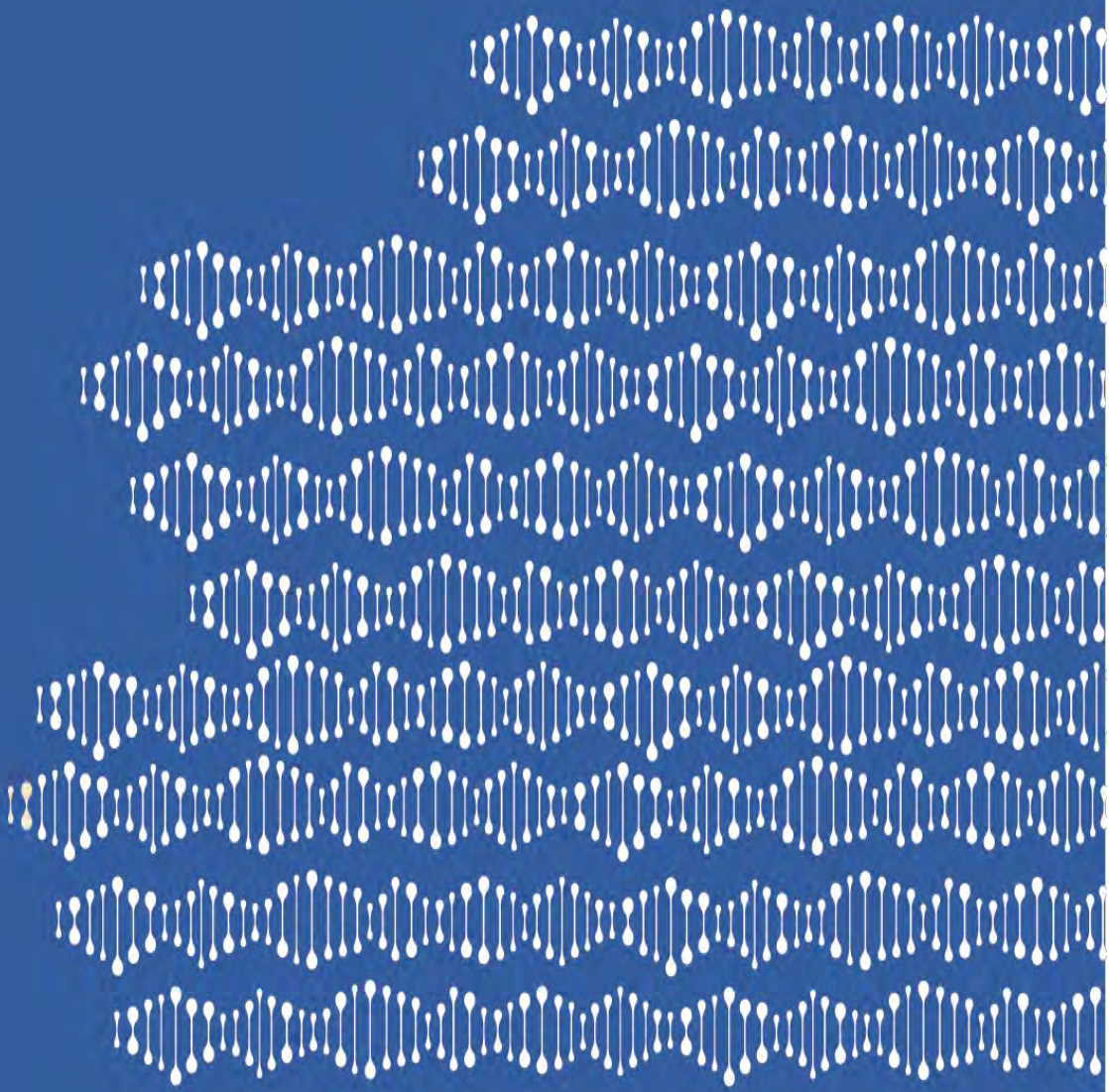
CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Meeting

August 21, 2019



CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

Oversight Committee Meeting Agenda

Texas State Capitol Extension
1100 Congress Avenue, Austin, Texas 78701
Room E1.012

August 21, 2019
9:00 a.m.

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

1. Call to Order
2. Roll Call/Excused Absences
3. Adoption of Minutes from the May 15, 2019 meeting — Tab 1
4. Public Comment
5. Grantee Presentation — Tab 2
6. Chief Executive Officer Report — Tab 3
7. Chief Compliance Officer Report and Compliance Certification of Grant Award Process — Tab 4
8. Chief Scientific Officer Report — Tab 5
   - Grant Award Recommendations
   - Proposed FY 2020 Cycle 2 Requests for Applications
9. Chief Product Development Officer Report — Tab 6
   - Grant Award Recommendations
   - Proposed FY 2020 Cycle 2 Requests for Applications
   - Product Development Review Council Membership
   - DP180042 contract change request
   - DP170043 contract change request
10. Chief Prevention Officer Report — Tab 7
    - Grant Award Recommendations
    - Proposed FY 2020 Cycle 2 Requests for Applications
11. Internal Auditor Report — Tab 8
    - Internal Audit Follow Up Procedures Report Over Procurement and P-Cards
    - FY 2020 Internal Audit Plan
12. Scientific Research and Prevention Program Committee Appointments — Tab 9
13. Advisory Committee Appointments — Tab 10
14. FY 2020 Honoraria Policy — Tab 11
15. Health & Safety Code Section 102.1062 Waivers — Tab 12
16. Resolution Transferring Management Authority to the Texas Treasury Safekeeping Trust Company — Tab 13
17. Amendments to 25 T.A.C. Chapter 703 — Tab 14
    - Final Order Approving Amendments to Chapter 703
    - Proposed Amendments to Chapter 703 and Authorization to Publish in *Texas Register* — Tab 15
18. Chief Operating Officer Report

19. Contract Approvals — Tab 16
    - Economic Assessment of the Cost of Cancer in Texas
    - Internal Auditor
    - Strategic Communications (contract renewal)
    - Due Diligence Services (contract renewal)
    - Grant Management Support Services (contract amendment)
    - Outside Legal Services (contract renewals)
    - Texas Treasury Safekeeping Trust Company Interagency Contract
20. Subcommittee Business — Tab 17
    - FY 2020 – 2021 Subcommittee assignments
21. Personnel - CEO
22. Election of Board Officers — Tab 18
23. Compliance Investigation Pursuant to Health & Safety Code § 102.2631
24. Consultation with General Counsel
25. Future Meeting Dates and Agenda Items — Tab 19
    - FY 2020 Meeting Dates
26. Adjourn

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Summary Overview of the August 21, 2019 Oversight Committee Meeting

This summary provides an overview of major agenda items and background on key issues for Committee consideration at the August 21, 2019 Oversight Committee meeting.

CEO Report
Wayne Roberts will present the CEO's report and address issues including a personnel update, grant funds available for FY 2019 and other topics.

Chief Compliance Officer Report
Vince Burgess will report on the status of required grantee reports, financial status report reviews, desk reviews and site visits, annual compliance attestation, single audit tracking, and training.

Chief Scientific Officer Report and Grant Award Recommendations
Dr. James Willson will provide an update on the Academic Research Program and present the Program Integration Committee's (PIC) 59 award recommendations for Individual Investigator Awards, Core Facility Support Awards, Early Translational Research Awards, High-Impact/High-Risk Research Awards, Collaborative Action Center, Collaborative Action Program Investigated Initiated Research Awards, Recruitment of First-Time, Tenure-Track Faculty Members, Recruitment of Rising Stars, and Recruitment of Established Investigators totaling $100,929,894. Dr. Willson will also present the proposed timeline and requests for applications (RFAs) for the second cycle of FY 2020.

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

Chief Product Development Officer Report and Grant Award Recommendation
Dr. WalkerPeach will provide an update on the Product Development Program. She will also present the PIC's four award recommendations for Texas Company, Texas Relocation Company, and Texas Seed Company Product Development Research Awards totaling $44,562,097. Dr. WalkerPeach will also present the proposed timeline and RFAs for the second cycle of FY 2020 as well as update the Oversight Committee on the proposed expansion of the Product Development Review Council by one member.

