Legislative Budget Board and miscellaneous legislators.

- I discussed miscellaneous CPRIT legislative issues with staff of Speaker Joe Straus on September 14.

- Dr. Garcia attended the Carson Leslie Foundation Golden Toast reception in Washington, D.C. on September 22 honoring U.S. Representatives Michael McCaul and Chris Van Hollen and attended the Congressional Childhood Cancer Caucus Summit the following day.

- Presiding Officer Pete Geren and I went to Culver City, California on September 23 with Texas A&M University System Chancellor John Sharp and members of his staff to discuss innovative cancer research and treatment initiatives with a UCLA faculty researcher.

- On September 24 Dr. Willson participated on the *Texas Tribune* Festival (Tribfest) panel "A Cure for Cancer". Other panelists were Lance Armstrong, State Representative Sarah Davis, MD Anderson President Ron DePinho and Jake Silverstein of the New York Times Magazine (moderator).

- Kristen Doyle, Heidi McConnell and I briefed Governor's Office staff on CPRIT's legislative issues on September 28.

- On September 28 Kristen Doyle, Heidi McConnell and I briefed representatives of the advocacy community on CPRIT's projects and upcoming legislative issues.

- Kristen Doyle, Heidi McConnell and I briefed Lieutenant Governor's Office staff on CPRIT's legislative issues on September 29.

- On September 30 Kristen Doyle, Heidi McConnell and I discussed upcoming legislative issues with staff of State Representative Sarah Davis.

- As a member of the advisory board for the Texas Health Improvement Network (THIN), Dr. Garcia participated in the October 1 THIN Advisory Meeting in Austin. The state established the network to address the urgent health care challenges and improve the health care system in the state.

- CPRIT staff (Dr. Willson, Dr. Garcia, Ramona Magid, Patty Moore, Kristen Doyle and I) visited the Texas A&M University System Office in College Station on October 5 to discuss CPRIT programs and RFAs with assorted TAMU component administrators.

- Michael Lang presented an overview of CPRIT's Product Development program at JLABS in Houston on October 12. JLABS is a Johnson & Johnson technology incubator providing shared services to startup companies. The presentation was attended by many prospective CPRIT grant applicants

- Heidi McConnell, Kristen Doyle and I attended the LBJ School of Public Affairs 2016 Biennial Legislative Communication Conference in Austin on October 13. At the

conference, Ursula Parks, Director of the Legislative Budget Board (LBB) announced that she expects two separate budget bills, one for the Senate and one for the House, to be introduced at the beginning of the 2017 legislative session.

- On October 18 Heidi McConnell and I briefed State Representative Tan Parker on CPRIT's activities and legislative issues.

- On October 20 Kristen Doyle, Heidi McConnell and I discussed CPRIT's activities and legislative issues with staff of State Representative John Zerwas.

- On October 25 I attended the Cancer Research Retreat in Houston at the invitation of State Representative Kyle Kacal. Baylor College of Medicine and MD Anderson researchers presented their research initiatives. State Representative Ken King also attended the event.

- I participated in Austin on a panel at the TexasOne Fall Supporters Luncheon hosted by the Texas Economic Development Corporation on October 27. My topic was Texas' current position in healthcare, bioscience and cancer research and how to improve it. Other panelists were Tom Kowalski (Texas Healthcare and Bioscience Institute), Carlton Schwab (Texas Economic Development Council) and Todd Staples (Texas Oil and Gas Association).

- Dr. Willson, Mike Lang, Patty Moore, Chris Cutrone and I attended a series of presentations on October 31 concerning CPRIT funded core facilities in the Texas Medical Center (TMC) and TMC collaborations. Multiple TMC institutions participated.

- I will go to Gatesville to update State Representative J.D. Sheffield on CPRIT activities on November 2.

- On November 7 in Houston Oversight Committee member Ned Holmes and I will update Lieutenant Governor Dan Patrick on CPRIT activities.

- Dr. Willson and Mike Lang will visit the University of Houston on November 11 to meet with faculty and to promote interest in CPRIT grant opportunities.

Compliance Program Update

Submission Status of Required Grant Recipient Reports

A delinquent report is produced by CPRIT's grant management system (CGMS) each week; this is the primary source used by CPRIT's compliance staff to follow up with grantees. CPRIT typically has 550+ grants that are either active or wrapping up grant activities and receives approximately 570 grantee reports each month.

As of the most recent CGMS report (October 24, 2016), seven required grantee reports from six entities have not been filed in the system by the set due date. Of the seven delinquent reports, two (29%) are Prevention grants, three (42%) are Academic Research grants, and two (29%) are Product Development grants. In most cases, CPRIT does not disburse grant funds until the required reports are filed. In some instances, grantee institutions may be ineligible to receive a

future award if required reports are not submitted. CPRIT's grant compliance specialists and grant accountants continue to review and process incoming reports and reach out to grantees to promptly resolve filing issues.

Financial Status Report Reviews

CPRIT's Grant Compliance Specialists performed 119 second level reviews of grantee Financial Status Reports (FSRs) during the month of October. Only one FSR 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

Ten desk reviews were performed during the month of October. Desk-based financial monitoring/reviews are conducted 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, procurement and contracting procedures and practices, current and past fiscal audits, subcontracting monitoring, and timeliness of required grantee report submission. Grant Compliance Specialists are working with fifteen grantees to remediate desk review findings.

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.

There are currently four grantees with outstanding audit findings. Grantees are given 30 days from the receipt of the audit to submit supporting documentation to demonstrate remediation efforts. Grant Compliance Specialists worked with two grantees to fully remediate audit report findings in October. There are currently no grantees with a delinquent audit report or a delinquent Corrective Action Plan (CAP). Grantees are unable to receive reimbursements or advances if they are delinquent in filing the required audit and corrective action plan, unless a request for additional time was submitted on or before the due date of the required audit and subsequently approved by CPRIT's CEO.

Training & Support

CPRIT staff conducted a new grantee training for Texas State University in San Marcos on October 6, 2016. In addition to a brief overview of CPRIT's history and mission, the training covered grantee reporting requirements, an overview of the compliance program, and a hands-on navigation of CPRIT's online grants management system.

CPRIT staff conducted a grantee training webinar on October 12, 2016 with approximately 130 grantee staff in attendance. The webinar focused on administrative rules changes, grantee reporting requirements, compliance program activities, and the grant closeout process. Grantees

also had the opportunity to ask questions during the training. This was the third webinar conducted for grantees this calendar year in support of the new 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.

Academic Research Program Update

FY 2017 Cycle 1 Academic Research and Applications

Applications submitted for FY 2017 Cycle 1 Academic Research awards are currently under review. The six Academic Research RFAs were released on February 19, 2016. Six peer review panels met in Dallas September 21-29 to conduct preliminary reviews for the 467 applications and full scientific reviews for 118 applications. The Program Integration Committee considered the Scientific Review Council's award recommendations on October 28. The award recommendations will be presented to the Oversight Committee on November 16, 2016. Table 1 displays information about the number of applications received, applications reviewed and applications receiving a full review for each of the six Academic Research RFAs.

Table 1: 17.1 Academic Research Application Data by Grant Mechanism

Grant Mechanism	Received	Reviewed	Full Review
Individual Investigator (IIRA)	292	287	64
Individual Investigator – Cancer in Children and Adolescents (IIRACCA)	45	42	15
Individual Investigator – Prevention and Early Detection (IIRAP)	35	33	8
Individual Investigator – Computational Biology (IIRACB)	44	42	5
ETRA – Early Translational Research	54	54	19
RTA – Research Training Awards	9	9	7
Total	479	467	118

* Note: Four awards for FY 2017 Cycle 1 Core Facility Support Awards-Competitive Renewal were approved September 14, 2016.

FY 2017 Academic Recruitment Cycles 17.1 – 17.3

CPRIT released three FY 2017 Academic Recruitment RFAs on June 21, 2016. Table 2 provides information about the number of nominations received in response to these RFAs. The Scientific Review Council reviews Academic Recruitment applications monthly. The Program Integration Committee considered the award recommendation for Cycles 17.1 and 17.2 at its October 28 meeting. The award recommendations will be presented at the November 2016 Oversight Committee Meeting. Nominations for Cycle 17.3 will be reviewed in November by

the Scientific Review Council and recommendations will be presented at the February Oversight Committee Meeting.

Table 2: 17.1, 17.2 and 17.3 Recruitment Data by Grant Mechanism

Grant Mechanism	Applications Submitted	Applications Reviewed
Established Investigator Award	3	2
Rising Stars	1	0
First Time, Tenure-Track Faculty	1	1
Total Recruitment Awards	**5**	**3**

FY 2017 Cycle 2 Academic Research Applications
CPRIT is accepting applications October 17, 2016 – January 16, 2017 for the following 17.2 Academic Research RFAs:

- Core Facilities Support Awards (RFA R-17.2- CFSA) establish or enhance core facilities (laboratory, clinical, population-based, or computer-based) that will directly support cancer research programs to advance knowledge of the causes, prevention, and/or treatment of cancer or improve quality of life for patients with and survivors of cancer. Award: Up to $3M (total costs) for the first 2 years and up to $1M (total costs) for each subsequent year; Maximum duration: 5 years

- High Impact/High-Risk Research Awards (RFA R-17.2-HIHR) 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. Award: Up to $200,000 (total costs); Maximum duration: 2 years

Product Development Research Program Update

FY 2016 Cycle 1 Product Development Research Awards
The Oversight Committee approved Product Development Research awards to Salarius Pharmaceuticals and Pelican Therapeutics at its May 2016 meeting. CPRIT executed the grant contract with Salarius on September 2, 2016. Pelican will execute their contract upon confirmation of required matching funds.

FY 2016 Cycle 2 Product Development Research Applications
Thirty-two applications were submitted in February 2016 for Review Cycle 16.2, making this among our largest submission pools. The applications proceeded through screening review, in-person presentations (13 applicants), and due diligence (7 applicants). The Product Development Review Council met on October 17 and recommended two companies for PIC consideration. The award recommendations will be presented at the November 16 Oversight Committee meeting.

FY 2017 Cycle 1 Product Development Research Applications
Twenty-five applications were submitted by the August 11 deadline. The screening review panel members evaluated the applications in September, selecting eight companies to present their applications at the peer review panel meetings held in Dallas the week of October 24. Following the in person presentations, the review panels put forward three applications for due diligence review. We anticipate presenting recommended awards at the February 2017 Oversight Committee meeting.

Prevention Program Update

FY 2017 Cycle 1 Prevention Awards
Five RFAs for Cycle 17.1 were released in May 2016. We received 36 applications by the August 30 deadline. After administrative review, five applications were withdrawn and 31 applications requesting $36,684,532 were assigned to the review panels. Peer review will take place December 5 - 8 in Dallas. Recommendations will go to the Oversight Committee for consideration in February 2017. Information about the applications submitted is provided by grant mechanism in Table 3.

Table 3: 17.1 Prevention Application Data by Grant Mechanism

Mechanism	Applications Reviewed	Requested Funding
Cancer Prevention Promotion and Navigation to Clinical Services	4	$1,588,990
Competitive Continuation/Expansion	10	$13,780,345
Dissemination of CPRIT-Funded Cancer Control Interventions	1	$300,000
Evidence-Based Cancer Prevention Services	16	$21,015,197
Total	**31**	**$36,684,532**

FY 2017 Cycle 2 Prevention Awards
CPRIT will release the RFAs listed below on November 17. Submissions will be due March 2, 2017, with peer review taking place in June. Recommendations will be presented to the Oversight Committee in August 2017.

- Evidence-Based Cancer Prevention Services
- Dissemination of CPRIT-Funded Cancer Control Interventions
- Cancer Prevention Promotion and Navigation to Clinical Services
- Colorectal Cancer Coalition
- Tobacco Control and Lung Cancer Screening

The Tobacco Control and Lung Cancer Screening RFA is a new grant mechanism. CPRIT will fund programs on tobacco prevention and cessation, as well as screening for early detection of lung cancer. 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.

Other activities
The Prevention program completed calls to the 14 grantees awarded in August to discuss budget, goals and objectives, and to address any questions.

Quarterly progress reports were submitted by September 15 and reviewed; the performance measures report for the Legislative Budget Board was prepared and submitted on October 7.

Advisory Committee Meetings

- The University Advisory Committee met on October 4, 2016, at the CPRIT Office in Austin. Mr. Geren and Dr. Rice were able to join the in-person meeting.

- The Advisory Committee for Childhood Cancer (ACCC) met by teleconference on October 26, 2016. Dr. Susan Blaney, ACCC Chair, is submitting nominations to CPRIT for consideration and approval to carry out the membership expansion endorsed by the Oversight Committee last year.

- The Product Development Advisory Committee Meeting met by teleconference on October 14, 2016. Ten committee members and three Oversight Committee members (Bill Rice, Dee Margo, and Craig Rosenfeld) participated. The advisory committee members provided input on several subjects, including royalty rates, eligibility of prior awardees, and award caps. The committee supported establishing different royalty rates for diagnostic/device firms than the rates incorporated in the current standard revenue sharing terms approved by the Oversight Committee in January 2015. Adopting a different royalty rate reflects the differences in business fundamentals between the diagnostic/device sector and the therapeutics sector, which has a higher profit margin. Advisory committee members affirmed that a simple, royalty-based, return structure is the best structure for CPRIT. The advisory committee members generally agreed that prior CPRIT awardees should remain eligible for future awards, and that the current $20 million award cap is appropriate.

Ongoing Royalty/Equity Monitoring and Management Project

The leadership teams for CPRIT and Texas Treasury Safekeeping Trust Company have met several times since August to explore whether the Trust Company can take on the managerial and disposition obligations related to potential assets resulting from CPRIT's revenue sharing agreements. The Texas Treasury Safekeeping Trust Company ("Trust Company") is a special purpose trust company whose mission is to preserve and grow the State's financial resources by competitively managing and investing them in a prudent, ethical, innovative and cost-effective manner while focusing on client needs. The Trust Company invests, manages, and oversees over $50 billion in assets. Investments include cash-equivalent funds such as the Texas Treasury Pool and separately managed portfolios for various Texas state agency clients.

Given the drug development life cycle, grantees will pay the largest portion of revenue sharing obligations *after* CPRIT's statutory end, currently set for August 31, 2021. An ongoing monitoring system to track CPRIT's grant investments is necessary to ensure that grantees are fulfilling their contractual obligations and to protect potential state assets. The tracking system should monitor CPRIT-funded projects at both academic institutions and public/private companies.

Changes to CPRIT's statute will be necessary to give the Trust Company final authority (as opposed to the Oversight Committee) to sell royalty/equity assets created by CPRIT funding. In the interim, CPRIT is exploring an interagency contract with the Trust Company to create a tracking process for cataloguing CPRIT royalty and equity rights. If the Trust Company is unable to provide this service and no other state entity is available, CPRIT will need to contract with a vendor.

Communications Update

- Grant Award announcements: A press release on the Academic Research awards approved by the Oversight Committee was sent to media on September 14.

- Website: We are working with TradeMark Media to redesign the website. The project is on schedule to be completed in early January.

- *2017 Innovations in Cancer Prevention and Research Conference*: The biennial conference will take place November 13-14, 2017, at the Austin Renaissance hotel. CPRIT executed the venue contract and sent a "Save the Date" announcement via CPRIT's listserv on October 5.

- Staff continues to respond to requests for information and prepare legislative briefing materials.

Operations and Finance Update

Audits

The FY 2016 financial audit is underway. The audit team from McConnell & Jones starts fieldwork at the CPRIT office on October 31. Oversight Committee members should have received an email request from Heidi McConnell to complete the Related Parties and Fraud Risk questionnaires for this audit. If you did not receive the request or have any questions about the forms, please contact Heidi McConnell.

Contracts

The procurement process for a new vendor to provide peer review monitoring services through a competitive Request for Proposal (RFP) has been completed. Business & Financial Management Solutions located in Austin is the successful vendor contracted for a not to exceed amount of $41,823 for services through the end of FY 2017 pending verification that no financial conflicts exist.

The procurement process for outside legal counsel has also been completed. Three firms - Baker & Botts, Yudell Isidore, and Vinson & Elkins - have been selected to provide these services pending Oversight Committee approval of the contracts at the November meeting as well as verification that no financial conflicts exist.

Upcoming Subcommittee Meetings

The dates and times for the upcoming November subcommittee meetings are listed below.

Subcommittee	Date & Time	
Board Governance	October 31	at 10:00 am
Audit	November 7	at 10:00 am
Prevention	November 8	at 10:00 am
Scientific Research	November 9	at 10:00 am
Product Development	November 10	at 10:00 am
Nominations	November 11	at 10:30 am

An agenda, call-in information and supporting material will be sent to the subcommittees one week prior to the meeting date.

*****

CPRIT has awarded **1,070** grants totaling **$1.676 billion**

- 172 prevention awards totaling $169.1 million
- 898 academic research and product development research awards totaling $1.507 billion

Of the $1.507 billion in academic research and product development awards,

- 29.2% of the funding ($440.0 million) supports clinical research projects
- 27.3% of the funding ($410.7 million) supports translational research projects
- 25.6% of funding ($385.0 million) supports recruitment awards
- 15.0% of the funding ($226.5 million) supports discovery stage research projects
- 2.9% of funding ($44.4 million) supports training programs.

CPRIT has 5 open Requests for Applications (RFAs)

- 3 Research Recruitment
- 2 Academic Research

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: JAMES WILLSON, M.D., CHIEF SCIENTIFIC OFFICER

SUBJECT: ACADEMIC RESEARCH PROGRAM UPDATE

DATE: NOVEMBER 7, 2016

FY16 Academic Research Awards

The overarching principles for awarding CPRIT funds are scientific excellence and impact on reducing the burden of cancer. During FY16, the program continued to offer RFAs for investigator initiated grants that address a variety of cancer research topics, core facility support awards, high risk/high impact awards, training awards and recruitment nominations. In addition, in an effort to stimulate research proposals that address Oversight Committee priorities that were underrepresented, a more targeted approach to solicitations of research proposals was taken. Additional RFAs were designed to stimulate applications that address Oversight Committee priorities for research in childhood and adolescent cancers, prevention and early detection, and computational biology and analytic methods.

Table 1 displays the funding by academic research program priorities in FY16.

Table 1: FY16 Funding by CPRIT Academic Research Program Priorities

Priorities Addressed	# Grants	Award Amount
A broad range of innovative, investigator-initiated academic research projects	84	$91,000,814
Enhance Texas' cancer research capacity and life sciences infrastructure	76	$145,645,372
Childhood cancers	13	$28,184,209
Prevention and early detection	17	$23,272,828
Computational biology and analytic methods	9	$24,600,567
Rare or intractable cancers	31	$42,255,865
Cancers of importance in Texas (Lung, Cervix, Liver)	38	$32,982,826

As shown in Table 2, in FY2016 CPRIT awarded $135,082,887 in Academic Research grants and awarded $99,220,000 in Recruitment Research grants as displayed in Table 3. The overall success rate for Applications submitted in response to RFAs was 17%.

Table 2: FY16 Academic Research Awards by RFA Mechanism

Funding Mechanism	Applications Received	Applications Awarded	Total Funding Awarded	Success Rates
Individual Investigator Research Awards (IIRA)	351	39	$34,740,000	11.11%
IIRA Cancer in Children and Adolescents	45	5	$6,110,000	11.11%
IIRA Computational Biology	50	1	$390,000	2.00%
IIRA Prevention and Early Detection	45	6	$6,550,000	13.33%
Multiple Investigator Research Awards	31	7	$37,792,887	22.58%
Core Facilities Support Awards	18	6	$30,340,000	33.33%
High-Impact/High Rick	153	21	$4,190,000	13.73%
Research Training Awards	13	4	$14,970,000	30.77%
Total	**706**	**89**	**$135,082,887**	**17.25%**

Table 3: FY16 Academic Recruitment Research Awards by RFA Mechanism

Funding Mechanism	Applications Submitted	Applications Awarded	Funding	Success Rate
Established Investigators Award	18	6	$36,000,000	33%
Rising Stars	13	6	$22,400,000	46%
First –Time Tenure Track Faculty Members	46	20	$40,820,000	43%
Total	**77**	**32**	**$99,220,000**	**42%**

FY17 Academic Research Grant and Recruitment Applications Under Review

FY17 Academic Research Cycle 1 and Recruitment Cycles 17.1, 17.2, 17.3, and 17.4 are currently under review. Table 4 displays output data by applications received, applications reviewed and applications receiving a full review for six Requests for Applications (RFAs) released on February 19, 2016.

Six peer review panels conducted preliminary reviews for 467 applications and full scientific reviews for 118 application, September 21-29 in Dallas. The Scientific Review Council and Program Integration Committee recommendations will be presented at the November 16, 2016 Oversight Committee meeting.

Table 4: 17.1 Academic Research RFA Data

17.1 RFA DATA			
Funding Mechanism	**Applications Received**	**Applications Reviewed**	**Applications Full Review**
IIRA	292	287	64
IIRACCA	45	42	15
IIRAP	35	33	8
IIRACB	44	42	5
ETR	54	54	19
RTA	9	9	7
Total	479	467	118

Table 5 displays Academic Recruitment output data for nominations received in response to three Requests For Applications (RFAs) released on June 21, 2016. The Scientific Review Council reviews Academic Recruitment applications monthly, award recommendation for 17.1 and 17,2 will be presented at the November 2016 Oversight Committee Meeting. Nominations for 17.3 and 17.4 will be reviewed in November by the Scientific Review Council and recommendations presented at the February Oversight Committee Meeting.

Table 5: 17.1, 17.2, *17.3, and *17.4 Recruitment Data

Funding Mechanism	Applications Submitted	Applications Reviewed
Established Investigator Award	5	2
Rising Stars	1	0
First Time, Tenure-Track Faculty	2	1
Total Recruitment Awards	**8**	**3**

*17.3 and 17.4 applications will be discussed by SRC on 11/10/16

FY 2017 Request for Academic Research Applications Opened on 10/17/16

- Core Facilities Support Awards (RFA R-17.2- CFSA)

Solicits applications from institutions to establish or enhance core facilities (laboratory, clinical, population-based, or computer-based) that will directly support cancer research programs to advance knowledge of the causes, prevention, and/or treatment of cancer or improve quality of life for patients with and survivors of cancer. Award: Up to $3M (total costs) for the first 2 years and up to $1M (total costs) for each subsequent year; Maximum duration: 5 years

- High Impact/High-Risk Research Awards (RFA R-17.2-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. Award: Up to $200,000 (total costs); Maximum duration: 2 years

Advisory Committee Meetings

The University Advisory Committee met on October 4, 2016 at the CPRIT Office in Austin. Mr. Geren and Dr. Rice were able to join the in person meeting.

The expanded membership of the Advisory Committee for Childhood Cancer approved by the Oversight Committee at the November 2015 meeting of the Oversight Committee has been implemented with nominations submitted to CPRIT by ACCC chair Dr. Susan Blaney. ACCC teleconference was held October 26, 2016.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

To:	OVERSIGHT COMMITTEE MEMBERS
From:	MICHAEL LANG, CHIEF PRODUCT DEVELOPMENT OFFICER
Subject:	PRODUCT DEVELOPMENT UPDATE
Date:	NOV 08, 2016

Summary and Recommendation

This memo provides an overview of Product Development activities since the last Oversight Committee meeting in September. Subjects include: status of applications under review, an update on the recent Product Development Advisory Committee meeting, a discussion of royalty rates, and a review of company eligibility criteria.

Product Development Application Review Process Updates

Product Development Review Cycle 16.2

Requests for Texas Company and Company Relocation applications were posted to CPRIT's website in December. Thirty-two applications were submitted, making this among our largest submission pools. The screening teleconference was held April 7 & 8. Thirteen of the 32 companies were selected to be invited to present at the Peer Review meeting on May 10-12. Seven companies were subsequently selected for due diligence. The Product Development Review Council (PDRC) met in October to review the diligence findings and recommended two applications for grant awards. The Program Integration Committee (PIC) unanimously approved both companies for recommendation to the Oversight Committee (OC).

Product Development Review Cycle 17.1

Requests for Texas Company and Company Relocation applications were posted to CPRIT's website in June. Twenty-five applications were submitted by August. The screening teleconference was held in September and eight of the 25 companies were selected to be invited to present at the Peer Review meeting on October 24-26. Three companies were selected for due diligence. We anticipate presenting any companies approved by the PDRC and PIC to the OC in February 2017.

Product Development Advisory Committee

At previous OC meetings we have discussed multiple Product Development policy issues. CPRIT recently reconstituted the Product Development Advisory Council (PDAC) to provide more input on these complex decisions. We convened the initial meeting of the new group on October 14. Ten members participated, split half between prior CPRIT awardees and half industry experts with no CPRIT affiliation.

The following subjects were discussed:

- The current 25%/75% Product Development/ Scientific Research funding ratio was discussed. The PDAC recommended increasing the Product Development funding ratio.
- The PDAC felt differential royalty rates for therapeutic companies versus drug and device companies were appropriate, based on the significant differences in business fundamentals between these industries.
- The PDAC discussed the advantages and disadvantages of maintaining a $20 million award cap. They recommend maintaining the current $20 million award cap as this level of funding is often required to demonstrate clinical proof of principle.
- The PDAC recommended allowing prior CPRIT awardees to continue to be eligible for future awards. I anticipate an increasing number of legacy awardees as:
    - Existing pool of legacy awardees will continue to grow;
    - Legacy awardees will be later stage projects;
    - Legacy awardees have greater resources that can develop improved applications versus smaller, earlier stage new applicants.

Royalty Rates and Structure

As noted above the Product Development Advisory Committee discussed the appropriateness of differential royalty rates for Therapeutic firms vs. Device or Diagnostic firms. CPRIT utilizes a standard royalty structure for all applicants irrespective of market sector. Until 4X grant, cumulative royalty payments are:

- ❑ 3% of Revenue for Cumulative Revenues between $5MM and $500MM
- ❑ 4% of Revenue for Cumulative Revenues between $500MM and $1 Billion
- ❑ 5% of Revenue for Cumulative Revenue > $1 Billion

After 4X grant, cumulative royalty payments are 1/2 % until patent expiration.

The therapeutics sector (drugs, biologics, vaccines, gene therapies) is characterized by large capital requirements, long development time, high attrition rate and high profitability. Other health care sectors (devices, diagnostics and services) have substantially different business attributes: smaller capital requirements, shorter development time, lower attrition rate and lower

profitability. CPRIT fixed standard awards are more attractive to therapeutics sector firms than other sectors.

Therapeutics industry profit margins are typically 20%. Hence CPRIT's initial royalty rate of 3% consumes 15% of annual profits. Average profit margins for other industry are in the 6% to 12% range. Hence CPRIT's initial royalty of 3% consumes between 25% and 50% of annual profits. Obviously CPRIT terms are most attractive to industry sectors where those terms are a smaller portion of company profits.

CPRIT has modeled alternative royalty scenarios. Under our current royalty structure a typical cancer drug would return 4x of a $15 million grant in about three years, after which royalty tail is affected. Over the drug's patent life the net royalty rate would be 1.67% of revenue and 8.5% of profits.

Similarly, under the current CPRIT royalty structure, a typical diagnostic company would repay 4x of a $5 million grant in seven years after which royalty tail is affected. Over the patent life the net royalty rate would be 2.4% of revenue and 36% of profits; much higher than for therapeutics firms. These are models of a nominal scenario. Actual royalty returns will vary widely.

We propose modifying the royalty structure for devices, diagnostics and services to 2.5% with 2.5x cap. This would reduce the net royalty rate to 1.33% of revenue and 20% of profits over the patent life. Aligning royalty rates to industry profitability should increase CPRIT attractiveness to lower margin industry sectors and increase their application rate. We will monitor applicants to assess if modified royalty rates are affecting applicant mix.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

November 9, 2016

Oversight Committee Members,

Pursuant to 25 T.A.C. § 703.7(j), I request that the Oversight Committee approve authority for CPRIT to advance grant funds upon execution of grant contracts for two companies that will be considered for Product Development grant awards at the November 16, 2016, Oversight Committee meeting. The companies have been recommended for grant awards by the Program Integration Committee (PIC). The Oversight Committee will consider the PIC's recommendations at the November 16, 2016, Oversight Committee meeting.

Although CPRIT disburses the majority of grant funds pursuant to requests for reimbursement, CPRIT may disburse grant funds in advance payments consistent with the General Appropriations Act, Article IX, § 4.03(a). Typically, the grant amount to be paid in advance is based upon the project year budget or tranche amount. All grant recipients, including those that receive advance payment of grant funds, are required to submit quarterly financial status reports that are reviewed and approved by CPRIT's financial staff. Failure to submit the financial status reports on a timely basis will result in forfeiture of reimbursement for expenses for the quarter and may result in grant termination and repayment of grant funds.

Advance payment of grant funds are needed because the projects proposed for grant awards involve clinical trials. Clinical trial contracts typically require substantial upfront payments. The cost structure for these contracted services is highly front loaded and service providers require substantial upfront payments. Advancing grant funds allows these projects to begin work as quickly as possible.

Sincerely,

Wayne R. Roberts,
CPRIT Chief Executive Officer

P.O. Box 12097 Austin, TX 78711 (512) 463-3190 Fax (512) 475-2563 www.cprit.state.tx.us

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 7, 2016

FY 2017 Cycle 1

Five RFAs for Cycle 17.1 were released in May 2016. Applications are due August 30. We received 36 applications. After administrative review, 5 were withdrawn and 31 applications requesting $36,684,532 were assigned to the review panels. Peer review will take place December 5 - 8 in Dallas.

Mechanism	# of Applications	Requested Funding
Cancer Prevention Promotion and Navigation to Clinical Services	4	**$** 1,588,990
Competitive Continuation/Expansion	10	$ 13,780,345
Dissemination of CPRIT-Funded Cancer Control Interventions	1	$ 300,000
Evidence-Based Cancer Prevention Services	16	$ 21,015,197
Total	**31**	**$ 36,684,532**

Recommendations will go to the Oversight Committee for consideration in February 2017.

FY 2017 Cycle 2

The following RFAs are being prepared for release on November 17:

- Evidence-Based Cancer Prevention Services
- Dissemination of CPRIT-Funded Cancer Control Interventions
- Cancer Prevention Promotion and Navigation to Clinical Services
- Colorectal Cancer Coalition
- Tobacco Control and Lung Cancer Screening is a new RFA.

  This mechanism seeks to fund programs on tobacco prevention and cessation, as well as screening for early detection of lung cancer. Through release of this RFA, CPRIT's goal is to stimulate more programs across the state thereby providing greater access for

underserved populations and reducing the incidence and mortality rates of tobacco-related cancers.

Submissions will be due March 2 with peer review meetings taking place in June. Recommendations will be presented to the Oversight Committee in August 2017.

Summary of FY16 Prevention Awards

The overarching principles for awarding CPRIT funds are to fund evidence-based interventions and their dissemination and to support the prevention continuum of primary, secondary, and tertiary prevention interventions. During FY16, in addition to RFAs for the delivery of evidence based clinical services and health promotion with navigation to services, the program offered two new RFAs. One of the new RFAs was for the packaging and dissemination of previously awarded CPRIT projects and the other for a one day breast and cervical cancer screening event offered in partnership with the College of American Pathologists Foundation.

Table 1 displays the funding by prevention program priorities in FY16.

Table 1: FY16 Funding by CPRIT Prevention Program Priorities

Priorities Addressed	# Grants*	Award Amount*
Prioritize populations and geographic areas of greatest need, greatest potential for impact	18	$18,650,900
Focus on underserved populations	26	$26,938,196
Increase targeting of preventive efforts to areas where significant disparities in cancer incidence or mortality in the state exist	14	$13,464,320

*Some grants address more than one priority therefore # of Grants and Award Amounts may be double counted.

As shown in Table 2, in FY2016 CPRIT awarded $26,938,196 in Prevention grants.

Table 2: FY16 Prevention Awards by RFA Mechanism

Funding Mechanism	# of Awards	Total Funding Awarded
Colorectal Cancer Coalition	2	$4,399,753
Continuation/Expansion	5	$6,985,102
Dissemination of CPRIT-Funded Cancer Control Interventions	4	$1,199,544
Evidence-Based Cancer Prevention Services	10	$13,126,028
Cancer Prevention Promotion and Navigation to Clinical Services	3	$1,179,645
See, Test & Treat® Program	2	$48,124
Total	**26**	**$26,938,196**

Other activities

The Prevention program completed calls to the 14 grantees awarded in August to discuss budget, goals and objectives, and to address any questions.

Quarterly progress reports were submitted by September 15 and reviewed; the performance measures report for the Legislative Budget Board was prepared and submitted on October 7.

Meetings and Presentations:

- I presented at the August 31 Texas Alliance for Colorectal Cancer Testing meeting in Houston. The Alliance is a statewide coalition of organizations that are providing colorectal cancer screening. The majority of members are CPRIT grantees.
- I attended the Carson Leslie Foundation Golden Toast reception in Washington, D.C. on September 22 honoring U.S. Representatives Michael McCaul and Chris Van Hollen and attended the Congressional Childhood Cancer Caucus Summit the following day.
- As a member of the advisory board for the Texas Health Improvement Network (THIN), I participated in the October 1 THIN Advisory Meeting in Austin. The state established the network to address the urgent health care challenges and improve the health care system in the state.

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 7, 2016

This report includes an update on Communications activities from August 17 to November 7, 2016.

Earned Media

The communication team conducted individual media outreach to secure positive coverage for CPRIT, including a Texas Monthly cover story featuring Dr. James Allison. Additionally, Dr. James Willson was featured in the Texas Tribune's TribFest as a panelist, which resulted in a portion of the coverage represented below.

Grant Awards Announcement: Following the Oversight Committee's approval, CPRIT distributed a press release on Aug. 17 to local, regional and national outlets announcing the awarding of 12 academic research grants and 14 prevention grants. On Sept. 14, CPRIT distributed a press release to local, regional and national outlets announcing the awarding of 14 academic research grants. Both announcements resulted in a portion of the coverage represented below.

Coverage: (Aug. 3 – Nov. 4, 2016)

- 15 articles featured CPRIT
- 100 additional articles mentioned CPRIT (stories primarily focused on work of grantees)

Coverage Highlights: (see clipped articles following report)

- August 17, 2016, San Antonio Business Journal, Pair of San Antonio Institutions Score Millions in Texas Cancer Research Funding
- August 23, 2016, BioNews Texas, CPRIT Awards $61.5M in 26 New Grants
- August 29, 2016, D Healthcare Daily, UT Southwestern Receives $13 Million in CPRIT Recruiting, Research Grants
- September 14, 2016, Austin Business Journal, Austin Hooks 2 Top Health Care Pros at a Cost of $8M
- September 28, 2016, The Daily Texan, Texas Tribune Festival: Panelists Declare "Golden Era" for Cancer Cure
- September 29, 2016, The Dallas Morning News, Texas Researchers are at the Forefront of the Breast Cancer Fight

- October 11, 2016, Temple Daily Telegram, Temple Cancer Center Gets $3.56 Million Grant
- October 12, 2016, Houston Chronicle, We Need to Change the Odds on Breast Cancer
- November 2016, Texas Monthly, The Iconoclast

Projects and Events

- Chris Cutrone, Senior Communications Specialist, started Oct 3rd.Chris brings considerable experience in communications, media relations and external relations, which includes working for numerous Texas elected officials and government agencies. He was most recently at the Office of Inspector General at the Texas Health and Human Services Commission.
- Website: We are working with TradeMark Media to redesign the website. The project is on schedule to be completed in early January.
- 2017 Conference: A contract with the Austin Renaissance hotel has been executed. The conference will take place Nov. 13-14, 2017. A "Save the Date" announcement was sent out via CPRIT's listserv on October 5. We are in the process of drafting requests for proposals for a registration and abstract management system.
- Media Training for the CPRIT Program Officers was conducted by Hahn Public Communications on November 2.
- Staff continues to respond to requests for information and prepare legislative briefing materials.

Meetings

- During a trip to Dallas to observe the Research peer review process on October 26-27, Chris had introductory meetings at UT Southwestern Medical Center with Steve Moore, Vice President of Communications, Marketing and Public Affairs and Angelica Marin-Hill, Vice President of Government Affairs and Policy.
- While at UTSW, Chris also met with Dr. Jinming Gao, recipient of two CPRIT research grants and a CPRIT product development grant, to get a briefing on his breakthroughs in nanotechnology and to plan a feature on his work for the CPRIT website.
- On October 28, Chris met with Brian Jammer, Vice Chancellor of Government Relations for the UT System, to discuss ways to better promote the work of CPRIT grant recipients at UT campuses.

SAN ANTONIO
BUSINESS JOURNAL

Pair of San Antonio institutions score millions in Texas cancer research funding

W. Scott Bailey
Reporter/Project Coordinator
San Antonio Business Journal

Aug 17, 2016

Two San Antonio organizations will share nearly $6 million from the latest funding round by the Cancer Prevention and Research Institute of Texas, which awarded 26 new grants totaling more than $61.5 million.

CPRIT awarded just under $4.6 million to the University of Texas at San Antonio for its Center for Innovative Drug Discovery – a joint organization co-founded by UTSA and the University of Texas Health Science Center at San Antonio. The funding will support the enhancement of shared cancer resource programs in South Texas.