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

Chief Prevention and Communications Officer Report and Grant Award Recommendations
Ramona Magid will update the Oversight Committee on the on the agency's prevention activities and present the PIC's ten award recommendations totaling $14,497,981. The recommended awards include Tobacco Control and Lung Cancer Screening; Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations; Evidence-Based Cancer Prevention Services; and Dissemination of CPRIT-Funded Cancer Control Interventions. Ms. Magid will also present the Prevention Program's proposed timeline and RFAs for the second cycle of FY 2020.

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

Internal Auditor Report
Weaver and Tidwell, CPRIT's internal auditor, will provide an internal audit update and present an internal audit report concerning follow-up procedures for p-cards and procurement. Weaver and Tidwell will also present the FY 2020 audit plan.

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

Appointments – Appointments to the Advisory Committees
Mr. Roberts will present new appointments to the Advisory Committee on Clinical Trials and the Product Development Advisory Committee. In addition, Mr. Roberts will update the Oversight Committee on the University Advisory Committee membership.

FY 2020 Honoraria Policy
Mr. Roberts will present CPRIT's FY 2020 honoraria policy for peer reviewers and discuss the proposed honoraria policy changes for each program.

Health & Safety Code § 102.1062 Waivers
Mr. Roberts will present the four conflict of interest waivers pursuant to Texas Health and Safety Code 102.1062. The FY 2020 waivers are for Don Brandy, Dr. John Hellerstedt, Will Montgomery, and the Review Council Members. The Oversight Committee approved similar waivers for these four for FY 2019.

Resolution Transferring Management Authority to the Texas Treasury Safekeeping Trust Company
CPRIT's statute authorizes the agency to transfer asset management to the Texas Treasury Safekeeping Trust Company (Trust Company). CPRIT staff recommends the potential assets

generated by the award contract with AlloVir (formerly ViraCyte) transfer to the Trust Company on or after August 21. The resolution approves transfer of the AlloVir assets and delegates authority to CPRIT's CEO to take all actions necessary to complete the transfer.

Amendments to 25 TAC Chapter 703
Ms. Eckel will present the final order approving amendments to the agency's Chapter 703 administrative rules, which the Oversight Committee provisionally approved at the May meeting. If approved, the amendments will become effective in September.

Ms. Eckel will also present proposed changes to Chapter 703 administrative rules. Legal staff will bring back these rule changes to the Oversight Committee for final approval in November after the public has an opportunity to comment on the proposed rule changes.

Chief Operating Officer Report and Contract Approvals
Heidi McConnell will discuss the operating budget, performance measures, and debt issuance history for the third quarter of FY 2019. She will also present recommendations for contract approvals for the following services: an economic assessment of the cost of cancer in Texas, internal audit, strategic communications due diligence services, grant management support services, outside legal services, and the Texas Treasury Safekeeping Trust Company interagency contract.

Subcommittee Business
The Nominations subcommittee will consider new subcommittee assignments for all members for fiscal year 2020-2021. The Oversight Committee must vote to approve the changes to subcommittee membership. CPRIT will provide the proposed subcommittee assignments to members after the Nominations subcommittee meets August 16.

Election of Board Officers
The Nominations subcommittee will recommend a slate of officers for FY 2020 – FY 2021 for the Oversight Committee's approval at the August meeting. The outgoing Oversight Committee Chair has worked with the Nominations subcommittee to develop the slate of officers. CPRIT will provide the proposed slate to member after the Nominations subcommittee meets August 16.

FY 2020 Meeting Dates
Mr. Roberts will present the proposed dates for the FY 2020 Oversight Committee quarterly meetings and the regular subcommittee meetings for Oversight Committee approval.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Meeting
May 15, 2019

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

Call to Order – Agenda Item 1

A quorum being present, Presiding Officer Will Montgomery called the Oversight Committee to order at 10:00 a.m.

Roll Call/Excused Absences – Agenda Item 2

Committee Members Present	Committee Members Absent
Bill Rice, M.D.	Angelos Angelou
Will Montgomery	
Mahendra Patel, M.D.	
Donald (Dee) Margo	
David Cummings, M.D.	
Craig Rosenfeld, M.D.	

MOTION:
On a motion by Dr. Rice and seconded by Mr. Margo, the Oversight Committee unanimously voted to approve the excused absence of Mr. Angelou.

Adoption of Minutes from the February 21, 2019 Meeting – Agenda Item 3 – Tab 1

MOTION:
On a motion by Mr. Margo and seconded by Dr. Cummings, the Oversight Committee unanimously voted to approve the minutes of the Oversight Committee meeting of February 21, 2019, as presented.

Public Comment – Agenda Item 4

There were no requests to provide public comment.

Chief Executive Officer Report – Agenda Item 5, Tab 2

Chief Executive Officer Wayne Roberts thanked the Texas Higher Education Coordinating Board Commissioner for use of their facilities for CPRIT's recent open meetings. Mr. Roberts introduced new IT department staff. He informed the Oversight Committee regarding the amount of funds

available for awards. Mr. Roberts updated members on the recent legislative approval of important CPRIT legislation, HB 39, HB 2507, and HJR 12.

Chief Compliance Officer Report – Agenda Item 6, Tab 3

Chief Compliance Officer Vince Burgess presented the Compliance Report for the past quarter's activities. He highlighted CPRIT's new enhanced desk review pilot that includes financial and match expenditure testing along with a deeper dive into prior repeat findings.

Mr. Burgess also informed members that the Compliance Program has implemented separate Annual Compliance Training webinars for each of CPRIT's three grant programs. He reported that grantees attending the March 2019 trainings provided positive feedback related to the new format.

Following his compliance report, Mr. Burgess certified that the review process for the Academic Research grant awards recommended for consideration by the Oversight Committee complied with CPRIT's statute and administrative rules.

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

Presiding Officer Montgomery recognized CPRIT Chief Scientific Officer Dr. James Willson. Dr. Willson presented the academic research program update and the 10 recruitment awards totaling $31,562,426 recommended by the CPRIT Scientific Review Council (SRC) and the Program Integration Committee (PIC) for the FY2019 recruitment cycles 19.7, 19.8 and 19.9. (Proposed Grant Award booklet, pages 7-16) He reported that one application, RR190038, withdrew application after the SRC meeting but prior to PIC meeting.

Academic Research Recruitment Slate

Rank	App ID	Candidate	Mechanism	Organization	Budget	Overall Score
1	RR190034	Samuel K. McBrayer, Ph.D.	Recruitment of First-Time, Tenure-Track Faculty Members	The University of Texas Southwestern Medical Center	$2,000,000	1.0
2	RR190059	Chengcheng Jin, Ph.D.	Recruitment of First-Time, Tenure-Track Faculty Members	The University of Texas Southwestern Medical Center	$2,000,000	1.0
3	RR190046	Yang Gao, Ph.D.	Recruitment of First-Time, Tenure-Track Faculty Members	Rice University	$2,000,000	1.0
4	*RR190038	Feng Yue, Ph.D.	Recruitment of Rising Stars	The University of Texas M. D. Anderson Cancer Center	$4,000,000	1.2
5	RR190052	Xiaojing J Gao, Ph.D.	Recruitment of First-Time,	Rice University	$2,000,000	1.6

			Tenure-Track Faculty Members			
6	RR190037	Suzanne D. Conzen, M.D.	Recruitment of Established Investigators	The University of Texas Southwestern Medical Center	$6,000,000	1.8
7	RR190054	Anthony M Mustoe, Ph.D.	Recruitment of First-Time, Tenure-Track Faculty Members	Baylor College of Medicine	$2,000,000	2.0
8	RR190056	Kevin J McHugh, Ph.D.	Recruitment of First-Time, Tenure-Track Faculty Members	Rice University	$2,000,000	2.0
9	RR190043	Yong Li, Ph.D.	Recruitment of Established Investigators	Baylor College of Medicine	$6,000,000	2.0
10	RR190058	Qing Zhang, Ph.D.	Recruitment of Rising Stars	The University of Texas Southwestern Medical Center	$4,000,000	2.0
11	RR190050	Christina Dieli-Conwright, Ph.D.	Recruitment of Rising Stars	The University of Texas M. D. Anderson Cancer Center	$3,562,426	2.6

*Note: #RR190038 withdrew application after SRC meeting but prior to Program Integration Committee meeting.

An Oversight Committee Member remarked that extraordinary talent continues to come to Texas through the CPRIT's recruitment program.

Conflict of Interest Notifications

Presiding Officer Montgomery informed members of his conflict of interest with all the proposed awards and requested that Vice Presiding Officer Dee Margo preside over the vote and discussion of the proposed awards.

Approval Process – Research Awards

The Oversight Committee agreed to take up the 10 award recommendations together in one vote, Vice Presiding Officer Margo called for a vote on consideration of the award recommendations.

MOTION:
On a motion made by Dr. Rice and seconded by Dr. Cummings, all Oversight Committee members present and able to vote approved the PIC's recommendations for the Recruitment of Established Investigators, Rising Stars and Recruitment of First-Time, Tenure-Track Faculty Members.

MOTION:
On a motion made by Dr. Rice and seconded by Dr. Rosenfeld, all Oversight Committee members present and able to vote approved the delegation of contract negotiation authority to CPRIT's CEO and staff and authorized the CEO to sign the contracts on behalf of CPRIT.

Presiding Officer Montgomery did not discuss or vote on any of the grant applications.

Following the vote, Dr. Willson referred the members to pages 4.11 and 4.12 of the meeting book and provided an overview of the current review cycles. He presented the proposed recruitment requests for FY20.1 applications (RFAs), as displayed on page 4.13 of the meeting book.

MOTION:
On a motion made by Dr. Rice and seconded by Dr. Patel, the Oversight Committee unanimously voted to approve the FY 2020 RFAs for recruitment awards.

Chief Prevention and Communications Officer Report – Agenda Item 8, Tab 5

Presiding Officer Montgomery recognized Chief Prevention and Communications Officer Dr. Becky Garcia to provide an update on the prevention program. Dr. Garcia presented a comprehensive overview of CPRIT's Prevention Program to date.

In recognition of Dr. Garcia's retirement, Presiding Officer Montgomery recognized her outstanding service to CPRIT and the state of Texas with a resolution from the Oversight Committee members. Mr. Roberts presented Dr. Garcia with a letter of congratulations from Governor and Mrs. Abbott.

Communications Report

Dr. Garcia discussed CPRIT's recent media coverage resulting from legislative developments and upcoming education outreach planning. She attributed the increased press and social media activity to CPRIT's increased collaboration efforts with grantee institutions and CPRIT's new website's digital newsroom.

She updated Committee members on the CPRIT Conference, which CPRIT will hold July 30-31, 2020, at the Austin Convention Center and the Fairmont Hotel. Dr. Garcia reported that Dr. Jim Allison will be the keynote speaker.

In response to an Oversight Committee member's question, Dr. Garcia confirmed that CPRIT sent a "save the date" notice about the conference and Dr. Allison's keynote to CPRIT's email listserve.

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

Presiding Officer Montgomery recognized Chief Product Development Officer Dr. Cindy WalkerPeach to provide an update on the product development program. She presented an overview of the Product Development Program activities from FY 2019 Cycle 1 (19.1) and FY 2019 Cycle 2 (19.2). In addition, Dr. WalkerPeach discussed planned activities for the upcoming FY 2020 Cycle 1 (20.1). She notified the Oversight Committee that one Product Development Review Council

(PDRC) member, Dr. Sandra Silberman, will step down from the PDRC effective May 28. PDRC Chair Dr. Jack Geltosky has recommended that a current CPRIT product development peer reviewer, Dr. Kelly Bolton, take the vacant seat on the PDRC effective June 1.

University Advisory Committee Annual Report – Agenda Item 12, Tab 9

Dr. Willson introduced Dr. Michelle Barton, Chair of the University Advisory Committee (UAC) to present the UAC's 2018 annual report and recommendations to the Oversight Committee and provide an overview of the UACs mission and member representation. Dr. Barton is a Professor in the Department of Epigenetics and Molecular Carcinogenesis and the Colin Powell Chair for Cancer Research at The University of Texas MD Anderson Cancer Center.

As part of her report (Tab 9 in the meeting packet), Dr. Barton noted that CPRIT support played a significant role in the development of NCI Comprehensive Cancer Centers at Baylor College of Medicine and The University of Texas Southwestern Medical Center and that continuation of the Academic Research support will result in additional NCI Comprehensive Cancer Centers in Texas.

In response to a question from an Oversight Committee member about the UAC's recommendation that CPRIT decrease emphasis on Multi-Investigator Research Awards (MIRAs), Dr. Barton responded that while the initial MIRAs supported strong research, grantees did not sustain the projects with new multi-investigator awards, e.g., NCI Program Project Grants or NCI Specialized Programs of Research Excellence.

Scientific Research and Prevention Program Committee Appointments – Item 10, Tab 7

Presiding Officer Montgomery laid out for discussion the Scientific Research and Prevention Program Committee Appointments.

> **MOTION:**
> On a motion made by Dr. Rosenfeld and seconded by Dr. Patel, the Oversight Committee unanimously voted to approve the five Scientific Research and Prevention Program Committee Appointments.

Advisory Committee on Childhood Cancer (ACCC) Appointment – Item 11, Tab 8

Presiding Officer Montgomery laid out for discussion the ACCC appointment.

> **MOTION:**
> On a motion made by Dr. Rosenfeld and seconded by Mr. Margo, the Oversight Committee unanimously voted to approve Dr. Theodore Laetsch's appointment to the Advisory Committee on Childhood Cancer.

Amendments to 25 T.A.C. Chapter 703 – Item 16, Tab 13

Presiding Officer Montgomery laid out for discussion the final order adopting rule changes to the Texas Administrative Code Chapter 703 and CPRIT's request to publish proposed changes to Chapter 703 rules.

MOTION:
On a motion by Dr. Rosenfeld and seconded by Mr. Margo, the Oversight Committee unanimously voted to approve the final order adopting rule changes to the Texas Administrative Code Chapter 703 and to approve the publication of the proposed changes to Chapter 703 in the Texas Register.

Clinical Trials Advisory Committee Annual Report – Agenda Item 12, Tab 10

Dr. Willson introduced Dr. Kent Osborne, Director of the Dan L. Duncan Comprehensive Cancer Center and Professor of Medicine and Molecular and Cellular Biology at Baylor College of Medicine, to present the Clinical Trials Advisory Committee (CTAC) 2018 annual report and recommendations to the Oversight Committee (behind tab 10 in the meeting packet).

In response to a question from an Oversight Committee member on the feasibility of early phase trials being conducted at rural hospitals, Dr. Osborne responded that patients eligible to participate in phase I trials or trials requiring access to Cancer Center technologies would be treated at the cancer center.

In response to a question from an Oversight Committee member regarding the potential to create a centralized Institutional Review Board amongst participating entities for efficiency purposes, Dr. Osborne responded the model will include this feature, but noted it is up to the entities to adopt it.

Product Development Advisory Committee Annual Report – Agenda Item 14, Tab 11

Presiding Officer Montgomery recognized Dr. Jonathan MacQuitty to present the Product Development Advisory Committee report (behind tab 11 in the meeting packet).

Responding to an Oversight Committee member's question about academic centers' interest in commercial development area. Dr. MacQuitty said that there is interest, and that the existing Product Development Seed Award provides funding to these types of early-stage academic startup companies. He noted that academic researchers do not typically have the industry experience necessary to design and execute preclinical development plans, and therefore it is better to create spin-out companies and attract the necessary development and management expertise.

Another member asked whether investors from outside of Texas are willing to invest in Texas-based companies. Dr. MacQuitty replied that there are investors both within and outside Texas that are willing to invest in Texas-based biotech companies.