The Center for Innovative Drug Discovery — co-founded by the University of Texas at San... more

FILE PHOTO / SAN ANTONIO BUSINESS JOURNAL

CPRIT also awarded more than $1.3 million to the Health Science Center in support of its Institute for Health Promotion Research and efforts to promote HPV vaccinations among Hispanic adolescents and young adults.

Wayne Roberts, CEO of CPRIT, said in a statement that the latest awards will "increases the momentum derived from our critical mass of cancer fighting energy" across the state.

Well over a third of the latest CPRIT funding – $27 million – is for five multi-investigator research grants. The University of Texas MD Anderson Cancer Center in Houston received most of that funding, with three multi-investigator grants totaling more than $17 million.

The University of Texas Medical Branch at Galveston was awarded $6 million in multi-investigator research grants from CPRIT, while the balance of this funding – more than $4.1 million – will go to the University of Texas Southwestern Medical Center in Dallas.

To date, CPRIT has awarded 1,059 grants totaling more than $1.64 billion.

http://www.bizjournals.com/sanantonio/news/2016/08/17/pair-of-san-antonio-institutions-score-millions-in.html

CPRIT Awards $61.5M in 26 New Grants

CAROLINA HENRIQUES AUGUST 23RD, 2016

The Cancer Prevention & Research Institute of Texas (CPRIT) recently awarded $61.5 million in 26 new research grants. To date, CPRIT has awarded 1,059 grants worth more than $1.64 billion.

Twelve of the new grants were provided through CPRIT's academic research program, five were CPRIT scholar recruitment grants, and 14 grants were given through CPRIT's prevention program.

CPRIT was launched in 2009 after Texas voters approved a 2007 constitutional amendment proposing a commitment of $3 billion to fight cancer. All CPRIT-funded research is conducted in the state of Texas by scientists at state institutions that reflect CPRIT's mission to attract and expand the state's research capabilities and create high-quality new jobs.

"With these new awards CPRIT increases the momentum derived from our critical mass of cancer fighting energy — from labs to researchers to prevention programs — across Texas," Wayne Roberts, CPRIT's chief executive officer, said in a press release.

Programs funded with CPRIT's help have reached all 254 counties in Texas; brought over 110 distinguished researchers to the state; and provided life-saving education, training, prevention and early detection services to Texans.

The total of $47.8 million in grants through CPRIT's academic research program included: $27 million for five Multi-Investigator Research grants which form collaborations among researchers from several Texas institutions; five grants totaling $10 million for the recruitment of emerging cancer scientists to academic institutions; and two core facilities grants, totaling $10 million, that will be focused on enhancing Texas' research capacity and life sciences-dedicated infrastructure.

The grants given through CPRIT's prevention program were awarded to support some of the most vulnerable populations in Texas. Those grants totaled $13.7 million.

CPRIT prevention grants focus on evidence-based interventions that include increasing human papillomavirus (HPV) vaccination rates; reducing the incidence of liver cancer through education and screening for hepatitis; and providing access to colorectal, breast, and cervical cancer screening.

https://bionews-tx.com/news/2016/08/23/cancer-prevention-research-institute-texas-awards-26-new-grants/

DALLAS/FORT WORTH
D HEALTHCARE Daily
THE BUSINESS OF HEALTHCARE IN NORTH TEXAS

Matt Goodman 08/29/2016

UT Southwestern Receives $13 Million in CPRIT Recruiting, Research Grants

The state's cancer research agency has awarded UT Southwestern more than $13 million for recruitment grants and initiatives delving into the details of cancer cell growth, targeted treatments, and screenings for disadvantaged yet high-risk populations.

Of that pot of money, the Cancer Prevention and Research Institute of Texas, or CPRIT, sent the academic center about $4 million in new recruitment grants, which will double the $4 million the school received back in May. To date, these recruitment grants have gone toward attracting 34 researchers to the Medical District institution. The school did not announce potential targets.

Another $9.7 million went to six research projects: an initiative that seeks to discover how cancer cells "fuel their growth;" a targeted effort to screen disadvantaged populations to determine whether they're genetically predisposed to developing colorectal cancer; and another that will go toward research aimed at using carbon radiation treatments to battle lung cancer.

UTSW's overall CPRIT haul since 2009 is up to $331 million. Statewide, Texas cancer centers have been awarded more than $1.64 billion.

http://healthcare.dmagazine.com/2016/08/29/ut-southwestern-receives-13-million-in-cprit-recruiting-research-grants/

AUSTIN BUSINESS JOURNAL

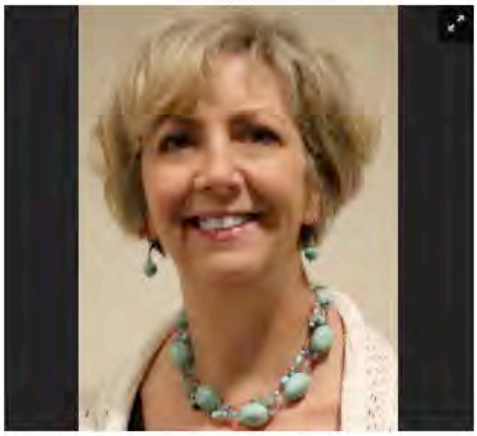
Will Anderson
Digital Editor
Austin Business Journal

Sep 14, 2016,

Austin hooks 2 top health care pros at a cost of $8M

Losses at the University of Colorado Denver and University of California, Berkeley are gains for the University of Texas.

UT's Dell Medical School has named S. Gail Eckhardt to head up its new cancer research center. Dr. Eckhardt will oversee the Livestrong Cancer Institutes at the medical school as inaugural director and an associate dean. She was previously head of medical oncology at the University of Colorado Denver's Anshutz Medical Campus.



S. Gail Eckhardt has been named director of the Livestrong Cancer Institutes at Dell... more

COURTESY OF DELL MEDICAL SCHOOL

It took a $6 million grant from the Cancer Prevention and Research Institute of Texas to help attract Dr. Eckhardt.

UT also hooked David Taylor from the University of California, Berkeley, with a $2 million state grant. CPRIT announced Wednesday 14 statewide grants totaling $50 million.

Before moving to Colorado, Dr. Eckhardt worked as as associate director of clinical research at UT's Cancer Therapy and Research Center in San Antonio. Her medical degree is from the University of Texas Medical Branch in Galveston.

Funded by a $50 million donation from the Livestrong Foundation, the Livestrong Cancer Institutes are tasked with developing integrated models of cancer treatment and promoting patient-focused care and research. They are part of Dell Medical School, which welcomed its first students to campus this summer.

Taylor is a post-doc at UC-Berkeley researching molecular biophysics and biochemistry.

http://www.bizjournals.com/austin/news/2016/09/14/austin-hooks-2-top-health-care-pros-at-a-cost-of.html

THE DAILY TEXAN
Serving the University of Texas at Austin community since 1900

AREEBA KHWAJA September 28, 2016

Texas Tribune Festival: Panelists declare "golden era" for cancer care

Fifty percent of all cancer cases are completely preventable, yet according to experts in the field, health care in Texas is not translating this number to real life.

A panel of cancer experts and policy leaders, including bicyclist Lance Armstrong and president of MD Anderson Cancer Center, Ronald DePinho, M.D., led a discussion on the future of cancer treatment at the Texas Tribune Festival on Saturday.

"Like millions of people, I sat in a doctor's office and was told, 'You have cancer,'" said Armstrong, a cancer survivor himself. "That's such a personal thing. Nothing prepares you for that."

Armstrong was diagnosed with cancer in 1996 and has now been cancer-free for almost 20 years. He said he appreciates the optimism surrounding treatment outlooks but emphasized that a "cure" for cancer will not happen overnight.

According to DePinho, cancer is an extremely complicated phenomenon that is a constellation of numerous different diseases. This complexity means that finding an all-encompassing "cure" is challenging.

"At its most elemental level, it is a disease of the genes," DePinho said, "Fortunately, after the Human Cancer Genome Project, we have a 'periodic table' for which genes are altered in which cancers, enabling us to develop new diagnostic devices and strategies."

Yet the panelists claimed that scientific knowledge is not what's stopping cancer treatment from advancing right now — it's access to health care. According to panel moderator Jake Silverstein, 17 percent of all Texans are uninsured, a staggeringly large number especially in comparison to other states.

"It doesn't matter what we can prevent or do. The most important thing is access to quality care," DePinho said. "The level of disparity is the greatest challenge we have in cancer, not so much the fact that we have a can have a huge impact today without a single new discovery."

State Representative Sarah Davis said limitations in budgeting and bipartisan politics play a role in health care access issues, but that the state has put forth its best efforts to provide care to Texans.

Additional issues such as a shortage of physicians and difficulty in reaching people of various different socioeconomic backgrounds within Texas only adds fuel to the fire, according to Davis.

"No one can deny that there is a healthcare problem in Texas," Davis said.

Yet the panelists emphasized how far cancer treatment has come in the last half decade. James Willson, CSO of Cancer Prevention and Research Institute of Texas, asserted that what's changed in treatment is the fact that knowledge has successfully been converted to drugs.

Looking to the future, cancer scientists are turning to new research in immunotherapy and information technology in the form of wearable devices. According to DePinho, while research is still needed to improve treatment options, a turning point has been reached where clinical proof of concepts has been established.

Specifically, the panelists discussed immunotherapy as the new wave in cancer treatment. These treatments fight cancer with patients' own immune systems by deactivating cancer's "brake" system, a mechanism that it engages to keep the immune system suppressed. Researchers at MD Anderson have discovered a new class of drugs that deactivates this braking mechanism and reawakens the immune system.

This kind of research is expected to grow quickly in the coming years in an effort to find a "cure" for cancer.

"Cancer's greatest vulnerability is knowledge … and this is the golden era for cancer [care]," DePinho said. "This decade will change medicine forever … Knowledge and technology have converged to a point that has enabled us to significantly impact the prevention and treatment of cancer, a disease for which there was previously no hope."

http://www.dailytexanonline.com/2016/09/28/texas-tribune-festival-panelists-declare-%E2%80%9Cgolden-era%E2%80%9D-for-cancer-care

The Dallas Morning News

Sabriya Rice, Business of Healthcare Reporter

SEP 29

Texas researchers are at the forefront of the breast cancer fight

Since President Richard Nixon declared the "War on Cancer" in 1971, the nation has made great strides in understanding and fighting the various forms of the disease.

Renewed focus is being propelled in part by the so-called "Cancer Moonshot," an initiative spearheaded by Vice President Joe Biden which hopes to invest a billion in federal funding to support cancer research and make a decade worth of advances in half the time.

As home to four of the nation's 69 National Cancer Institute-designated cancer centers, including two comprehensive cancer centers, Texas researchers have been at the forefront.

When it comes to breast cancer, they are delving into novel approaches that go beyond surgery and chemotherapy, and seeking knowledge about the demographic factors that impact which patients develop and recover from the disease.

Hospitals, health systems, drug makers and research labs in Texas received more than $31 million to support breast cancer research in 2015, from various mechanisms granted by the National Institutes of Health, the National Center for Health Statistics and the Centers for Disease Control & Prevention.

They also have received more than $75 million to support breast research from the Cancer Prevention Research Institute of Texas, which has been funding research and product development in the state since 2007.

About 40,450 individuals in the United States, including 2,780 in Texas, are expected to die from breast cancer in 2016, according to the American Cancer Society. About 16,800 new diagnoses of breast cancer are expected in the state this year.

Here are just few of the projects statewide by cancer centers that are tackling the disease.

Personalizing the approaches

While a lot of headway has been made in fighting certain types of breast cancer, triple-negative is an aggressive form of the disease that does not respond to many targeted therapies.

That's made the condition a focal point for cancer researchers, including for Dr. Jennifer Litton, associate professor of breast medical oncology at the M.D. Anderson Cancer Center in Houston.

Dr. Jennifer Keating Litton, associate professor in the department of breast medical oncology, at the University of Texas M. D. Anderson Cancer Center in Houston. File

"We're hoping to unlock specifics for patients," Litton explained. "It's not just about identifying who is at higher risk, but linking the hereditary cancer gene with potentially better therapeutics." she said.

The center has been taking a different approach to treating women with triple-negative. Women who have the disease are biopsied so that genetic and protein material can be evaluated before and after they begin chemotherapy. Patients who respond well to chemo continue being treated according to the standard of care. Others are triaged into clinical trials based on specific genetic information learned in the biopsy.

Litton says this approach is getting newer, more targeted therapies to the right patients. "Patients can get therapy when they're first diagnosed, and we're seeing improved outcomes," Litton said.

Uncovering ancestral connections

Women of many races develop triple-negative, but it's most common among African-Americans.

Researchers from the University of Texas Southwestern's Harold C. Simmons Comprehensive Cancer Center in Dallas decided to find out what just over 90 triple-negative patients from various ethnic groups had in common.

To do so, they looked at mitochondrial DNA- the type of genetic information passed from mothers to their children, and found eye-opening results.

Study participants had all self-reported their ethnic background, but DNA revealed that about a dozen of the women were not the ethnicity they originally thought, explained Dr. Roshni Rao, lead author of a study published in September in the journal Cancer.

A pattern was found linking many of the triple-negative patients to Nigeria, Cameroon and Sierra Leone. "It opens up a whole new area of research," Rao explained. "An ethnicity you may not even be aware you have may increase the risk of this aggressive type of cancer."

UT Southwestern will continue to explore the ancestry impact.

Tapping into the body's immune system

But the focus isn't just on genetics. Cancer researchers in Texas are also looking at the body's immune system and trying to figure out how to trigger it to help ward of cancer.

"This field has exploded in the past few years. It's totally different from looking at genomics and personalized medicine," explained Dr. Virginia Kaklamani, who leads the breast cancer program at the Cancer Therapy & Research Center at the UT Health Science Center in San Antonio.

The concept is simple, she says. Basically, cancer is smart enough to shut down the mechanism the body uses to kill it.

The cancer center is conducting clinical trials on drugs that help reactivate the immune system, so to speak. While the field is emerging, researchers are excited about early results.

Immunotherapy is one of several topics that will be discussed this December during one of the largest gatherings of breast cancer researchers in the U.S., the San Antonio Breast Cancer Symposium.

Creating targeted, less invasive treatments

By looking to the past, patients can truly see how breast cancer advancements have evolved, suggested Dr. Kent Osborne, director of the Baylor College of Medicine's Dan L. Duncan designated Comprehensive Cancer Center in Houston.

He recalls how 40 years ago most women had to undergo a radical mastectomy, the surgical removal of the breast, chest muscles, and all of the lymph nodes under the arm. "But despite the mastectomy many patients still had recurrence," he recalls.

Fast-forward to today, and researchers are hoping targeted therapy can determine which patient needs which type of treatments, potentially limiting invasive treatments to only those who actually need them.

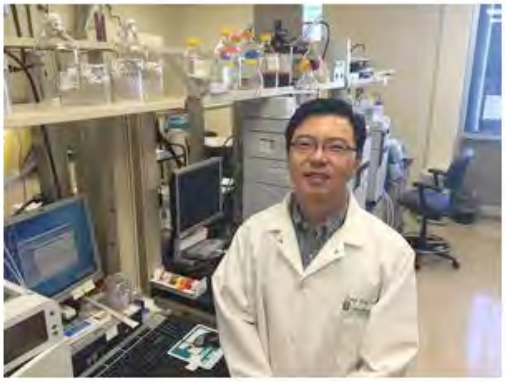
"That's where we're going," Osborne said. "Looking at an individual patient's tumors, then identifying which pathways to target for their treatment."

http://www.dallasnews.com/business/health-care/2016/09/29/texas-researchers-forefront-breast-cancer-fight

tdtnews.com TEMPLE DAILY TELEGRAM

JANICE GIBBS | October 11, 2016

Temple cancer center gets $3.56 million grant



Temple cancer center gets $3.56 million grant

Dr. Jung-Hee Woo, director of Baylor Scott & White's Central Texas cancer research facility, was awarded a $3.56 million grant from the Cancer Prevention and Research Institute of Texas. The grant will support Baylor Scott & White Health Research Institute's Investigational New Drug Production Core Facility.

Dr. Jung-Hee Woo, director of Baylor Scott & White's Central Texas cancer research facility, was awarded a $3.56 million grant from the Cancer Prevention and Research Institute of Texas. The grant will support Baylor Scott & White Health Research Institute's Investigational New Drug Production Core Facility.

"With this support, we have a great opportunity to expand cancer drug production capabilities and lower a financial barrier to test innovative new drugs in cancer patients," Woo said in a release.

He said researchers plan to produce at least four new cancer drugs in the next three years.

"To improve cancer therapy, scientific discoveries from cancer research must be translated into practical applications, such as new drug development," Woo said.

"New drugs need to be produced in specialized facilities, with qualified equipment and trained personnel for compliance with FDA regulations. For these reasons, the limiting factor in new drug production is often related to production costs."

New drugs need to be produced in specialized facilities, with qualified equipment and trained personnel for compliance with FDA regulations.

http://www.tdtnews.com/news/article_e86549d8-8f77-11e6-b0d7-f3f68def653a.html

HOUSTON CHRONICLE

October 12, 2016

We need to change the odds on breast cancer

By Josh W. Newby

In the middle of Breast Cancer Awareness Month, on Oct. 13, sits a day focused entirely on the type of breast cancer that is the leading killer among women aged 20–59 years: Metastatic breast cancer. The good news is this sort of cancer is getting increased attention and funding, and with technology delivering us more sophisticated tools to fight it, there's a very real possibility it will be cured in this century.

It's helpful to take a bit of time to learn about the disease, understand the availability of clinical trials as an option, and make yourself familiar with the good news on funding — which is now available both from federal sources as well as state sources in Texas.

Until 2009, metastatic breast cancer was rarely mentioned during Breast Cancer Awareness Month. Nine determined patients traveled to Washington, D.C., that summer to see if they could change that, and they did: Both houses of Congress passed a unanimous resolution to dedicate a single day of this month to putting patients and their needs in front of the public.

Cancer that remains in the breast can be cured in most cases. Metastasis occurs when cancer cells travel to vital organs. Right now, the disease is treatable, but not curable. An estimated 155,000 Americans are currently living with metastatic breast cancer, and it accounts for over 40,000 deaths annually.

Perhaps most damaging to progress is that very few patients participate in clinical trials. Clinical trials are treatment studies on new therapies, which is a method to obtain FDA approval of new treatments. The advantage of participating in a clinical trial is you might get access to a lifesaving drug years before the general public does. One estimate is that less than 5 percent of patients with metastatic breast cancer are in a clinical trial. Much more needs to be done to improve awareness about and access to clinical trials. Many patients are simply unaware that participating in a clinical trial might be an option.

From the patient's perspective, clinical research is a difficult world to navigate, but in the setting of an incurable disease it is absolutely critical. There are several resources like the Metastatic Breast Cancer Alliance available to help patients and families learn more about clinical research, find support services and navigate the system.

Recent research into breast cancer has been extensive and remarkable. However, current treatments can be arduous, the standard of care not well established and treatment is not matched to individual cancers. In other words, precision medicine in metastatic breast cancer still has room to improve.

With the launch of the Cancer Moonshot program by the White House earlier this year, greater attention has been brought in the need to support cancer research. This means real funding — although exactly how much has yet to be determined. Here in Texas, the Cancer Prevention and Research Institute of Texas, which was founded in 2007, focuses on expediting cancer research enhancing potential for breakthroughs that can lead to a cure. The state of Texas issued CPRIT $3 billion in bonds to fund study for a cure. CPRIT also recruits some of the top clinicians and scientists to work at cancer centers such as Baylor College of Medicine, MD Anderson and UT Southwestern with multiple focusing on metastatic breast cancer.

My mother, Theresa Newby Harpole, was an early-stage breast cancer survivor who battled metastatic breast cancer for more than three and a half years before passing away Thanksgiving Day 2013. Together, we established Theresa's Research Foundation with a mission to solely fund metastatic breast cancer research and improve the quality of lives of those impacted by this disease.

With collaboration from scientists, oncologists, advocates, industry leaders and patients, together we can accelerate metastatic breast cancer research with a goal of extending lives, improving quality of life and providing better treatment options for patients.

We must emphasizing the critical need for more research funding, and participation in and awareness of clinical research trials in order to change the odds and cure metastatic breast cancer hopefully in my lifetime.

Newby is founder and executive director of Theresa's Research Foundation, based in Houston.

Where to find a Goodnight saddle, a Gutenberg Bible, and the keys to the Alamo **by Jordan Breal**

Texas Monthly

THE NATIONAL MAGAZINE OF TEXAS

CAN THIS MAN CURE CANCER?

THE UNLIKELY STORY of a quirky, rebellious researcher from Alice and the breakthrough that has revolutionized medicine

by ERIC BENSON

WHEN MY DAD WAS MAYOR BY THE TEXANIST

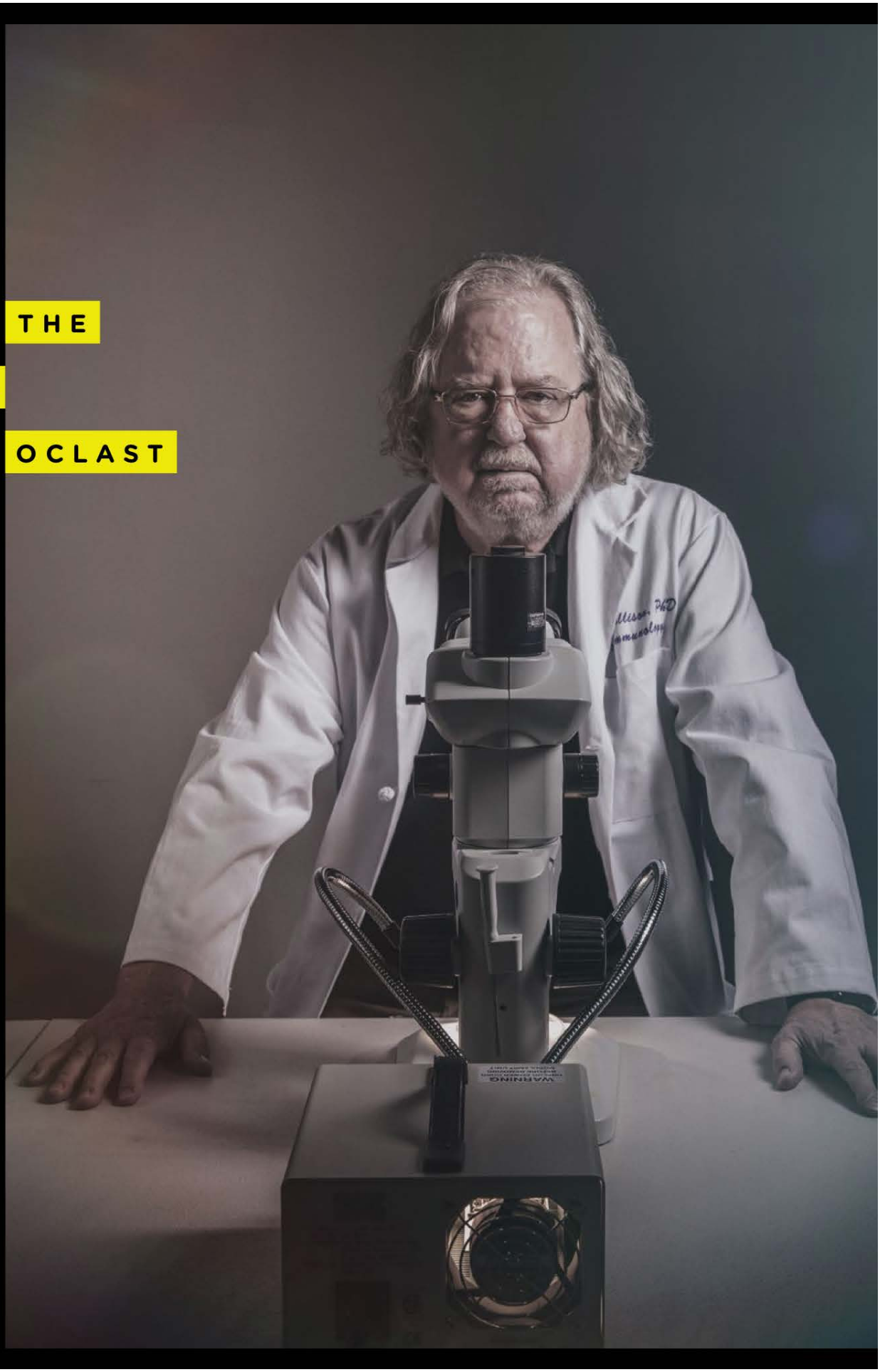
YES, I LOVE MY #$%*@! HOUSTON ASTROS by JOHN NOVA LOMAX

BEN FOUNTAIN ON JERRY JONES, STEVE MARTIN, AND GOING HOLLYWOOD by STEPHEN HARRIGAN

CAN THIS MAN CURE CANCER? | TEXASMONTHLY.COM | VOLUME 44 | ISSUE 11

11.16

THE ICON-OCLAST



JIM ALLISON has always gone his own way—as a small-town-Texas kid who preferred books to football, and as a young scientist who believed the immune system could treat tumors when few others did. And that irreverence led him to find a potential CURE FOR CANCER.

by ERIC BENSON

PHOTOGRAPHS BY LEANN MUELLER

COURTESY OF JIM ALLISON

In

MAY 2001 A MIDDLE-AGED WOMAN named Sharon visited her oncologist for what she thought could be her final appointment. Two months earlier, Sharon had been diagnosed with metastatic melanoma, and her condition was already well beyond dire. Her liver was riddled with metastases, a massive tumor was slowly collapsing her left lung, and fluid was pooling in the pleural cavity of her chest. Doctors didn't expect her to live more than a few weeks.

At the time, metastatic melanoma was a death sentence. When melanoma is localized—known as stage 0 or stage 1—it is threatening but easily cured with surgery. But when the disease spreads and finds a home in other organs, it transforms into a brutal killer, resistant to radiation, chemotherapy, and, until recently, everything else doctors had devised. When Sharon was diagnosed, just two drugs had ever received FDA approval to treat her stage-4 disease: a chemotherapeutic agent that had never shown a survival benefit and an immune-boosting white-blood-cell protein called interleukin-2, which worked only sporadically and was so toxic that dosing it was, according to Antoni Ribas, one of Sharon's doctors, "the equivalent of giving a patient a septic shock every eight hours for five days."

Sharon, a mother of two from the Los Angeles suburb of Woodland Hills, went about exhausting her bad options. After seeing Ribas for the first time in March, she had undergone treatment with interleukin-2. It succeeded only in sending her to the ICU. The next month, Ribas had administered an experimental vaccine that in other patients had worked with little more than lottery odds. Sharon hadn't won the lottery.

Now, as she sat in an office at UCLA's Jonsson Comprehensive Cancer Center, Sharon needed to decide whether to continue fighting the disease. She had one more option, a new drug that would come to be known as ipilimumab, which was then beginning its initial phase I trial at a private oncologist's office in Long Beach. Phase I trials mark the first time a drug is given to patients. The trials aren't designed to determine the efficacy of a treatment; they are designed to determine whether it is even safe for humans. If Sharon volunteered for the ipilimumab trial, she would be one of the first patients to ever receive the drug.

Ipilimumab was based on a new approach to fighting cancer, the first in a class of drugs called checkpoint inhibitors. Instead of attacking cancer cells directly, checkpoint inhibitors unleash the body's own T cells—the soldiers of the immune system—to fight malignancies. Without the presence of these drugs, tumors are able to press on the "brakes" on the surface of T cells—these brakes are known as checkpoints—that halt the body's immune response in its tracks. Checkpoint inhibitors disable these brakes, allowing T cells to sustain an attack against the tumors. Still, when Ribas told Sharon about the drug, this was little more than a theory. In experiments on mice, ipilimumab had performed wonders: tumors vanished, relapses were squashed before they began, cancer was cured. But promising animal results have a poor track record of translating to humans, particularly when the results involve the immune system and cancer. "Nobody had faith in this responding long term," Ribas told me.

Ribas, though, was a cautious believer. A colleague once likened Ribas's pursuit of immunotherapy treatments to a man who climbs to the top of the Empire State Building, throws 100 marbles off the side, and watches as 99 plummet to the ground and a single one stays floating in midair. He told Ribas, "You are studying the one that stays floating."

So when Ribas sat down with Sharon, he offered some reasons for guarded optimism. He believed that miraculous recoveries were possible, and with enough study, they might even transform into widely applicable science. But Ribas was also practical enough to know his patient's chances. Sharon had no good options. "What else could you do?" Ribas told me. "Either it was that or go into hospice care."

OPENING SPREAD: Allison, photographed in Houston on September 9, 2016. THIS PAGE: Allison conducting research at the MD Anderson facility outside Smithville, where he worked from 1977 to 1984. NEXT SPREAD: Allison with his research partner and wife, Padmanee Sharma.

Sharon didn't deliberate for long. She didn't expect a miracle, but she hoped that ipilimumab might let her live to see her son graduate from high school. The ceremony was a month away.

Fifteen years later, James P. Allison, the chairman of the department of immunology at the University of Texas's MD Anderson Cancer Center, in Houston, would stand at a lectern in Baylor College of Medicine's Cullen Auditorium describing Sharon's case to a crowd of two hundred clinicians, scientists, and students. Allison had met Sharon only once, but few people could speak with more authority on her case. That's because the 68-year-old Allison had been the scientific pioneer and indomitable advocate behind her last-ditch treatment.

Projected above Allison were images from two CT scans. The scan on the left showed Sharon's torso in May 2001, a massive tumor impinging her left lung, the pleural effusion flooding her chest. The scan on the right also showed Sharon's chest, but this image was clean, normal, empty. The scan showed only some scar tissue and two functioning lungs. Above the two slides were the words "The longest survivor on ipilimumab?"

"This is my favorite slide," Allison said. "She got a single injection of ipilimumab, and six months later her tumors were completely gone."

The phase I trial had been a tentative beginning, but it represented the start of a seismic shift in the landscape of oncology. Not only had Sharon returned rapidly to a healthy life from the brink of death, but her own immune system—not a surgeon's scalpel or high-energy X-rays or toxic chemicals—had saved her. In the decade and a half that followed, the field of immunotherapy would transform from a Hail Mary intervention into the fourth pillar of cancer treatment.

From the fifties until the very recent past, oncologists focused their energies on three approaches to battling cancer: surgery, radiation, and chemotherapy. In the dark humor of the cancer ward, these are known as "cut," "burn," and "poison." Over this period, politicians and activists mounted a sweeping war on cancer modeled on the Apollo program and the Manhattan Project; the federal government, nonprofit institutions, pharmaceutical companies, and private citizens dedicated untold billions to finding a cure; and generations of doctors still depended largely on early detection and prevention, cycling through drugs whose effectiveness was often measured by the few extra months of life they could provide.

The rise of immunotherapy hasn't shifted that reality overnight, but it has sent a new jolt of energy into an age-old dream: that maybe, just maybe, medical science can turn terminal cancers into survivable conditions. Since the FDA approved ipilimumab, in 2011, median survival rates have increased and the number of people experiencing lasting responses has spiked not only for metastatic melanoma but for several other common, previously-all-but-fatal malignancies, among them advanced cancers of the lung, kidney, and bladder. In the past two years alone, the FDA has approved three second-generation checkpoint inhibitors, and two other arms of immunotherapy—cancer vaccines and a therapeutic approach known as adoptive T cell transfer, in which a patient's own T cells are engineered outside the body and reinjected into the bloodstream—are showing ever-more-promising results.

"FIFTY YEARS FROM NOW, IT'LL BE UNUSUAL FOR SOMEONE TO DIE OF CANCER—IT'LL BE LIKE PNEUMONIA. AND IT'S OUR HOPE THAT WE CAN COMPRESS THAT TIME TO MORE LIKE TEN OR FIFTEEN YEARS."

The clinical successes have not gone unnoticed. Pharmaceutical companies are locked in a multibillion-dollar arms race to develop new and better drugs, billionaire philanthropists—among them Sean Parker and Michael Bloomberg—have helped set up dedicated immunotherapy centers, and more and more patients are receiving and benefitting from immune-modulating treatments. When former president Jimmy Carter was dying of metastatic melanoma in 2015, his doctors at MD Anderson gave him the checkpoint inhibitor Keytruda and watched as his T cells eradicated the tumors in his brain and liver. Now patients suffering from metastatic melanoma ask for the "Jimmy Carter drug."

"Fifty years from now, it'll be unusual for someone to die of cancer—it'll be like

pneumonia," Patrick Hwu, a melanoma oncologist at MD Anderson who works closely with Allison, told me. "And it's our hope that we can compress that time to more like ten or fifteen years." This would be an astounding accomplishment. In 2016 an estimated 595,690 people will die of cancer in the United States alone.

If immunotherapy leads the way to cancer cures in the coming decade, it'll be tempting to look back on its development as inevitable, a breakthrough that was merely waiting for technology and biological research to make it possible. This would be true to some extent—scientists have hypothesized for over a century about the potential for the immune system to beat back tumors—but such a view would overlook the human choices and biases that shape the course of science. It would also overlook the power of small groups of individuals to spark major advances by bucking conventional wisdom and seeking out new frontiers. In other words, it would ignore the life of Jim Allison—a shaggy-haired, patchily bearded son of small-town South Texas whose creativity, diligence, and zest for pursuing a seemingly quixotic path far from the front lines of cancer research have added up to a revolution.

First, Allison labored for years on the fringes of the cancer world, working in a little-known lab in his home state—still evolving into the leader of cancer treatment it is now—where he began to make a series of biological discoveries that upended how science understood T cells. Then, in a flash of brilliance, he envisioned how those discoveries could be used to create a drug to combat cancer. And finally—over a frustrating, grueling, and ultimately triumphant decade-and-a-half-long quest—he evangelized for the potential of such a drug, trying to convince legions of skeptics that immunotherapy could not only work but potentially save countless lives. Many of his peers expect that he will soon win the Nobel Prize, and they have already bestowed on him lofty praise. "It is rare that such a sea change can be traced to any one individual," asserted the scientific journal *Cell* in 2015, after Allison won the Lasker-DeBakey Clinical Medical Research Award, "but the advent of checkpoint therapy would have been highly unlikely without the efforts of James Allison."

WHEN I FIRST MET ALLISON, in May, he was fresh off visiting with two icons. He had recently returned from a conference at the Vatican, where he'd been invited to speak on a panel about the progress of immunotherapy, and, not long before, he'd scored a dream gig, playing harmonica onstage with his musical hero, Willie Nelson. (Allison's regular musical counterparts are a band of blues-playing cancer researchers known as the Checkpoints.) True to form, he recounted his experience in the Holy See with a lack of diplomatic awe. "Someone asked me which was more exciting, playing with Willie or meeting the pope," Allison said. "That's not a very good question."

Allison's playful irreverence is not an affect. As a whip-smart kid growing up 45 minutes west of Corpus Christi in the town of Alice, he cultivated it as a survival mechanism. He was born in 1948, the youngest of three brothers, and his family had deep roots in Texas. His father was a country doctor and Air Force Reserve flight surgeon, the son of shoe-shop owners near Waco whose forebears had fought with General John Bell Hood's Texas Brigade in the Civil War. Allison's mother, an Alice native, passed down family lore about cattle drives up the Chisholm Trail. "She had an aunt who had this thousands-and-thousands-of-acres ranch near George West with this big house on top of a hill," Allison remembered. "It almost looked like *Giant*."

Allison never really fit into the Alice of the fifties and early sixties. He didn't like football—being on the bottom of a pile once was enough. His older brothers, six and eight years his senior, were jocks who "thought I was kind of worthless because all I did was read." He was bored with small-town life and got his kicks in his garage laboratory, dissecting frogs and building small explosives that he'd ignite in the woods. ("They were like small firecrackers," Allison laughed. "It turns out, in my years of meeting a lot of scientists and having a few drinks, there are a surprising number of people who built bombs.") When his guidance counselor suggested that he might like to channel his enthusiasm into enrichment science courses at

the University of Texas at Austin during the summer after eighth grade, he jumped at the chance.

Still, Allison's youth in South Texas shaped him and his sense of mission profoundly. When Allison was a boy, his mother fell ill with lymphoma. He didn't know what cancer was, but he knew what he saw; undergoing radiation treatment with an advancing disease, his mother looked increasingly gaunt and had painful burns on her skin. One afternoon, when Allison was eleven, he was leaving his house to go swimming at the local country club with some friends. "Then somebody came out and said, 'No, he's gotta come back,'" Allison said. "And so I went back, and they said, 'Come and see your mom.'" He was holding his mother's hand when she died.

The tragedy forced Allison to become more independent. His father was grief-stricken at home and often absent on the weekends for duty in the Air Force Reserve. His brothers were already deep into their teen years and had little time for him. So Allison ended up spending hours with his homemade bombs in the woods.

Before his senior year, Allison learned that his high school's biology teachers refused to teach evolution for religious reasons. He asked to see the course syllabus and grew irate. "It was classification and a little bit of citric acid cycle stuff, and that was about it," Allison recalled. "I said, 'I'm not going to take this.' You can't teach biology without Darwin. It's like teaching physics without Newton!" With the help of his father and a few sympathetic teachers, he worked out a deal to take an advanced high school biology correspondence course offered through UT. He never looked back.

Next to Alice, UT-Austin, where Allison arrived in June 1965 at age sixteen and stayed until finishing his Ph.D., in 1973, felt like Valhalla. After ditching his premed track ("I didn't really have the discipline to memorize stuff"), he became fascinated with immunology. T cells had only recently been discovered and were still disputed science.

"My professor Bill Mandy taught about them in class, but when I would go to his office and chat with him about stuff, he'd say he didn't believe in them necessarily," Allison said. This made Allison only more interested in the immune system; the field was wide open, full of both mysteries and extraordinary potential. In one experiment, he gave a mouse a tumor, cured the animal with an enzyme used to treat human leukemia, then reinjected the same mouse with more tumors. This time the mouse rejected the cancer without treatment. Its immune system recognized the tumors as enemies.

"I couldn't have done that today, because you'd have to write a protocol and think of an experiment," Allison said. "I was just in the mouse room, and I said, 'I think I'll just inject that guy!'"

Allison's sense of play and spontaneity wasn't confined to the mouse room. G. Barrie Kitto, a recently retired UT biochemistry professor who Allison worked with, remembers the young researcher devising a novel method to clean test tubes using an acetone spray, then accidentally burning off all his hair when he lit up a cigarette next to the highly flammable product. (Kitto: "He looked like Telly Savalas." Allison: "It only singed off my eyebrows, and I quit smoking after that.") When Allison decided he wanted to stay on as a graduate student, the biochemistry department's professors had to meet specially to discuss his case. "Jim's grades were either A's or F's," Kitto told me. "If Jim thought a class was useless, he just walked out | CONTINUED ON PAGE 176

THE ROYAL TREATMENT

Five Texas organizations that are also fighting the good fight.

HOUSTON METHODIST

HOUSTON

Established: 1919

Houston Methodist treats nineteen types of cancer. It reportedly allocates $135 million toward research annually and has led clinical trials that have successfully eliminated metastases in mice and shown positive results in treating certain types of metastatic breast cancer.

THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER

DALLAS

Established: 1943

The University of Texas Southwestern Medical Center is a 231-acre campus with thirteen cancer-care programs, including one that centers on kidney cancer. It has the largest thoracic oncology program in the country.

BAYLOR CHARLES A. SAMMONS CANCER CENTER

DALLAS

Established: 1976

Baylor treats patients with all types of malignancies; however, its main focus is lung, colon, breast, leukemia, lymphoma, myeloma, prostate, and gynecologic cancers. It is currently participating in one of the world's largest breast-cancer-prevention trials.

TEXAS ONCOLOGY

STATEWIDE

Established: 1986

Texas Oncology, which conducts research and clinical trials, has more than 175 cancer facilities, including 48 that provide chemotherapy, radiation, diagnostic imaging, and lab and pharmacy services all in one place.

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS (CPRIT)

AUSTIN

Established: 2007

This agency was formed when the state authorized up to $3 billion in bonds to fund cancer research and prevention programs. It was embroiled in a scandal involving allegations of lax grant oversight, and the Legislature passed reforms in 2013. According to CPRIT, it has attracted more than one hundred researchers and their labs to Texas and helped deliver more than 2.7 million prevention services.

THE ICONOCLAST

CONTINUED FROM PAGE 97

and never bothered to drop it." The graduate school admitted Allison anyway.

Two of Allison's colleagues from different eras of his life described his prevailing philosophy as "work hard, play hard," and at UT in the late sixties and early seventies, he had no trouble finding kindred spirits. Allison and his friends relished spending all day in the lab, taking an early evening break to drink 90-cent pitchers of Lone Star, then heading back to campus to continue their experiments deep into the night. On the weekends, they'd hit the Armadillo World Headquarters, the Split Rail, and the Soap Creek Saloon, or drive out to the Hill Country for days of canoeing and nights at the old dance halls in Luckenbach and Gruene.

After UT, Allison did a postdoctoral stint at the Scripps Clinic, in La Jolla, California, but he soon found a permanent professional home back in Texas. MD Anderson had opened a new scientific research facility on the edge of Buescher State Park, just outside Smithville, and as Allison describes it, the vibe was that of a science summer camp. Nearly everyone was in their twenties and thirties. Most of them lived within a few miles of one another, and all the scientists pitched in to help with one another's experiments. As he had often been at UT, Allison was the ringleader of both the seriousness and the fun. He had a Norton Commando 850 motorcycle, and he would spearhead group outings to discuss the latest journal articles over hamburgers at Hut's, in nearby Austin, piling colleagues into a 1954 Mercedes sedan that he'd rebuilt.

At the time, the holy grail of immunology was identifying the T cell antigen receptor, and at Smithville, Allison launched himself into the hunt. The antigen receptor, then only theorized, is the mechanism that allows T cells to "see" foreign invaders. If you could figure out how T cells recognized their enemies, the thinking went, then you might be able to tweak them to better engage with all manner of maladies.

In 1982 Allison published a paper in the *Journal of Immunology*—considered far from a top-tier publication—that reported the results of his first groundbreaking experiment: he had found a protein on the surface of T cells that looked to be the coveted antigen receptor. Allison had enough evidence to make a supposition, but not quite enough to fully prove his case. Still, the paper changed his career.

"I didn't have a pedigree. I was at this place nobody had ever heard of. I wasn't on the tour of the big meetings or anything," Allison remembers. But more-established scientists found the work compelling, and soon the University of California at Berkeley offered him a position on the faculty.

"I was really nervous about it, because it was big-time science," Allison said. "I was afraid I would get into one of those competitive things where it's cutthroat and everyone is trying to outcompete everyone else, no matter the cost." He made the leap anyway. He'd have more resources and a better chance of doing work that would really matter.

When Allison left for Berkeley, in late 1984, he didn't think of himself as a cancer researcher. He worked with petri dishes and lab mice, not humans, and he'd never come anywhere close to devising medical treatments. Yet cancer lingered in the back of his mind.

"It's like that Jerry Jeff Walker song: 'With one eye on my lady and one eye on the open road,'" Allison told me. "I was thinking most about the immune system, but I was also looking down the road a little bit, thinking, 'Okay, how can I pull this over?'"

Allison's mother was not the only member of his family to die from cancer. As a young man, Allison watched as an uncle died of melanoma and another succumbed to lung cancer. As a middle-aged scientist, Allison buried one of his brothers, who had been ravaged by an aggressive prostate cancer. In 2005, less than a week after his brother had died, Allison got a prostate biopsy and received a diagnosis of cancer himself. Surgeons removed Allison's prostate, and he has had no recurrence. Earlier this year, a few of Allison's MD Anderson colleagues noticed a mass on his nose and advised him to see a dermatologist. The mass was invasive melanoma, and the tip of Allison's nose is now punctuated by a crescent-shaped scar. "The guy helping me through the surgery prep said, 'We want to get this out before you have to get that drug of yours,'" Allison told me. "I said, 'Yeah, I don't want that.'"

Given Allison's family history, it's not surprising that cancer eventually became the focus of his research, but he knew enough about the history of immunotherapy to proceed carefully. For nearly as long as doctors have known about cancerous tumors, they have been trying to cure them with an immune response. This history dates at least as far back as the ancient Egyptian physician Imhotep—who tried to eliminate tumors by causing an infection at their sites—and encompasses, more recently, the notable efforts of a New York bone surgeon named William Coley, who, starting in the 1890s, treated his sarcoma patients with an immune-stimulating bacterial concoction that came to be called Coley's toxins. Coley treated nearly nine hundred patients with the toxins over a four-decade period, achieving a cure rate of more than

10 percent. But these efforts are footnotes in the history of humanity's fight against cancer. Even when they succeeded, their results were difficult to replicate, and they were initiated with far more experimental brio than scientific knowledge.

When Allison began to train his one eye on the open road of using the immune system to battle cancer, in the eighties, the perception that immunotherapy was essentially pseudoscience still predominated in the field. As science journalist Stephen S. Hall writes in his book *A Commotion in the Blood*, a 1997 history of immunotherapy, "tumor immunology had become something of a scientific red-light district: a seedy intellectual neighborhood of fantasy and wishful thinking, a landscape littered with hulks of abandoned hypotheses and charred reputations."

Allison avoided the seediness by sticking to the confines of his academic labs, but he watched as heavily hyped immunotherapies produced results little better than Coley's. Interferon, proteins released by cells in the body in response to attacks by foreign invaders, was developed as an anti-cancer therapy, and it was touted in both *Time* and *Life* as a potential wonder drug. It worked only occasionally. Interleukin-2, the white-blood-cell protein that would fail to halt tumor growth in Sharon in 2001, garnered even more attention. "Cancer Breakthrough" announced a *Fortune* cover story in November 1985. A *New York Times* special report, an NBC News segment with Tom Brokaw, and a *Newsweek* feature soon followed, as did billions of dollars in investment. But interleukin-2, like interferon, turned out to work only rarely, and even though it gained FDA approval, it proved so toxic that it was never widely prescribed.

Even the failed expectations, though, weren't as perilous for the field of cancer immunotherapy as a simple question: Was it even possible for T cells to distinguish between a healthy cell and a cancer cell? Did the immune system see cancer cells simply as "self," or was there anything about them that registered as "non-self"? A cancer cell, after all, isn't a foreign invader, like a bacteria or a virus. It's a human cell gone haywire, dividing uncontrollably as it kills off body tissue. Was there anything in a cancer cell that would reveal itself to the immune system as an enemy?

In 1976 a British scientist named Harold Hewitt had published an exhaustively researched paper that to many observers had settled the matter once and for all. After twenty years of studying tumors in mice, Hewitt concluded that only tumors caused by direct injection of cancer cells were immunogenic. Spontaneous cancers, the kind that actually arise in humans, were invisible to the immune system.

Allison didn't take Hewitt's study as the last word. He found the conclusions overly sweeping. But in the aftermath of Hewitt's paper and the repeated failures of immunotherapy wonder drugs, studying the immune system with a focus on cancer treatment was widely thought to be a fool's errand.

"The eighties were the dark decade for tumor immunology," Philip Greenberg, the head of immunology at the Fred Hutchinson Cancer Research Center, in Seattle, and one of Allison's oldest and closest friends, told me. (Greenberg, who looks like a skinny Jerry Garcia, once accompanied Allison to a sold-out Willie Nelson concert in Maui, where they gained entrance after being mistaken for members of the band.) "The field had difficulty attracting really good scientists, so in terms of numbers, it was small but it was also shallow," Greenberg continued. "That was part of the problem: the quality of the science really wasn't there."

The true believers like Allison and Greenberg had to simply ignore the doubters and instead focus on the potential promised by those few miracle cures. After all, interferon and interleukin-2 hadn't failed entirely. A few patients had responded, and their doctors had watched as their now-turbocharged immune systems melted away their tumors.

"It may have been foolish enthusiasm of youth," Greenberg told me, "or maybe it was a grandiose idea that you can do something bigger than other people can do, but I think Jim and I and other people in the field saw enough signals that it could work that we weren't willing to believe that it just couldn't."

Allison weathered tumor immunology's dark decade by doubling down on studying T cells. As other scientists were rushing out new cancer treatments with more hype than results, Allison focused narrowly on understanding the biological mechanism of the immune system. And as each major discovery helped show the way to the next, he laid a deep foundation for the medical applications—the life-saving checkpoint-inhibitor drugs—that would eventually come.

When Allison had published his groundbreaking 1982 article on the T cell antigen receptor, many scientists had thought that the process of T cell activation would be akin to flipping a light switch. If the antigen receptor recognized an invader, the T cell would turn on. If not, the T cell would stay off. But as scientists began to learn more about T cells in the mid-eighties, it became clear that the mechanism for their activation was more complicated. T cells weren't like light bulbs that could be turned on and off with a simple

switch. They were more like cars, which don't start moving until a key turns the ignition and a foot presses down on a gas pedal. In this formulation, the antigen receptor was the ignition, and some as yet unidentified part of the T cell—a so-called co-stimulatory molecule—was the gas pedal. Only when a T cell received positive signals from both the antigen receptor and the co-stimulatory molecule would it initiate a response.

In 1988 Allison's team at Berkeley showed that the T cell's gas pedal was a molecule on its surface called CD28. It was a major discovery, but Allison and others quickly realized that even this didn't fully explain T cell activation. A T cell receiving positive signals from both CD28 and the antigen receptor wouldn't always sustain an attack. Other unknown regulatory mechanisms—likely other co-stimulatory molecules—had to be present.

Around this time, a graduate student named Max Krummel arrived in Allison's lab and began to study another potential T cell co-stimulatory molecule called cytotoxic T-lymphocyte-associated protein 4, or CTLA-4. "CTLA-4 looked like CD28," Krummel told me. "If you lined them up next to each other, they had a lot of things in common in terms of how they were organized. People think that in science you do things with really brilliant insights, but sometimes it's fairly straightforward. In this case, it was, if it looks similar and they're in T cells and one of them kind of does something important, let's check out this other one."

Before Krummel could figure out what CTLA-4 did, though, another lab beat him to it. Peter Linsley, a scientist at Bristol Myers Squibb, published a paper showing that CTLA-4 was indeed another co-stimulatory molecule. CTLA-4 didn't do anything on its own, Linsley discovered. But if the T cell antigen receptor and CD28 became activated first, then turning on CTLA-4 sent the T cell into overdrive. Allison and Krummel were both disappointed to have been scooped, but they continued with their CTLA-4 experiments anyway. "I don't think we'd have even done it, except that we were far enough along the track that we thought we might as well continue to look at CTLA-4 with our own eyes," Krummel said.

As Krummel continued to conduct his experiments on CTLA-4, he had an insight. To engage a specific molecule on the surface of the T cell, scientists use a tool called a monoclonal antibody, in effect a specially designed protein that fits into a given receptor like a key into a lock. Krummel thought he was looking for a gas pedal, so he built an antibody that he likened to a brick. The idea was that he'd place it "on top" of CTLA-4, keeping the gas pedal floored. And it worked: the T cells became highly active. But as the data piled up and Krummel and Allison looked at the evidence, they realized another mechanism might be driving it. Maybe CTLA-4 wasn't a gas pedal at all. Maybe it was the opposite; maybe it was a brake. And maybe the antibody "brick" that Krummel had built wasn't sitting on top of a gas pedal. Maybe it was sitting under a brake. Maybe the T cell wasn't going into overdrive because two gas pedals were being engaged simultaneously. Maybe Krummel's antibody was inhibiting a T cell's ability to stop itself.

Once Krummel realized this was a possibility, he began to play. He figured out a way to make the antibody press on the brake instead of disabling it, making the T cell come to a screeching halt. Then he engaged both the gas pedal (CD28) and the brake (CTLA-4) simultaneously, measuring their relative strength. "My dad drives a non-stick with two feet; he can push on the brake with his left foot and the accelerator with his right foot, and sometimes, because he's older, he does both," Krummel said. "That's basically what the experiment was. You could make things move faster or slower, working one against the other. That was a pretty exciting moment."

Krummel wasn't alone in his discovery. The lab of Jeff Bluestone, an immunologist at the University of California–San Francisco, had also studied CTLA-4 and come to the same conclusion. But Linsley, the Bristol Myers Squibb scientist, didn't immediately accept the results and neither did many others in the scientific community. "We got to have a lot of fun at meetings," Allison told me. "It was back when people weren't as polite as they are these days. There was usually a fair amount of yelling going on, insults, at least at the meetings where there wasn't any press."

When Krummel began his experiments on CTLA-4, he had been pursuing a narrow, basic science question: What does the CTLA-4 molecule do? But once he'd figured that out, he and Allison began to talk about what this discovery meant. "This is one of these things that I remember very vividly," Krummel said. "We were just standing at a whiteboard going, 'If we can push T cells whichever way we want, what are all the different ways we'd want to put it into different animal models?'"

Allison had a target in mind. By that time, it was clear that T cells could recognize tumors—Hewitt had been wrong—but before they could fully react against them, something caused the T cells to abort their attack. Allison hypothesized that tumors had evolved to activate CTLA-4, essentially stopping T cells from seeing their target as hostile. If Allison could insert an antibody to inhibit CTLA-4—the brick under the brake—then maybe tumors would be unable to halt the T cell. Allison devised a plan to inject Krummel's antibody into tumor-stricken mice and assigned the experiment to a postdoc in his lab named Dana Leach. When Leach showed Allison the initial results in late November 1994, Allison was speechless. "I thought we would slow the tumors down, but we completely cured the mice," Allison remembers.

Allison insisted on repeating the experiment immediately, this time in a blind study with a control group. Leach injected the mice, but Berkeley was letting out for winter break, and only Allison remained in the lab to observe the results. For the first two weeks, the tumors in all the mice grew, and Allison thought that perhaps Leach had bungled the initial experiment. But then the tumors in half of the mice—the treated animals—began to regress dramatically.

It would be hard to overstate the magnitude of these results. By showing that T cells could eradicate tumors so effectively, Allison's team had made a breakthrough that would alter the fields of immunology and cancer treatment. And the potential impact wasn't lost on them. When Krummel showed that CTLA-4 was a braking mechanism, it was a triumph of basic

science, advancing our understanding of how T cells function. Everyone in the lab felt good and sipped a little champagne—though the fact that Bluestone's group had published first tempered the celebration. Allison realized that these new tumor results were much bigger. "We didn't talk about that outside the lab for several months," Allison said.

In March 1996 the journal *Science* published "Enhancement of Antitumor Immunity by CTLA-4 Blockade," a paper written by Allison, Krummel, and Leach. It is only three pages long, but the results speak for themselves: by injecting a CTLA-4 antibody into mice, Allison's team had turned the immune system against cancer. Not long after Allison saw the mouse tumors evaporating, he'd realized what his next step needed to be. He couldn't just publish a paper. He and UC-Berkeley needed a patent on the CTLA-4 antibody and its biological process. "With that, we could go out and convince companies, 'You can make a drug based on this.'"

Allison likes to tell a story from his time at the research facility in Smithville when Ernestine Glossbrenner, his eighth-grade algebra teacher, who had gone on to become Alice's state representative, asked if he would testify in front of the House Committee on Public Education at the state capitol. It was 1981, and a newly elected representative from Longview named Mike Martin had introduced a bill to mandate the teaching of "creation science" alongside the theory of evolution in public schools. Glossbrenner thought Allison, a veteran of the Darwin wars, might have something to say about it.

"This guy was an absolute nutcase," Allison remembers. "The discourse was him saying, 'Well, if you put out a Ford and leave it there, it don't turn into a Cadillac.'"

Allison's default mode of speech is unhurried and a little gruff, but when he gets going on the right subject, he flies into arias of excitement. Speaking on the House floor about the cretins who would force creationism down the throats of Texas schoolchildren, Allison plainly had a ball. Allison lampooned men like Martin, who claimed evolution was controversial and only a theory. "While the theory of gravity is still controversial, apples do indeed fall down," he roared. He extolled the virtues of Darwin's discoveries. "Evolution enjoys almost universal acceptance among scientists . . . because it has been supported by observation and experimentation in the one hundred and twenty years since it was originally described!" And he skewered so-called creation science as an "archaic, inferior, and false view." But Allison made his strongest and most surprising claim against Martin's

bill when he argued that evolution could help create a better future.

Evolution was not only about dinosaurs and fossils and the development of apes and humans, Allison told the committee. It was "intimately involved in our understanding of how the immune system in the body learns to recognize what is self and what is nonself, what is a normal cell and what is a malignant cell, and even how to detect and eliminate that cancer cell from the body." Evolution, Allison continued, would help us "devise strategies to manipulate the immune responses to eliminate diseases." Fifteen years before the publication of the revelatory paper in *Science*, Allison was already trying to convince anyone who would listen that using the immune system to cure cancer wasn't just possible, it was based on the most fundamental principles of our world. (Martin's bill would fail, and he resigned from office amid a bizarre attempted assasination scandal and perjury charges.)

Allison's testimony at the statehouse would prove good practice for what came after he unveiled his tumor findings to the world. As Allison made the rounds of biotech firms, trying to convince them to turn the CTLA-4 discovery into a drug, he was greeted with indifference. The past failures of immunotherapy were proving a serious impediment.

"The pitch was, 'Hey, look, we've gotten this to work in mice. Let's try some pilots to get this to work in humans,'" said Krummel, who accompanied Allison to some of the early meetings. "We weren't exactly getting laughed at, but it was sort of, 'Hey, that's a nice result, but it's never going to really do anything.'"

Even when Allison got a firm interested, the path was full of land mines. After presenting his tumor results at a conference in Southern California, he'd convinced Alan Korman, a scientist at a small Colorado-based biotech firm called NeXstar Pharmaceuticals, to take a chance on developing an anti-CTLA-4 cancer drug. But NeXstar's development of the drug stalled, and both Allison and Korman grew frustrated. "It was clear that they weren't going to be able to contribute, and I said, 'Either try a new technology or give us the patent back, and they wouldn't do either,'" Allison recalls. "I was really pissed."

A new path appeared when Korman enlisted the help of Nils Lonberg, the scientific director of another small biotech firm, Medarex. Lonberg had experience with transgenic mice, which are genetically modified to have immune systems that mirror humans', and these specimens would allow him to create a fully human anti-CTLA-4 antibody quickly. Korman, Lonberg, and Allison joined forces in February 1998, and soon, Medarex bought the license on Allison's patent. In June 2000 ipilimumab entered its first phase I clinical trials. The plan was to try out the drug on prostate cancer and melanoma. Prostate cancer yielded some positive results, but nothing miraculous. The melanoma trial saw fewer patients respond to the treatment, but in Sharon's case—in which tumors melted away within weeks—there was more than enough cause for hope.

"When we opened these trials, I had patients from all over the world volunteering for the studies," Ribas told me. "Patients learned quickly that this was the only realistic chance they had of beating this disease long-term. When they wouldn't qualify for the clinical trials, a few people would say, 'You're killing my wife,' or my daughter, or my husband."

But in truth, a cure was far from assured. Of the seventeen people who took ipilimumab in that first trial, Sharon was one of only three responders. And nasty side effects became apparent. In a minority of patients, releasing the brakes on T cells caused a host of symptoms, among them colitis and lung inflammation. Many patients needed to go on hormone therapy because the drug caused vital glands to malfunction. In early trials, several patients died, not of metastatic melanoma but of exposure to ipilimumab itself. Some clinicians said the drug was the most toxic they'd ever administered. At conferences and in journals, immunotherapy skeptics saw interleukin-2 all over again.

Allison wasn't overseeing the trials—he's not a medical doctor, after all, nor did he work for Medarex—but he realized that ipilimumab might very well fail without a concerted campaign on its behalf, and he threw himself into the fray. In 2004 Allison left Berkeley to take a position at New York City's Memorial Sloan Kettering Cancer Center. The area was the epicenter of the push for ipilimumab: Medarex was ninety minutes away, in Princeton, New Jersey, and Memorial Sloan Kettering was performing many of the clinical trials. "I figured if I went there, I'd be able to have influence," Allison said. "My plan was to be a nuisance."

Side effects weren't ipilimumab's only problem. As Medarex partnered with Bristol Myers Squibb on larger melanoma trials of ipilimumab, the drug's efficacy was called into question. In the initial phase III trials, a patient would be considered to have responded to ipilimumab only if his or her overall tumor load shrank by 50 percent after twelve weeks. This was a standard chemotherapy endpoint, but it proved ill-suited to the new drug.

From Allison's first mouse trials onward, it was apparent that patients responding to checkpoint inhibitors would look different from patients responding to chemotherapy.

In the mice, some tumors had actually grown before eventually receding, and even Sharon, the model ipilimumab patient, had a recurrence of lung lesions a year after her nearly instantaneous recovery. Sharon, like the mice, likely experienced what is now known as "pseudo-progression." Tumors grew not because the disease was progressing but because the immune system was hyperactive. But before this concept had been widely accepted, it threatened to derail the entire checkpoint-inhibitor field.

"Those twelve-week scans showed absolute, undeniable growth of tumors, yet the patients felt better, and they would sometimes have regression six weeks later," Jedd Wolchok, a Memorial Sloan Kettering oncologist who led several of the trials, told me. "We argued that there should be a different sort of endpoint: overall survival. It required the trials to be open for much longer, and it cost much more money to do a trial like that, but it was really the gold standard."

Pfizer had been pursuing its own anti-CTLA-4 drug, and upon seeing poor tumor progression results, it abandoned development in April 2008. But Bristol Myers Squibb, which would eventually purchase Medarex, agreed to change the endpoint of a key phase III trial to overall survival, and the decision paid off. The results were presented at the American Society of Clinical Oncology's annual conference in June 2010. Just 11 percent of the patients met the tumor-shrinkage criteria, but the drug improved median overall survival—the point at which half of the patients remain alive—from a little over six months for the control group to ten months for the ipilimumab-dosed group. This wasn't just an incremental improvement. Many of those who survived past ten months experienced more-robust results: about 22 percent of the ipilimumab patients were alive three years after treatment. The FDA approved the drug in March 2011.

"That trial represented two really important milestones," Wolchok told me. "One was that it showed that there could be an intervention that improved overall survival in melanoma"—no treatment had ever done that before—"and second, it showed that there was an immunotherapy that could improve overall survival in a large, randomized international phase III trial. It validated our field for the first time."

Some of the most prominent skeptics of immunotherapy had already started coming around. This had become clear to Allison in June 2005, when, in the midst of the ipilimumab trials—with the drug's fate and that of the entire immunotherapy field far from certain—Allison was invited to speak at a major

cancer conference at New York's Cold Spring Harbor Laboratory. The mecca of molecular biology, Cold Spring Harbor is the longtime home of James Watson, the brilliant and unabashedly thorny co-discoverer of the DNA double helix. The conference's organizers had given Allison an opening-night speaking slot, sharing the bill with some of the war on cancer's most decorated veterans: Dennis Slamon, Mina Bissell, and Allison's boss at Memorial Sloan Kettering, the Nobel laureate Harold Varmus. Allison was excited, but he went into the night with more than a little trepidation. He realized that not only was he the sole immunologist scheduled to speak, he was the only immunologist who had been invited to attend.

"I thought, 'Shit, these guys are going to kill me and cook me and eat me,'" Allison said. "Some friend had warned me, 'So-and-so, he *hates* tumor immunology.' These were very prominent cancer researchers that were just outspoken. And when I got there to speak, they were all in the front row scowling at me—Jim Watson, Chuck Sherr, very smart people. I thought, 'If I don't do it right, I'm going to blow this whole thing.'"

By then Allison could recite in his sleep the cancer establishment's rap against immunotherapy: The whole field was hocus-pocus, they said, just a rung above snake oil. Immunologists took credit for a few miraculous cures that they couldn't explain, then shrugged off low response rates and fuzzy science as inevitable steps on the road to progress. Allison came with a plan to circumvent this line of attack. Instead of leading off his talk with stories of miracle cures or bragging about the promising data from clinical trials, he focused first on the biology of checkpoint inhibitors—on fundamental science. Allison walked the scientists through what amounted to his life's work—T cell activation, co-stimulation, the role of the CTLA-4 molecule, and the dramatic changes in the immune system that came from using checkpoint inhibitors. "Then I said, 'If it works this way, then here's a way you can treat cancer, and so we tried it, and here's what happened,'" Allison said. "After I gave the talk, Jim Watson came up to me and said, 'Well, Jim, you've almost made me believe that the immune system can do something about cancer.'"

The twentieth floor of the T. Boone Pickens Academic Tower offers a dramatic view of the Texas Medical Center, a sprawling city of hospitals, clinics, research buildings, office towers, and parking garages within the famously sprawling city of Houston. The center is home to 54 nonprofit institutions, including medical schools affiliated with UT, Texas A&M, and Baylor. It has more than 50 million developed square feet, making it the biggest medical complex in the world. And its signature institution is MD Anderson, which since its creation by the Texas Legislature, in 1941, has grown into the world's largest and perhaps most renowned cancer hospital.

"At MD Anderson, our network of sister institutions reaches one third of the earth's population," said president Ronald A. DePinho as we both stared out the window at the expanse below. "This is Texas's gift to the world."

An early-summer rain was pelting the city, but as we stood in his corner office, DePinho was in a gung ho mood. Wearing a state of Texas pin and a stars-and-stripes tie, in an office decorated with pictures of him smiling next to George H. W. Bush, Bill and Hillary Clinton, and Jimmy Carter, DePinho could have been mistaken for a head of state, and as he made clear, that's more or less what he is.

"The stats are approximately twenty-one thousand individuals, singular focus on cancer, multidisciplinary culture of patient care and research," DePinho continued. "We publish ten papers per day; our research budget is over $800 million. We have the world's largest cancer clinical trials engine. All of that infra-

structure allows us to take advantage of the new capabilities."

Immunotherapy is at the center of these new capabilities, and DePinho's full-on embrace of it is a sign of how much the institutional perception of the field has shifted. DePinho told me that he'd once viewed immunotherapy as "more phenomenology than really rigorous science." Now he's chosen to make immunotherapy a centerpiece of his administration. When DePinho had arrived at MD Anderson, in 2011, one of his first orders of business was launching the Moon Shots Program, a series of intensive research efforts that seek to "make a giant leap" for patients by quickly and drastically reducing mortality in thirteen common cancers. Every one of those research efforts has an immunotherapy component. And when DePinho began to poach star talent from other institutions—another key plank of his leadership—Allison was his first target.

By the time the potential of checkpoint inhibitors was becoming clear, in the late aughts, Allison was already a highly respected scientist. But in the four years since his arrival in Houston, in late 2012, he has become one of the cancer world's biggest stars. In addition to his post at MD Anderson, he is the director of the scientific advisory council of the Cancer Research Institute, the leader of Sean Parker's Immunotherapy Dream Team, and a member of vice president Joe Biden's blue-ribbon panel on cancer. He has also received nearly every prestigious award for which he is eligible, including the $1.3 million Tang Prize, funded by Taiwanese entrepreneur Samuel Yin, and the $3 million Breakthrough Prize in Life Sciences, backed by Mark Zuckerberg, Sergey Brin, and other Silicon Valley luminaries. (Allison now drives both a Tesla and a Porsche Boxster with the vanity license plate "CTLA-4.")

Allison's return home has come with other perks and honors as well. UT System chancellor William McRaven named Allison his 2015 Texan of the Year. More thrillingly, Allison scored an invitation to play onstage with Willie Nelson. The two men, in fact, had crossed paths onstage once before. As a postdoc, in La Jolla in 1975, Allison had crashed a party celebrating the album *Red Headed Stranger,* introduced himself to Nelson, and ended up leading the singer and his band to an open-mic night, where Allison sat in on harmonica. Forty years later, Nelson's longtime harmonica player, Mickey Raphael, read an article in the *Dallas Morning News* about Allison, and he was touched by the scientist's work. "I lost my girlfriend to ovarian cancer," Raphael told me. "I know the drill. I spent a lot of time in hospice with her. I got off the

Forecast

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road and was with her to the end." Raphael felt that a guy like Allison who was trying to defeat cancer deserved a special reward, so he figured "maybe I'll do a reverse Make-A-Wish."

One night, Allison showed me an iPhone video of the performance from earlier this year, at the Redneck Country Club, in suburban Houston, and he beamed as he watched the footage. He's onstage standing next to Ray Wylie Hubbard, bopping around as Nelson sings "Roll Me Up and Smoke Me When I Die." Then Raphael cues up "Dr. Jim," and Allison whips out his harmonica and starts to wail. "I'm very kinetic—I'm used to playing the blues," Allison explained. "When I went out and started playing those blues riffs, Willie said, 'Whoa, that's not Mickey!'" (Raphael's appraisal of Allison's performance: "He could play.")

The official story of Allison's return to Texas is that both MD Anderson and the state—through the Cancer Prevention and Research Institute of Texas—invested heavily in his recruitment, dedicating more than $50 million to bolster the cancer hospital's immunotherapy research capacity. "Beyond those specific investments, Jim saw the comprehensive commitment to fully translate his brilliant ideas into lifesaving clinical trials, and so it was the obvious choice for us to have him and for him to be here," DePinho said. But it didn't take long for me to realize that this wasn't the only reason Allison had come home. "Well, it wasn't all scientific," he admitted sheepishly.

A few hours after I'd visited DePinho in his office, Allison and I were walking through the third level of South Campus Research Building 1, where we were about to begin a tour of MD Anderson's immunotherapy platform, a kind of meta-laboratory where tumor tissue from dozens of immunotherapy clinical trials is studied in exhaustive detail. Then, seemingly out of nowhere, a woman in a white lab coat popped into the hall in front of us, waved, and called out, "Mind if I steal him for a minute?" Allison dutifully lumbered off in her direction.

The woman was Padmanee Sharma, an M.D./Ph.D. who's the scientific director of the immunotherapy platform, a professor of genitourinary medical oncology and immunology, and also, since 2013, Allison's wife. (Both were previously married.) Several people in the halls of MD Anderson, upon learning that I was writing about Allison, mentioned that the pair was "an unusual couple," and they are—gloriously so. Sharma is 46—slim, energetic, and as much fun as her husband—a Guyanese immigrant who spent her teen years as a latchkey kid in Queens, New York; gave birth to three daughters before she turned 30; and pioneered a new approach to studying the

effect of immunotherapy drugs on tumors before she had her first faculty appointment, at MD Anderson, in 2004. Sharma met Allison in 2005, when she asked him for a letter of recommendation to help secure a grant to fund her immunotherapy research; they started dating, and he proposed to her not long after. Sharma turned him down.

"It wasn't my idea of how to make my career," she said. But that wasn't a final no. They continued seeing each other when they could. By the time Allison arrived in Houston, Sharma was a full professor with tenure, and she no longer felt she'd be forever known as Mrs. James P. Allison.

"Of course, Jim had another wonderful statement that helped," Sharma told me. "He was like, 'Seriously, Pam, nobody can stand either one of us, so we better get married. Who else is going to talk T cells with you all day?'" (Allison's take on their pairing, as he looked at a photo of the two of them in formal dress: "Beauty and the beast.")

The immunotherapy platform is the core of Allison and Sharma's research, and it is dedicated to a simple question: Why don't more people respond to immunotherapy? Ipilimumab significantly reduces cancer cells in about 20 percent of stage-4 melanoma patients, a remarkable improvement from past treatments but far short of a universal cure. Two second-generation checkpoint inhibitors that block another "brake" known as PD-1 have increased this response rate to 50 percent, and trials combining ipilimumab and anti-PD-1 drugs have improved survival rates further. But we're still a long way from turning metastatic melanoma into pneumonia, and that particular malignancy has been considered the most susceptible to an immune response. There are now four FDA-approved checkpoint inhibitors: Bristol Myers Squibb's Opdivo, Merck's "Jimmy Carter drug" Keytruda, Genentech's Tecentriq, and ipilimumab, which is marketed under the name Yervoy by Bristol Myers Squibb. In addition to being approved for metastatic melanoma, the drugs have gotten the green light to treat non–small cell lung cancer, kidney cancer, bladder cancer, head and neck cancer, and Hodgkin's lymphoma. These and other checkpoint inhibitors are currently in trials for a host of other malignant diseases, among them brain cancer, breast cancer, ovarian cancer, and prostate cancer.

In all of these cancers, and with all of these drugs, the final results remain uncertain, a fact underscored in August when Opdivo unexpectedly failed to meet its endpoint in a lung cancer trial, and Bristol Myers Squibb plummeted $20 billion in market value in a single day. It's possible that checkpoint in-

hibitors could become the standard-of-care treatment in the majority of metastatic cancers—the fourth pillar transforming into the very foundation of cancer therapy. It's also possible that the development of checkpoint inhibitors could stall out close to the current levels of effectiveness, with science unable to push survival rates much higher. These are widely celebrated drugs, but when immunotherapy researchers drop their marbles off the observation deck of the Empire State Building, the majority of those marbles still fall to the ground. The question now is, How can you make more of them stay floating in midair?

By the time Allison returned to the immunotherapy platform, I was already in the middle of a tour with two of his colleagues, Jorge Blando and Luis Vence. As we walked through the lab, Blando showed me a machine that cuts tumor tissue (taken from immunotherapy patients) into tiny slices—"like a ham," Vence added—allowing scientists to see the location of biomarkers on the treated cells and ascertain whether there are patterns common to patients who respond to the treatment and those who don't. Vence performs a similar analysis, but instead of slicing tumor tissue, he places it in a giant metal box called a Helios machine, then blasts it with a plasma torch that is as hot as the surface of the sun.

"It'll measure forty things," Allison, now standing next to us, said of the machine. "The idea is that the computer then will reassemble that in forty dimensions of data."

I looked puzzled at what this meant. So did Allison.

"I really can't even figure out what that's going to look like. It's very new—we're a beta-test site."

But this technology isn't merely serving an academic interest. It's being used to address what Allison sees as a potential obstacle to the immunotherapy revolution. "After taking so long to get the clinic to understand the science, now the clinic is way beyond the science," Allison said, meaning doctors are testing out new drugs and new combinations of drugs without anyone understanding—Allison very much included—exactly what they do to the human body. Such experimentation is an inevitable part of medicine, of course. When lives are at stake, you go with what works, not with what you can explain in an elite journal. But, Allison believes, an everything-and-the-kitchen-sink approach that dispenses with scientific research could very quickly return immunotherapy to its phenomenological past. In the short run, you might see a few more miracle cures (and more patients with debilitating side effects). In the long run, Allison told me, "if you don't do the fundamental science, then you're going to ensure that everything

is incremental—you're going to ensure that things are done in baby steps. You're not going to have the really big thing."