A member asked Dr. MacQuitty's opinion of the Product Development Program's current application success rate of 9.5% (number of applications vs. funded awards). Dr. MacQuitty responded that the number of companies funded by CPRIT to date is a more appropriate metric. He suggested that enlarging the overall pool of product development awards approved by CPRIT will increase the number of potentially successful therapeutic and diagnostic innovations hitting the market.

A member asked Dr. MacQuitty about whether CPRIT should be thinking about a recruitment program for product development personnel for entities across Texas. Dr. MacQuitty replied that it is a possibility.

Responding to an Oversight Committee member's question about whether CPRIT should consider combining funding with a venture capital group. Dr. MacQuitty said that a dedicated fund with commercial involvement may be worthy of consideration.

An Oversight Committee member inquired whether Dr. MacQuitty recommends that CPRIT have a booth at annual cancer research meetings such as ASCO, ASH and AACR and other relevant conferences for outreach purposes. Dr. MacQuitty responded that the approach may be an advisible way to increase the number of applications.

Internal Auditor Report – Agenda Item 15, Tab 12

Presiding Officer Montgomery recognized CPRIT internal auditor Dan Graves with Weaver and Tidwell to present the summary audit report (beginning on page 12-11 of the meeting book.) He directed the committee to the completed *Internal Audit Follow-Up Procedures Report over Post-Award Grant Contracting and Monitoring* and summarized the status of procurement and P-cards, information security, and communications follow-up procedures reports.

MOTION:
On a motion by Dr. Cummings and seconded by Mr. Margo, the Oversight Committee unanimously voted to approve the *Internal Audit Follow-Up Procedures Report over Post-Award Grant Contracting and Monitoring*.

Chief Operating Officer Report – Agenda Item 17, Tab 14

Chief Operating Officer Heidi McConnell updated Oversight Committee members on CPRIT operations, including the operating budget, CPRIT performance measures, and debt issuance.

Fiscal Year 2020 Bond Issuance Resolution – Agenda Item 18, Tab 15

Ms. McConnell summarized CPRIT's FY2020 bond issuance resolution, which CPRIT will submit to the Texas Public Finance Authority. She expects that the Texas Public Finance Authority will issue approximately $231.3 million in commercial paper notes. Ms. McConnell advised that CPRIT may need to modify the program description should CPRIT receive funding at the $300 million annual amount in the state budget for the 2020-2021 biennium.

MOTION:
On a motion by Dr. Cummings and seconded by Dr. Rice, the Oversight Committee unanimously voted to approve the resolution to request the Texas Public Finance Authority to issue debt on CPRIT's behalf in fiscal year 2020.

Contract Approvals – Agenda Item 19, Tab 16

Ms. McConnell presented three contract actions for Oversight Committee consideration and approval: an amendment to the due diligence evaluation contract with ICON, a renewal of the grant management support services contract renewal with SRA International, Inc. (a CSRA Company), and a catering contract with Austin Convention Center Catering (for the CPRIT 2020 conference.)

MOTION:
On a motion by Mr. Margo and seconded by Dr. Rice, the Oversight Committee unanimously voted to approve the contract amendment with ICON, the contract renewal with SRA International, Inc. (a CSRA Company), and a contract with Austin Convention Center Catering.

Subcommittee Business – Agenda Item 20

Not taken up.

Compliance Investigation Pursuant to Health & Safety Code 102.2631 – Agenda Item 21

Not taken up.

Consultation with General Counsel – Agenda Item 22

Not taken up.

Future Meeting Dates and Agenda Items – Agenda Item 23

Presiding Officer Montgomery reminded members that the Oversight Committee will meet August 21 at the Texas Capitol.

Adjourn – Agenda Item 24

MOTION:
There being no further business, the Oversight Committee unanimously approved a motion to adjourn made by Dr. Cummings and seconded Dr. Angelou.

Meeting adjourned at 12:32 p.m.

_____ _____

Signature Date

Funda Meric-Bernstam, M.D.

Department Chair, Department of Investigational Cancer Therapeutics, The University of Texas MD Anderson Cancer Center, Houston, TX

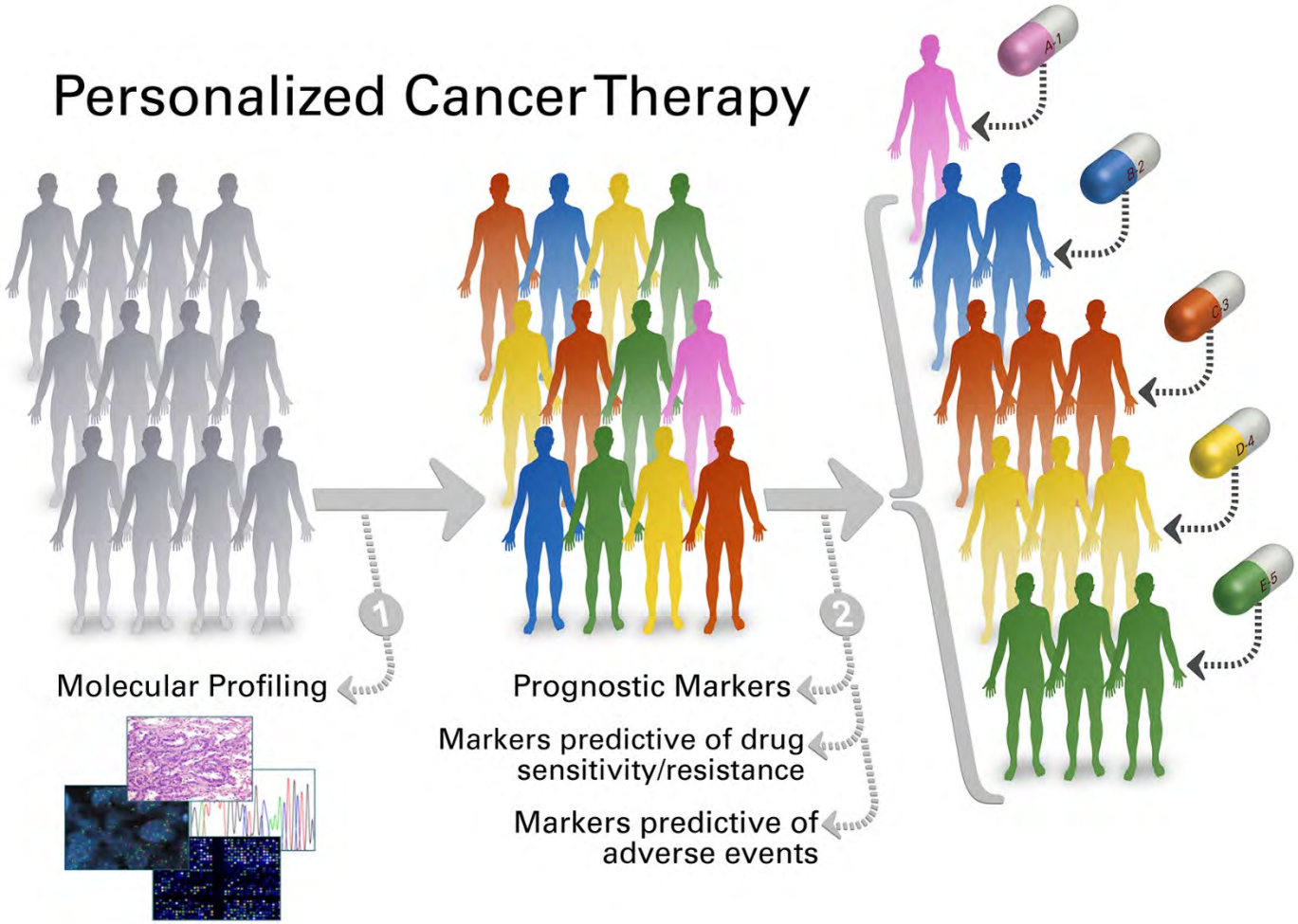
Funda Meric-Bernstam is the Chair of the Department of Investigational Cancer Therapeutics -- the Phase I Program at MD Anderson Cancer Center, the Medical Director of the Institute for Personalized Cancer Therapy (IPCT), and The Nellie B. Connally Chair in Breast Cancer at MD Anderson Cancer Center. Dr. Meric-Bernstam has a basic and translational research program that is focused on molecular therapeutics to delineate the mechanism of action of each agent targeting this pathway and the molecular alterations useful to prospectively identify patients who will benefit most from each agent, and optimal combination therapies. Her clinical research is focused on Phase I /II trials with focus on novel mechanisms of action, novel combination therapies and biomarkers to predict and monitor drug response. As the Medical Director of the Institute for Personalized Cancer Therapy at MD Anderson, she has not only led large efforts of genomic testing within the institution, but has a) helped build a framework for rapid assessment of actionability of genomic alterations; b) established a Precision Oncology Decision Support Team who can provide point of care input for actionability; c) launched the public website "http://www.personalizedcancertherapy.org" providing access to expert curation of information on therapeutic relevance of specific genes/variants; d) created databases and clinical trial alert systems to facilitate accrual to genotype-selected trials across the institution; and e) monitors trial enrollment after genomic testing to identify approaches to obstacles to trial enrollment.