When Allison talks about his work, he likes to be bold. He doesn't shy away from the word "cure." But he can be pragmatic about his role too. "As much as I say we shouldn't be satisfied with moving the median, if you move over survival just another six months, then maybe another trial opens up with a new drug or a new combination that does better," he said. He may not work in the cancer ward, but he's not a fantasist. He knows that until the next major advance comes along, immunotherapy remains more often a form of triage than a miracle elixir.

In June Sharma invited me to come meet some of her patients so I could see what the effects of immunotherapy actually look like. A few weeks later, I arrived at the Mays Clinic, the home of MD Anderson's genitourinary department, and found Sharma rushing purposefully but good-naturedly between examination rooms. There were sixteen kidney and bladder cancer patients on her schedule that day, all with stage-4 disease, and by the time I arrived, Sharma had already broken the news to two patients that they were failing to respond to treatment. "We had to talk about whether it was time for hospice," she said. "They were going to decide whether to go on another trial or go home to their families."

This was the awful reality of treating patients with advanced disease: eventually you had such talks with far more patients than ones you sent home with a clean bill of health. But that didn't mean there weren't moments to celebrate.

Sharma was eager for me to meet one of the few patients she'd been treating since the start of her career at MD Anderson, a retired Army lieutenant colonel named Michael Lee Lanning, who now spent much of his time writing military histories. Like Allison, Lanning was a small-town-Texas child of the fifties—he had grown up on a ranch near Sweetwater—and like Allison, he'd gotten out of Dodge as fast as he could. (For Lanning, that meant A&M and a platoon in Vietnam.) Lanning had been diagnosed with metastatic kidney cancer at age 59, and he'd been given such a poor prognosis by every doctor that he figured he might not make it to 60. But he refused to go home, and he'd come to Sharma looking for a sunnier forecast. Their first appointment was rough.

"He wanted someone to tell him ten years," Sharma said.

"I said, 'Give me something!'" Lanning replied.

"I told you the likelihood is that you would

die of cancer. We didn't have a therapy. I was giving the facts," Sharma said.

"Very cold," Lanning replied, shaking his head in jest. They were good friends now, and he liked needling her. "'Cold bitch' is what I said to my wife when I walked out. But you know what? She had to be. She tells people, 'You're dying,' and that's what she told me. She was very up front."

That was more than a decade ago. In the intervening years, Lanning would take a succession of targeted chemotherapies, and his cancer would beat a retreat, only to come roaring back.

"I've gone through a lung removal. I had a brain tumor. I got down to one hundred and forty pounds; I couldn't stand, I couldn't keep food down, and everything I ate I couldn't taste," Lanning said. "I remember getting the brain tumor out, and once I could finally walk again, I would walk ten steps; the next day I did twenty, the next forty, and back up."

Lanning had lived in Phoenix during the first years of his treatment with Sharma, and when he'd see local doctors to check up on his condition, it wasn't unusual for them to give him "a bottle of codeine and the phone number for hospices." But unwilling to resign himself to a terminal diagnosis, he kept coming back to Sharma.

Sometimes, Lanning felt, the treatment was worse than the cancer. After his first dose of chemotherapy, he ended up in the emergency room. "I'm not a tough guy, but I spent a lot of time with tough people—Airborne, Rangers, that type of thing—so I thought I was pretty tough until I took that medicine." But even when they found chemotherapies that worked and were more tolerable, the drugs proved to be temporary fixes. Last year, Lanning's tumors were once again advancing, and Sharma put him on a combination of ipilimumab and radiation. So far, Lanning's tumors have remained stable.

"If it comes back, I don't know," Lanning said. "But when I got this, I was hoping I would make sixty. I'll be seventy in September."

"And we have more immunotherapies if this one doesn't work, so we're not done," Sharma said.

"Is that right?" Lanning said. "Look, I don't think people are going to jump up on the steps of MD Anderson and say, 'They've cured cancer with this thing.' In fact, I think that whole 'Making Cancer History' campaign at MD Anderson is mostly bullshit propaganda money-raising stuff anyway."

But Lanning had gotten good news that day, and he was feeling a little less cynical than he liked to let on. "So far, this immunotherapy is a hell of a good scrip," he said to Sharma. "Tell your husband thank you."

Recommendations for Prevention Peer Review Panels

- Kevin T. Brady, M.P.H.
- Gregory Connolly, D.M.D., M.P.H.
- Michael P. Eriksen, Sc.M., Sc.D.

Product Development Peer Review Panels

- Colin Turnbull, Ph.D.

Kevin T. Brady

Senior Advisor, Strategy, policy and Communications Branch
Division of Global HIV and TB
Centers for Disease Control and Prevention
Retired

From March 2012 until September 2016, Kevin Brady served as a Senior Public-Private Partnerships Specialist, technically advising and assisting the Division leadership in the development, implementation and evaluation of Public-Private Partnerships (PPP) strategies and interventions that support the President's Emergency Plan for AIDS Relief (PEPFAR). Specifically, he managed existing public-private partnerships in strategic information, informatics and health systems strengthening to advance PEPFAR programs. Partnerships include: Pink Ribbon Red Ribbon, International Laboratory projects, and Nurse Education and training collaborations with a value of over $75 million from cash and in-kind contributions.

From March 2006 to 2013, Kevin was detailed to the CDC Foundation (CDCF) as the Associate Vice President for Programs. In this role, he was a liaison between the CDC and CDCF to expand public health's science base through studies, projects, and research. He routinely interacted with corporate leaders, senior CDC leadership, CDCF personnel, government officials, and other key stake holders to mutually collaborate on key public health initiatives. He was the day-to-day supervisor for the Program staff and managed over 200 active projects; in 2010/2011 the Program portfolio included approximately $45 million newly funded national and international projects with a total value of approximately $200 million.

Prior to the CDC Foundation, he worked at the CDC for 13 years, in the position of Deputy Director, Division of Cancer Prevention and Control (DCPC). The Division is responsible for the development and management of cancer prevention, early detection and control initiatives. In addition to the surveillance, research, and communications activities DCPC conducts, the Division administers the National Breast and Cervical Cancer Early Detection Program, the Nation Program of Cancer Registries, and the National Comprehensive Cancer Control Program.

He has spent his career working in human services. Before CDC, he was the Assistant Director for Research Administration and Professional Education at the Epilepsy Foundation of America. He also worked previously as a Health Planner for both the New York City Department of Health and Columbia Presbyterian Medical Center.

He holds a B.S. from the University of Maryland in Special Education/Elementary Education and a M.P.H. from Columbia University in Health Administration.

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EXPERIENCE:

Centers for Disease Control and Prevention (CDC), Atlanta, GA — **Jan. 1993 – Sept. 2016**

Center for Global Health — **Jan. 2016 – Sept. 2016**
Division of Global HIV/AIDS and TB (DGHT)
Senior Advisor/Health Scientist, Strategy Team
Strategy, Policy and Communications Branch
Retired

- Serve as a senior public-private partnerships specialist, technically advising and assisting the Division management in the provision the development, implementation and evaluation of Public-Private Partnerships (PPP) strategies and interventions.

- Managed existing public-private partnerships in strategic information, informatics and health systems strengthening to advance DGHT programs. Partnerships include: Pink Ribbon Red Ribbon, International Laboratory Branch partnerships, Global TB and ARC Nurses initiative.

- Senior government Point of Contact for the Pink Ribbon Red Ribbon initiative that coordinated efforts among twenty-one partners; presently in Zambia, Botswana, Tanzania, and Ethiopia.

- As a member of the newly formed Strategy Team, helped to determine priorities and implement the actions to support the Division's global mission.

- Responsible for approximately $75 million of public–private partnership cash or in-kind contributions.

Center for Global Health — **Mar. 2012 – Dec. 2015**
Division of Global HIV/AIDS (DGHA)
Senior Advisor, Private Sector Engagement
US Office of Global AIDS Coordinator (OGAC)
(Federal employee on executive loan)

- Detailed to the OGAC to serve as a senior public-private partnerships specialist, technically advising and assisting the Director of Private Sector Engagement in the provision of overall leadership and guidance on the development, implementation and evaluation of Public-Private Partnerships (PPP) strategies

and interventions that support the President's Emergency Plan for AIDS Relief (PEPFAR).

- Managed existing public-private partnerships in strategic information, informatics and health systems strengthening to advance PEPFAR programs. Partnerships included: Pink Ribbon Red Ribbon, International Laboratory Branch partnerships and NEPI collaboration in South Africa.

- Facilitated technical aspects of public-private partnership development, including conducting risk assessments to ensure risk is shared and appropriate; conducting due diligence on proposed partners. Worked with PEPFAR's implementing agencies to facilitate formal agreement process.

The CDC Foundation **Mar. 2006 – Mar. 2012**

Associate Vice President for Programs

(Federal employee on executive loan)

- Assisted the Vice President (VP) for Programs as a liaison between the CDC and the CDC Foundation (CDCF) to expand public health's science base through studies, projects, and research. Interacted with corporate leaders, senior CDC leadership, CDCF personnel, government officials, and other key stake holders; acts as the VP in her absence.
- With the VP for Programs, the President and CEO of the CDCF and other senior Foundation leadership, helped establish goals, policies, program strategies, objectives, priorities, time frames, and methods for evaluating performance and outputs of agreements between CDCF and CDC; facilitated the development of new CDCF budgetary/staff initiatives.
- Day-to-day supervisor for nine Program Officers, a budget analyst, administrative assistant, and nine contract staff; managed over 200 active projects; in 2010/2011 the Program portfolio included approximately $45.0 million newly funded national and international projects; total of approximately $145.0 million current funding level.
- Directly managed CDC Foundation specific program initiatives: Meta-Leadership; Worksite Wellness; Combating Dengue Fever in Indonesia; Tobacco Messaging; and other projects.

National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP)
Division of Cancer Prevention and Control (DCPC)

March 2004 – March 2006, Acting Director (September 2001 – March 2004, Deputy Director)

- Responsibilities included: day-to-day management of all Division activities; collaboration with Center's administrative and fiscal staff; meeting weekly with Branch Chiefs to review progress and problem-solve; and approval of all Division hiring, policy development, and program implementation.
- Managed approximately 145 staff and an annual budget of $300 million; organized into three Branches - Program Services, Epidemiology and Applied Research, and Cancer Surveillance.

September 1999 - September 2001, Assoc. Director, Office of Program and Policy Information (OPPI)

- Responsible for Division's information activities: maintained the Internet home page; a legislative database; a toll-free voice information system, and a library of publications and written documents relating to DCPC activities.
- Responsible for partnership development; maintained relations with existing partners and worked with new collaborations to promote the Division's cancer activities and health messages for prevention and early detection with breast, cervical, colorectal, prostate, ovarian and skin cancers.
- Directly supervised eleven staff - eight professional and three support staff; responsible for responding to all public and congressional inquiries; developed promotion opportunities for Division activities; and monitored legislative actions that impacted on cancer prevention issues.

NCCDPHP

May - September 1999, Associate Director for Program Operations

- Responsible for planning, organizing and directing the day-to-day operations of the Center. Participated with the Director, Deputy Director, and senior management staff in formulating and implementing the organization's goals, objectives, and activities. NCCDPHP had over 700 employees and a budget of approximately $650 million.
- Directly responsible for the management of the Center's budget, personnel, and facilities operations.
- Center representative for the agency's CDC/ATSDR Strategic Plan for Public Health Workforce Development.

DCPC

June 1998 – May 1999, Acting Deputy Director and Acting Associate Director, OPPI – see above

August 1995 - June 1998, Assist. Chief, Program Services Branch (PSB)

- PSB managed the National Breast and Cervical Cancer Early Detection Program (NBCCEDP); monitored cooperative agreements to health agencies in all fifty states, 5 territories, the District of Columbia, and fifteen tribes/tribal organizations; program funding at $184 million Congressional appropriation.
- Responsible for the day-to-day management and operations of all Branch activities; act as Branch/Division lead as needed.
- Management lead for program development of special initiatives, e.g., partnership with National Cancer Institute's Cancer Information Service; development of the Division's Office of Health Communications; and coordination of Branch Team Building.
- Responsible for Branch-wide fiscal planning and monitoring of contracts and cooperative agreements for all program development and implementation.

January 1993 - August 1995, Chief, Program Operations and Education Section

- As Section Chief, directly supervised 12 health professionals whose responsibility was to liaison with cooperative agreements and lead special projects (i.e., initiatives with priority populations, provide training for NBCCEDP issues, etc.)

ASSISTANT DIRECTOR, Research Administration and Professional Education, Epilepsy Foundation of America (EFA), Landover, MD — **Mar. 1987- Jan. 1993**

HEALTH CONSULTANT, Southern Maryland Health Systems Agency, Clinton, MD — **Oct. 1986-Mar. 1987**

PLANNING SPECIALIST, New York City Department of Health, Office of Planning and Evaluation — **Nov. 1984-Mar.1986**

ASSISTANT DIRECTOR OF PLANNING, Columbia-Presbyterian Medical Center Health Sciences Administration, New York, NY — **Oct. 1982-Nov. 1984**

SPECIAL ASSISTANT, Assoc. Commissioner of the Office of New York City Affairs, State Department of Health, New York, NY — **Fall 1982**

PROGRAM DIRECTOR, Work Activity Center, Massachusetts Hospital School, Canton, MA — **1980-81**

SPECIAL NEEDS TEACHER, Massachusetts Hospital School — **1977-80**

EDUCATION:
Columbia University, M.P.H., Health Administration, 1983
University of Maryland, B.S., Special Education/Elementary Education, 1976

Gregory Connolly

Dr. Gregory Connolly is a Professor of Research at Northeastern University Schools of Law and Bouve School of Health Sciences. He was Professor of the Practice of Public Health at the Harvard School of Public Health's Center for Tobacco Control from 2004 - 2014 and prior the director of the Massachusetts Tobacco Control Program from 1996-2004. He has published over 200 scientific articles on tobacco use, effects on health and control.

He actively translates knowledge into advancing public health policies and programs in other states, the federal level and other nations. He is credited with passage of the federal Smokeless Tobacco Health Education Act, ending use of U.S. trade sanctions to compel foreign nations to import U.S. cigarettes and testified before the US Congress on over twenty occasions. He was the second American to be awarded the Surgeon General's Medallion by C. Everett Koop.

He designed directed and was responsible for the evaluation of the Massachusetts Tobacco Control Program that reduced consumption by 60% from 2003-2004 and actively worked with other states, federal agencies and the World Health Organization to establish similar programs while at Harvard.

Currently, he is researching Risk Reduction (Tobacco) Products for their propensity to reduce harm and potential to enhance addiction and population use. He actively translates his findings into governance policies for regulation for tobacco products at the state, federal and international level with the intent of eliminating tobacco use by mid-21st century.

Curriculum Vitae

Gregory Niles Connolly, D.M.D., M.P.H.
Belmont, Massachusetts 02478

Date & Place of Birth:
February 15, 1949, Boston, Massachusetts

Education:
1970 Biology, BA Holy Cross College
1974 Dentistry, DMD Tufts University, School of Dental Medicine
1978 Healthcare Administration, MPH Harvard School of Public Health

Post Doctoral Training:
1975 Residency in General Practice Dentistry, Brockton Veterans Administration Hospital

Licensure:
1975 to Present, Dentistry, Massachusetts Board of Registration in Dentistry

Academic Appointments:
2005- Professor of the Practice of Public Health
Department of Social and Behavioral Sciences
Director, Center for Global Tobacco Control,
Harvard School of Public Health
1990-1992, Lecturer, Department of International Health,
Harvard School of Public Health
1982-1985, Instructor, Harvard School of Dental Medicine
1980-1986, Instructor, Boston University School of Dentistry

Honors and Distinctions:

David Yen Memorial Award	
Asian Pacific Association for Tobacco Control	2007
Campaign for Tobacco Free Kids	
Mike Synar Memorial Award	2003
Canada's Non-Smokers' Rights Association	
Lifetime Achievement Award	2003
Entertainment Industries Council of Massachusetts	
Prism Award	2002
American Association of State and Territorial Dental Directors	
Outstanding Achievement Award	2002
New England Public Health Association	
Timothy Johnson Award	2001
The Commander of the Third Class	
Of Our Most Noble Order of the Crown of Thailand	2000

Massachusetts Health Council	
Outstanding Achievement Award	1999
Boston Magazine	
Faces of Boston	1994
US Public Health Service Inspector General's Office	
Integrity Award	1993
American Association of Public Health Dentistry	
Special Merit Award	1990
American Dental Association	
Presidential Citation	1988
Massachusetts Public Health Association	
Alfred Frechette Award	1988
James M. Dunning Award	1986
United States Public Health Service	
The Surgeon General's Medallion	1986

Major Professional Service:

National

Food and Drug Administration	
Member Tobacco Products Scientific Advisory Committee	2010-2011
Dana-Farber/Harvard Cancer Center	2005-
American Lung Association	
Tobacco Action Committee	2004-
Louisiana Tobacco Cessation and Prevention Program	
Scientific Advisory Board	2003-
Tobacco Control Resource Center, Northeastern University	
Board of Directors	2003-
American Legacy Foundation	
Board of Directors	2000-2002
Blue Cross Blue Shield of Minnesota	
Scientific Advisory Board	2007-2009
American Cancer Society	
Tobacco Control Advocacy Group	2000-
National Public Issues Committee	1988-1990
California Tobacco Control Program	
Tobacco Evaluation Committee	1992-1998
Interfaith Council on Corporate Responsibility	
Tobacco Shareholder Resolution Committee	1986-
Massachusetts State Health Coordinating Council	
Member	1978-1981
Massachusetts League of Neighborhood Health Centers	
Member	1976-1978

Brighton Allston Community Health Center	
Board of Directors	1973-1975
Board of Health Town of Belmont, Mass. Member	1974-1975

International

Public Health Foundation of India	
Advisory Committee Member	2010-
Healthy Israel 2020: Israel Department of Health	
Health Behavior Committee	2006-2008
World Health Organization	
Scientific Advisor	2008 -
Member, Scientific Advisory Committee	
On Tobacco Product Regulation	2000-2003
Member, Expert Advisory Panel on Smoking and Health	1987-2002
Chairman, Study Group on Smokeless Tobacco	1987
Asian Pacific Association for Tobacco Control	2005-
Board of Directors	1989-1994

Professional Societies:

American Public Health Association	1975-
American Dental Association	1975-
National Media Spokesperson	
Consultant, Council on Dental Health and Health Planning	
Society for Research on Nicotine and Tobacco	2003-
Association of State and Territorial Dental Directors	1987-1992
President	1983
Massachusetts Public Health Association,	
Member	1974-

Major Academic Administrative Responsibilities:

Harvard School of Public Health

Reaccreditation Committee	2009-2011
Acting Director, Division of Public Health Practice	2009-2010
Director, Tobacco Control Research Program	2004-2010

Massachusetts Department of Public Health

Scientific Advisor, Tobacco Control Program	2003-2005
Director, Tobacco Control Program (Annual Budget $36 Million per year)	1993-2003
Project Director, CDC/OSH Comprehensive Tobacco Control Campaign (Annual Budget $1.3 Million)	1999-2003
Project Director, US FDA Massachusetts Tobacco Enforcement Program (Annual Budget $300,000)	1997-2000

Director, Division of Dental Health (Annual budget $2.1 Million) 1980-1992

Boston Department of Health and Hospital
Assistant Director, Bureau of Community Dental Programs 1978-1980
South Boston Community Health Center
Dental Director 1975-1980

Editorial Boards

Associate Editor, Tobacco Control (BMJ) 1993-
Editorial Board, Tobacco Use Insights Libertas Press 2008-
Reviewer, for Numerous Journals 1988-

Major Research Interests

The effects of comprehensive tobacco control programs and policies and on social norms, harm, use and population impact

Effects of tobacco product design, constituents, nicotine and marketing on abuse potential, perceptions, use, harm and population impact

Enhancing the science base for regulation of tobacco products and their marketing

Global tobacco control

Governance of the tobacco industry, its globalization and trade in products and methods for the application of science and human rights to protect public health

Methods for the elimination and use of manufactured tobacco products

Selective Services to the Public Health

1984-6. Conducted the first scientific assessment of harm of smokeless tobacco (SLT) (NEJM 1986) and was responsible for enacting the first in the nation policy requiring health warning on SLT packages

1986. Credited with passage of the federal Comprehensive Smokeless Tobacco Health Education Act (Pl 96-222)

1986. Cochaired the WHO Study Group on Smokeless Tobacco that led to a ban of the introduction of SLT in EU, Australia, Israel, New Zealand and multiple other nations

2006-2010. Convened three international meetings of scientists, public health, fire and elected officials on adoption of reduced ignition propensity (RIP) standards which resulted in laws in 50 states, Canada, Australia, the EU and South Africa

1986-2004. Designed, implemented, researched and evaluated effects on use and health of the Massachusetts Tobacco Control Program. A comprehensive, socially based intervention (annual budget $ 36 million/the largest per capita expenditure for tobacco control). Elements of the scientifically proven model was adopted by other states, CDC's Best Practices for Tobacco Control and the World health Organization's Framework Convention of Tobacco (FCTC)

1986-90. Ended the use of 301 US trade sanctions compelling South East nations to import and market US Cigarettes based on securing Congressional support and action

1989. Testified at GATT (precursor to the World Trade Organization) on behalf of WHO on a US trade complaint against the Thai ban on import of US cigarettes. GATT ruled the market be opened but any public health policy recommended by WHO could be adopted to curb competition. WHO subsequently developed the FCTC

Recent Grants and Awards

$1,600,000	2000-2004 RO1 National Cancer Institute PI - Review and Analysis of Tobacco Industry Documents on the Design and Constituents of Tobacco Products
$ 600,000	2004-2007 Flight Attendants Medical Research Institute Distinguished William Cahan Professorship
$2,400,000	2004-2008 RO1 National Cancer Institute PI - Design and Characterization of Tobacco Products: Review and Analysis of Tobacco Industry Documents
$1,500,000	2004-2007 American Legacy Foundation PI - New Tobacco Products and PREPs, Design, Marketing and Consumer Perceptions.
$ 250,000	2006-2009 Annual Training Program for Comprehensive Tobacco Control in the Eastern Mediterranean Region (HSPH/Cyprus Institute for Public Health, PI - Flight Attendants Medical Research Foundation and others
$ 76,000	2007-2008 All Ireland Cancer Control Irish Government and National Cancer Institute
$ 186,000	2005-2009 National Cancer Institute

Co-PI Evaluation of Reduced ignition Propensity Cigarettes
(Subcontract Roswell Park Cancer Institute)

$ 600,000 2006-2011 National Cancer Institute
Co PI - Laboratory Assessment of Tobacco Use Behavior and Exposure to Toxins among Users of New Tobacco Products
(Subcontract Georgetown Medical School)

$ 45,000 2010 First Israeli National Conference on Tobacco and Health

$ 25,000 2007-2008 PI - International Tobacco Control
Raymond P. Lavietes Foundation

$ 100,000 2007-2011
Flight Attendants Medical Research Institute
PI - Evaluation of the Masking of Secondhand Smoke Exposure through Paper Additives

$1,300,000 2008-2012 National Cancer Institute
PI - Subjective and Behavioral Response to Potential Reduced Tobacco Product (PREP) Design and Marketing

$ 52,830 2008-2009 Flight Attendants Medical Research Institute
PI - Evaluation of the Massachusetts Smoke-free Air Law

$1,600,000 2009-2012 Behrakis Foundation
PI - Making Smoking History in Greece

$ 178,000 2010-2011 PI - National Cancer Institute (Supplement to Existing RO1)
Subjective and Behavioral Response to Potential Reduced Tobacco Product Design and Market

$ 275,000 2013 2014 Global Conference on Tobacco Products and Proceedings
PI Harvard Global Health Institute and Multiple Donors

$1,300,000 2010-2015 National Cancer Institute
PI - RO1 Characterization of Design of Cigarettes

$ 275,000 2013-2016 National Institute of Health/Food and Drug Administration
PI R21 Substantial Equivalence and Tobacco Product Regulation

$ 300,000 2013-2016 American Legacy Foundation
PI Acquisition and Analysis of Tobacco Industry Submissions
To the Food and Drug Administration

Bibliography

Peer-reviewed journals

1. Tavares, M., Connolly, G.N., *Mercury Exposure in Massachusetts Dental Offices.* J Mass Den Soc 1980: 29:18-21.

2. Connolly, G.N., Silversin, J., *The Crisis in Financing a Dental Education i*n *Massachusetts.* J Massachusetts Dental Society 1981: 30:26-29.

3. Jenson, M.C., Douglass, C.W., Connolly, G.N., *Survey of Massachusetts Nursing Dental Consultants.* J Dent Res 1982: 61:179.

4. Weintraub, J., Douglas, C.W., Connolly, G.N., *Attitudes Toward Dental Health and Utilization of Dental Services by Massachusetts Consumers*. J Mass Den Soc. 1983: 32:17-20.

5. Connolly, G.N., Silversin, J., Traudeau, E., *A Study of Dental Manpower in Massachusetts.* J Mass Den Soc 1983: 32:32-35.

6. Weintraub, J.A., Connolly, G.N., Lambert, C.C., Douglas, C.W., *What Massachusetts Residents Know About Fluoridation.* J of Pub Health Dent. 1985: 45:240-245.
7. Weintraub, J.A., Connolly, G.N., O'Donnell, J., *The Effect of General Practice* Residency Training in Providing Dental Care to the Developmentally *Disabled.* J Dent Ed 1985: 45:321-323.

8. Connolly, G.N., Winn, D.M., Hecht, S.S., Henningfield, J.E., Walker, B.W., Hoffman. *The Reemergence of Smokeless Tobacco*. NEJM 1986: 314:1020-1027.

9. Callanen, V.A., Weintraub, J.A., French, D.P., Connolly, G.N., *Developing a Sealant Program, the Massachusetts Approach*. J of Pub Health Dent 1986: 46:141-146.

10. Guinta, J.L., Connolly, G.N., *the Reversibility of Leukoplakia Caused by Smokeless Tobacco*. JADA 1986: 113:50-52.

11. Connolly, G.N., *Smokeless Tobacco Health Hazards and Regulatory Issues*. Int Dig Hlth Leg 1987: 38:170-180.

12. Connolly, G.N., *Public Policy Issues Associated with Nicotine.* Pharm. Biochem. Behavior 1988: 27: 44.

13. Connolly, G.N., *Popularity of Smokeless Tobacco among Adolescents*. Medical Aspects of Human Sexuality 1988: 22:44.

14. Connolly, G.N., Orleans, T.C., Kogan, M., *Use of Smokeless Tobacco in Major League Baseball*. NEJM 1988: 318:1281-1285.

15. Connolly, G.N., *Back to the Future with Oral Snuff*. British Journal of Addiction 1990: 85:1102-1104.

16. Bednarsh, H., Connolly, G.N., *Infection Control Practices of Massachusetts Dentists 1986-1988*. Journal of the Massachusetts Dental Society 1990: 39:82-87.

17. Connolly, G.N., *Tobacco, Trade and Eastern Europe*. World Smoking and Health 1991: 16: 11-12.

18. Connolly, G.N., *Banning Oral Snuff.* Lancet 1991: 37:1484 (letter).

19. Shane, T.E., Daynard, R.A., Connolly, G.N., *Tobacco use as sociologic carcinogen: the case for a public health approach*, Cancer Prevention.1992: 1-15.

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22. Slade, J., Connolly, G.N., Davis, R.M., Douglas, C.E., Henningfield, J.E., Hughes, J.R., Kozlowski, L.T., Myers, M., *Report of the Tobacco Policy Research Study Group on Tobacco Products*. Tobacco Contract (supplement) 1992: 1:54-59.

23. Connolly, G.N., Western Cigarettes and Celebrities in Asia. Priorities 1993: 17-20.

24. Connolly, G.N., *Violence and Winston Travel Tour* (letter) Tobacco Control 1993: 2:44.

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26. Connolly, G.N., *The marketing of nicotine addiction by one oral snuff manufacturer,* Tobacco Control 1995; 4: 73-79.

27. Johnson, R.K., Wang, M., Smith, M.S., Connolly, G.N., *The Association between Parental Smoking and the Diet Quality of Low Income Children*. Pediatrics 1996: 97:1-6.

28. Harris, J., Connolly, G.N., Davis, B., *Cigarette Smoking Before and After Excise Tax Increase and Anti-Smoking Campaign in Massachusetts, 1990-1996*. MMWR 1996: 45(44): 966-970.

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35. Wayne, G.F., Connolly, G.N., *How Cigarette Design Can Affect Youth Initiation into Smoking: Camel Cigarettes 1983-93*. Tobacco Control. 2002:11: i32-38.

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47. Carpenter, C.M., Ferris Wayne, G., Connolly, G.N., *Designing Cigarettes for Women: New Findings from the Tobacco Industry Documents.* Addiction, June; 2005; 200 (6):837-51.

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50. Gray, N., Henningfield, J.E., Benowitz, N.L., Connolly, G.N., Dressler, C., Kagerstrom, K., Jarvis, M.J., Boyle, P., *Toward a comprehensive long term nicotine policy.* Tobacco Control. June, 2005 14 (3): 161-5.

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52. Carpenter, C., Ferris Wayne, G., Connolly, G.N., Pauly, J., Koh, H. *New Cigarette brands with candy flavors that appeal to youth,* Health Affairs. November, 2005.

53. Nadel, J., Rees, V., Connolly, G.N., *Disparities in Global Tobacco Harm Reduction* AJPH. December, 2005.

54. Cullen, D.M., Ferris Wayne, G., Connolly, G.N., *Deciphering the Internal Code Used by the Tobacco Industry.* Tobacco Control. December, 2005; 14; 429-432.

55. Ferris Wayne, G., Henningfield, J., Connolly, G.N., *Brand differences of free-base nicotine delivery in cigarette smoke: view of the tobacco industry documents.* Tobacco Control 2006; 15: 189-198.

56. Carpenter, C., Connolly, G.N., Travers, G., Hyland A., Cummings, K.M., *Health meetings do not belong in smoky cities,* Tobacco Control February 2006; 15: (1).

57. Biener, L., Reimer, R.L., Wakefield, M., Szczypka, G., Rigotti, N., Connolly, G.N., *Impact of Smoking Cessation Aids and Mass Media Among Recent Quitters*, Am J Prev Med 2006; 30 (3).

58. Henningfield, J.E., Connolly G.N., Kemper K.E. Gitchell J.G., Pinney J.M., *Clean Cut Cigarettes: Fictitious Launch Foreshadows Actual Tobacco Industry Strategy.* Tobacco Control 2006; 15:341-342.

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63. Carpenter, C., Ferris Wayne, G., Connolly, G.N., *The role of Sensory Perception in the Development and Targeting of Tobacco Products,* Addiction 2006; 102:136-147.

64. Connolly, G.N., Alpert, H.R., Wayne, G.F., Koh, H., *Trends in nicotine yield in smoke and its relationship with design characteristics among popular U.S. Cigarette brands, 1997-2005,* Tobacco Control. 2007; 000 1-9.

65. Kabir, Z., Connolly, G.N., Clancy, L., *Recent lung cancer patterns in younger age-cohorts in Ireland,* Ulster Medical Journal 2007; 76 (2) 83-87.

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67. Kabir, Z., Clancy, L., Connolly, G. N., *Tobacco control efforts: where is India now?* (Correspondence) The Lancet. Vol. 370, July 14, 2007.

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product, Marlboro UltraSmooth, Nicotine and Tobacco Research. Volume 9, Number 11, November 2007 1197-1206.

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74. Kabir, Z., Connolly, G.N., Clancy, L. *Sex-differences in lung cancer cell-types? An epidemiologic study,* Ulser Medical Journal. 2008; 77 (1) 1-5.

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77. Christophi, C.A., Kolokotroni, O., Alpert, H.R., Warren, C.W., Jones, N.R., Demokritou, P., Connolly, G.N., *Prevalence and Social Environment of Cigarette Smoking in Cyprus Youth*, BMC Public Health 2008; 8: 190, June, 2008.

78. Kabir, Z., Connolly, G.N., Clancy, L., Koh, H.K., Capewell, S., *Reduced Coronary Heart Disease Deaths and Decreased Smoking Prevalence in Massachusetts, 1993-2003.* American Journal of Public Health, August 2008. Vol. 98, No.8: 11-13.

79. Kreslake, J.M., Ferris Wayne, G., Alpert, H.R., Koh, H.K., Connolly, G.N., *Tobacco Industry Control of Menthol in Cigarettes and Targeting of Adolescents and Young Adults,* American Journal of Public Health, September 2008, Vol. 98, No. 9, 1-9.

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from 1989 to 2004, The European Journal of Public Health. Published online Nov.5, 2008.

84. Rees, V.W., Wayne, G.F., Connolly, G.N., *Puffing Style and Human Exposure Minimally Altered by Switching to a Carbon-Filtered Cigarette,* Cancer Epidemiology Biomarkers Prev 2008; 17 (11).

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10. Connolly, G.N. Garagiola, J., *It's Time Major League Baseball Made Tobacco History* (editorial) JADA 1995: 126: 1121-1241.
11. Connolly, G.N., *Tobacco Trade and Eastern Europe.* In: Slama K, ed. Tobacco and Health. New York: Plenum Press, 1995.
12. Connolly, G.N., *Policies Regulating Cigars.* In Burns DM ed. Cigars: Health Effects and Trends. Smoking and Health, Monograph No. 9, Rockville MD, National Institutes of Health, National Cancer Institute, NIH publication no. 98-4302, 1998.
13. Connolly, G.N., *Smokeless Tobacco in Developed Countries: An Epidemic Prevented.* In Durstin B. Jamorozich eds. The Global War: Proceedings of the Seventh World Conference on Smoking or Health. Perth, Australia: Health Department of Western Australia, 1999: 120-125.
14. Connolly, G.N., *Smokes and Cyberspace: A Public Health Disaster in the Making.* (editorial) Tobacco Control 2001: 10:229.
15. Tomar, S.L., Connolly, G.N., Wilkenfeld, J., Henningfield, J.E. *Declining Smoking in Sweden: Is Swedish Match Getting the Credit for Swedish Tobacco Control's Efforts?* (commentary) Tobacco Control. 2003: 12:368-371.

Letters

1. Connolly, G.N., Walker, B.W., *Restrictions in Importation of Tobacco by Japan, Taiwan and South Korea* (letter). NEJM 1987: 1416-17.
2. Connolly, G.N., Blum, A., Richards, J.W., *Smoke Screen around Oral Snuff* (letter). Lancet II: 166.
3. Slade J., Connolly, G.N., *Nicotine From Aerosol Rod* (letter). AJPH 1987: 77:1229.
4. Connolly, G., Harris, J., *Evaluating Anti-smoking Campaigns*. JAMA 1998: 280-965 (letter).
5. Connolly, G.N., *Mass Media Campaigns: Australia, UK, USA,* Letter, Tobacco Control 2000; 9 (2).
6. Connolly, G.N., response to letter from J. E. Swauger (R.J. Reynolds Tobacco), *Eclipse: does it live up to its health claims*? (letter) Tobacco Control. 2003 12:112.
7. Connolly, G.N., Alpert, H.R., *Trends in the Use of Cigarettes and Other Tobacco Products, 2000-2007,* (Research Letter) JAMA, June 11, 2008, 2629-2630.
8. Vardavas C., Behrakis, P., Connolly, G.N., Beware tobacco companies' spurious financial arguments. BMJ 2011; 342: d1145 (letter)
9. Rosen, L. J., Haim, G., Connolly, G.N., *Political will ushers in a new era for tobacco control in Israel.* The Lancet. Vol. 378; (letter) November 12, 2011.

Educational Materials

1. Orleans, C.T., Connolly, G.N. Workman, S., *Beat the Smokeless Habit: Smokeless Tobacco Cesstion Guide 1991.* ROW Sciences, Rockville, MD, National Cancer Institute, Bethesda, Maryland, Major League Baseball, New York: 1-16.
2. Favat, P. (Director), Connolly, G.N. (Executive Producer). *I Can't Breathe: an educational Video with accompanying teaching guide*. Boston 2000. Arnold Communications Inc.

Interventions/Patents: None

Teaching Experience:

1990-1991 Instructor Approaches to International Tobacco Control	Harvard School of Public Health	Primary
1994-2003 Summer Internships Massachusetts Department of	Tufts University School of Medicine	Advisor & Mentor

Public Health Public Health Students	Boston University School of Public Health Harvard School of Public Health	
2005-Present	Emerson College	Guest Lecturer
2004-Present Approaches to International Tobacco Control HSPH-SHH 249-01 (Fall 2)	Harvard School of Public Health	Primary Instructor
2005-2006 Managing a Mass Media Campaign HSPH-SHH-279-01 (winter)	Harvard School of Public Health	Primary Instructor
2005-Present Tutorials	Harvard School of Public Health	Primary Instructor
2005-2009 ProSeminar HSPH-SHH-233-01 (fall 1)	Harvard School of Public Health	Primary Instructor
2009-Present HSPH- SHH 506 (Fall 2) Public Health Practice, Leadership & Justice	Harvard School of Public Health	Primary Instructor

Michael Eriksen

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Co-Principal Investigator for the Global Health Institute –
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Principal Investigator for the GSU Tobacco Center of Regulatory Science

Dr. Michael Eriksen is an international public health expert and educator with more than 30 years of experience. Dr. Eriksen is the founding Dean of Georgia State's School of Public Health and Principal Investigator of the Georgia State University Tobacco Center of Regulatory Science (TCORS). Funding from a $19 million grant from the FDA and the NIH supports the TCORS team as it focuses on both the human and economic factors that contribute to decision making related to tobacco products. He has served as the Co-Principal Investigator for the Global Health Institute - China Tobacco Control Partnership at Emory University since 2008. He also serves as Director of Georgia State University's Partnership for Urban Health Research and Center of Excellence in Health Disparities Research.

Prior to his current positions, Dr. Eriksen served as a Senior Advisor to the World Health Organization in Geneva and was the longest-serving Director of CDC's Office on Smoking and Health (1992-2000). In that role, he led in developing tobacco control policy for the United States while also expanding the Office to include international efforts. Dr. Eriksen has been Director of Behavioral Research at the M.D. Anderson Cancer Center. He has recently served as an advisor to the Bill & Melinda Gates Foundation, the Robert Wood Johnson Foundation, the American Legacy Foundation and the CDC Foundation.

Dr. Eriksen has published extensively on tobacco prevention and control and has served as an expert witness of behalf of the U.S. Department of Justice and the Federal Trade Commission in litigation against the tobacco industry. He is Editor-in-Chief of *Health Education Research,* co-authored all five editions of *The Tobacco Atlas,* and been designated as a Distinguished Cancer

Scholar by the Georgia Cancer Coalition. He was the first health official to formally participate in tobacco trade negotiations, both with Taiwan and Korea, and he was also a member of the U.S. Working Group to plan for negotiations for the Framework Convention on Tobacco Control. Dr. Eriksen is a recipient of the WHO Commemorative Medal on Tobacco or Health and a Presidential Citation for Meritorious Service by former President Bill Clinton. He is Past President and Distinguished Fellow of the Society for Public Health Education, and has been a member of the American Public Health Association for over 40 years.

Dr. Eriksen received a Bachelor of Arts in Social and Behavioral Sciences from Johns Hopkins University, and both a Master and a Doctor of Science in Public Health from Johns Hopkins University's School of Hygiene and Public Health.

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EDUCATION

Doctor of Science, 1983
The Johns Hopkins University
School of Hygiene and Public Health

Master of Science, 1976
The Johns Hopkins University
School of Hygiene and Public Health

Bachelor of Arts, 1972
The Johns Hopkins University
Homewood Campus

ACADEMIC EXPERIENCE

09/2014 – Present
Dean and Regents' Professor
School of Public Health
Georgia State University
Atlanta, Georgia

07/2012 – 09/2014
Dean and Professor
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Georgia State University
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11/2002 – 07/2012
Director and Professor
Institute of Public Health
Georgia State University
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04/1992 – 11/2001	Adjunct Associate Professor of Cancer Prevention Department of Behavioral Science The University of Texas MD Anderson Cancer Center Houston, Texas
11/1986 – 11/1992	Faculty Associate Center for Health Promotion Research and Development The University of Texas Health Science Center Houston, Texas
11/1988 – 1992	Visiting Lecturer University of Limburg Maastricht, The Netherlands
11/1986 – 11/1992	Director Behavioral Research Program Associate Health Educator Assistant Professor of Cancer Prevention Department of Cancer Prevention & Control The University of Texas M.D. Anderson Cancer Center Houston, Texas
11/1986 – 11/1992	Assistant Professor of Behavioral Sciences The University of Texas Health Science Center Houston, Texas
06/1975 – 05/1978	Health Educator Rural Dental Health Program School of Dental Medicine University of Pennsylvania Philadelphia, Pennsylvania

PROFESSIONAL EXPERIENCE

11/2000 – 08/2002	CDC Distinguished Consultant Assigned to World Health Organization Geneva, Switzerland
11/1996 – 08/2002	Senior Executive Service of the United States of America

11/1992 – 11/2000	Director Office on Smoking and Health National Center for Chronic Disease Prevention and Health Promotion Centers for Disease Control and Prevention Atlanta, Georgia
03/1982 – 03/1986	Director Preventive Medicine and Health Education Pacific Bell San Francisco, California
03/1978 – 03/1982	Community Health Educator (50% time) Health Education Center State of Maryland Department of Health and Mental Hygiene Baltimore, Maryland
10/1972 – 06/1973	Teacher William S. Baer School Baltimore City Public Schools Baltimore, Maryland

COURSES TAUGHT AT GEORGIA STATE UNIVERSITY

Spring 2016	PH 7020	Principles of Tobacco Control
Fall 2015	PH 7020	Principles of Tobacco Control
Spring 2015	PH 7020	Principles of Tobacco Control
Fall 2014	PH 7020	Principles of Tobacco Control
Summer 2014	PH 7020	Principles of Tobacco Control
Spring 2014	PH 7020	Principles of Tobacco Control
Fall 2013	PH 8190	Presenting and Critiquing Research
Fall 2012	PH 8190	Presenting and Critiquing Research
Spring 2012	PH 7600	Global Health
Fall 2011	PH 7020	Principles of Tobacco Control
Spring 2011	PH 7600	Global Health
Fall 2010	PH 7020	Principles of Tobacco Control
Spring 2010	PH 7600	Global Health
Fall 2009	PH 7020	Principles of Tobacco Control
Spring 2008	PH7140	Social and Behavioral Aspects of Public Health
Fall 2007	PH7140	Social and Behavioral Aspects of Public Health
Summer 2007	PH 7020	Principles of Tobacco Control
Spring 2007	PH 7019	Public Health Research Methods
Spring 2007	PH7140	Social and Behavioral Aspects of Public Health
Fall 2006	PH7140	Social and Behavioral Aspects of Public Health
Summer 2006	PH 7020	Principles of Tobacco Control
Spring 2006	PH 7300	Urban Health

Fall 2005	PH7140	Social and Behavioral Aspects of Public Health
Summer 2005	PH 7020	Principles of Tobacco Control
Spring 2005	PH 7300	Urban Health
Fall 2004	PH7140	Social and Behavioral Aspects of Public Health
Fall 2003	PH7140	Social and Behavioral Aspects of Public Health
Summer 2003	PH 7020	Principles of Tobacco Control

PUBLICATIONS

Journal Articles

1. Majeed, B.A., Weaver, S.R., Whitney, C.F., Slovic, P., Pechacek, T.F., **Eriksen, M.P.** (2016). Changing Perceptions of Harm of E-Cigarettes among U.S. Adults, 2012-2015. *American Journal of Preventive Medicine*, Accepted August 2016.

2. Nyman, A., Sterling, K., Weaver, S., Majeed, B., **Eriksen, M.** (2016) Little cigars and cigarillos: Users, perceptions, and reasons for us. *Tobacco Regulatory Science*, 2(3): 239-251. doi: <http://dx.doi.org/10.18001/TRS.2.3.4>

3. Pechacek, T., Nayak, P., Gregory, K., Weaver, S, **Eriksen, M.** (2016) The potential that electronic nicotine delivery systems can be a disruptive technology: results from a national survey. *Nicotine & Tobacco Research*. doi: < 10.1093/ntr/ntw102>

4. Weaver, S., Majeed, B. Pechacek, T., Nyman, A., Gregory, K., **Eriksen, M**. (2016) Use of electronic nicotine delivery systems and other tobacco products among USA adults, 2014: results from a national survey. *International Journal of Public Health*, 61(2): 177-88. doi: < 10.1007/s00038-015-0761-0. Epub 2015 Nov 12>

5. Koplan, J., **Eriksen, M**. (2015) Smoking cessation for Chinese men and prevention for women. *The Lancet*, 386(10002): 1422-1423. doi: <http://www.sciencedirect.com/science/article/pii/S014067361500416X>

6. Majeed, B., Dube, S., Sterling, K., Whitney, C., **Eriksen, M**. (2015) Opinions About Electronic Cigarette Use in Smoke-Free Areas Among U.S. Adults, 2012. *Nicotine & Tobacco Research*, 675-681. doi: <10.1093/ntr/ntu235>. (refereed)

7. Dube, S., Pathak, S., Nyman, A., **Eriksen, M**. (2015). Electronic Cigarette and Electronic Hookah: A Pilot Study Comparing Two Vaping Products. *Preventive Medicine Reports*, 2: 953-958. doi: <http://www.sciencedirect.com/science/article/pii/S2211335515001540> (refereed)

8. Chandora, R., Whitney, C., Weaver, S., **Eriksen, M**. (2015) Changes in Georgia Restaurant and Bar Smoking Policies from 2006 to 2012. *Prev Chronic Dis,* 12:140520. doi: <http://dx.doi.org/10.5888/pcd12.140520>. (refereed)

9. Yu, S., Koplan, J., **Eriksen, M.**, Yao, S., Redmon, P., Song, J., Uretsky, E., Huang, C. (2015). The effects of antismoking messages from family, school, and mass media on smoking behavior and smoking intention among Chinese adolescents. *Journal of Health Communication: International Perspectives*, 0: 1-9. doi: <http://dx.doi.org/10.1080/10810730.2015.1018561>. (refereed)

10. Mehta, N., Zhang, C., Hua, X., Redmon, P., **Eriksen, M.**, Koplan, J., Ali, M. (2014). Tobacco smoking among government employees in six cities in China. *Heart Asia*, 6(1): 179-183. doi: <http://dx.doi.org/10.1136/heartasia-2014-010557>. (refereed)

11. Majeed, B., Dube, S., Sterling, K., Whitney, C., **Eriksen, M.** (2014). Opinions about electronic cigarette use in smoke-free areas among U.S. adults, 2012. *Nicotine & Tobacco Research*. Article in press. doi: <http://dx.doi.org/10.1093/ntr/ntu235>. (refereed)

12. Kegler, M., Hua, X., Solomon, M., Wu, Y., Zheng, P., **Eriksen, M.** (2014). Factors associated with support for smoke-free policies among government workers in six Chinese cities: a cross-sectional study. *BMC Public Health*, 14(1130): 1-8. doi: <http://dx.doi.org/10.1186/1471-2458-14-1130>. (refereed)

13. Redmon, P., Koplan, J., **Eriksen, M.,** Li, S., Kean, W. (2014). The role of cities in reducing smoking in China. *International Journal of Environmental Research and Public Health*, 11(10): 10062-10075. doi: <http://www.mdpi.com/1660-4601/11/10/10062>. (refereed)

14. **Eriksen, M.P.**, Nyman, A.L., Whitney, C.F. (2014). Global tobacco use and cancer: findings and solutions from *The Tobacco Atlas*. *Cancer Control 2014.* (invited)

15. Okosun, I., Annor, F., Dawodu, E., **Eriksen, M.P.** (2014). Clustering of cardiometabolic risk factors and risk of elevated HbA1c in non-Hispanic White, non-Hispanic Black and Mexican-American adults with type 2 diabetes. *Journal of Diabetes & Metabolic Syndrome: Clinical Research & Reviews*, 8(2): 75-81 doi: <http://dx.doi.org/10.1016/j.dsx.2014.04.026>. (refereed)

16. Sterling, K., Moore, R., Pitts, N., Duong, M., Ford, K., **Eriksen, M.P.** (2013). Exposure to celebrity-endorsed small cigar promotions and susceptibility to use among young adult cigarette smokers. *Journal of Environmental and Public Health* . Vol. 2013, Article ID 520286. doi: <http://dx.doi.org/10.1155/2013/520286>. (refereed)

17. Huang, C., Koplan, J., Yu, S., Li, C., Guo, C., Liu, J., Li, H., Kegler, M., Redmon, P., and **Eriksen, M.** (2013). Smoking experimentation among elementary school students in China: influences from peers, families, and the school environment. *PLoS ONE* 8(8): e73048. doi: <http://dx.doi.org/10.1371/journal.pone.0073048>. (refereed)

18. Huang, C., Guo, C., Yu, S., Feng, Y., Song, J., **Eriksen, M.P.**, Redmon, P., and Koplan, J. (2013). Smoking behaviours and cessation services among male physicians in China: evidence from a structural equation model. *Tobacco Control*. Published Online First: 10 July 2013. <http://dx.doi.org/10.1136/tobaccocontrol-2012-050884>. (refereed)

19. Koplan, J.P., **Eriksen, M.P.**, Chen, L., and Yang, G. (2013). The value of research as a component of successful tobacco control in China. *Tobacco Control*, 0: 1-3. <http://dx.doi.org/ 10.1136/tobaccocontrol-2013-051054>. (invited)

20. Okosun, I.S., Annor, F.B., Seale, J.P., and **Eriksen M.P.** (2012). Abdominal adiposity and family income-to-poverty ratio in American women. *Obesity Research in Clinical Practice*. <http://dx.doi.org/10.1016/j.orcp.2012.12.002>. (refereed)

21. **Eriksen, M.P.**, Rothenberg, R. (2012). Special issue: community-based participatory research. *Health Education Research*, 27(4): 553-554. (invited)

22. Moore, L.C., Clark, P.C., Lee, S.Y., **Eriksen, M.P.**, Evans, K., and Smith, C.H. (2012). Smoking cessation in women at the time of an invasive cardiovascular procedure and 3 months later. *Journal of Cardiovascular Nursing*. Available at http://www.ncbi.nlm.nih.gov/pubmed/ 23001066. (refereed)

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25. Wen, C.P., Cheng, T.Y.D, Tsai, S.P., Chan, H.T., Hsu, H.L., and **Eriksen, M.P.** (2009). Are Asians at greater mortality risks for being overweight than Caucasians? Re-defining obesity for Asians. *Public Health Nutrition*, 12(4): 497-506. Epub 2008 Jun 12. (refereed)

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27. **Eriksen, M.P.**, and Chaloupka, F. (2007). The economic impact of clean indoor air laws. *CA Cancer Journal for Clinicians*, 57(6): 367-378. (refereed)

28. **Eriksen, M.P.** (2006). Are there public health lessons that can be used to help prevent childhood obesity? *Health Education Research,* 21: 753-754. (invited)

29. Wen, C.P., Peterson, R.A., Cheng, T.Y., Tsai, S.P., **Eriksen, M.P.**, and Chen, T. (2006) Paradoxical increase in cigarette smuggling after the market opening in Taiwan. *Tobacco Control*, 15(3): 160-165. (refereed)

30. **Eriksen, M.P.** (2006). The potential for prevention**.** *Health Education Research*, 21(5): 303-304. (invited)

31. **Eriksen, M.P.** (2006). Entering the 21st century**.** *Health Education Research,* 21(2): 173-174. (invited)

32. Warren, C.W., Jones, N.R., **Eriksen, M.P.** and Asma, S. (2006). Global Tobacco Surveillance System (GTSS) collaborative group. Patterns of global tobacco use among young people and implications for future chronic disease burden in adults. *Lancet,* 367(9512): 749-753. (refereed)

33. Okosun, I.S., Boltri, J.M., Hepburn,V.A., and **Eriksen, M.P.** (2006). Trends in abdominal obesity in young people: United States 1988-2002. *Ethnicity & Disease*, 16(2): 338-344. (refereed)

34. Okosun, I.S., Boltri, J.M., Hepburn, V.A., **Eriksen, M.P.**, and Davis-Smith, M. (2006). Regional fat localizations and racial/ethnic variations in odds of hypertension in at-risk American adults. *Journal of Human Hypertension*, 20(5): 362-371. (refereed)

35. Hsu, C.C., Levy, D.T., Wen, C.P., Cheng, T.Y., Tsai, S.P., Chen, T., **Eriksen, M.P.**, and Shu, C.C. (2005). The effect of market opening on trends in smoking rates in Taiwan. *Health Policy*, 74(1): 69-76**.** (refereed)

36. Okosun, I.S., Seale, J.P., Daniel, J.B., and **Eriksen, M.P.** (2005). Poor health is associated with episodic heavy alcohol use: evidence from a national survey. *Public Health*, 119(6): 509-517. (refereed)

37. **Eriksen, M.P.** (2005). 1985–2005: Twenty years of excellence**.** *Health Education Research*, 20(2): 125-127. (invited)

38. Wen, C.P., Cheng, T.Y., Lin, C.L., Wu, H.N., Levy, D., Chen, L.K., Hsu, C.C., **Eriksen, M.P.**, Yang, H.J., and Tsai, S.P. (2005). The health benefits of smoking cessation for adult smokers and for pregnant women in Taiwan. *Tobacco Control*, 14 Suppl 1: i56-61. (refereed)

39. Wen, C.P., Tsai, S.H., Cheng, T.Y., Chen, C.J., Levy, D.T., Yang, H.J., and **Eriksen, M.P.** (2005). Uncovering the relationship between betel quid chewing and cigarette smoking in Taiwan. *Tobacco Control*, 14 Suppl 1: i16-22. (refereed)

40. Wen, C.P., Cheng, T.Y., **Eriksen, M.P.**, Tsai, S.P., and Hsu, C.C. (2005). The impact of cigarette market opening in Taiwan. *Tobacco Control*, 14 Suppl 1: i4-9. (refereed)

41. Wen, C.P., Cheng, T.Y., and **Eriksen, M.P.** (2005). How opening the market for cigarettes led to an increase in betel quid use in Taiwan. *Public Health*, 119(10): 940-944. (refereed)

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44. Green, L.W., **Eriksen, M.P.**, Bailey, L., and Husten, C. (2000). Achieving the implausible in the next decade's tobacco control objectives. *American Journal of Public Health*, 90(3): 337-339. <http://ajph.aphapublications.org/doi/pdf/10.2105/AJPH.90.3.337>. (refereed)

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46. **Eriksen, M.P.**, Green, L.W., Bailey, L., and Pechacek, T. (2000). Global tobacco trends spark hope, sound alarm. *Global Health & Environment Monitor,* 8(2): 1-2. (invited)

47. **Eriksen, M.P.** (1999). Best practices for comprehensive tobacco control programs: opportunities for managed care organisations. *Tobacco Control,* 9 Suppl 1: i11-14. (refereed)

48. Fishman, J.A., Allison, H., Knowles, S.B., Fishburn, B.A., Woollery, T.A., Marx, W.T., Shelton, D.M., Husten, C.G., and **Eriksen, M.P.** (1999). State laws on tobacco control – United States, 1998. *Morbidity and Mortality Weekly Report. CDC surveillance summaries / Centers for Disease Control*, 48(3): 21-40. (refereed)

49. **Eriksen, M.P.** (1999). Social forces and tobacco in society. *Nicotine & Tobacco Research,* 1(1): S79-80. (invited)

50. Housten, T., Kolbe, L.J., and **Eriksen, M.P.** (1998). Tobacco-use cessation in the '90s—not "adults only" anymore. *Preventive Medicine*, 27(5 pt 3): A1-2. (refereed)

51. **Eriksen, M.P.** (1998). Panel Session II—Linking to public health resources. Introduction. *Tobacco Control,* 7: S26. (invited)

52. **Eriksen, M.P.** (1998). Panel Session II—Linking to public health resources. Closing remarks. *Tobacco Control,* 7: S35. (invited)

53. **Eriksen, M.P.**, and Gottlieb, N.H. (1998). A review of the health impact of smoking control at the workplace. *American Journal of Health Promotion,* 13(2): 83-104. (refereed)

54. Caraballo, R.S., Giovino, G.A., **Eriksen, M.P.,** Pechacek, T.F., and Richter, P. (1998). Racial and ethnic differences in serum cotinine levels of cigarette smokers: Third National Health and Nutrition Examination Survey. *Journal of the American Medical Association*, 280(2): 135-139. (refereed)

55. Caraballo, R.S., Giovino, G.A., Pechacek, T.F., Mowery, P.D., Richter, P.A., Strauss, W.J., Sharp, D.J., **Eriksen, M.P.**, Pirkle, J.L., and Maurer, K.R. (1998). Racial and ethnic differences in serum cotinine levels of adult cigarette smokers, Third National Health and Nutrition Examination Survey, 1988-1991. *Journal of the American Medical Association*, 280(2): 135-139. (refereed)

56. Brownson, R.C., **Eriksen, M.P.**, Davis, R.M., and Warner, K.E. (1997). Environmental tobacco smoke: health effects and policies to reduce exposure. *Annual Review of Public Health*, 18: 163-85. (refereed)

57. Zhu, B.P., Lin, Y.W., Giovino, G.A., Pechacek, T., Husten, C.G., and **Eriksen, M.P.** (1996). Cigarette smoking and lung cancer: historical perspectives and current challenges. *Advances in Epidemiology*, vol. 9. Ed. Z. Li. Beijing: China Science and Technology Press, 87-103. (refereed)

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62. Pollay, R.W., Siddarth, S., Siegel, M., Haddix, A., Merritt, R.K., Giovino, G.A., and **Eriksen, M.P.** (1996). The last straw? Cigarette advertising and realized market shares among youths and adults, 1979-1993. *Journal of Marketing,* 60(2): 1-16. (refereed)

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75. Satcher, D., and **Eriksen, M.P.** (1994). The paradox of tobacco control. *Journal of the American Medical Association,* 271(8): 62-78. (refereed)

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105. **Eriksen, M.P.**, Green, L.W., and Fultz, F.G. (1988). Principles of changing health behavior. *Cancer,* 62(8 Suppl): 1768-1775. (refereed)

106. **Eriksen, M.P.** (1988). Cancer prevention in workplace health promotion. *Journal of the American Association of Occupational Health Nurses*, 36(6): 266-270. (refereed)

107. **Eriksen, M.P.**, LeMaistre, C.A., and Newell, G.R. (1988). Health hazards of passive smoking. *Annual Review of Public Health,* 9: 47-70. (refereed)

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114. Gielen, A.C., **Eriksen, M.P.**, Daltroy, L.H., and Rost, K. (1984). Factors associated with the use of child restraint devices. *Health Education Quarterly,* 11(2): 195-206. (refereed)

115. **Eriksen, M.P.**, and Gielen, A.C. (1983). The application of health education principles to automobile child restraint programs. *Health Education Quarterly,* 10(1): 30-55. (refereed)

116. **Eriksen, M.P.**, Kennedy, S.L. and Cormier, P.P. (1979). Innovative program for dental health. *Nutrition News,* 42(3): 9-10. (refereed)

117. Cormier, P.P., **Eriksen, M.P.**, Kennedy, S.L., and Diamond, J.J. (1978). Dental health knowledge tests: their development, implementation and evaluation. *The Journal of School Health,* 48(10): 610-615. (refereed)

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Book Chapters

1. **Eriksen, M.**, and Whitney, C.F. (2013). Risk factors: tobacco. *Global Handbook on NCDs and Health Promotion*. Ed. D.V. McQueen. New York: Springer Press.

2. Lyn, R., Moore, B.J. and **Eriksen, M.P.** (2010). The application of public health lessons to childhood obesity prevention. *Childhood Obesity Prevention: International Research, Controversies and Interventions.* Eds. J. O'Dea and M.P. Eriksen. New York: Oxford University Press.

3. **Eriksen, M.P.**, Lyn, R., and Moore, B.J. (2010). The application of public health lessons to stemming the obesity epidemic. *Understanding Obesity: Biological, Psychological and Cultural Influences.* Eds. S.R. Akabas, S.A. Ledeman, and B.J. Moore. Oxford, U.K.: Wiley-Blackwell Publishers.

4. **Eriksen, M.P.** and Green, L.W. (2009). Reducing tobacco use. *Principles of Public Health Practice*, *Third Edition*. Eds. F.D. Scutchfield and C.W. Keck. New York: Delmar Learning.

5. Daynard, R.A., Gottlieb, M.A., Sweda, E.L., Friedman, L.C., and **Eriksen, M.P**. (2007). Prevention and control of diseases associated with tobacco use through law and policy. *Law in Public Health Practice, Second Edition*. Eds. R.A. Goodman, R.E. Hoffman, W. Lopez, G.W. Matthews, M.A. Rothstein, and K.L. Foster. New York: Oxford University Press.

6. **Eriksen, M.P.**, Green, L.W., Husten, C.G., Pederson, L.L., and Pechacek, T.F. (2007). Thank you for not smoking: the public health response to tobacco-related mortality in the United States. *Silent Victories: The History and Practice of Public Health in Twentieth Century America*. Eds. J.W. Ward and C. Warren. 423-436. New York: Oxford University Press.

7. **Eriksen, M.P.** (2004). Lessons learned from public health efforts and their relevance to preventing childhood obesity. *Preventing Childhood Obesity: Health in the Balance*. Eds. J.P. Koplan, C.T. Liverman, and V.I. Kraak. 343-375. Institute of Medicine, Washington, D.C.: National Academies of Sciences Press.

8. **Eriksen, M.P.** and Green, L.W. (2002). Progress and next steps in reducing tobacco use in the United States. *Principles of Public Health Practice, Second Edition*. Eds. D. Scuthfield and W. Keck. New York: Delmar Learning.

9. Pechacek, T.F., Asma, S., Blair, N. and **Eriksen, M.P.** (1998). Tobacco: global burden and community solutions. *Evidence Based Cardiology, Second Edition*. Eds. S. Yusuf, J.A. Cairns, A.J. Camm, E.L. Fallen, and B.J. Gersh. 103-113. London: BMJ Books.

10. Fielding, J.E., Husten, C.G., and **Eriksen, M.P.** (1998). Tobacco: health effects and control. *Public Health & Preventive Medicine, Fourteenth Edition*. Eds. R.B. Wallace, B.N. Doebelling, and J.M. Last. 817-846. Stamford: Appleton and Lange.

11. Giovino, G.A., Tomar, S.L., Reddy, M.N., Peddicord, J.P., Zhu, B.P., Escobedo, L.G., and **Eriksen, M.P.** (1996). Attitudes, knowledge, and beliefs about low-yield cigarettes among adolescents and adults. *Smoking and Tobacco Control Monograph No 7. The FTC Cigarette Test Method for determining Tar, Nicotine, and Carbon Monoxide Yields of U.S. Cigarettes, Report of the NCI Expert Committee*. 39-57. Bethesda, MD: National Cancer Institute.

12. **Eriksen, M.P**. (1992). School intervention for prevention. *Prevention of Coronary Heart Disease: A Skills-Based Approach*. Eds. I.S. Ockene and J.K. Ockene. 541-551. Boston: Little, Brown and Company.

13. Kondo, A.T., and **Eriksen, M.P.** (1990). Tobacco use. *Health and Safety Beyond the Workplace*. Eds. L.J. Cralley, L.V. Cralley, and W.C. Cooper. New York: Wiley and Sons.

14. **Eriksen, M.P.** (1989). Policies restricting smoking in public places and the workplace. *Reducing the Health Consequences of Smoking: 25 Years of Progress: A Report of the Surgeon General: 1989 Executive Summary*. 556-580. Center for Chronic Disease Prevention and Health Promotion.

15. Parkinson, R.S., and **Eriksen, M.P**. (1987). Workplace smoking control in the United States: economic, health, legal, programmatic and policy issues. *Health and Fitness in the Workplace*. Ed. S.H. Klarreich. 355-372. New York: Praeger Press.

16. **Eriksen, M.P**. (1987). Workplace health promotion. *Handbook of Health Education, Second Edition*. Eds. P.M. Lazes, L.H. Kaplan, and K.A. Gordon. 281-320. Rockville, MD: Aspen Publishers.

Books

1. **Eriksen, M.P.**, Mackay, J., Schluger, N., Gomeshtapeh, F. I., and Drope, J. (2015). *The Tobacco Atlas, Fifth Edition*. Atlanta: American Cancer Society; New York: World Lung Foundation.

2. **Eriksen, M.P.**, Mackay, J., and Ross, H. (2012). *The Tobacco Atlas, Fourth Edition*. Atlanta: American Cancer Society; New York: World Lung Foundation.

3. O'Dea, J., and **Eriksen, M.P.** (Eds.) (2010). *Childhood Obesity Prevention: International Research Controversies and Interventions.* New York: Oxford University Press.

4. Shafey, O., **Eriksen, M.P.**, Ross, H., and Mackay, J. (2009). *The Tobacco Atlas, Third Edition.* Atlanta: American Cancer Society.

5. Mackay, J., **Eriksen, M.P.**, and Shafey, O. (2006). *The Tobacco Atlas, Second Edition.* Atlanta: American Cancer Society.

6. Mackay, J.M., and **Eriksen, M.P**. (2002). *The Tobacco Atlas, First Edition*. Geneva: World Health Organization.

7. Parkinson, R.S., Beck, R.N., Collings, G.H., **Eriksen, M. P.**, Green, L.W., McGill, A.M., Pearson, C.E., and Ware, B.G. (1982). *Managing Health Promotion in the Workplace: Guidelines for Implementation and Evaluation*. Palo Alto: Mayfield Publishing.

Other Publications

1. **Eriksen, M.,** Whitney, C. & Faustino, E. (2016). Principles of Tobacco Control: Extinguishing the Habit. E-Book. Georgia State University. <http://publichealth.gsu.edu/free-e-book-tobacco-cessation-research>.

2. **Eriksen, M.P.**, and Whitney, C.F. Smoking cessation (2015). Smoking Cesssation. In D.V. McQueen (Ed.), *Oxford Bibliographies in Public Health*. New York: Oxford University Press. <http://www.oxfordbibliographies.com/view/document/obo-9780199756797/obo-9780199756797-0116.xml>.

3. **Eriksen, M.P.**, and Whitney, C.F. www.*TobaccoPortal.org*. Georgia State University, Institute of Public Health, 2012.

4. **Eriksen, M.P.** (1987). Cancer prevention programs in the workplace, Workplace Wellness Media Report, Washington Business Group on Health/Office of Disease Prevention and Health Promotion, Department of Health and Human Services, Washington, D.C.

5. **Eriksen, M.P.** (1982). The modification of smoking behavior among asbestos-exposed workers [Doctoral Dissertation], The Johns Hopkins University School of Hygiene and Public Health, Baltimore, Maryland.

6. **Eriksen, M.P**. (1976). An evaluation of the effectiveness of an informal learning situation on increasing the nutritional knowledge of health professionals [Masters Thesis], The Johns Hopkins University School of Hygiene and Public Health, Baltimore, Maryland.

FUNDING

External Research

2014-2016	Pfizer, Inc Diffusion of Tobacco Control Fundamentals to Other Large Chinese Cities Georgia State University P.I. Michael P. Eriksen, Sc.D.	$849,632
2013-2018	National Institutes of Health P- 50 1P50DA036128-01 Georgia State University Tobacco Center of Regulatory Science P.I. Michael P. Eriksen, Sc.D.	$19 million
2010 – 2015	National Institutes of Health P-20 1P20MD004806-01 Georgia State University Center of Excellence Syndemics of Health Disparities P.I. Michael P. Eriksen, Sc.D.	$6.7 million
2008 – 2014	Bill & Melinda Gates Foundation Global Tobacco Technical Assistance Consortium Subcontract with Emory University P.I. Jeff Koplan, M.D. Co-P.I. Michael P. Eriksen, Sc.D.	$407, 805
2004 – 2011	Healthcare Georgia Foundation Policy Leadership for Active Youth (PLAY) P.I. Michael P. Eriksen, Sc.D.	$485,007
2010 – 2013	Health Resources and Service Administration (HRSA) UB6HP20158-01-02 Georgia Public Health Training Centers Subcontract with University of Georgia P.I. Michael P. Eriksen, Sc.D.	$1 million

2003 – 2009	Georgia Cancer Coalition Distinguished Cancer Clinician and Scientist P.I. Michael P. Eriksen, Sc.D.	$750,000
2005 – 2008	CDC Prevention Research Center Subcontract with Morehouse School of Medicine Cancer Prevention Control Research Network P.I. Michael P. Eriksen, Sc.D.	$85,750
2003 – 2007	Healthcare Georgia Foundation "Georgia Tobacco Policy Project (G-TOPP)" P.I. Michael P. Eriksen, Sc.D.	$240,000
2004 – 2007	American Legacy Foundation "Georgia Tobacco Policy Project (G-TOPP)" P.I. Michael P. Eriksen, Sc.D.	$80,000
2006 – 2011	Department of Justice Facilitating Re-entry of HIV Positive Persons from Prison to the Community P.I. Michael P. Eriksen, Sc.D.	$93,723
1989 – 1994	National Cancer Institute 1U01-CA51671-01 "Workwell - Cancer Prevention for Rural Energy Workers" P.I. Michael P. Eriksen, Sc.D.	$2.1 million
1988 – 1991	National Heart, Lung & Blood Institute 1RO1-HL41278-01 "A Lung Risk Reduction Intervention Model for Painters" P.I. Chris Y. Lovato, Ph.D. Co-Investigator: Michael P. Eriksen, Sc.D.	$1.8 million
1987 – 1991	National Cancer Institute 1RO1-CA45970-01 "Integrating Tobacco Prevention Programs in Schools" P.I.: Guy Parcel, Ph.D. Co P.I. Michael P. Eriksen, Sc.D.	$2 million
1989	Physician Oncology Education Program "Physician Leadership in Controlling Tobacco in Texas" P.I. Michael P. Eriksen, Sc.D.	$75,000

Internal Research

2004 – Present	Partnership for Urban Health Research (PUHR)	$2 million/year

SCHOLARLY ACTIVITY WITH STUDENTS

Dissertation Committees, Member:

Ban Majeed, (2014), Georgia State University
Leslie C. Moore, (2011), Georgia State University
Glenn E. Hagerstrom, (2010), Georgia State University
Jean O'Conner (2009), University of North Carolina Chapel Hill
Amy Gottlieb (2008), University of Texas, Austin, Department of Health Education

Thesis Committees, Chaired, Georgia State University:

Samantha Bourque (2016)
Elif Alyanak (2015)
Farah Raoof (2013)
Ichhya Pant (2012)
Missale Ayele (2011)
Erdenekhuu Nansalmaa (2011)
Lod C. Hambanou (2010)
Susan Henderson (2010)
Zakia Maroof (2010)
Michael Brandon Talley (2010)
Carrie F. Whitney (2010)
Thomas Jeffrey Doker (2009)
Panji Fortuna Hadisoemarto (2009)
Phuongthao Tuyen Lam (2009)
Amy Carolina Mistretta (2009)
Ren Peterkin (2009)
Jonathan A. Powell (2009)
Hari Prasad Ravipati (2009)
Laura Pople Bracci (2008)
Regine Alexandra Emilien (2008)
Saman Faisal (2008)
Jessica Howell (2008)
Yugi Huang (2008)
Ban A. Majeed (2008)
Eryn M. Marchiolo (2008)
Shaunta Shanelle Parker (2008)
Kelly K. Stimpert (2008)
Sardar Ahmad (2007)
Jennifer E. Boehm (2007)

Meredith M. Madden (2007)
Danielle Salas (2007)
Samina Shariff (2007)
Malikah Waajid (2007)
Shaunta S. Parker (2007)
Amy V. Patel (2006)
Margaret Watson (2006)

HONORS AND AWARDS

2012	Charles C. Shepard Science Award Centers for Disease Control and Prevention Outstanding Scientific Contribution to Public Health Comparison of Serum Cotinine Concentration within and across Smokers of Menthol and Nonmenthol Cigarette Brands among Non-Hispanic Black and Non-Hispanic White U.S. Adult Smokers, 2001-2006
2008	Gold Honorary Award Poland Health Promotion Foundation
2007	Admitted to Phi Beta Delta Honor Society for International Scholars
2007	Charles C. Shepard Science Award Centers for Disease Control and Prevention Nominee for Warren et al paper in Lancet
2005	Certificate of Recognition for Service House Study Committee on Children: Newborns to Age Five Georgia General Assembly
2003 – 2009	Georgia Cancer Coalition Distinguished Cancer Clinician and Scientist
2002	Charles C. Shepard Science Award Centers for Disease Control and Prevention Outstanding Scientific Contribution to Public Health The Surgeon General's Reports on Smoking and Health
2000	Presidential Citation Rank of Meritorious Executive, Senior Executive Service
2000	U.S. Department of Health and Human Services Secretary's Award for Distinguished Service

1998	Distinguished Fellow Society for Public Health Education
1998	Commemorative Medal Tobacco OR Health Program World Health Organization
1998	The 2nd Annual Roger Fossum Award New Hampshire Public Health Association
1997	U.S. Department of Health and Human Services Secretary's Award for Distinguished Service
1996	The 2nd Annual Jeffrey P. Koplan Award National Center for Chronic Disease Prevention and Health Promotion Centers for Disease Control and Prevention
1996	One of 96 Southerners to Watch *The Atlanta Journal-Constitution*
1995	Public Health Service Superior Service Award
1994	Public Health Service Special Recognition Award
1986	Contributing to a Smoke-Free Society Certificate of Recognition American Cancer Society California Division
1985	Certificate of Recognition American Cancer Society California Division
1985	Breast Health Program National Honors Citation American Cancer Society
1983	Project Kids in Safety Seats (KISS) Program Excellence Award Society for Public Health Education
1978 – 1981	Occupational Health Education Fellow National Institute of Occupational Safety and Health Educational Resource Center Training Grant Recipient