Precision Oncology Decision Support Core

Getting to the Right Patient, with the Right Drug at the Right Time

Funda Meric-Bernstam, M.D.

Chair, Department of Investigational Cancer Therapeutics (Phase I Program)
Medical Director, Sheikh Khalifa Ben Zayed Al Nahyan Institute for Personalized Cancer Therapy
The University of Texas MD Anderson Cancer Center

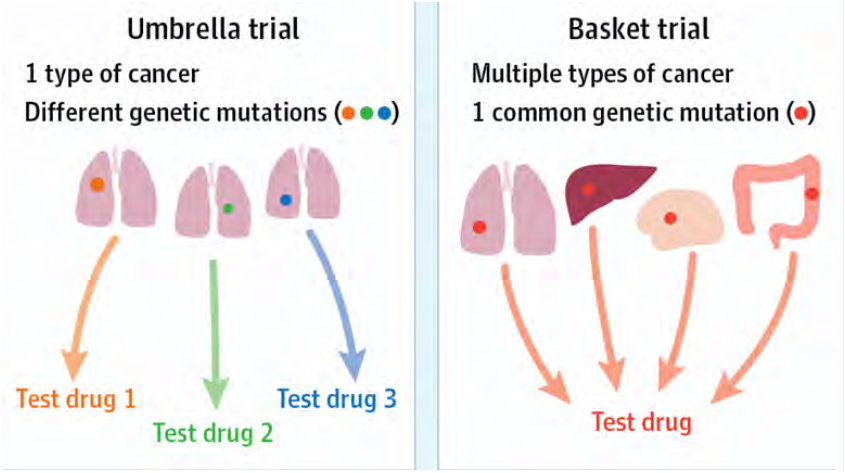


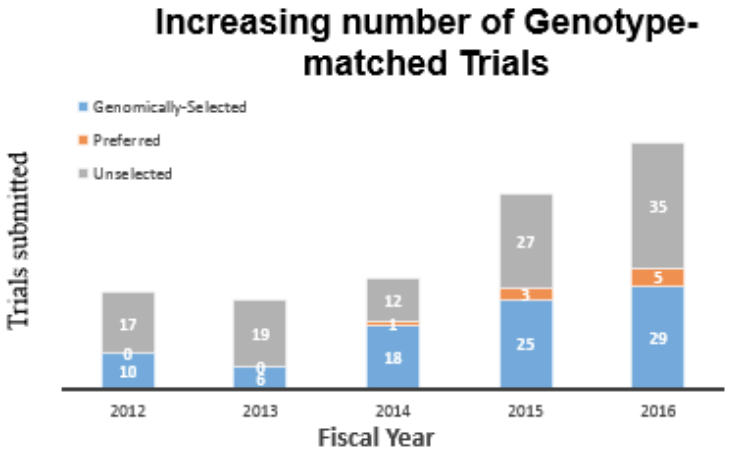
Personalizedcancertherapy.org

Genomically Informed Targeted Therapy

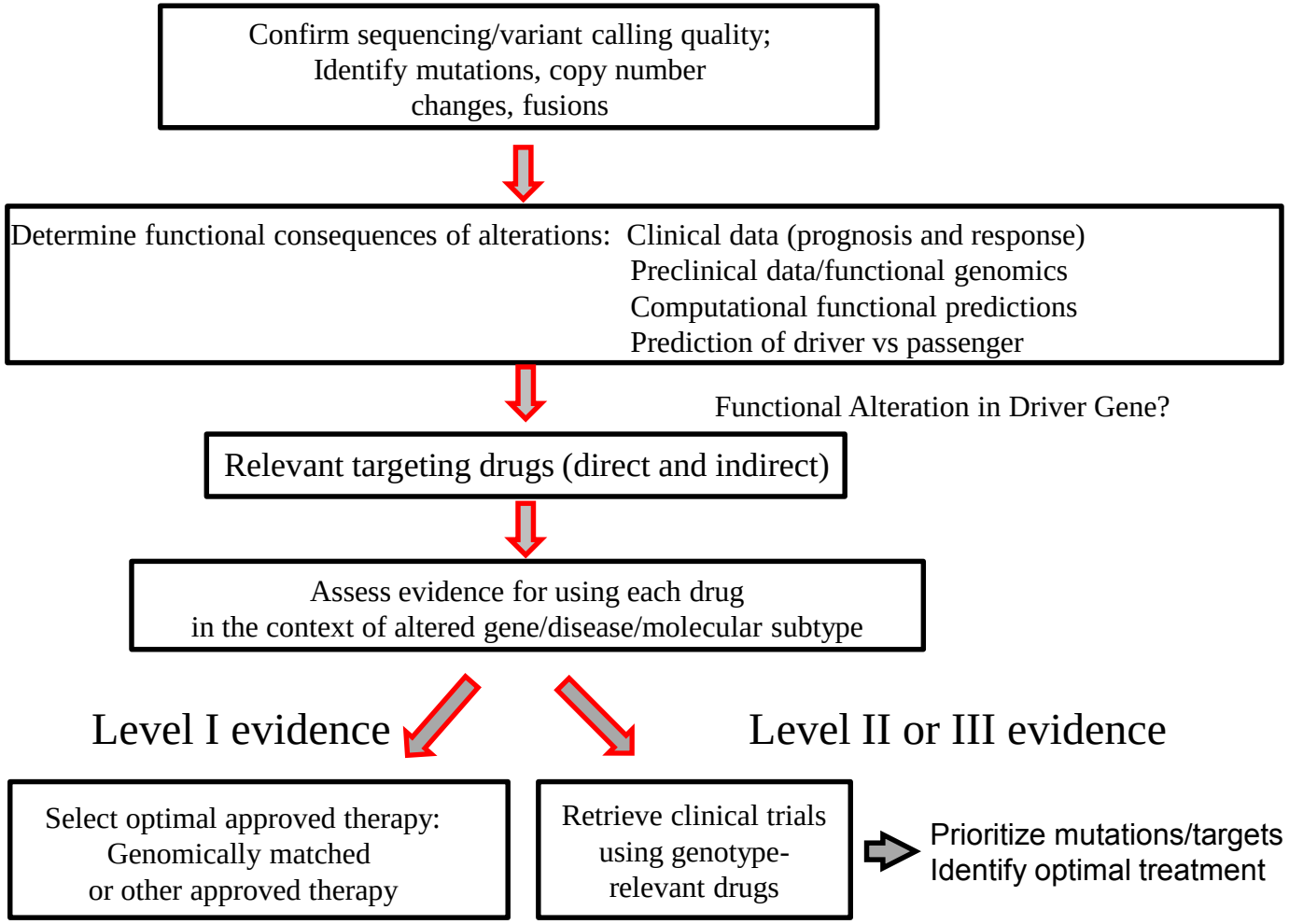
- Identifying genomic alterations that are
  - Drivers of tumor growth and progression
  - Targetable directly or indirectly with approved or investigational agents
- Mutations
  - Somatic and germline
  - SNVs and indels
- Copy number changes
  - Amplifications/deletions
- Fusions

Increasing Number of Genomically Informed Trials





West, JAMA Oncology, 2017



Meric-Bernstam, *JNCI* 2015

Need for Medical Decision Support

PODS Core
Goals & Objectives

Goal: The overarching goal of the proposed Core is to deliver high quality, comprehensive clinical research support for patients undergoing molecular testing for consideration of entry onto targeted therapeutic trials across the state of Texas.