SERVICE TO THE UNIVERSITY, COLLEGE AND ACADEMIC UNIT

2012 – Present	Dean, Institute of Public Health
2002 – 2012	Director, Institute of Public Health
2010 – 2011	University Strategic Planning Committee
2008 – Present	Advisory Board, Center for Research on School Safety, School Climate and Classroom Management, Georgia State University
2008 – Present	Member, CHHS Strategic Planning Committee
2007 – 2008	Member, GSU Strategic Planning Committee
December 2006	GSU Commencement Speaker
May 2005	GSU Commencement Speaker
2004 – Present	Director, Partnership for Urban Health Research
2004 – 2010	Member, Senate Committee on Academic Programs
2004 – 2010	Member, Senate Research Committee
2004 – 2006	Member, CHHS Academic Affairs Committee
2004 – 2006	Member, Senate Budget Committee
2004 – 2005	Member, GSU Strategic Planning Committee

SERVICE ACTIVITIES IN PROFESSIONAL ORGANIZATIONS

Editor-in-Chief	*Health Education Research*
Honorary Editor-in-Chief	*World Journal of Tobacco or Health*

Editorial Boards

2004 to present	*Health Education and Behavior*
1992 to 2003	*Tobacco Control: An International Journal*
1986 to 2013	*American Journal of Health Promotion*
1984 to1990	*Advances in Health Education and Promotion*
1984 to 1987	*Health Education Quarterly*

Elected Offices	Society for Public Health Education
1987 to 1988	President
1986 to 1987	President-Elect
1985 to 1987	Board of Trustees
1982 to 1984	Treasurer
1978 to 1981	Board of Trustees
Manuscript Review	*Annals of Epidemiology* *Tobacco Control* *American Journal of Public Health* *Preventive Medicine* *Health Promotion Practice* *Health Education and Behavior* *Social and Preventive Medicine*
Society Memberships	American Public Health Association Society for Public Health Education

SERVICE TO THE COMMUNITY

2014-Present	Director, Pacific Institute for Research and Evaluation (PIRE) Board of Directors
2006 – 2010	Advisor to the Bill & Melinda Gates Foundation
2006 – 2009	Advisor to the CDC Foundation
2004 – Present	International Advisory Board National Action Plan on NCD Prevention and Control Pakistan
2004 – Present	Advisory Committee National Health Research Institute Taiwan
2004 – 2010	Senior Program Consultant Substance Abuse Policy Research Program Robert Wood Johnson Foundation
2000 – 2006	Expert witness for the US Department of Justice
1998	Expert witness to the Federal Trade Commission

1993 – 1996	Robert Wood Johnson Foundation National Advisory Committee Tobacco Policy Research Program
1988 – 1992	Evaluation Advisory Panel National Leadership Coalition on AIDS
1986 – 1992	Chair, American Public Health Association Anti-Tobacco Initiative Public Health Education Section
1986 – 1992	Scientific Advisory Committee American Foundation for AIDS Research
1986 – 1992	Committee Member Cancer Education in the Workplace International Union against Cancer
1984 – 1992	Advisor/Reviewer National Institutes of Health NCI/NHLBI/NIDA
1984 – 1987	Chairman Workplace Subcommittee California Division American Cancer Society
1984 – 1986	Chairman Health Promotion Committee San Francisco Employers Group on Health
1983 – 1992	Board of Directors Americans for Nonsmokers' Rights

ADDITIONAL SIGNIFICANT ACTIVITIES

Congressional Testimonies

June 24, 1998	Congressional Children's Caucus: Teen Tobacco Use
April 1, 1998	Senate Committee on Environment and Public Works: Secondhand Smoke

March 17, 1998	Senate Committee on Commerce, Science, and Transportation: Smokeless Tobacco
March 3, 1998	Senate Committee on Commerce, Science, and Transportation: Tobacco Advertising
February 10, 1998	Senate Committee on Labor and Human Resources: Preventing Teen Tobacco Use
December 9, 1997	House Subcommittee on Health and the Environment: Preventing Teen Tobacco Use
November 11, 1994	House Subcommittee on Health and the Environment: Smokeless Tobacco

Colin Turnbull, PhD: Profile

Education

BSc Pharmacy, Heriot Watt University, Edinburgh, UK

PhD Organic Chemistry, Aston University, Birmingham, UK
Area of research: Synthesis and Chemical Characterization of Anti-tumor Triazenes

Pharmaceutical Industry Experience

Dr Turnbull`s experience in the Pharmaceutical Industry spans 25 years, with senior management positions in both research and commercial functions, including:
– General Manager, Pharmaceutical Division, Schering-Plough, France
– Vice President, Worldwide Phase 4 Clinical Research, and Vice President, Worldwide Health Economics Research, Schering-Plough Corporation, US
– Vice President and Head, Oncology Clinical Research, Schering-Plough Research Institute, US
– Chairman, Oncology Drug Development Team, Schering-Plough Research Institute, US

Consulting Experience

- Dr Turnbull has over 11 years experience carrying out due diligence on cancer drug acquisition candidates for Pharmaceutical and Biotechnology industry clients. This experience extends to several hundred putative cancer drugs representing multiple mechanisms of action, and to all phases of clinical research. Consulting assignments generally have included strategic regulatory and clinical planning.
  As a Scientific Reviewer of research grant applications to CPRIT, Dr Turnbull has developed a deep understanding of the critical success factors in preparing cancer research grant applications to academic and venture capital funding organizations. Together with his extensive experience in performing due diligence assessment of cancer drug acquisition targets, and his Pharmaceutical Industry experience in cancer drug development, this background uniquely qualifies Dr Turnbull to assist clients optimize funding applications to both academic and venture capital organizations.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE ROBERTS, CEO, REBECCA GARCIA, PHD, CHIEF PREVENTION AND COMMUNICATIONS OFFICER
SUBJECT:	2017 PROGRAM PRIORITIES
DATE:	NOVEMBER 7, 2016

Recommendation:

That the Oversight Committee adopt the 2017 program priorities as recommended by the Oversight Committee program subcommittees.

Background:

The Oversight Committee approved the first set of 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 2016 in November 2015. In the fall of 2016 the Oversight Committee Subcommittees worked with the Program officers and respective Advisory Committees to review and update the program priorities for 2017.

THE 2017 PROGRAM PRIORITIES DOCUMENT TO BE HANDED OUT.

The draft document will be updated after the Program Subcommittee meetings occurring the week of November 7, 2016.

FY 2016 Summary of Funding by Program Priorities

The following tables summarize the priorities addressed by the grants awarded in FY16.

Table 1: FY16 Funding by Academic Research Program Priorities

Priorities Addressed	# of Grants*	$ Amount*
A broad range of innovative, investigator-initiated academic research projects	84	$91,000,814
Enhance Texas' cancer research capacity and life sciences infrastructure	76	$145,645,372
Childhood cancers	13	$28,184,209
Prevention and early detection	17	$23,272,828
Computational biology and analytic methods	9	$24,600,567
Rare or intractable cancers	31	$42,255,865
Cancers of importance in Texas (Lung, Cervix, Liver)	38	$32,982,826

*Some grants address more than one priority therefore number of grants and award amounts may be double counted.

Table 2: FY16 Funding by Product Development Research Program Priorities

Priorities Addressed	# of Grants*	$ Amount*
Funding projects at Texas companies and relocating companies that are most likely to bring important products to the market	3	$53,933,366
Providing funding that promotes the translation of research at Texas institutions into new companies able to compete in the marketplace		
Identifying and funding projects to develop tools and technologies of special relevance to cancer research, treatment, and prevention		
Early translational research (priority across programs)	3	$53,933,366
Enhance Texas' research capacity and life science infrastructure (priority across programs)	3	$53,933,366
Rare and intractable cancers, including childhood cancers (Academic Research priority)	3	$53,933,366

*the 3 grants awarded in FY16 address 4 of the 6 priorities.

Table 3: FY16 Funding by Prevention Program Priorities

Priorities Addressed	# of Grants*	$ Amount*
Prioritize populations and geographic areas of greatest need, greatest potential for impact	18	$18,650,900
Focus on underserved populations	26	$26,938,196
Increase targeting of preventive efforts to areas where significant disparities in cancer incidence or mortality in the state exist	14	$13,464,320

*Some grants address more than one priority therefore # of Grants and Award Amounts may be double counted.

November 2016 Oversight Committee
Internal Audit Status Report
As of October 31, 2016

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

2016 Internal Audit Plan

Weaver completed and submitted all 2016 Internal Audit Plan reports to the required state oversight agencies. We also submitted a draft of the FY 2016 Annual Internal Audit Report, to the following entities:

- Governor's Office of Budget, Planning, and Policy
- State Auditor's Office
- Legislative Budget Board
- Sunset Advisory Commission

A final copy of the FY 2016 Annual Internal Audit Report will be sent to the state oversight agencies, once it has been approved by the Oversight Committee.

2017 Internal Audit Plan and Schedule

Weaver plans to perform the following internal audits in FY 2017.

NEW INTERNAL AUDITS		
Internal Audit	**Description**	**Timing**
Training	Internal Audit will include an evaluation of risks and internal controls in place related to CPRIT's Training practices. Employee Technical Training, Oversight Committee Training, Employee Compliance and Ethics Training, and Grantee Training and Onboarding.	January 2017
Pre-Award Grant Management	Internal Audit will include an evaluation of risks and internal controls in place related to CPRIT's Pre-Award Grant Management process. Activities to be evaluated will include the RFA Review Process, Conflicts of Interest, Peer Review (including travel coordination), and Grant Application Approval.	February 2017
Internal Agency Compliance	Internal Audit will include an evaluation of risks and internal controls in place related to CPRIT's Internal Agency Compliance practices. Activities to be evaluated will include Disclosures, Ethics Policy and Compliance and Code of Conduct.	February 2017
Procurement and P-Cards	Internal Audit will include an evaluation of risks and internal controls in place related to the CPRIT's Procurement practices. Activities to be evaluated will include Purchase Orders, Bidding and Awards, Contract Negotiation and Approval, Vendor Management and Selection, Vendor Acceptance, Vendor Set-up, P-card Program, P-card Purchases, Central Travel Card, and Employee Travel Cards.	May and June 2017

Weaver will perform follow-up procedures for the following audits in 2017.

FOLLOW-UP PROCEDURES		
Follow-Up	**Description**	**Timing**
IT Security	Internal Audit will perform follow-up procedures on the 11 findings from the 2016 Internal Audit to ensure corrective action has been taken.	January and February 2017
Revenue	Internal Audit will perform follow-up procedures on the two findings from the 2016 Internal Audit to ensure corrective action has been taken.	May 2017
Commodity and Service Contracts	Internal Audit will perform follow-up procedures on the five findings from the 2016 Internal Audit to ensure corrective action has been taken.	May 2017
Cash Management	Internal Audit will perform follow-up procedures on the one finding from the 2016 Internal Audit to ensure corrective action has been taken.	May 2017

Additional engagements will be performed at the request of management or the Oversight Committee.

Alyssa G. Martin, CPA, MBA, Internal Auditor
Executive Partner
Weaver and Tidwell L.L.P

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

FISCAL YEAR 2016 ANNUAL INTERNAL AUDIT REPORT

NOVEMBER 1, 2016

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CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
FISCAL YEAR 2016 INTERNAL AUDIT REPORT
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I. Compliance with Texas Government Code, Section 2102.015: Posting the Internal Audit Plan, Internal Audit Annual Report, and Other Audit information on Internet Web site

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

The Cancer Prevention and Research Institute of Texas (CPRIT or the agency) will post this report and its 2017 Internal Audit Plan on its website at www.cprit.state.tx.us following adoption by the Oversight Committee at its next quarterly meeting on November 16, 2016, and no later than December 1, 2016.

CPRIT will include a detailed summary of the weaknesses, deficiencies, or other concerns raised by performance of the audit plan as they are identified or by November 1, 2017. CPRIT will also update the posting with the corrective action taken to address the weaknesses, deficiencies, wrongdoing or other concerns identified in the internal audits.

II. Internal Audit Plan for Fiscal Year 2016

The internal audits planned and performed for Fiscal Year 2016 were selected to address the agency's highest risk areas, based on the 2015 Internal Audit Risk Assessment conducted during the fall of 2014, which included input from CPRIT management. The audits conducted during fiscal year 2016 as listed below.

Internal Audit	Report #	Report Date	Current Status
Internal Audit Over Commodity and Service Contracts	IA #01-16	May 13, 2016	This report was issued on June 10, 2016. Follow-up procedures to verify that corrective action has been performed are included in the implemented 2017 Internal Audit Plan.
Internal Audit Over Information Security	IA #02-16	August 3, 2016	The report was issued August 26, 2016. Follow-up procedures to verify that corrective action has been performed are included in the implemented 2017 Internal Audit Plan.
Internal Audit Over Revenue	IA #03-16	July 6, 2016	This report was issued on August 15, 2016. Follow-up procedures to verify that corrective action has been performed are included in the implemented 2017 Internal Audit Plan.
Internal Audit Over Cash Management	IA #04-16	August 12, 2016	This report was issued August 26, 2016. Follow-up procedures to verify that corrective action has been performed are included in the implemented 2017 Internal Audit Plan.
Internal Audit Follow-Up Over Grant Management	IA #05-16	June 9, 2016	The report was issued July 15, 2016. No issues.
Internal Audit Follow-Up Over Information Technology	IA #06-16	August 3, 2016	The follow-up procedures over Information Technology were integrated with the Internal Audit over Information Security report issued August 26, 2016.

III. Consulting Services and Nonaudit Services Completed

As defined in the Institute of Internal Auditors' International Standards for the Professional Practice of Internal Auditing and the Government Auditing Standards, 2011 Revision, Sections 3.33 – 3.58, CPRIT completed the following consulting and non-audit services for FY 2016:

Weaver consulted with CPRIT on the agreed upon procedures that detail the required audit steps to be completed for CPRIT grant recipients by an independent auditor to satisfy the State Single Audit requirements and CPRIT policies and procedures.

CohnReznick LLP was engaged by CPRIT to perform grant compliance monitoring services to ensure that CPRIT grant recipients are in compliance with Texas Uniform Grant Management Standards and CPRIT policies and procedures.

CohnReznick FY2016 Grant Compliance Monitoring Reports

Report Name	Report #	Report Date	Current Status
Angelo State University	PP120108	February 26, 2016	Completed. No Findings Identified.
Angelo State University	PP150086	June 17, 2016	Completed. No Findings Identified.
Baylor College of Medicine	RR150005	March 21, 2016	Completed. No Findings Identified.
Baylor College of Medicine	RR140038	March 21, 2016	Completed. No Findings Identified.
Baylor College of Medicine	R1306	March 31, 2016	Completed. No Findings Identified.
Baylor College of Medicine	RR150009	April 4, 2016	Completed. No Findings Identified.
Baylor College of Medicine	R1304	April 5, 2016	Completed. No Findings Identified.
Baylor College of Medicine	RP150648	May 5, 2016	Completed. No Findings Identified.
Baylor College of Medicine	R1314	May 13, 2016	Completed. No Findings Identified.
Baylor College of Medicine	RP150587	June 8, 2016	Completed. No Findings Identified.
Baylor College of Medicine	R1223	February 29, 2016	One finding identified. Remediation testing will occur in FY 2017.
Baylor College of Medicine	R1313	April 5, 2016	One finding identified. Remediation testing will occur in FY 2017.
Baylor College of Medicine	RP130256	May 5, 2016	One finding identified. Remediation testing will occur in FY 2017.
Baylor College of Medicine	RP110471-C3	May 26, 2016	One finding identified. Remediation testing will occur in FY 2017.

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Report Name	Report #	Report Date	Current Status
Baylor College of Medicine	RP110471-P3	May 26, 2016	One finding identified. Remediation testing will occur in FY 2017.
Baylor College of Medicine	RP110708-C1	April 4, 2016	Two findings identified. Remediation testing will occur in FY 2017.
Baylor College of Medicine	RP120092	April 13, 2016	Two findings identified. Remediation testing will occur in FY 2017.
Baylor College of Medicine	RP110553-P1	June 8, 2016	Two findings identified. Remediation testing will occur in FY 2017.
Baylor College of Medicine	RP110553-AC	June 13, 2016	Two findings identified. Remediation testing will occur in FY 2017.
Baylor College of Medicine	RP110553-C1	June 13, 2016	Three findings identified. Remediation testing will occur in FY 2017.
Baylor College of Medicine	RP110784	April 18, 2016	Seven findings identified. Remediation testing will occur in FY 2017.
Baylor Research Institute	RP110553-C3	June 13, 2016	Completed. No Findings Identified.
Baylor Research Institute	RP150638	August 4, 2016	Completed. No Findings Identified.
Baylor University	RP140399	August 4, 2016	Completed. No Findings Identified.
CerRx, Inc.	CP130023	April 5, 2016	Completed. No Findings Identified.
Immatics Biotechnologies	DP150029	November 19, 2015	Completed. No Findings Identified.
Legacy Community Health Services	PP140208	November 17, 2015	Completed. No Findings Identified.
Mercy Ministries of Laredo	PP120198	November 17, 2015	Completed. No Findings Identified.
MHMR of Tarrant County	PP120216	February 29, 2016	Completed. No Findings Identified.
MHP, Inc. Promoviendo Vidas Saludables	PP150078	November 17, 2015	Completed. No Findings Identified.
Pulmotect, Inc.	CP120014	November 17, 2015	Completed. No Findings Identified.
Rice University	RR150044	May 4, 2016	Completed. No Findings Identified.
Rice University	RP110532-C2	June 1, 2016	Completed. No Findings Identified.
Rice University	RP140024-AC	August 4, 2016	Completed. No Findings Identified.

Report Name	Report #	Report Date	Current Status
Rice University	PP130032	August 10, 2016	Completed. No Findings Identified.
Rice University	RP140132	August 15, 2016	Completed. No Findings Identified.
Rice University	RR140073	May 10, 2016	One finding identified. Remediation testing will occur in FY 2017.
Rice University	RR140081	July 7, 2016	One finding identified. Remediation testing will occur in FY 2017.
Rice University	RP120713-P2	August 5, 2016	One finding identified. Remediation testing will occur in FY 2017.
Rice University	R1110	August 15, 2016	Two findings identified. Remediation testing will occur in FY 2017.
Rice University	R1111	February 12, 2016	Three findings identified. Remediation testing will occur in FY 2017.
Texas A&M University	RR150038	May 13, 2016	Completed. No Findings Identified.
Texas A&M University	RP150559	August 18, 2016	Completed. No Findings Identified.
Texas A&M University	PP160032	August 18, 2016	Completed. No Findings Identified.
Texas A&M University	RP140781	August 16, 2016	One finding identified. Remediation testing will occur in FY 2017.
Texas A&M University Health Science Center Institute of Biosciences and Technology	RP110532-AC	April 12, 2016	Two findings identified. Remediation testing will occur in FY 2017.
Texas A&M University System Health Science Center	PP130090	September 28, 2015	Completed. No Findings Identified.
Texas A&M University System Health Science Center	RP150637	June 28, 2016	Completed. No Findings Identified.
Texas A&M University System Health Science Center	RP150578	June 29, 2016	Completed. No Findings Identified.
Texas A&M University System Health Science Center	RP150703	July 6, 2016	Completed. No Findings Identified.
Texas A&M University System Health Science Center	PP160048	July 11, 2016	Completed. No Findings Identified.
Texas A&M University System Health Science Center	RP160051	July 18, 2016	Completed. No Findings Identified.
Texas A&M University System Health Science Center	RP110441-P3	August 18, 2016	Completed. No Findings Identified.
Texas A&M University System Health Science Center	PP150025	January 28, 2016	Two findings identified. Remediation testing will occur in FY 2017.

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Report Name	Report #	Report Date	Current Status
Texas A&M University System Health Science Center	RR140053	February 12, 2016	Two findings identified. Remediation testing will occur in FY 2017.
Texas A&M University System Health Science Center	DP150086	January 28, 2016	Three findings identified. Remediation testing will occur in FY 2017.
Texas Agrilife Extension Service	PP150089	July 11, 2016	Two findings identified. Remediation testing will occur in FY 2017.
Texas AgriLife Research	RP150454	August 24, 2016	Completed. No Findings Identified.
Texas Agrilife Research	RP160589	August 25, 2016	Completed. No Findings Identified.
Texas Tech University	RP150720	August 25, 2016	Completed. No Findings Identified.
Texas Tech University	RP140298	August 25, 2016	Completed. No Findings Identified.
Texas Tech University	RP140840	September 7, 2016	Completed. No Findings Identified.
Texas Tech University	RP140478	September 8, 2016	Completed. No Findings Identified.
Texas Tech University Health Science Center at El Paso	PP140211	October 23, 2015	Completed. No Findings Identified.
Texas Tech University Health Science Center at El Paso	RP120528	September 28, 2015	Two findings identified. Remediation testing will occur in FY 2017.
Texas Tech University Health Sciences Center	RP121060	September 28, 2015	Completed. No Findings Identified.
Texas Tech University Health Sciences Center	RP130547	October 19, 2015	Completed. No Findings Identified.
Texas Tech University Health Sciences Center	RP110786	October 20, 2015	Completed. No Findings Identified.
Texas Tech University Health Sciences Center	RP130266	October 23, 2015	Completed. No Findings Identified.
Texas Tech University Health Sciences Center	PP130068	November 23, 2015	Completed. No Findings Identified.
Texas Tech University Health Sciences Center	PP150031	January 28, 2016	Completed. No Findings Identified.
Texas Tech University Health Sciences Center	PP150009	January 28, 2016	Completed. No Findings Identified.
Texas Tech University Health Sciences Center	PP130083	November 20, 2015	One finding identified. Remediation testing will occur in FY 2017.
Texas Tech University Health Sciences Center	PP130071	December 4, 2015	One finding identified. Remediation testing will occur in FY 2017.

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Report Name	Report #	Report Date	Current Status
Texas Tech University Health Sciences Center	RP150416	April 4, 2016	One finding identified. Remediation testing will occur in FY 2017.
Texas Tech University Health Sciences Center	RP150656	July 11, 2016	One finding identified. Remediation testing will occur in FY 2017.
Texas Tech University Health Sciences Center	PP140033	December 4, 2015	Three findings identified. Remediation testing will occur in FY 2017.
The Bridge Breast Network	PP140026	November 17, 2015	Completed. No Findings Identified.
The Methodist Hospital Research Institute	RP110532-C1	October 23, 2015	Completed. No Findings Identified.
The Methodist Hospital Research Institute	RP110444-P3	November 6, 2015	Completed. No Findings Identified.
The Methodist Hospital Research Institute	DP150099	January 28, 2016	Completed. No Findings Identified.
The Methodist Hospital Research Institute	RP150611	June 20, 2016	Completed. No Findings Identified.
The Methodist Hospital Research Institute	RP121048	September 21, 2015	One finding identified. Remediation testing will occur in FY 2017.
The Methodist Hospital Research Institute	RP110444-C2	November 6, 2015	One finding identified. Remediation testing will occur in FY 2017.
The Methodist Hospital Research Institute	RP140315	February 12, 2016	One finding identified. Remediation testing will occur in FY 2017.
The Methodist Hospital Research Institute	R1112	November 23, 2015	Three findings identified. Remediation testing will occur in FY 2017.
The University of North Texas Health Science Center at Fort Worth	PP130074	November 23, 2015	Completed. No Findings Identified.
The University of North Texas Health Science Center at Fort Worth	PP120213	November 5, 2015	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas at Arlington	RP150711	September 7, 2016	Completed. No Findings Identified.
The University of Texas at Arlington	RP110465-C2	June 8, 2016	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas at Austin	RP140328	August 15, 2016	Completed. No Findings Identified.
The University of Texas at Austin	DP150087	September 1, 2016	Completed. No Findings Identified.
The University of Texas at Austin	RP150346	September 7, 2016	Completed. No Findings Identified.

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Report Name	Report #	Report Date	Current Status
The University of Texas at Austin	R1106	March 1, 2016	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas at Austin	R1116	March 21, 2016	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas at Austin	R1214	April 4, 2016	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas at Austin	R1202	May 26, 2016	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas at Austin	RP110782	May 26, 2016	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas at Austin	R1120	March 21, 2016	Two findings identified. Remediation testing will occur in FY 2017.
The University of Texas at Austin	RP110532-P1	March 21, 2016	Two findings identified. Remediation testing will occur in FY 2017.
The University of Texas at Austin	RP110465-P4	May 26, 2016	Two findings identified. Remediation testing will occur in FY 2017.
The University of Texas at Austin	R1118	March 1, 2016	Four findings identified. Remediation testing will occur in FY 2017.
The University of Texas at Dallas	RP150713	August 15, 2016	Completed. No Findings Identified.
The University of Texas at Dallas	RP140544	August 15, 2016	Completed. No Findings Identified.
The University of Texas Health Science Center at Houston	PP120086	April 5, 2016	Completed. No Findings Identified.
The University of Texas Health Science Center at Houston	RR150104	August 23, 2016	Completed. No Findings Identified.
The University of Texas Health Science Center at Houston	RP150014	September 2, 2016	Completed. No Findings Identified.
The University of Texas Health Science Center at Houston	PP140183	September 6, 2016	Completed. No Findings Identified.
The University of Texas Health Science Center at Houston	RP160015	September 6, 2016	Completed. No Findings Identified.
The University of Texas Health Science Center at Houston	RP160235	September 6, 2016	Completed. No Findings Identified.
The University of Texas Health Science Center at Houston	RP150551	May 5, 2016	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas Health Science Center at Houston	R1307	May 23, 2016	One finding identified. Remediation testing will occur in FY 2017.

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Report Name	Report #	Report Date	Current Status
The University of Texas Health Science Center at Houston	RP110776	July 11, 2016	Three findings identified. Remediation testing will occur in FY 2017.
The University of Texas Health Science Center at Houston	R1215	April 5, 2016	Seven findings identified. Remediation testing will occur in FY 2017.
The University of Texas Health Science Center at San Antonio	RP150600	May 5, 2016	Completed. No Findings Identified.
The University of Texas Health Science Center at San Antonio	PP120089	February 12, 2016	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas Health Science Center at San Antonio	RR140072	May 5, 2016	Seven findings identified. Remediation testing will occur in FY 2017.
The University of Texas M.D. Anderson Cancer Center	RP120348	March 23, 2016	Completed. No Findings Identified.
The University of Texas M.D. Anderson Cancer Center	R1227	April 5, 2016	Completed. No Findings Identified.
The University of Texas M.D. Anderson Cancer Center	R1312	April 5, 2016	Completed. No Findings Identified.
The University of Texas M.D. Anderson Cancer Center	R1301	April 11, 2016	Completed. No Findings Identified.
The University of Texas M.D. Anderson Cancer Center	R1213	April 11, 2016	Completed. No Findings Identified.
The University of Texas M.D. Anderson Cancer Center	R1203	April 11, 2016	Completed. No Findings Identified.
The University of Texas M.D. Anderson Cancer Center	RR140052	May 4, 2016	Completed. No Findings Identified.
The University of Texas M.D. Anderson Cancer Center	RR140071	May 4, 2016	Completed. No Findings Identified.
The University of Texas M.D. Anderson Cancer Center	PP150054	May 4, 2016	Completed. No Findings Identified.
The University of Texas M.D. Anderson Cancer Center	RP150535	May 4, 2016	Completed. No Findings Identified.
The University of Texas M.D. Anderson Cancer Center	RR150039	May 4, 2016	Completed. No Findings Identified.
The University of Texas M.D. Anderson Cancer Center	RP130090	May 13, 2016	Completed. No Findings Identified.
The University of Texas M.D. Anderson Cancer Center	RP130297	May 13, 2016	Completed. No Findings Identified.
The University of Texas M.D. Anderson Cancer Center	RP110465-P2	May 17, 2016	Completed. No Findings Identified.
The University of Texas M.D. Anderson Cancer Center	RP110471-P2	February 29, 2016	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas M.D. Anderson Cancer Center	RP110553-P4	March 21, 2016	One finding identified. Remediation testing will occur in FY 2017.

Report Name	Report #	Report Date	Current Status
The University of Texas M.D. Anderson Cancer Center	R1218	April 5, 2016	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas M.D. Anderson Cancer Center	R1205	April 11, 2016	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas M.D. Anderson Cancer Center	R1108	February 29, 2016	Two findings identified. Remediation testing will occur in FY 2017.
The University of Texas M.D. Anderson Cancer Center	RP120214	May 13, 2016	Two findings identified. Remediation testing will occur in FY 2017.
The University of Texas M.D. Anderson Cancer Center	RP110471-C1	June 1, 2016	Two findings identified. Remediation testing will occur in FY 2017.
The University of Texas M.D. Anderson Cancer Center	R1005	March 23, 2016	Three findings identified. Remediation testing will occur in FY 2017.
The University of Texas Medical Branch at Galveston	RP140020-AC	September 2, 2016	Completed. No Findings Identified.
The University of Texas Medical Branch at Galveston	RP140020-P1	September 6, 2016	Completed. No Findings Identified.
The University of Texas Medical Branch at Galveston	RP140020-C3	September 6, 2016	Completed. No Findings Identified.
The University of Texas Medical Branch at Galveston	RP140020-C3	September 7, 2016	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP140021-P3	September 28, 2015	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP140021-AC	September 29, 2015	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP140021-P2	September 29, 2015	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	R1103	September 29, 2015	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP130189	September 30, 2015	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP130172	October 7, 2015	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP130312	October 7, 2015	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP130409	October 19, 2015	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP130464	October 19, 2015	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP130513	October 19, 2015	Completed. No Findings Identified.

Report Name	Report #	Report Date	Current Status
The University of Texas Southwestern Medical Center	RP130603	October 19, 2015	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP130607	October 19, 2015	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP130109	October 19, 2015	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP130212	October 19, 2015	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP130362	October 19, 2015	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP130427	October 19, 2015	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP130515	October 20, 2015	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP110441-P1	October 23, 2015	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP110465-AC	October 23, 2015	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP110441-C1	November 9, 2015	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP110595-P3	November 9, 2015	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP110562-C1	November 9, 2015	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP110441-P2	November 9, 2015	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP110465-P1	November 9, 2015	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP110486-P2	November 11, 2015	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP110562-P1	November 11, 2015	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP110486-AC	November 12, 2015	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP110708-C3	November 16, 2015	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP110708-P1	November 16, 2015	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP110708-AC	November 16, 2015	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP150498	February 12, 2016	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP150242	February 12, 2016	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP150356	February 12, 2016	Completed. No Findings Identified.

Report Name	Report #	Report Date	Current Status
The University of Texas Southwestern Medical Center	RP150386	February 12, 2016	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP150456	February 12, 2016	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP150485	February 12, 2016	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	R1225	February 12, 2016	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP150164	February 24, 2016	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RR150032	February 25, 2016	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RR150033	March 2, 2016	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RR150010	March 10, 2016	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	PP150053	June 20, 2016	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	PP150061	June 20, 2016	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP150573	June 20, 2016	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP150590	June 20, 2016	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP150632	June 20, 2016	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP150596	July 11, 2016	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP160089	July 11, 2016	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP160268	July 11, 2016	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP160255	July 14, 2016	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP160157	July 15, 2016	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP160180	July 15, 2016	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP160211	July 15, 2016	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP160307	July 15, 2016	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP160318	July 15, 2016	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP160340	July 15, 2016	Completed. No Findings Identified.

Report Name	Report #	Report Date	Current Status
The University of Texas Southwestern Medical Center	RP160440	July 15, 2016	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP150676	July 18, 2016	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RR150058	July 18, 2016	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RR150059	July 18, 2016	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RR150089	July 18, 2016	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP160493	July 18, 2016	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP160030	August 4, 2016	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	RP160520	August 12, 2016	Completed. No Findings Identified.
The University of Texas Southwestern Medical Center	R1107	September 28, 2015	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP130145	October 19, 2015	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP120960	October 20, 2015	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	R1117	October 20, 2015	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP140021-P4	October 20, 2015	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP110486-P3	November 6, 2015	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP110562-AC	November 6, 2015	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP110441-AC	November 9, 2015	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP110465-P3	November 9, 2015	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP130629	November 12, 2015	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP140320	November 16, 2015	One finding identified. Remediation testing will occur in FY 2017.

Report Name	Report #	Report Date	Current Status
The University of Texas Southwestern Medical Center	R1222	December 2, 2015	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP140141	December 4, 2015	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP140143	December 7, 2015	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP140233	December 16, 2015	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP140661	December 16, 2015	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP140367	December 16, 2015	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	PP140182	December 17, 2015	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP140140	December 21, 2015	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP140672	December 21, 2015	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP120670-AC	December 21, 2015	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP120670-C1	December 21, 2015	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP140402	December 21, 2015	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP120670-P4	December 29, 2015	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP120670-C3	January 5, 2016	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP120670-P3	January 5, 2016	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP120717-AC	January 5, 2016	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP120717-C1	January 5, 2016	One finding identified. Remediation testing will occur in FY 2017.

Report Name	Report #	Report Date	Current Status
The University of Texas Southwestern Medical Center	RP140285	January 6, 2016	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP120718-AC	January 6, 2016	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP120717-P2	January 6, 2016	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP120685-AC	January 8, 2016	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP120718-C1	January 11, 2016	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP120685-P2	January 12, 2016	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP120685-P3	January 28, 2016	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP120717-P1	January 28, 2016	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP120717-P3	January 28, 2016	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP120732-AC	January 28, 2016	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP120718-P1	January 28, 2016	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RR140036	February 12, 2016	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RR140082	March 17, 2016	One finding identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	R1208	September 28, 2015	Two findings identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP130272	October 19, 2015	Two findings identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	R1115	October 20, 2015	Two findings identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP110708-C2	November 6, 2015	Two findings identified. Remediation testing will occur in FY 2017.

Report Name	Report #	Report Date	Current Status
The University of Texas Southwestern Medical Center	RP110771	November 16, 2015	Two findings identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP110708-P3	November 16, 2015	Two findings identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	R1212	November 16, 2015	Two findings identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	R1209	November 16, 2015	Two findings identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP110486-P5	November 23, 2015	Two findings identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	R1221	November 30, 2015	Two findings identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	R1220	December 2, 2015	Two findings identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP120685-C1	December 29, 2015	Two findings identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP140412	January 6, 2016	Two findings identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP120718-P2	January 28, 2016	Two findings identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP120718-P3	January 28, 2016	Two findings identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP120732-C2	January 28, 2016	Two findings identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP120732-P1	January 28, 2016	Two findings identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	DP150051	January 28, 2016	Two findings identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	DP150077	January 28, 2016	Two findings identified. Remediation testing will occur in FY 2017.

Report Name	Report #	Report Date	Current Status
The University of Texas Southwestern Medical Center	RP140655	January 28, 2016	Two findings identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP120718-C2	January 28, 2016	Two findings identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP120732-P3	January 28, 2016	Two findings identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RR140084	February 12, 2016	Two findings identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RR140023	February 12, 2016	Two findings identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RR140042	February 17, 2016	Two findings identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP140449	November 16, 2015	Three findings identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	R1117	November 20, 2015	Three findings identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP110708-P2	November 23, 2015	Three findings identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	R1216	November 23, 2015	Three findings identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP140152	December 2, 2015	Three findings identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP130166	September 15, 2015	Four findings identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	R1008	November 17, 2015	Four findings identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	R1308	February 12, 2016	Four findings identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RR140025	February 12, 2016	Four findings identified. Remediation testing will occur in FY 2017.

Report Name	Report #	Report Date	Current Status
The University of Texas Southwestern Medical Center	R1207	September 21, 2015	Five findings identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP120613	December 2, 2015	Five findings identified. Remediation testing will occur in FY 2017.
The University of Texas Southwestern Medical Center	RP140110	September 29, 2015	Six findings identified. Remediation testing will occur in FY 2017.
University Health System	PP120217	April 4, 2016	Completed. No Findings Identified.
University of Houston	RP130553	August 30, 2016	Completed. No Findings Identified.
University of Houston	RP150343	September 1, 2016	Completed. No Findings Identified.
University of Houston	RR150088	September 8, 2016	Completed. No Findings Identified.
University of Houston	RP110444-AC	May 10, 2016	One finding identified. Remediation testing will occur in FY 2017.
University of Houston	RP110444-P1	May 26, 2016	One finding identified. Remediation testing will occur in FY 2017.
University of Houston	RP110444-C1	May 17, 2016	Two findings identified. Remediation testing will occur in FY 2017.
University of Houston	RR140013	May 26, 2016	Two findings identified. Remediation testing will occur in FY 2017.
University of Houston	RP130258	November 2, 2015	Seven findings identified. Remediation testing will occur in FY 2017.
Val Verde Regional Medical Center	PP150071	November 17, 2015	Completed. No Findings Identified.

Other consulting and nonaudit services were provided by Grant Thornton. CPRIT engaged Grant Thornton as the third party to observe each in-person and telephone conference Peer Review Panel meeting and ensure compliance with conflict of interest and staff participation requirements.

Grant Thornton issued the following reports during fiscal year 2016:

Review Panel	Report #	Report Date	Current Status
Product Development			
15.4 Due Diligence	2015-10-12-PDEV	10/20/2015	Complete
16.1 PD-1 screening teleconference	2015-10-30-PDEV	11/9/2015	Complete
16.1 PD-2 screening teleconference	2015-10-29-PDEV	11/9/2015	Complete
16.1 PD – 1 onsite	2015-12-03-PDEV	12/11/2015	Complete
16.1 PD – 2 onsite	2015-12-01/02-PDEV	12/11/2015	Complete
16.1 PD Due diligence/PDRC	2016-03-21-PDEV	3/30/2016	Complete
16.2 PDP-1 screening teleconference	2016-04-07-PDEV	4/14/2016	Complete
16.2 PDP-2 screening teleconference	2016-04-08-PDEV	4/14/2016	Complete
16.2 PDP 1 In person review	2016-05-10/11-PDEV	5/20/2016	Complete
16.2 PDP 2 In person review	2016-05-12-PDEV	5/20/2016	Complete
Academic Research			
16.1 Clinical & Translational Cancer Research and Translational Cancer Research	2015-09-29-RES	10/7/2015	Complete
16.1 Cancer Prevention Research Panel	2015-09-30-RES	10/7/2015	Complete
16.1 Imaging Technology and Informatics Research	2015-10-01-RES	10/7/2015	Complete
16.1 BCR-2	2015-10-05-RES	10/13/2015	Complete
16.1 BCR-1	2015-10-06-RES	10/13/2015	Complete
16.1 Cancer Biology	2015-10-07-RES	10/13/2015	Complete
16.1 SRC	2015-10-23-RES	10/27/2015	Complete
16.2-.3 Recruits	2015-10-19-RES	10/26/2015	Complete
1-PDEV6.4 recruits	2015-11-12-RES	11/20/2016	Complete
16.5-.6 recruits	2016-01-14-RES	1/25/2016	Complete
16.7 SRC (recruits)	2016-02-11-RES	2/19/2016	Complete
16.8 SRC (recruits)	2016-03-24-RES	3/31/2016	Complete
16.2 SRC meeting (research apps)	2016-03-29-RES	4/5/2016	Complete
16.2 Cancer Prevention Research Panel	2016-03-09-RES	3/18/2016	Complete
16.2 Clinical & Translational Research and Translational Cancer Research	2016-03-9/10-RES	3/21/2016	Complete
16.2 Imaging Technology and Informatics Research	2016-03-11-RES	3/21/2016	Complete
16.2 BCR-1	2016-03-14-RES	3/21/2016	Complete
16.2 Cancer Biology	2016-03-15-RES	3/21/2016	Complete
16.2 BCR-2	2016-03-16-RES	3/25/2016	Complete

Review Panel	Report #	Report Date	Current Status
16.9 Recruitment	2016-04-14-RES	4/20/2016	Complete
16.10 Recruitment	2016-05-26-RES	6/3/2016	Complete
16.11 Recruitment	2016-06-16-RES	6/21/2016	Complete
16.12 Recruitment	2016-07-14-RES	7/25/2016	Complete
	Prevention		
16.1 Prevention panel 1	2016-07-14-RES	9/30/2015	Complete
16.1 PRC	2015-10-23-PREV	10/29/2015	Complete
16.2 Prevention Panel 1	2016-05-23/24-PRE	6/3/2016	Complete
16.2 Prevention Panel 2	2016-05-24/25-PRE	6/3/2016	Complete
16.2 PRC	2016-07-01-PREV	7/12/2016	Complete

IV. External Quality Assurance Review

In accordance with professional standards, and to meet the requirements of the Texas Internal Auditing Act, Internal Audit is required to undergo an external quality assurance review at least once every three years. Weaver's review was performed in October 2013.

System Review Report

October 4, 2013

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

We have reviewed the system of quality control for the accounting and auditing practice of Weave and Tidwell, L.L.P. (the firm) applicable to non-SEC issuers in effect for the year ended May 31, 2013. Our peer review was conducted in accordance with the Standards for Performing and Reporting on Peer Reviews established by the Peer Review Board of the American Institute of Certified Public Accountants. As a part of our peer review, we considered reviews by regulatory entities, if applicable, in determining the nature and extent of our procedures. The firm is responsible for designing a system of quality control and complying with it to provide the firm with reasonable assurance of performing and reporting in conformity with applicable professional standards in all material respects. Our responsibility is to express an opinion on the design of the system of quality control and the firm's compliance therewith based on our review. The nature, objectives, scope, limitations of, and the procedures performed in a System Review are described in the standards at www.aicpa.org/prsummary.

As required by the standards, engagements selected for review included engagements performed under *Government Auditing Standards*; audits of employee benefit plans, audits performed under FDICIA, and examinations of service organizations (Service Organizations Control (SOC) 1 and 2 engagements).

In our opinion, the system of quality control for the accounting and auditing practice of Weaver and Tidwell, L.L.P. applicable to non-SEC issuers in effect for the year ended May 31, 2013, has been suitably designed and complied with to provide the firm with reasonable assurance of performing and reporting in conformity with applicable professional standards in all material respects. Firms can receive a rating of *pass, pass with deficiency(ies)* or *fail*. Weaver and Tidwell, L.L.P. has received a peer review rating of *pass*.

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V. Internal Audit Plan for Fiscal Year 2017

The Internal Audit Plan was submitted to the Audit Subcommittee of the CPRIT Oversight Committee. The Audit Subcommittee approved the plan on September 6, 2016, and the Oversight Committee subsequently approved the plan on September 14, 2016. Below is the 2017 Internal Audit Plan submitted to the agency's Oversight Committee based on the results of the 2016 Internal Audit Risk Assessment update. The approved internal audit plan was submitted to the State Auditor's Office prior to November 1, 2016.

Fiscal Year 2017 Internal Audit Plan		
Audit Area	Risk Rating	Estimated Hours
Procurement and P-Cards	High	300-325
Pre-Award Grant Management	High	210-245
Internal Agency Compliance	High	225-250
Training Programs	Moderate	250-270

The internal audit over procurement and P-cards will address selected contract management and purchasing requirements of Senate Bill 20 (84th Legislature).

Planned follow-up procedures for fiscal year 2016 to verify and communicate with Management the remediation efforts of prior Internal Audit Recommendations.

Fiscal Year 2017 Follow-up Procedures		
Audit Area	Risk Rating	Estimated Hours
Information Security	High	90-110
Commodity and Service Contracts	High	50-70
Revenue	Moderate	40-50
Cash Management	Moderate	30-40

The 2016 Internal Audit Risk Assessment resulted in nine Significant Activities rated as "High" risk. Four of the nine Significant Activities are not included in the fiscal year 2017 Internal Audit Plan. Those risks are as follows:

1. **Post-Award Grant Monitoring** – Pre-Award Grant Monitoring was not included in the 2017 Internal Audit Plan. Pre-Award Grant Monitoring was included in the 2015 Internal Audit Plan, and was included in 2016 Follow-Up Procedures.
2. **Governance** – Governance was not included in the 2017 Internal Audit Plan. Governance was included in the 2014 Internal Audit Plan, and was included in 2015 follow-up procedures.
3. **Disaster Recovery and Business Continuity Planning** – Disaster Recovery and Business Continuity Planning was not included in the 2017 Internal Audit Plan.
4. **Information Technology Services** – Information Technology Services was not included in the 2017 Internal Audit Plan. Information Technology Services was included in the 2015 Internal Audit Plan, and was included in the 2016 Follow-Up Procedures.

The 2015 Internal Audit Risk Assessment was updated as part of the 2016 Internal Audit Plan. Information technology risk, including information security risk, was considered throughout the risk assessment process. Information technology risk was considered for significant processes of CPRIT to arrive at the overall risk rating for each process.

VI. External Audit Services Procured in FY 2016

CPRIT engaged McConnell & Jones, LLP, a certified public accounting and consulting firm, as their external auditors for FY 2016. McConnell & Jones, LLP is registered with the Public Company Auditor Oversight Board (PCAOB).

VII. Reporting Suspected Fraud and Abuse

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

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

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

To:	**OVERSIGHT COMMITTEE MEMBERS**
From:	**KRISTEN PAULING DOYLE, GENERAL COUNSEL** **CAMERON L. ECKEL, STAFF ATTORNEY**
Subject:	**CHAPTER 701, 702 AND 703 RULE CHANGES PROPOSED FOR FINAL ADOPTION**
Date:	**NOVEMBER 8, 2016**

Summary

The proposed administrative rule changes to Chapters 701, 702 and 703, originally considered by the Oversight Committee in August, are ready for final adoption. CPRIT received comments from one grantee institution regarding the proposed changes. The Board Governance Subcommittee met on October 31 to discuss the rule changes with CPRIT legal staff. The Subcommittee recommends that the Oversight Committee adopt the rule changes as originally proposed. Once the Oversight Committee approves the final orders, CPRIT will submit the rule changes to the Secretary of State and the changes 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. CPRIT staff conducted an extensive review of existing procedures related to grant applications and grant awards earlier this year. Fifty-three different rule changes affecting 27 administrative rules resulted from this review. The proposed rule changes, preliminarily approved by the Oversight Committee in August, affect various aspects of policies guiding CPRIT's grant review, grant contracting, and grant monitoring processes. The attached chart provides a summary of each of the proposed changes. Most of the changes are non-substantive or clarifying revisions meant to align the agency's administrative rules with current practices. There are seven new rules or rule sections that are substantive changes; these rules are shaded in yellow on the attached chart.

CPRIT published the proposed rules in the September 2 edition of the *Texas Register*, as well as solicited public comment via CPRIT's website. Texas Tech University System (TTUS) submitted a comment regarding a reference in § 703.13 to OMB Circular A-133 Audits. TTUS indicated that the reference has been superseded and recommended an updated title. CPRIT

supports the suggested change; however, TTUS' proposed change may be outside of the scope of this rulemaking. The proposed change will be addressed in a future rulemaking project.

The Board Governance Subcommittee met on October 31 to review the public comments and final orders with CPRIT's General Counsel. The Subcommittee recommends the Oversight Committee approve the final orders adopting the proposed rule changes.

Next Steps

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

Proposed Administrative Rule Changes – Chapters 701, 702 and 703	
Chapter 701	
§ 701.3 Definitions	§ 701.3 Clarifies that grantee institutions may designate an alternate Authorized Signing Official (ASO) in the grant management system; the change updates the definition to recognize alternate ASOs. Proposed change conforms the administrative rule to existing practice.
§ 701.7 Compliance Program	§ 701.7(c)(2)(C) Clarifies the frequency of the Chief Compliance Officer's reporting obligation. The statute requires that the Chief Compliance Officer report on the grantees' compliance with CPRIT's administrative rules and contractual requirements at least annually. In practice, the Chief Compliance Officer makes this report at the quarterly Oversight Committee meetings. Proposed change conforms the administrative rule to existing practice.
§ 701.9 Report and Compliance of Compliance Violations	§ 701.9(a) Adds "fraud, waste, and abuse" to the list of suspected compliance violation investigations the Chief Compliance Officer oversees. Proposed change conforms the administrative rule and description of Chief Compliance Officer's duties to existing practice.
	§ 701.9(b) Adds allegations of "fraud, waste, and abuse" to the types of confidential reports that may made CPRIT's Ethics Hotline. Proposed change conforms the administrative rule to existing practice.
§ 701.19 - Advance Payment of Grant Funds **New Title: Texas Location for Grant Awards**	§ 701.19 Deletes text. Text is moved to new rule § 703.23(a) "Disbursement of Grant Award Funds" NEW RULE - Substantive Adds new text related to Texas location requirements for grantees.
§ 701.27 Publicly Available Institute Reports and Records	§ 701.27(15) Recognizes exceptions to the gift reporting requirements already adopted in § 702.7(f).

Chapter 702	
§ 702.7 Acceptance of Gifts and Donations by the Institute	§ 702.7(c)(3)(4) Removes references to "Executive Committee" and makes conforming changes (e.g. replacing vote by Executive Committee to a majority vote by the Oversight Committee.) Clarifies that the CEO will create a report for potential gifts valued in excess of $1 million.
	§ 702.7(f)(3) Clarifies that the conference fees referred to in this paragraph are for a conference hosted by CPRIT.
§ 702.9 Code of Conduct	§ 702.9(c)(16) Changes the individual designated to receive reports of gifts from Chief Executive Officer to Chief Compliance Officer. Proposed change conforms the administrative rule to existing practice and CPRIT's Code of Conduct.
§ 702.13 Disclosure of Conflicts of Interest and Recusal from Review	§ 702.13(a)(1) The statute requires Oversight Committee members and PIC members provide "written notice" of a conflict of interest to the CEO. The change clarifies that the member's designation of a conflict of interest via the grant review portal constitutes the required notice. Proposed change conforms the administrative rule to existing practice.
	§ 702.13(b)(1) The statute requires peer review committee members to provide "written notice" of a conflict of interest to the CEO. Like the proposed change to § 703.13(a)(1), this change clarifies that the member's designation of a conflict of interest via the grant review portal constitutes the required notice. Proposed change conforms the administrative rule to existing practice.
§ 702.19 Restriction on Communication Regarding Pending Grant Awards	§ 702.19(e) Clarifies that notice to the Oversight Committee is made at the time the communication restriction waiver is granted by the CEO and that the waiver is publicly available via the CEO affidavit. Proposed change conforms the administrative rule to existing practice.

Chapter 703	
§ 703.3 **Grant Applications**	§ 703.3(b)(3) Adds new subsection indicating that CPRIT may cap the number of applications submitted by an entity responding to a particular request for applications. Institutional limits, if any, on the number of applications that an entity may submit are included in the request for applications. CPRIT uses institutional limits when a large number of submissions are expected in response to a request for applications. Proposed change conforms the administrative rule to existing practice.
	§ 703.3(e) Deletes text requiring applicants to provide information regarding product development prospects. As currently written, this appears to be a global requirement applicable to all grant mechanisms. In practice, the request for applications will specifically request information about product development prospects if it is necessary for the review process. Adds new text clarifying that CPRIT may limit the number of times an applicant may resubmit an application not recommended in a previous grant review cycle. Proposed new text conforms the administrative rule to existing practice.
	§ 703.3(g)(1) – (3) New text clarifies process for extending the deadline for application submission, including specifying the individual responsible for approving the extension request. Proposed change conforms the administrative rule to existing practice.
	§ 703.3(i)(A) Replaces deleted text with new text clarifying the requirement to provide a capitalization table is limited to Product Development grant applicants.
	§ 703.3(j) Proposed change conforms the administrative rule to the grant contract, which requires the grantee to certify that the entity, employees, and collaborators/contractors working on the project are not debarred, suspended, ineligible, or otherwise excluded from another federal or state grant award.
	§ 703.3(k)(3) Adds new subsection authorizing CPRIT to withdraw a Product Development grant application from consideration if the applicant does not submit the application fee within seven business days following the application deadline. Proposed change conforms the administrative rule to existing practice.

§ 703.5 Scientific Research and Prevention Programs Committees	§ 703.5(a) Adds text to include post-award review of grantee progress reports to the list of the peer review activities peer review committee members may perform. Proposed change conforms the administrative rule to existing practice.
§ 703.6 Grants Review Process	§ 703.6(d)(3) Adds a new subsection requiring that the PIC/Oversight Committee take final action on the Review Council's recommendations in the same fiscal year that Review Council submits its formal recommendations to the PIC and the Oversight Committee. Proposed change conforms the administrative rule to existing practice and is consistent with the statute.
	§ 703.6(f) Adds text regarding Oversight Committee members' attendance at peer review meetings. Proposed change conforms the administrative rule to existing practice.
	§ 703.6(i) Adds text requiring CPRIT employees and Oversight Committee members attending peer review meetings to complete the post-review compliance statement. This new requirement documents compliance with the conflict of interest rules.
§ 703.7 Program Integration Committee Funding Recommendations	§ 703.7(d)(8) Adds new subsection to specify that a list of deferred applications should be provided to the Oversight Committee at the time the PIC submits its award recommendations. Proposed change conforms the administrative rule to existing practice.
§ 703.8 Oversight Committee Consideration of Program Integration Funding Recommendations	§ 703.8(1)(B) Adds text clarifying that the Chief Compliance Officer documents any variances in a grant application, as well as the grant review process. Proposed change conforms the administrative rule to existing practice.
	§ 703.8(2) Replaces the CEO's proposed "corrective actions" with "good cause" when considering variances affecting award recommendations. This language clarifies that variances may occur in the application; it does not change how variances are documented or what action the Oversight Committee may be take. Proposed change conforms the administrative rule to existing practice.
	§ 703.8(3) Adds subsection clarifying that the Oversight Committee may take up and vote on more than one application. The Oversight Committee typically votes on awards as a slate rather than individual recommendations. Proposed change conforms the administrative rule to existing practice.
	§ 703.8(4)

	Replaces "failure to follow" with "not approving."
§ 703.10 Awarding Grants by Contract	§ 703.10(23) Adds new subsection indicating that the grantee is legally responsible for the integrity of the fiscal and programmatic management of the organization. Proposed change conforms the administrative rule to grant contract terms regarding grantee responsibility.
	§ 703.10(24) Adds new subsection indicating that the grantee is legally responsible for the actions of its employees and research collaborators, including third parties, involved in the project. Proposed change conforms the administrative rule to grant contract terms regarding grantee responsibility.
§ 703.11 Requirement to Demonstrate Available Funds for Cancer Research Grants	§ 703.11(e) Replaces "yearly" with defined term "project year."
	§ 703.11(h) Replaces "period" with defined term "project year."
§ 703.12 Limitation on Use of Grant Funds	§ 703.12(b) Deletes text related to unallowable expenses. Text is moved to new rule § 703.26 "Allowable Expenses."
§ 703.13 Audits and Investigations	§ 703.13(b) Adds text related to the single audit determination form that grantees must submit, including raising the minimum amount necessary to trigger the audit requirement.
	§ 703.13(e) New subsection (e) clarifies acceptable standards for agreed upon procedures audits.
§ 703.14 Termination, Extension, Close-Out of Grants and De-Obligation of Unused Grant Funds	§ 703.14(c)(1) Deletes "only" and adds text indicating CPRIT's decision is final. Proposed deletion will reduce confusion among grantees; the additional text conforms the administrative rule to existing practice.
	§ 703.14(c)(2) Adds text clarifying the process a grantee must follow to request a no cost extension outside of the rule's timeframe. Proposed change conforms the administrative rule to existing practice.
	§ 703.14(c)(3) Adds text clarifying process for requesting and approving no cost extensions. Proposed change conforms the administrative rule to existing practice.
	§ 703.14(d) Adds text clarifying due date of final financial status report (FSR); similar non-substantive change made to (d)(1). Proposed change makes the due date of the final FSR consistent with the due date

	of other FSRs. There is some confusion under the current rule about due date of the final FSR when the contract ends in the middle of a fiscal quarter. Additional text clarifies that the final Progress Report and other required reports, which are collectively referred to as "close out documents" may have a different due date (90 days from the termination date of the grant contract) than the FSR due date.
	§ 703.14(e) Adds text clarifying that the agency may make allowable costs adjustments up to 90 days after the final FSR is approved. Proposed change clarifies the period when CPRIT may make costs adjustments to a grant after the termination date.
	§ 703.14(h) – NEW SECTION Adds new subsection authorizing CPRIT to de-obligate grant award funds not expended at the termination of the grant contract. The proposed change is necessary so that CPRIT may make available grant funds to other projects or statutory purposes when grant funds are unused at the time the grant terminates.
§ 703.15 **Multiyear Grant Projects** **New Title:** **Fiscal Policies Applicable to Grant Awards**	§ 703.15 Deletes text related to multiyear projects. Deleted text is incorporated in § 703.8(3)(A) and new rules §§ 703.24 and 703.25. NEW RULE – Fiscal Policies Applicable to Grant Awards Adds new text related to required fiscal policies. The proposed changes codify agency practice.
§ 703.16 **Intellectual Property Agreement**	§ 703.16(c) Deletes text that is not applicable to all grants.
	§ 703.16(d)(6) Deletes subsection that is not applicable to all grants.
§ 703.17 **Revenue Sharing Standards**	§ 703.17(e) Adds new subsection about revenue sharing. The proposed rule change is consistent with the agency's standard revenue sharing standards.
§ 703.21 **Monitoring Grant Award Performance**	§ 703.21(a) Replaces "Chief Executive Officer" with "Chief Compliance Officer." The proposed change is consistent with agency practice.
	§ 703.21(b)(1) Deletes text regarding FSR due dates; text is moved to new rule § 703.24.
	§ 703.21(b)(2)

	Deletes text regarding FSR due dates, waiver of reimbursement for failing to timely submit FSRs, and appeal of waiver. Deleted text is moved to new rule § 703.24. Adds new text regarding monitoring timely submission of reports and withholding reimbursement until delinquent reports are submitted and approved. The proposed change is consistent with agency practice.
	§ 703.21(b)(3)(E) Removes clause indicating that a grant manager performs the evaluation; CPRIT relies upon peer reviewers or contractors with subject matter expertise to perform the evaluation. The proposed change is consistent with agency practice.
New Rule § 703.23 Disbursement of Grant Award Funds	New § 703.23 Clarifies CPRIT's policies regarding disbursing grant funds by reimbursement or advancement. The new rule incorporates text from § 701.19.
New Rule § 703.24 Financial Status Reports	New § 703.24 Addresses requirements for quarterly and final financial status reports. The new rule incorporates text originally from § 703.21(b)(1) and(2)
New Rule § 703.25 Grant Award Budget	New § 703.25 Codifies existing practice specified in the grant contract regarding approved budgets, including budget transfer requests.
New Rule § 703.26 Allowable Costs	New § 703.26 Codifies existing practice specified in the grant contract regarding allowable costs. Incorporates deleted text from 703.12 regarding unallowable costs.

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 ("CPRIT" or "the Institute") adopts the amendments to §§ 701.3, 701.7, 701.9, 701.19, and 701.27 regarding the definition of Authorized Signing Official; Chief Compliance Officer report frequency; fraud, waste, and abuse; electronic signature policy; and reporting requirements on the Institute's public website. The proposed amendments were published in the September 2, 2016, issue of the *Texas Register* (41 TexReg 6629).

Reasoned Justification

§ 701.3 is amended to include designated alternates in the Institute's definition of "Authorized Signing Official."

§ 701.7 is amended to require the Chief Compliance Officer to report at least quarterly, instead of annually, to the Oversight Committee regarding grantee compliance with Institute rules.

§ 701.9 is amended to include fraud, waste, and abuse, as part of the compliance program. The proposed amendment adds reports and investigations of fraud, waste, and abuse to the activities that the Chief Compliance Officer oversees.

§ 701.19 is amended to replace all of the current text relating to advance payment of grant award funds with text that outlines requirements for Texas location for grant awards and to change the name of the rule to "Texas Location for Grant Awards." The proposed rule sets out specific actions a grantee may take to demonstrate a Texas location sufficient to be eligible for a grant award.

§ 701.27 is amended to clarify the information that needs to be reported on the Institute's public website. The Institute is required to report all gifts, grants, or other consideration given to an Oversight Committee member, Institute employee, or Program Integration Committee. The proposed amendment makes it clear that that the gifts covered by the exceptions specified by Texas Administrative Code Rule § 702.7, related to gifts, grants, or consideration, do not need to be posted on the Institute's public website.

Summary of Public Comments and Staff Recommendation

No public comments to the proposed rule amendments were received.

The rule changes are adopted under the authority of the Texas Health and Safety Code Annotated, §§ 102.108 and 102.251, which provides the Institute with broad rule-making authority to administer the chapter, including rules for awarding grants.

Certification

The Institute hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

To be filed with the Office of Secretary of State on November 18, 2016.

TITLE 25. HEALTH SERVICES

PART 11. CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CHAPTER 702. Institute Standards on Ethics and Conflicts, Including the Acceptance of Gifts and Donations to the Institute

The Cancer Prevention and Research Institute of Texas ("CPRIT" or "the Institute") adopts the amendments to §§ 702.7, 702.9, 702.13, and 702.19 regarding acceptance of gifts, registration fees paid for the Institute conference, gift reporting to the Chief Compliance Officer, how Oversight Committee members, Program Integration Committee members, and Scientific Research and Prevention Programs Committee members provide written notice of conflicts of interest, and how those conflicts are disclosed; and how waivers of the restriction on communication granted by the Chief Executive Officer are provided to the Oversight Committee and disclosed publicly . The proposed amendments were published in the September 2, 2016, issue of the *Texas Register* (41 TexReg 6635).

Reasoned Justification

§ 702.7 is amended in several ways. The first proposed amendment, to § 702.7(c)(3), clarifies that the Oversight Committee may vote by a simple majority accept gifts of cash, stock, bonds, or personal property with a value in excess of $10,000. Section 702.7(c)(4) is amended to require that the Chief Executive Officer prepare a report for the Oversight Committee related to any proposed gifts to the Institute of cash, stock, bonds, or personal property with a value over $1,000,000 and any gifts of real property, regardless of value. Section 702.7(f)(3) is amended to clarify that any registration fees paid to the Institute for a conference hosted by the Institute do not constitute consideration subject to the reporting requirement.

§ 702.9 is amended to require an Oversight Committee member, Institute employee, or Program Integration Committee member to report any gifts to the Chief Compliance Officer rather than the Chief Executive Officer.

§ 702.13 is amended to clarify how Oversight Committee members, Program Integration Committee members, and Scientific Research and Prevention Programs Committee members provide written notice of conflicts of interest, and how those conflicts are disclosed. The proposed rule makes it clear that the individual's declaration of conflicts of interest made through the agency's designated electronic portal constitutes appropriate written notice.

§ 702.19 is amended to clarify the process for making waivers granted pursuant to this section publicly available. The proposed amendment requires the Chief Executive Officer to provide the Oversight Committee written notice of any waiver granted at the time that it is granted and to include the waiver in the Chief Executive Officer's affidavit for grant award recommendations.

Summary of Public Comments and Staff Recommendation

No public comments to the proposed rule amendment were received.

The rule changes are adopted under the authority of the Texas Health and Safety Code Annotated, §§ 102.108 and 102.251, which provides the Institute with broad rule-making authority to administer the chapter, including rules for awarding grants.

Certification

The Institute hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

To be filed with the Office of Secretary of State on November 18, 2016.

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 amendments to §§ 703.3, 703.5, 703.6, 703.7, 703.8, 703.10, 703.11, 703.12, 703.13, 703.14, 703.15, 703.16, 703.17, and 703.21 regarding institutional limits on grant applications, grant application resubmissions, competitive renewals, submitting more than one application, submission deadline extensions, sources of funding, grant ineligibility, application fees for product development research grantees, review of grant recipient progress reports, when grant application recommendations must be acted on by the Oversight Committee, requirements of Institute employees and Oversight Committee members who attend peer review meetings, Program Integration Committee recommendations sent to the Oversight Committee, how the Chief Executive Officer may recommend considering applications with variations, how the Oversight Committee votes on grant recommendations, grantee responsibilities, single audit determination, no cost extensions, final Financial Status Reports, revenue sharing, who within the Institute is responsible for directing grant award monitoring, grantee documentation of Financial Status Reports, and various typographical corrections that do not substantively change administrative rules. Additionally, the Institute proposes new rules §§ 703.23, 703.24, 703.25, and 703.26 relating to disbursement of grant award funds, financial status reports, grant award budgets, and allowable costs. The proposed amendments and new rules were published in the September 2, 2016, issue of the *Texas Register* (41 TexReg 6641).

Reasoned Justification

The proposed rule changes and new rules provide clarity for grant applicants and grant recipients related to the review, approval, disbursement, and monitoring of Institute grant award funds.

§ 703.3 has several proposed amendments affecting grant applications. The first proposed amendment adds § 703.3(b)(3) allowing the agency to set a limit on the number of applications that may be submitted by an entity for a particular grant award mechanism. Section 703.3(e) is amended to allow the Institute to limit the number of times a grant application may be resubmitted to the Institute. Section 703.3(g), which explains the process for requesting an extension to the application deadline, is amended to clarify that any extension is at the discretion of the Chief Program Officer and any request for such an extension must be made to the CPRIT Helpdesk via electronic mail within 24 hours of the closure of the application submission deadline. An extension to the submission deadline will only be granted for good cause, which will be documented by the Institute. Section 703.3(i) is amended to clarify that only product development applicants are required to provide a capitalization table that includes individuals or entities that have an investment, stock or rights in the company. Section 703.3(j) is amended to clarify that any grant application submitted by an entity or personnel that is debarred, suspended, and ineligible or otherwise excluded form participation in federal or state grant awards is not eligible to receive a grant from the Institute. Section 703.3(k) is amended to allow the agency to

withdraw a product development application if the application fee is not received within seven business days of the application submission deadline.

§ 703.5 is amended to expand peer review activities of Scientific Research and Prevention Program Committee members to include post award evolution of grant progress reports submitted to the Institute by grant recipients.

§ 703.6 is amended to clarify that a final grant award recommendation by a review council must be acted on by the Oversight Committee within the same state fiscal year. Section 703.6 is also amended to clarify that Oversight Committee members may attend peer review meetings as non-participating observers. If an Institute employee or Oversight Committee member attends a peer review meeting, the individual must certify in writing that the employee or Oversight Committee member complied with the Institute's conflict of interest rules.

§ 703.7 is amended to clarify that a list of deferred grant award recommendations, if any, must be provided at the same time the Program Integration Committee submits its list of grant award recommendations to Oversight Committee.

§ 703.8 is amended to clarify the variances in the grant review process as well as any grant applications that the Chief Compliance Officer is required to identify at the time that the Chief Compliance Officer certifies the grant award recommendations. Section 703.8 is further amended to clarify that the Chief Executive Officer may recommend good cause for considering a process variance reported by the Chief Compliance Officer. The proposed amendment to Section 703.8(3) clarifies that the Oversight Committee may vote on more than one grant award recommendation at a time unless an Oversight Committee member requests taking up a grant recommendation individually. Lastly, Section 703.8(4) is amended to replace "failure to follow" with "not approving."

§ 703.10 is amended to add two grant contract requirements. The first proposed change requires the grantee to accept legal responsibility for the integrity of the fiscal and programmatic management of the organization. The second proposed change requires the grantee to acknowledge responsibility for the actions of its employees and other research collaborators, as well as enforcing the grantee's standards of conduct.

§ 703.11 is amended clarify that matching funds may be certified on a project year basis. Additionally, the consequences for not providing matching certification are expanded to include suspension of reimbursements an advances for project costs. Section 703.11 is further amended to clarify that the project year is the period to use when determining whether a grant recipient appropriately expended matching funds.

§ 703.12 is amended to delete text related to unauthorized expenses. Guidance regarding allowable costs, including a list of unauthorized expenses, is now provided in the new proposed rule Section 703.26.

§ 703.13 is amended to clarify when a single audit determination form is due. The proposed amendment also increases the annual threshold that triggers the grantee's requirement to submit an audit from $500,000 to $750,000 in state award funds. This section is further amended to

include a description of acceptable agreed upon procedures agreement sufficient to fulfill the audit requirement.

§ 703.14 is includes several proposed amendments. The first amendment adds the de-obligation of grant award funds to the title of § 703.14. As reflected in the proposed amendment for new subsection (h), the rule change authorizes the Institute to de-obligate unspent grant award funds when the grant award contract is terminated and make those funds available for any purpose authorized by Texas Health and Safety Code Chapter 102. Section 703.14 is also amended to clarify the process for requesting, considering and approving no-cost extensions. Section 703.14(d) is amended to clarify that the final Financial Status Report is due within 90 days following the end date of the last state fiscal quarter that includes the grant termination date. These proposed amendment distinguishes a final Financial Status Report from other close out documents and clarifies for grant recipients the specific due date of the final Financial Status Report. Section 703.14(e) is amended to clarify that the Institute may make upward or downward adjustments to allowable costs requested for reimbursement up to 90 days following the approval of close out documents or the final Financial Status Report, whichever is later.

§ 703.15 is amended to replace the current title with "Financial Policies Applicable to Grant Awards." The proposed amendment replaces the current text with requirements related to the grant recipient's financial management systems, fiscal controls and accounting procedures.

§ 703.16 is amended to clarify how grant award proceeds may be used to pay for costs associated with commercialization activities. Section 703.16 is further amended to remove text that requires a grant recipient to report at least annually describing commercialization activities for the project results. If a grant recipient has received a product development grant award, the grant recipient is already required to provide this information pursuant to terms of the grant award contract. Deleting subsection (d)(6) makes it clear that other grant recipients are not required to report this information.

§ 703.17 is amended to add a new subsection clarifying that the revenue sharing obligation is continuous so long as the product resulting from the Institute supported project enjoys governmental exclusivity.

§ 703.21 is amended to clarify that grant award monitoring activities are under the direction of the Chief Compliance Officer. Section 703.21(b)(2) is further amended to remove text concerning financial status reports. The deleted text is moved to new rule § 703.24, related to Financial Status Reports. Section 703.21(b)(3)(E) is amended to remove the grant manager as the reviewer of progress reports.

§ 703.23 is a proposed new rule concerning disbursement of grant award funds. The new rule incorporates text that has been moved from § 703.19 (advance payment of grant funds) and clarifies Institute practices concerning reimbursement and advancement of grant funds. The new rule provides limits on the amount of award funds that may be advanced and guidance regarding expending award funds prior to seeking additional advances. The rule makes it clear that the Institute maintains the right to limit or restrict advance funds and may disburse the last 10% of

total award funds using reimbursement instead of advancement. The proposed rule also provides guidance related to disbursing grant funds as a reimbursement for expenses already incurred.

§ 703.24 is a proposed new rule related to a financial status report (FSR). The proposed rule incorporates text that has been moved from § 703.21(b)(1) and (2) as well as clarifies requirements for preparing and submitting FSRs, including deadlines and the waiver appeals process.

§ 703.25 is a proposed new rule related to grant award budgets. The proposed rule addresses appropriate budget categories, budget transfers, and carry forwards of unspent budget funds during a project year.

§ 703.26 is a proposed new rule concerning allowable costs and incorporates text that has been moved from § 703.12. The proposed new rule defines an allowable costs and lists examples of expenses that the Institute considers unallowable costs. The rule clarifies that an allowable costs must be incurred during the contract term, unless a grant recipient has received written approval from the Institute's Chief Executive Officer. The Institute makes it clear that the Institute's decision regarding whether an expense is allowable is final.

Summary of Public Comments and Staff Recommendation

CPRIT received one comment from the public regarding the proposed rule changes. Kimberly Turner, Chief Audit Executive with the Texas Tech University System, indicated that Texas Tech agrees with the proposed rule changes but noted that a reference in § 703.13 to OMB Circular A-133 has been superseded. Ms. Turner suggested an updated reference to "Uniform Administrative Requirements, Cost Principles and Audit Requirements for Federal Awards, Subpart F." CPRIT supports the suggested change; however, the proposed change may be outside of the scope of this rulemaking. CPRIT declines to make the change at this time and will instead address the change in a future rulemaking project.

The rule changes are adopted under the authority of the Texas Health and Safety Code Annotated, §§ 102.108 and 102.251, which provides the Institute with broad rule-making authority to administer the chapter, including rules for awarding grants.

Certification

The Institute hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

To be filed with the Office of Secretary of State on November 18, 2016.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

To:	**OVERSIGHT COMMITTEE MEMBERS**
From:	**KRISTEN PAULING DOYLE, GENERAL COUNSEL** **CAMERON L. ECKEL, STAFF ATTORNEY**
Subject:	**PROPOSED CHAPTER 703 RULE CHANGES**
Date:	**NOVEMBER 8, 2016**

Summary

CPRIT staff recommends that the Oversight Committee approve the publication in the *Texas Register* of two proposed changes to CPRIT's administrative rules in Chapter 703. The proposed changes, including any revisions suggested during the public comment period, will be brought to the Oversight Committee in February for final approval.

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 establishes policies guiding CPRIT's grant review, grant contracting, and grant monitoring processes through CPRIT's administrative rules. CPRIT staff proposes the following changes to the agency's administrative rules for the Oversight Committee's consideration:

- § 703.13(e)(4) – The proposed amendment replaces a reference to OMB Circular A-133 that has been superseded. The amendment reflects the updated reference.

- § 703.25(f)(1) – The proposed amendment corrects a previous rule change that inadvertently altered current practice with regard to the carry forward of unspent grant funds from one budget year to the next. CPRIT currently allows grantees to carry forward automatically unspent funds from one budget year to the next budget year, so long as the amount to be carried forward in each budget line item does not amount to 25% or more of the total line item amount budgeted for that year. The grantee must provide justification if the amount to be carried forward is 25% or more, which CPRIT must approve. The rule as proposed in August lowered the permissible carry forward amount the grantee must justify to 10% of the total grant amount. CPRIT does not intend to alter current practice. The proposed change provides clarity and aligns the

administrative rule with existing processes. CPRIT does not expect the proposed change, which re-establishes present practices, to be controversial.

The Board Governance Subcommittee met on October 31 to review the proposed amendments and recommends that the Oversight Committee approve publication.

Next Steps

Once approved by the Oversight Committee, the proposed rule changes will be published in the *Texas Register* and be available through CPRIT's website. The public may provide input via written comments for at least 30 days from the time that the changes are available in the *Texas Register*. Any comments on the proposed rules will be summarized and provided to the Oversight Committee for consideration before the rules are formally adopted at the February meeting.

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 § 703.13(e) regarding guidance for government auditing standards and to § 703.25 regarding approval of a grantee's request to carry forward unspent project year funds into the following project year.