Objective 1: To develop, maintain and assess the utility of a comprehensive knowledgebase that annotates all somatic variants seen at MD Anderson

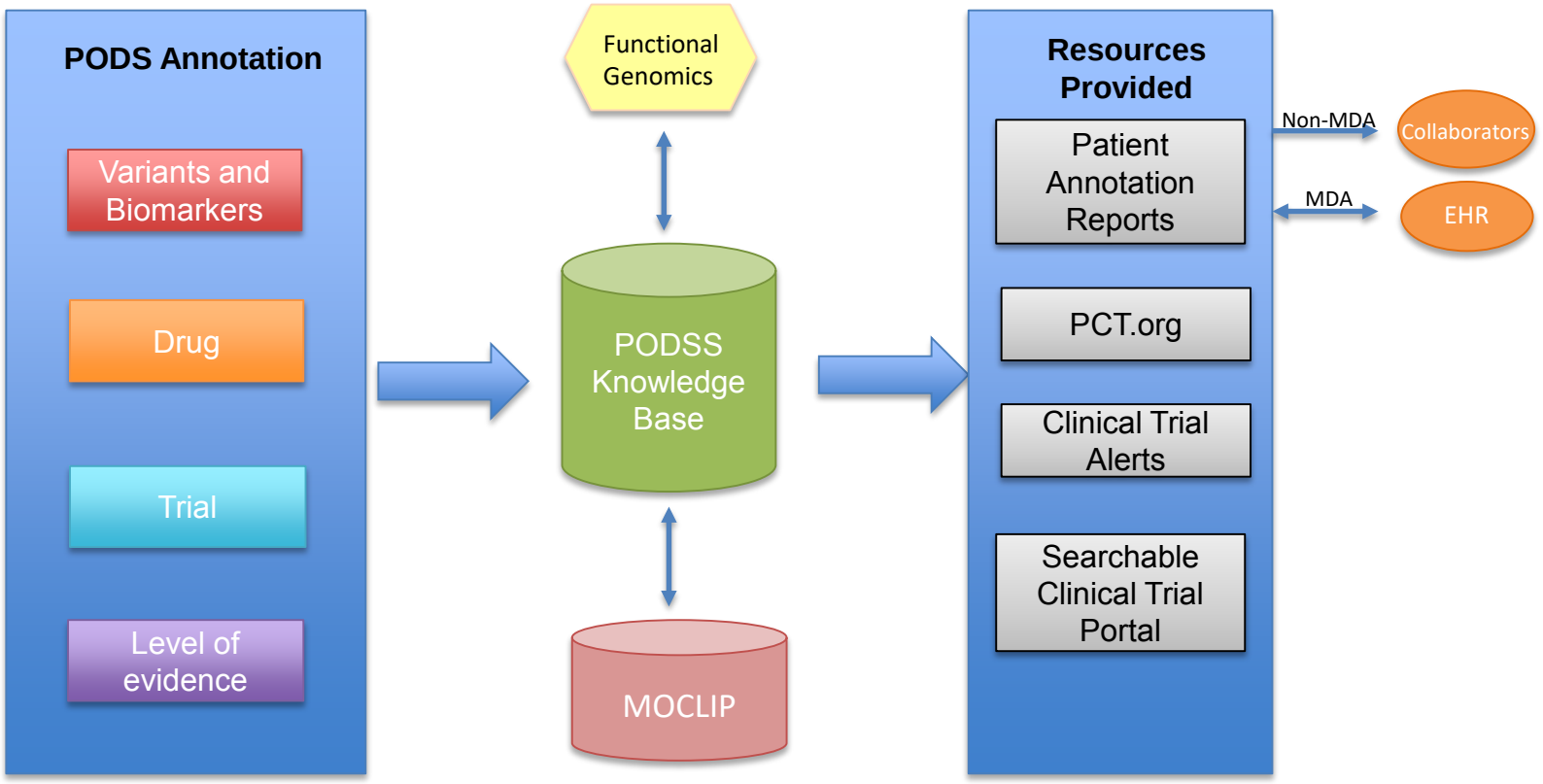
Objective 2: To develop, maintain and assess the utility of a comprehensive clinical trial database that annotates all genotype-selected and genotype-relevant trials available in the state of Texas and throughout the United States

Objective 3: To develop and assess utility of a pipeline for delivery of molecular annotation reports and clinical trial alerts on a per-patient basis

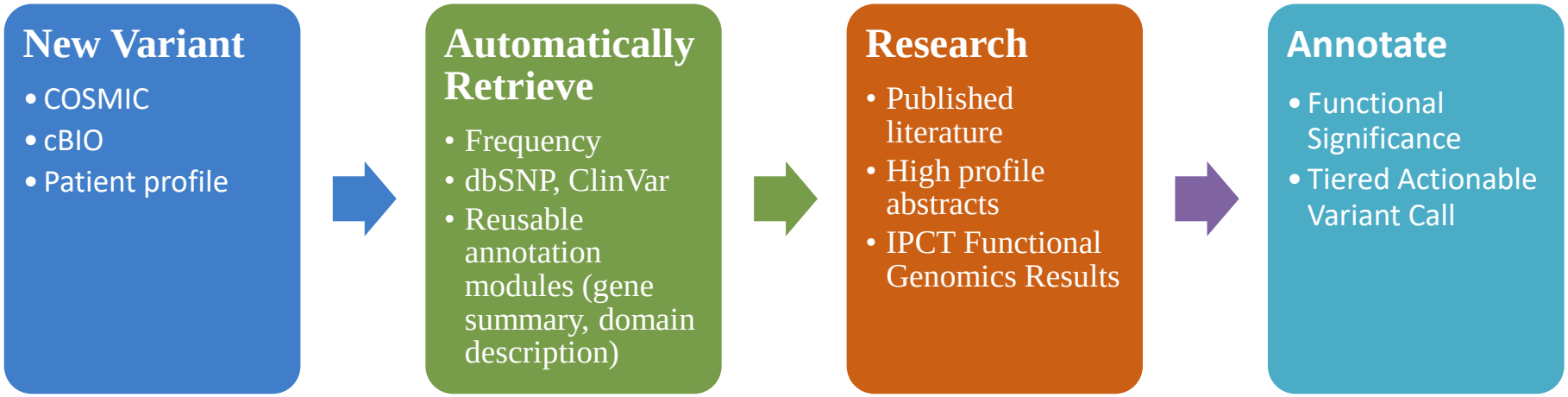
Objective 4: To integrate tumor-specific, multi-omic and additional clinical data to the knowledgebase

Objective 5: To perform experimental functional characterization of variants of unknown significance (VUSs)

Precision Oncology Decision Support Core: Annotation and Dissemination of Knowledge



PODS Variant Annotation Pipeline



Alteration Knowledge Base Stats

Annotated Alterations	11,264
Actionable Alterations	4,950

PODS Core
Goals & Objectives

Goal: The overarching goal of the proposed Core is to deliver high quality, comprehensive clinical research support for patients undergoing molecular testing for consideration of entry onto targeted therapeutic trials across the state of Texas.

Objective 1: To develop, maintain and assess the utility of a comprehensive knowledgebase that annotates all somatic variants seen at MD Anderson

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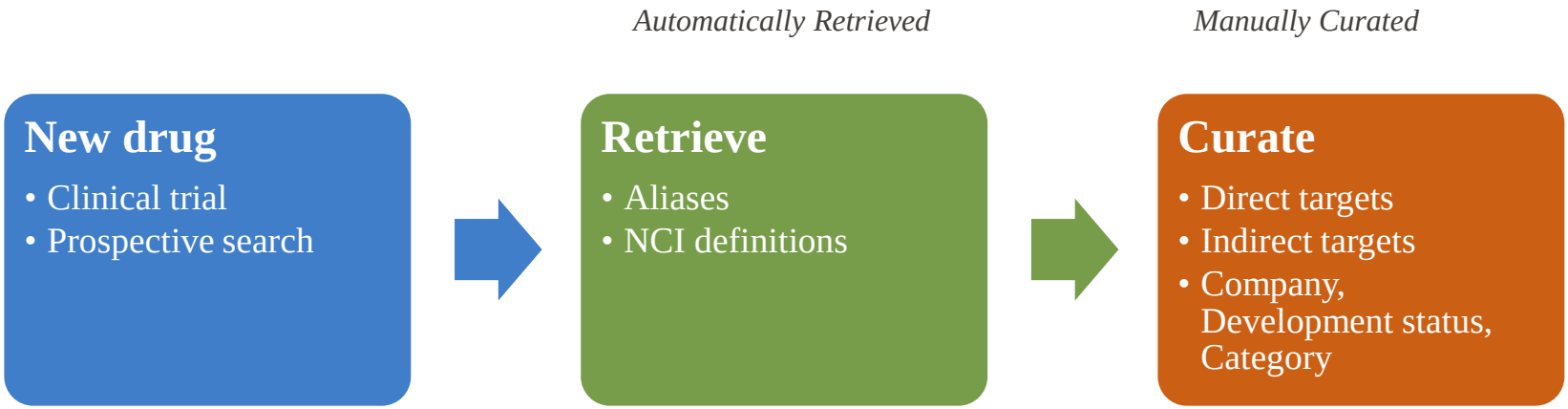
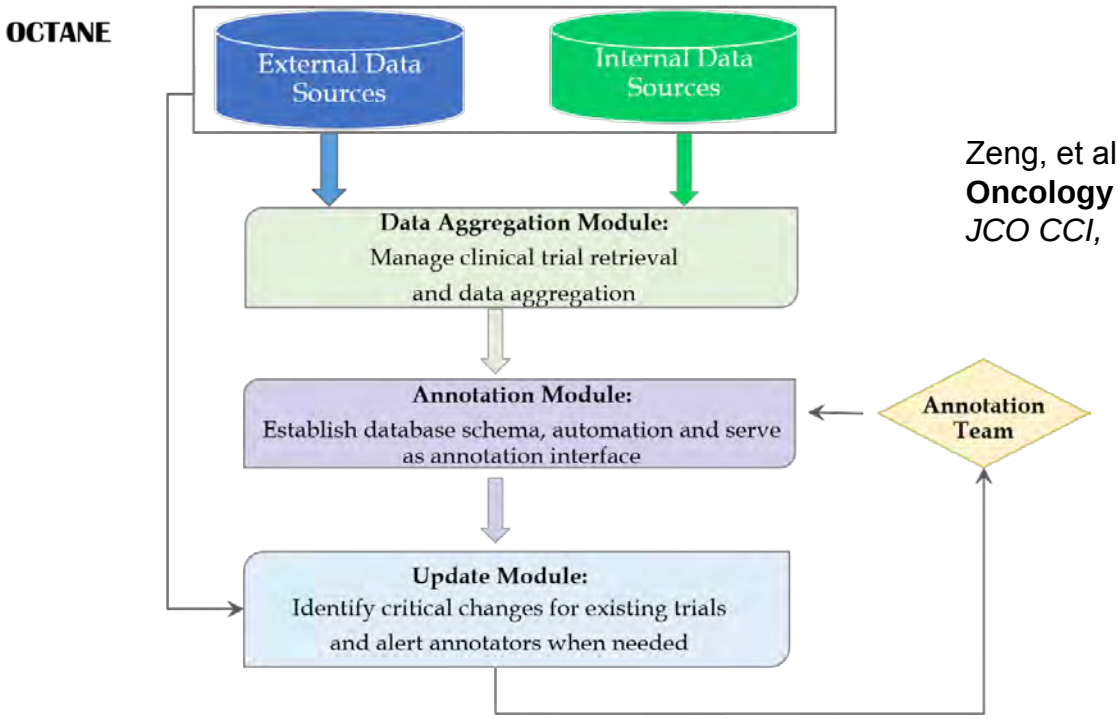
Objective 5: To perform experimental functional characterization of variants of unknown significance (VUSs)

Drug Curation Process



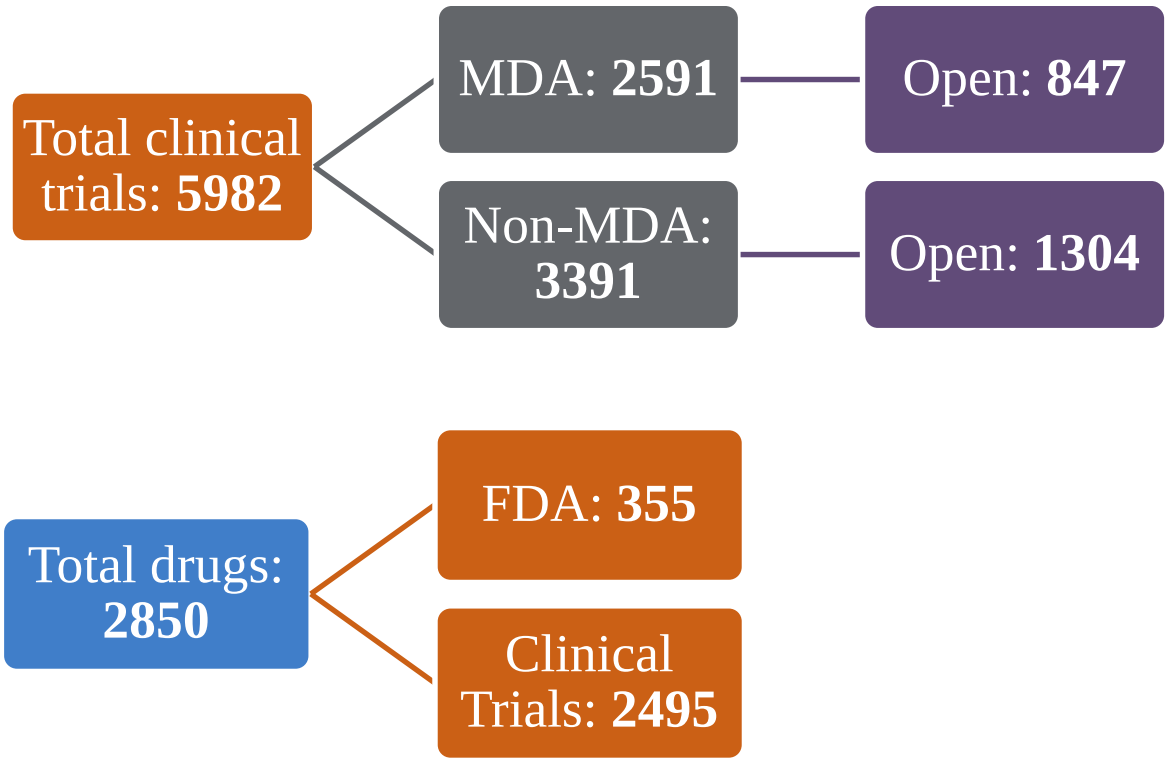
OCTANE: Oncology Clinical Trial Annotation Engine



Zeng, et al. **OCTANE: Oncology Clinical Trial Annotation Engine**. *JCO CCI*, 2019

-Trial curation including detailed genomic and other biomarker requirements
- Annotation based on full protocol when available
- Key clinical and genomic criteria,
- Slot availability by cohort