Background and Justification

The proposed amendment to § 703.13(e)(4) replaces a reference to OMB Circular A-133 that has been superseded. The change clarifies guidance for government auditing standards. The proposed amendment to § 703.25 clarifies that a request to carry forward unspent grant funds from one project year to the next requires Institute approval if the amount of the unexpended budget line item balance is 25% or more of the line item amount for the year. Section 703.25 already allows grantees to requests a carry forward of unspent funds. This change aligns § 703.25 with the Institute's current practice. All other requirements regarding carry forward requests remain the same in § 703.25.

Fiscal Note

Kristen Pauling Doyle, 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 as a result of enforcing or administering the rules.

Public Benefit and Costs

Ms. Doyle has determined that for each year of the first five years the rule changes are in effect the public benefit anticipated as a result of enforcing the rules will be clarification of policies and procedures the Institute will follow to implement its statutory duties.

Small Business and Micro-business Impact Analysis

Ms. Doyle has determined that the rule changes shall not have an effect on small businesses or on micro businesses.

Written comments on the proposed rule changes may be submitted 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 23, 2017. Parties filing comments are asked to indicate whether or not they support the rule revisions 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 rule changes are proposed under the authority of the Texas Health and Safety Code Annotated, §§ 102.108 and 102.251, which provide the Institute with broad rule-making authority to administer the chapter and to issue rules regarding the procedures for awarding grants. Kristen Pauling Doyle, the Institute's General Counsel, has reviewed the proposed amendments and certifies the proposal to be within the Institute's authority to adopt.

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

RULE § 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 end of the Grant Recipient's fiscal year during which the Grant Contract was terminated.

(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 ~~Circular A-133 audits~~ 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.

RULE § 703.25 Grant Award Budget

(a) The Grant Contract shall include an Approved Budget that reflects the amount of the Grant Award funds to be spent for each Project Year.

(b) All expenses charged to a Grant Award must be budgeted and reported in the appropriate budget category.

(c) Actual expenditures under each category should not exceed budgeted amounts authorized by the Grant Contract as reflected on the Approved Budget for each Grant Award.

(d) Recipients may make transfers between or among lines within budget categories listed on the Approved Budget so long as the transfer fits within the scope of the Grant Contract and the total Approved Budget; is beneficial to the achievement of project objectives; and is an efficient, effective use of Grant Award funds.

(e) All budget changes or transfers require Institute approval, except that the Grant Recipient may make budget changes or transfers without prior approval from the Institute for expenses not specified in the equipment category if:

(1) The total dollar amount of all changes of any single line item (individually and in the aggregate) within budget categories other than equipment is not more than 10% of the amount in that line item;

(2) The transfer will not increase or decrease the total grant budget; and

(3) The transfer will not materially change the nature, performance level, or scope of the project.

(f) A Grant Recipient awarded a Grant Award for a multiyear project that fails to expend the total Project Year budget may carry forward the unexpended budget balance to the next Project Year.

(1) If the amount of the unexpended ~~budget~~ balance for a budget line item in a Project Year exceeds ~~ten~~ twenty-five percent ~~(10%)~~ (25%) or more of the total ~~Grant Award~~ budget line item amount for that year, ~~the~~ Institute ~~must approve~~ approval is required before the Grant Recipient may ~~the~~ carry forward the unexpended balance to the next Project Year.

(2) For a budget carry forward requiring Institute approval, the Grant Recipient must provide justification for why the total Grant Award amount should not be reduced by the unexpended balance.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	KRISTEN DOYLE, GENERAL COUNSEL
SUBJECT:	UPDATE - ROYALTY/EQUITY MONITORING AND MANAGEMENT PROJECT
DATE:	NOVEMBER 9, 2016

Summary

All CPRIT grantees are contractually obligated to share with the state a portion of the revenue resulting from a CPRIT-funded project. It may be several years before a product resulting from a CPRIT-funded project reaches the market and generates revenue. CPRIT's revenue sharing obligation generally takes the form of royalty payments, but equity ownership is also an option. Given the long drug development life cycle, CPRIT needs a comprehensive system to track grantees' royalty and equity commitments. CPRIT does not have the resources or personnel to implement a long-term monitoring system or actively manage equity assets. The Texas Treasury Safekeeping Trust Company (Trust Company), which is part of the Comptroller's Office, provides these services for other assets owned by the state. Staff is exploring options for the Trust Company to construct a comprehensive database of potential royalty and equity ownership interests. The Trust Company may also be able to manage assets generated by CPRIT-funded projects. Reassigning management responsibilities, including the authority to sell royalty/equity assets, will require a statutory change. Staff anticipates legislation will be filed in the upcoming session to authorize the transfer of management responsibilities.

Background

CPRIT's statute requires CPRIT grantees to share with the state a portion of the proceeds generated by the grant projects. The revenue sharing agreement should balance the state's opportunity to benefit monetarily from a CPRIT-funded project while avoiding onerous terms that restrict or stop further project development. Every CPRIT grant contract includes revenue sharing terms intended to provide a fair and reasonable yield on the state's investment by taking into account its statutory public mission to accelerate development of cancer treatments and cures and stimulate company formation and job growth in Texas.

CPRIT grantees have paid the state $3,135,203 in revenue sharing payments as of September 30, 2016. CPRIT's grant investments have overwhelmingly been in research that will lead to cancer therapeutics. Long development cycles and high attrition rates characterize drug development, with large returns for the few projects that successfully navigate the regulatory process. A smaller portion of CPRIT's grant investments have been in cancer tools or diagnostics. While

tools and diagnostics generally have a faster path to market and revenue, these do not typically realize similarly large returns like cancer therapeutics.

Tracking Royalty/Equity Interests Created by CPRIT Projects

CPRIT currently relies upon a self-reporting system for grantee royalty payments. Grantees provide information about any revenue generated by CPRIT-funded projects as part of the required annual progress reporting process. CPRIT's compliance program confirms the revenue sharing information when it performs on-site grantee reviews.

As CPRIT-funded projects move further through the regulatory and development process over the next several years we expect more intellectual property to be licensed and products to reach the market. Given the long drug development life cycle, grantees will pay the largest portion of revenue sharing obligations after CPRIT's statutory end, currently set for August 31, 2021. In addition to the long development cycle, there are several issues inherent to bioscience investments that make the process of monitoring revenue sharing agreements more difficult. Another company or multiple companies may buy the CPRIT-funded company or the underlying drug license before the project makes money. Distribution partnerships and royalty stacking agreements add another layer of complexity. CPRIT-funded projects may create derivative technologies and compounds that create a revenue stream; these will need to be identified and tracked.

An ongoing monitoring system to track CPRIT's grant investments is necessary to ensure that grantees are fulfilling their contractual obligations and to protect potential state assets. The tracking system should monitor CPRIT-funded projects at both academic institutions and public/private companies.

Managing and Disposing of CPRIT's Royalty/Equity Assets

CPRIT investments have generated asset holdings with potentially significant monetary value. Most CPRIT investments have royalty-based return; however, CPRIT also holds equity in three companies. The Oversight Committee is responsible for management decisions regarding royalty streams and equity ownership resulting from CPRIT funded grants. CPRIT does not have the resources or personnel to actively manage royalty and equity assets. Open meeting laws which require public notice and open discussion may also complicate the Oversight Committee's ability to fulfill its fiduciary duties.

Texas Treasury Safekeeping Trust Company

The leadership teams for CPRIT and Texas Treasury Safekeeping Trust Company ("Trust Company") have met several times since August to explore whether the Trust Company can take on the managerial and disposition obligations related to potential assets resulting from CPRIT's revenue sharing agreements. The Trust Company, which operates under the Texas Comptroller, is a special purpose trust company whose mission is to preserve and grow the State's financial resources by competitively managing and investing them in a prudent, ethical, innovative, and

cost-effective manner while focusing on client needs. The Trust Company invests, manages, and oversees over $50 billion in assets. Investments include cash-equivalent funds such as the Texas Treasury Pool and separately managed portfolios for various Texas state agency clients. When the Legislature ended the Emerging Technology Fund (ETF) in 2015, it designated the Trust Company to take over the management and disposition of the state's ownership in more than 80 companies that received ETF awards.

Looking Ahead

CPRIT is exploring an interagency contract with the Trust Company to create a tracking process for cataloguing CPRIT royalty and equity rights. If the Trust Company is unable to provide this service and no other state entity is available, CPRIT may contract with a vendor through our procurement process. Changes to CPRIT's statute will be necessary to give the Trust Company final authority (as opposed to the Oversight Committee) to sell royalty/equity assets created by CPRIT funding. We are discussing these issues with legislative staff and anticipate legislation will be filed in the upcoming session to authorize the transfer of management responsibilities.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

To:	**OVERSIGHT COMMITTEE MEMBERS**
From:	**HEIDI MCCONNELL, CHIEF OPERATING OFFICER**
Subject:	**AMENDMENT TO THE FY 2017 GRANT MANAGEMENT SUPPORT SERVICES CONTRACT WITH SRA INTERNATIONAL, INC., A CSRA COMPANY**
Date:	**NOVEMBER 7, 2016**

Recommendation

CPRIT staff recommends that the Oversight Committee approve an amendment to the contract with SRA International, Inc., a CSRA Company (CSRA) in the amount of $1,226,787 for modified services to the contract including:

1) A Service Organization Control (SOC) 2, type 2 report on the grants management platform to assess the system and the suitability of the design of controls;
2) Enhancements to the grants management platform to address functionality such as updating reporting capabilities, adding a workflow reset, adding grantee out of office delegation assignment, and status changes for grants that decline an award or are terminated early;
3) The addition of consensus paragraphs to peer review summary statements for academic and product development research applications;
4) Review and objective assessment of patient advocate peer reviewer applications submitted to CPRIT; and
5) The additional administration of grant application supporting documentation in the grants management system, currently maintained outside the system, in order to produce an automated grant pedigree.

These additional services are necessary to improve efficiency and effectiveness of the grant management processes and address an internal audit finding.

Background

While CPRIT completed a competitive solicitation for these services relatively recently in June 2016, most of these items were not anticipated at the time the request for proposal was developed. One example is that the need for the patient advocate reviewer application assessment did not arise until summer 2016. Similarly, the Chief Scientific Officer had been on board only one month when the request for proposal was finalized in April, so he did not identify the need for a consensus paragraph on peer review summary statements until a few months later after he became more familiar with the peer review documentation. CPRIT staff anticipated that there would most likely be some enhancements to the chosen vendor's grants management system but could not specify those enhancements until a vendor was selected through the competitive process because the enhancements would be related to the chosen vendor's system

The FY 2017 CSRA contract is currently $7,038,659. This amendment would increase the contract by 18%. The contract terms allow the agency to increase the contract up to 25% if necessary.

This contract amendment will also require approval by the LBB.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: KRISTEN DOYLE, GENERAL COUNSEL

SUBJECT: APPROVAL OF OUTSIDE COUNSEL CONTRACTS FOR FY 2017

DATE: NOVEMBER 9, 2016

Recommendation

CPRIT staff recommends approval of outside counsel contracts for FY 2017 for Vinson & Elkins, LLP ($125,000) and Baker Botts, LLP ($125,000). These firms will join Yudell Isidore, PLLC, to provide legal advice and evaluation services regarding the intellectual property and revenue sharing agreements associated with CPRIT grants during FY 2017. The Office of the Attorney General must approve all outside counsel agreements prior to contract execution.

Although CPRIT seeks contract approval for FY 2017, the request for proposals includes an option to renew the three outside counsel contracts for up to four additional one-year periods. The renewal periods, if exercised, will extend the outside counsel contract through August 31, 2020. If CPRIT decides to exercise its option to extend one or more of the contracts, CPRIT staff will seek approval from the Oversight Committee and the Office of the Attorney General at the appropriate time.

Background and Proposal Evaluation

CPRIT relies on outside legal counsel with expertise in intellectual property (IP) to conduct a review of companies' IP estate as part of the due diligence process. The IP due diligence is not a re-review of the grant application but serves as an independent analysis of the IP and associated licenses underlying the company's planned drug, device, diagnostic, technology, or service proposed for CPRIT funding. The Product Development Review Council uses information gained through the IP due diligence process to finalize their grant award recommendations.

CPRIT issued a request for proposals (RFP) for outside counsel services in September. The scope of services sought by CPRIT includes advice regarding all aspects of IP and revenue sharing associated with CPRIT grant award contracts. CPRIT's contract team evaluated the six proposals submitted to the agency in response to the RFP. After a preliminary evaluation by the CPRIT contract team, three firms were invited to interview in person.

Based upon the evaluations and interviews, the CPRIT contract team recommends approving outside counsel contracts with three firms: Vinson & Elkins, LLP; Baker Botts, LLP; and Yudell Isidore, PLLC. CPRIT prefers contracting with multiple firms. The practice allows the agency to

balance the workload and avoid potential conflicts of interest between the firms and the companies under review.

The initial term of each contract covers FY 2017. At CPRIT's sole option, each contract may be renewed for up to four additional one-year periods. The option to extend the contract provides service continuity, particularly when review cycles cross fiscal years. Oversight Committee approval will be sought at the appropriate time if CPRIT elects to extend one or more of these contracts beyond FY 2017. The Office of the Attorney General must also approve outside counsel contracts and contract amendments, including extensions.

The outside counsel contracts are based on an hourly rate. The firms are paid based solely on the number of hours worked; there is no guaranteed minimum payment. The cost of each assessment varies based upon the complexity of the IP information and issues presented, as well as the volume of documents to be reviewed. Generally, the price per IP due diligence company project ranges from $10,000 - $20,000.

Government Code § 669.003 Restriction Not Applicable

Section 669.003 of the Texas Government Code restricts a state agency from entering into a contract with an entity that employs a current or former executive head of a state agency until four years have passed. The agency may overcome the restriction if the agency's governing body votes to approve the contract and the Legislative Budget Board is notified of the terms of the proposed contract. Out of an abundance of caution, Vinson & Elkins, notified CPRIT at the time the firm submitted its proposal that one of its partners, Barry Smitherman, was previously appointed Chairman of the Public Utility Commission of Texas (2004 – 2011) and elected to the Railroad Commission of Texas (2011 – 2014). Mr. Smitherman will not perform any work on the CPRIT contract.

CPRIT appreciates Vinson & Elkins bringing this issue to our attention. It is my legal opinion that the § 669.003 restriction does not apply. The statute defines "executive head of a state agency" to mean the director, executive director, commissioner, administrator, chief clerk, or other individual who is appointed by the state agency's governing body or by another state or local officer to act as the chief executive or administrative officer of the agency. Mr. Smitherman's position as an appointed commissioner at Public Utility Commission (PUC) qualifies as an executive head of a state agency under the statute; however, the four-year restriction has run since he left the PUC in 2011. He was elected to his position at the Railroad Commission, which places Mr. Smitherman outside the statutory definition of executive head.

Yudell Isidore FY 2017 Contract

The Oversight Committee already approved the option to renew CPRIT's existing outside counsel contract with Yudell Isidore through FY 2017 for $150,000 at the August Oversight Committee meeting. Although additional approval is not required for FY 2017 services, information about the Yudell Isidore selection by the Contract Team is included for the record in the event that CPRIT requests contract approval for legal services in FY 2018.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	HEIDI MCCONNELL, CHIEF OPERATING OFFICER
SUBJECT:	CHIEF OPERATING OFFICER REPORT
DATE:	NOVEMBER 7, 2016

CPRIT Financial Overview for FY 2016, Quarter 4

FY 2016, Quarter 4 Operating Budget

For the fourth quarter of FY 2016, CPRIT has expended or encumbered approximately $16.3 million, or 93%, of the agency's $17.7 million administrative budget between the Indirect Administration and Grant Review and Award Operations strategies. This administrative budget includes approximately $208,000 in expenses for the 2015 conference. Otherwise, the primary items of expenditure remain staff salaries and service contracts, particularly the contract with CSRA for pre- and post-award grant management support services.

During this quarter, CPRIT received $870,368 in revenue sharing payments which were deposited into the General Revenue Fund (0001), bringing the total revenue sharing collected for FY 2016 to $921,686. Total revenue sharing payments received since CPRIT's inception through the end of August 2016 were approximately $3.1 million.

FY 2016, Quarter 4 Performance Measures

In October 2016, CPRIT reported performance to the LBB on all five measures that must be reported, including fourth quarter performance for the two output measures with quarterly reporting and the other three with annual reporting. CPRIT met or exceed the targeted performance in four of the five performance measures. CPRIT did not achieve the target for the Number of People Served by Institute Funded Prevention and Control Activities because the grant activities have not changed from year to year and the agency did not anticipate meeting the targeted number doubled from the prior year.

Debt Issuance History

The Texas Public Finance Authority (TPFA) issued $60 million in commercial paper notes on CPRIT's behalf in August 2016 bringing the total commercial paper notes issued for FY 2016 to $147.5 million. In FY 2017, TPFA also issued $58 million in commercial paper notes in October on CPRIT's behalf.

FY 2016 Annual Financial Report

CPRIT completed the FY 2016 Annual Financial Report on November 4, 2016, well ahead of the November 20th deadline and submitted it to the Office of the Comptroller of Public Accounts, Governor's Office, Legislative Budget Board, and State Auditor's Office. The McConnell & Jones LLP audit team, the independent audit firm engaged to perform our annual financial audit, are currently reviewing the documentation related to the FY 2016 AFR. The results of that audit

will be available in early December and will be reported to Audit Subcommittee at a special meeting scheduled for December 13.

Cancer Prevention and Research Institute of Texas
Quarterly Financial Report
As of August 31, 2016

Indirect Administration (B.1.1.)

		2016 Appropriated	2016 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
1001	Salaries and Wages	$ 1,413,921	$ 1,064,491		$ 1,274,218	(209,727)	120%	$ 1,274,218	$ (209,727)
1002	Other Personnel Costs	51,000	51,000		18,894	32,106	37%	18,894	32,106
2001	Professional Fees and Services	1,015,500	947,015		727,969	219,047	77%	727,969	219,047
2003	Consumable Supplies	26,651	26,651		18,513	8,138	69%	18,513	8,138
2004	Utilities	64,921	64,921		29,589	35,332	46%	29,589	35,332
2005	Travel	36,095	36,095		42,623	(6,528)	118%	42,623	(6,528)
2006	Rent-Building	-	18,485		22,374	(3,889)	0%	22,374	(3,889)
2007	Rent-Machine and Other	24,995	24,995		24,537	458	98%	24,537	458
2009	Other Operating Expenses	349,402	689,786		211,985	477,801	31%	211,985	477,801
	Subtotal - Indirect Administration (B.1.1.)	**$ 2,982,485**	**$ 2,923,439**	**0.98%**	**$ 2,370,701**	**$ 552,738**	**81%**	**$ 2,370,701**	**$ 552,738**

Grant Review and Award Operations (A.1.3.)

		2016 Appropriated	2016 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
1001	Salaries and Wages	$ 2,679,624	2,686,966		$ 2,776,413	$ (89,447)	103%	$ 2,776,413	$ (89,447)
1002	Other Personnel Costs	3,726	3,726		65,223	(61,497)	0%	65,223	(61,497)
2001	Professional Fees and Services	11,040,000	11,663,352		10,804,207	859,145	93%	10,804,207	859,145
2003	Consumable Supplies	-	-		-	-	0%	-	-
2005	Travel	42,516	42,516		45,947	(3,431)	108%	45,947	(3,431)
2006	Rent - Building	33,534	33,534		24,673	8,861	74%	24,673	8,861
2007	Rent-Machine and Other	7,763	7,763		1,966	5,797	25%	1,966	5,797
2009	Other Operating Expenses	-	82,300		3,500	78,800	4%	3,500	78,800
	Conference		252,185		231,704	20,481	92%	231,704	20,481
	Subtotal - Grant Operations (A.1.3.)	**$ 13,807,163**	**$ 14,772,342**	**4.94%**	**$ 13,953,633**	**$ 818,709**	**94%**	**$ 13,953,633**	**$ 818,709**

Grants

		2016 Appropriated	2016 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
4000	Grants - Prevention (A.1.2)	$ 28,340,035	$ 28,021,129		$ 13,247,742	$ 14,773,387	47%	$ 13,247,742	$ 14,773,387
4000	Grants - Research (A.1.1.)	251,955,763	$ 253,621,283		189,781,712	$ 63,839,571	75%	189,781,712	63,839,571
	Subtotal - Grants	**$ 280,295,798**	**$ 281,642,412**	**94.09%**	**$ 203,029,454**	**$ 78,612,958**	**72%**	**$ 203,029,454**	**$ 78,612,958**
	Grand Totals	**$ 297,085,446**	**$ 299,338,193**	**100.00%**	**$ 219,353,789**	**$ 79,984,405**	**73%**	**$ 219,353,789**	**$ 79,984,405**

Cancer Prevention and Research Institute of Texas

Cancer Prevention and Research Institute Fund Account - 5136

As of August 31, 2016

	08/01/2016 thru 08/31/2016	AY 16 Year to Date as of 08/31/2016
Beginning Balance : 08/01/2016		**$ 600,506**
Increases:		
(1)	$ -	$ -
(2)	-	
Total Increases	**$ -**	**$ 600,506.00**
Reductions:		
Expenditures - Appropriated	$ -	$ -
	$ -	$ -
	$ -	$ -
Total Reductions	**$ -**	**$ -**
Ending Balance, 08/31/2016		**$ 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, 2016

		08/01/2016 thru 08/31/2016	AY 16 Year to Date as of 08/31/2016
Beginning Balance : 08/01/2016			$ -
Increases:			
(1)	License Plate Revenue Received	$ 1,037.65	$ 13,553.86
	Interest allocation License Plate Revenue	145.81	145.81
Total Increases		**$ 1,183.46**	**$ 13,699.67**
Reductions:			
	Expenditures - Appropriated	$ (3,606.85)	$ (13,699.67)
		-	-
		-	-
Total Reductions		**$ (3,606.85)**	**$ (13,699.67)**
Ending Balance, 08/31/2016			**$ -**

Note:

Cancer Prevention and Research Institute of Texas

Appropriated Receipts - 666

As of August 31, 2016

		08/01/2016 thru 08/31/2016	AY 16 Year to Date as of 08/31/2016
Beginning Balance : 08/01/2016			**$ 62,102.00**
Increases:			
(1)	Product Development Application Fees Received	$ 19,000.00	$ 76,000.00
(2)	Appropriated Receipts applied to payments	$ -	$ -
(3)	Conference Registration Fees	$ 1,050.00	$ 185,930.00
(4)	Conference Registration Fees-Credit Card	$ -	$ 4,153.37
Total Increases		**$ 20,050.00**	**$ 266,083.37**
Reductions:			
	Conference Expenditures - Appropriated	$ -	$ (227,615.51)
	Credit Card Fees Expended		$ (4,153.37)
		$ -	$ -
Total Reductions		**$ -**	**$ (231,768.88)**
Ending Balance, 08/31/2016			**$ 96,416.49**

Cancer Prevention and Research Institute of Texas

General Revenue Fund Account - 0001

As of August 31, 2016

		08/01/2016 thru 08/31/2016	AY 16 Year to Date as of 08/31/2016
Beginning Balance : 08/01/2016			**$ -**
Increases:			
(1)	Revenue Sharing / Royalties	$ 5,150.00	$ 921,686.23
Total Increases		**$ 5,150.00**	**$ 921,686.23**
Reductions:			
	Expenditures - Appropriated	$ -	$ -
	Sweep Account	$ (5,150.00)	$ (921,686.23)
		$ -	$ -
Total Reductions		**$ (5,150.00)**	**$ (921,686.23)**
Ending Balance, 08/31/2016			**$ -**

Note:

Cancer Prevention and Research Institute of Texas
FY 2016, 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	114,072	125,498	150,596	167,690	557,856	69.73%
Number of Entities Relocating to TX for Cancer Research Related Projects	2.00	0.00	0.00	0.00	2.00	2.00	100.00%
Annual Age-adjusted Cancer Mortality Rate	155.3	N/A	N/A	N/A	N/A	152.8	98.39%
Number of Published Articles on CPRIT-Funded Research Projects	450	N/A	N/A	N/A	N/A	1,281	284.67%
Number of New Jobs Created and Maintained	315	N/A	N/A	N/A	N/A	3,835	1217.46%

Variance Explanations

Number of People Served by Institute Funded Prevention and Control Activities
The types of services provided through CPRIT's prevention grants has changed. Grants focus more on individual clinical services or patient education than on mass education activities that reach large numbers of people.
Number of Published Articles on CPRIT
CPRIT used historical experiencee from the grant awards in its portfolio at the time the projection was developed. That portfolio has grown, resulting a larger number of published articles about the results of the grant projects.
Number of New Jobs Created and Maintained
CPRIT used historical experiencee from the grant awards in its portfolio at the time the projection was developed. That portfolio has grown, resulting a larger number of jobs created and maintained by the grantees.

CPRIT Commercial Paper and G.O. Bond Issuance

Fiscal Year	Amount Appropriated	Dated Issued	Amount Issued	Amount Issued for Fiscal Year	Commercial Paper or GO Bond Issuance	Series	Comments	Interest Rate
2010	$ 225,000,000	September 9, 2009	$ 9,100,000		Commercial Paper Notes	Series A, Taxable		
2010		September 9, 2009	$ 3,600,000		Commercial Paper Notes	Series B, Tax-Exempt	Defeased with cash July 2011	
2010		March 12, 2010	$ 63,800,000		Commercial Paper Notes	Series A, Taxable		
2010		August 26, 2010	$ 148,500,000		Commercial Paper Notes	Series A, Taxable		
				$ 225,000,000				
2011	$ 225,000,000	September 7, 2010	$ 11,800,000		Commercial Paper Notes	Series A, Taxable		
2011		August 10, 2011	$ 50,775,000		G.O. Bonds	Taxable Series 2011	Par amount of new money	Fixed Rate Bonds All-In-True Interest Cost 4.0144%
2011		August 10, 2011	$ 232,045,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2011	Par amount of refunding; Refunded $233.2M of GOCP CPRIT Series A (9/9/09, 3/12/09, 8/26/09, 9/7/10)	Fixed Rate Bonds All-In-True Interest Cost 4.0144%
				$ 62,575,000				
2012	$ 300,000,000	September 7, 2011	$ 3,200,000		Commercial Paper Notes	Series A, Taxable		
2012		December 8, 2011	$ 3,200,000		Commercial Paper Notes	Series A, Taxable		
2012		March 2, 2012	$ 12,300,000		Commercial Paper Notes	Series A, Taxable		
2012		June 21, 2012	$ 15,000,000		Commercial Paper Notes	Series A, Taxable		
2012		August 16, 2012	$ 42,000,000		Commercial Paper Notes	Series A, Taxable		
				$ 75,700,000				
2013	$ 300,000,000	September 6, 2012	$ 9,600,000		Commercial Paper Notes	Series A, Taxable		
2013		May 16,2013	$ 13,400,000		Commercial Paper Notes	Series A, Taxable		
				$ 23,000,000				
2014	$ 300,000,000	November 25, 2013	$ 55,200,000		Commercial Paper Notes	Series A, Taxable		
2014		March 13, 2014	$ 47,000,000		Commercial Paper Notes	Series A, Taxable		
2014		June 17, 2014	$ 60,300,000		Commercial Paper Notes	Series A, Taxable		
2014		July 8, 2014	$ 233,280,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2014	Par amount of refunding; Refunded $237.88M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 3.327184%
				$ 162,500,000				
2015	$ 300,000,000	November 5, 2014	$ 57,600,000		Commercial Paper Notes	Series A, Taxable		
2015		April 29, 2014	$ 112,000,000		Commercial Paper Notes	Series A, Taxable		
2015		June 26, 2015	$ 75,000,000		Commercial Paper Notes	Series A, Taxable		
				$ 244,600,000				

CPRIT Commercial Paper and G.O. Bond Issuance

Fiscal Year	Amount Appropriated	Dated Issued	Amount Issued	Amount Issued for Fiscal Year	Commercial Paper or GO Bond Issuance	Series	Comments	Interest Rate
2016	$ 300,000,000	September 22, 2015	$ 55,400,000		Commercial Paper Notes	Series A, Taxable		
2016		October 29, 2015	$ 300,000,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2015C	Par amount of refunding; Refunded $300M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 3.299867%
2016		October 29, 2015	$ 69,800,000		G.O. Bonds	Taxable Series 2015C	Disbursed to CPRIT January 2016	Fixed Rate Bonds All-In-True Interest Cost 3.299867%
2016		May 16, 2016	$ 92,100,000		Commercial Paper Notes	Series A, Taxable		
2016		August 29, 2016	$ 60,000,000		Commercial Paper Notes	Series A, Taxable		
				$ 277,300,000				
2017	$300,000,000	October 19, 2016	$ 58,000,000		Commercial Paper Notes	Series A, Taxable		
				$ 58,000,000				
TOTAL ISSUED TO DATE				**$ 1,128,675,000**				

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	VINCE BURGESS, CHIEF COMPLIANCE OFFICER
SUBJECT:	CHIEF COMPLIANCE OFFICER REPORT
DATE:	NOVEMBER 7, 2016

The Chief Compliance Officer is responsible for apprising the Oversight Committee and the Chief Executive Officer of institutional compliance functions and activities. The required reporting includes quarterly updates to the Oversight Committee on CPRIT's compliance with applicable laws, rules, and agency policies (T.A.C. § 701.7). In addition, the compliance officer will inquire into and monitor the timely submission status of required grant recipient reports and notify 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

A delinquent report is produced by CPRIT's grant management system (CGMS) each week; this is the primary source used by CPRIT's compliance staff to follow up with grantees. CPRIT typically has 550+ grants that are either active or wrapping up grant activities and receives approximately 570 grantee reports each month.

As of the most recent CGMS report (October 31, 2016), 22 required grantee reports from 12 entities have not been filed in the system by the set due date. Of the 22 delinquent reports, 15 (68%) are Academic Research grants, five (23%) are Prevention grants, and two (9%) are Product Development Research grants. In most cases, CPRIT does not disburse grant funds until the required reports are filed. In some instances, grantee institutions may be ineligible to receive a future award if required reports are not submitted. CPRIT's grant compliance specialists and grant accountants continue to review and process incoming reports and reach out to grantees to promptly resolve filing issues.

FSR Reviews

CPRIT's Grant Compliance Specialists performed 418 second level reviews of grantee Financial Status Reports (FSRs) during the months of September and October. Eight FSRs (2%) 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

Twenty-seven desk reviews have been performed so far this fiscal year. Desk-based financial monitoring/reviews are conducted 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, procurement and contracting procedures and practices, current and past fiscal audits, subcontracting monitoring, and timeliness of required grantee report submission. Grant Compliance Specialists are working with fifteen grantees to remediate desk review findings.

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 their 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.

There are currently four grantees with outstanding audit findings. Grantees are given 30 days from the receipt of the audit to submit supporting documentation to demonstrate remediation efforts. Grant Compliance Specialists worked with two grantees to fully remediate audit report findings in October. There are currently no grantees with a delinquent audit report or a delinquent Corrective Action Plan (CAP). Grantees are unable to receive reimbursements or advances if they are delinquent in filing the required audit and corrective action plan, unless a request for additional time was submitted on or before the due date of the required audit and subsequently approved by CPRIT's CEO.

Annual Compliance Attestation (Self-Certification)

Grantees are required to 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 proactively work with grantees towards full compliance prior to a desk review or on-site review. Attestations were sent to grantees on Friday, October 28, 2016, and are due by December 31, 2016.

Training & Support

CPRIT staff conducted a new grantee training for Texas State University in San Marcos on October 6, 2016. In addition to a brief overview of CPRIT's history and mission, the training covered grantee reporting requirements, an overview of the compliance program, and a hands-on navigation of CGMS.

Additionally, CPRIT staff conducted a grantee training webinar on October 12, 2016, with approximately 130 grantee staff in attendance. The webinar focused on administrative rules changes, grantee reporting requirements, compliance program activities, and the grant closeout process. Grantees also had the opportunity to ask questions during the training. This was the third webinar conducted for grantees this calendar year in support of the new 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.

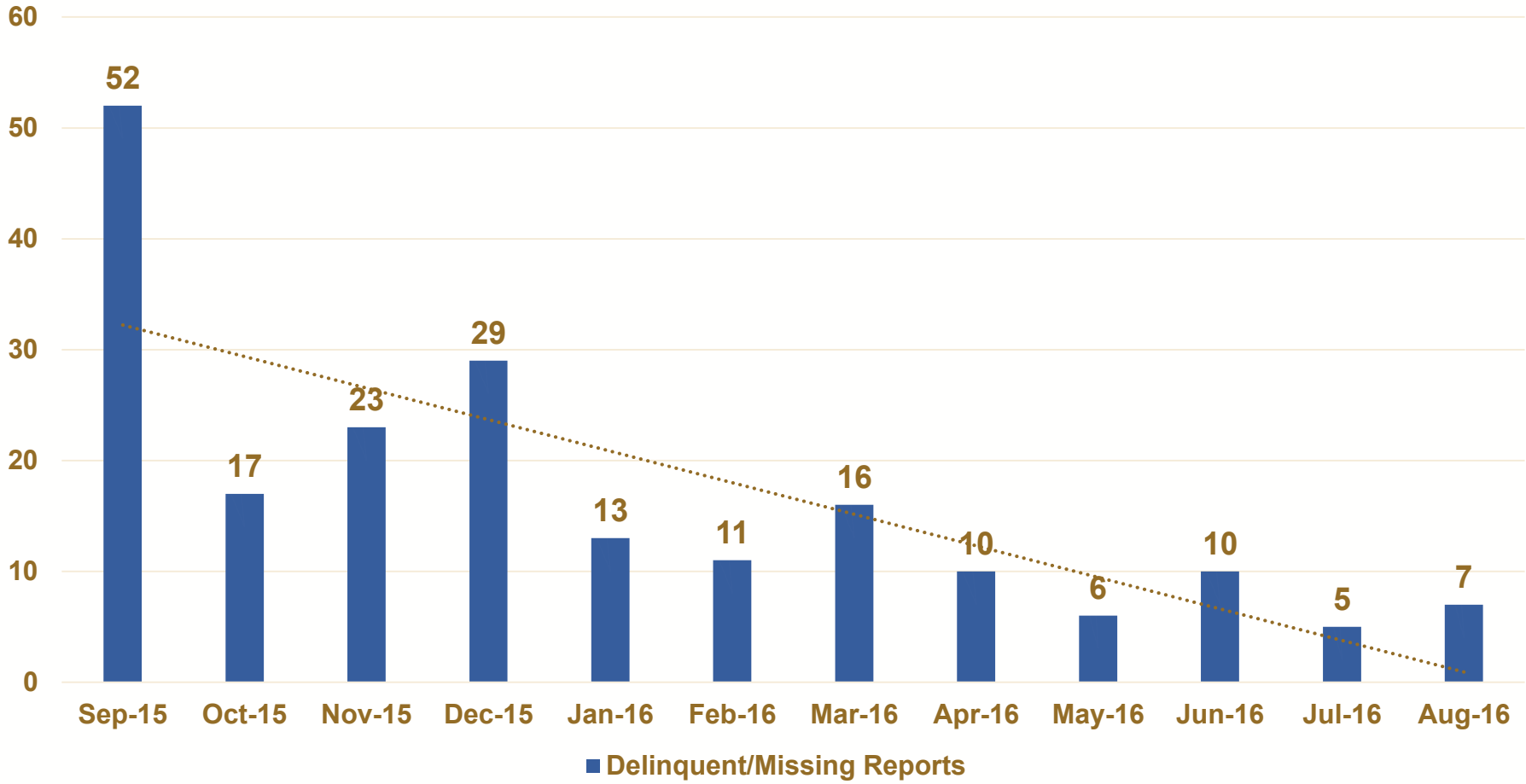
FY16 Compliance Program Activities Summary

During FY16, the Compliance Program worked to strengthen existing compliance functions and to identify additional compliance activities that support the integrity and transparency of CPRIT's agency processes. Some of the highlights from FY16 are:

- **Grant Recipient Report Monitoring** – The number of delinquent reports showed a steady decline throughout FY16. The number of delinquent reports decreased from 52 in September 2015 to 7 in August 2016, an 85% decline in delinquent reporting.
- **Compliance Monitoring Reviews** (Desk and On-site) – The Compliance team performed over 330 compliance reviews (308 desk reviews, 24 on-site reviews) during FY16. This is a substantial increase (over 500%) from the 63 reviews completed in FY15.
- **Training and Education** – In FY16, the Compliance team developed a comprehensive training for new grantees and active grantees. CPRIT staff conducted two training webinars, three new grantee trainings, participated in UT Southwestern Medical Center's Research Demonstration Training Series, and the National Council of University Research Administrator's (NCURA) Region V Meeting, training over 500 grantee staff in all.
- **Second-level Reviews of Financial Status Reports (FSR's)** – The Compliance team performed a second-level review of over 2,400 FSRs.

- **Single Audit Reviews** – The Compliance team reviewed over 50 audit reports and worked with 22 grantees to remediate audit findings.
- **Annual Compliance Attestation** – The Compliance team developed an annual compliance attestation process, reviewed 56 attestations submitted by grantees, and worked with 12 grantees to remediate deficiencies.

Grant Recipient Report Monitoring – FY 2016 Delinquent/Missing Reports



Reports Submitted: Approximately 6,800/Annually, Average 570/Monthly