Annotation Stats



PODS Core
Goals & Objectives

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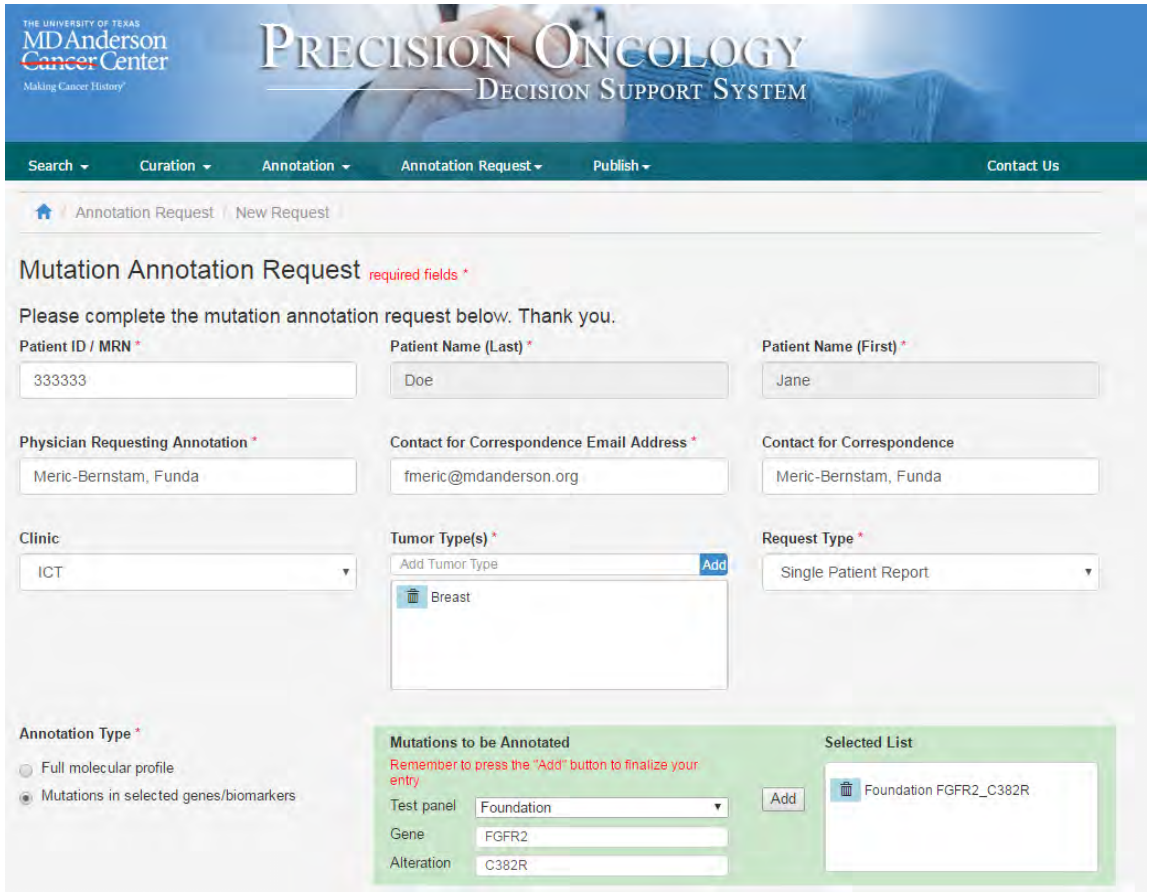
Web-based Patient Annotation Request Form



- Can request for MDA or non-MDA patients
- For MDA, pt demographics retrieved from Epic
- Can request annotation of all or select alterations/biomarkers on a panel(s)
- Clinician-initiated requests for treatment decisions
- PODS initiated requests to proactively provide annotation reports for specific patient populations and collaborations
- **Reports my internal email and deposited into EPIC**

Annotation Table

Clear Functional Significance Call

Summarized Research

Clear Alteration-Level Actionability Calls

Tested Panel	Assay Type	Report Date	Report#	Allelic frequency / cfDNA (%)	Copy Number / Level	Gene	Alteration	Functional Significance	Annotation	Actionable Gene	Actionable Variant	Actionable For
Foundation Medicine - FoundationOneHeme	Tumor-based NGS	04/25/2018	TRF	N/A	N/A	NTRK3	ETV6-NTRK3	Activating	**Biomarker Summary:** TrkC protein (product of *NTRK3* gene) is a kinase that controls cell proliferation, differentiation, apoptosis, and cell survival in response to… **Functional Annotation:** The ETV6-NTRK3 fusion, typically associated with t(12;15)(p13;q25), consists of the dimerization domain from ETV6 and the tyrosine kinase domain from NTRK3, resulting in a constitutively active tyrosine kinase (PMID:9462753)… **Potential Therapeutic Implications:** *NTRK3* gene fusions have shown to be oncogenic and potentially targetable with TRK inhibitors… **Tumor Type-Specific Annotation:** Although this fusion has not been documented in chondrosarcoma, it has been reported in other types of sarcoma, including congenital fibrosarcoma and Ewing sarcoma (COSMIC; PMID:9462753; PMID:25010205)…	YES	YES: Literature based	For treatment with TRK inhibitors
Foundation Medicine - FoundationOneHeme	Tumor-based NGS	04/25/2018	TRF	N/A	N/A	BRCA2	L1227fs*5	Inactivating: Inferred	**Biomarker Summary:** The *BRCA2* gene encodes the breast cancer 2 early onset (BRCA2) protein, a tumor suppressor that regulates… **Functional Annotation:** Although this alteration has not been functionally characterized, it is inferred to be inactivating. BRCA2 L1227fs*5 is located in the… **Potential Therapeutic Implications:** There have been multiple preclinical and clinical studies that suggest *BRCA2*-deficient tumors demonstrate improved response to PARP inhibition…	YES	YES: Inferred	For treatment with platinum-based chemotherapy and PARP inhibitors
Foundation Medicine - FoundationOne Heme	Tumor-based NGS	04/25/2018	TRF	N/A	N/A	ATM	T2934A	Unknown	**Biomarker Summary:** *ATM* encodes a serine/threonine kinase, and belongs to the superfamily of phosphatidylinositol 3-kinase-related… **Functional Annotation:** ATM T2934A has not directly characterized. It is located in the C-terminal catalytic phosphatidylinositol-3 kinase… **Potential Therapeutic Implications:** *ATM* mutations that result in its loss-of-function may sensitize cells to treatment with PARP inhibitors..	YES	Potentially	For treatment with PARP inhibitors

For all alterations within an actionable gene/biomarker

Frequency and Non-Actionable Section

Aggregated frequencies

Frequency in all tumor types

Gene	Alteration	cBIO	COSMIC	CMS50	T200	*Germline in T200 dataset
BRCA2	L1227fs*5	0 / 11671 (0%)	0 / 17609 (0%)		0 / 2859 (0%)	
ATM	T2934A	0 / 11932 (0%)	0 / 25223 (0%)	0 / 12541 (0%)	0 / 2859 (0%)	
JAK1	L710V	0 / 9953 (0%)	1 / 20741 (<1%)	0 / 12541 (0%)	0 / 2859 (0%)	
BAP1	A648V	0 / 10853 (0%)	0 / 16387 (0%)		0 / 2859 (0%)	

*The T200 dataset is a research-based panel testing paired normal and tumor samples. Variants previously detected as germline in this patient population using this panel are indicated here.

The PODS team routinely assesses the availability of targeted therapies within clinical trials. Below is a list of alterations that is not considered actionable at this time. We will include annotations of this alteration type when supportive evidence for actionability is found.

* Foundation Medicine - FoundationOneHeme-TRF Microsatellite Status_Stable
* Foundation Medicine - FoundationOneHeme-TRF CIC_P1319L
* Foundation Medicine - FoundationOneHeme-TRF Tumor Mutation Burden_Low

Alterations where gene/biomarker and/or alteration type are not actionable

Clinical Trial Tables

MD ANDERSON CLINICAL TRIALS

The PODS team has identified the following clinical trials that may be relevant to your patient's alterations. Please note the following: although this list has been filtered by its relevance to your patient's gene and disease type, further consultation regarding enrollment eligibility and availability of clinical trial slots should be discussed with respective PI and/or clinical trial coordinator.

Biomarker-Selected Trials

Selected Biomarker(s)*	Drugs**	Title	NCTID	MDACC Protocol ID	Phase	PI	Dept
NTRK3_Fusion	Larotrectinib	A Phase 1 Study of the Oral TRK Inhibitor LOXO-101 in Adult Patients With Solid Tumors	NCT02122913	2014-1056	Phase 1	Hong, David S.	Investigational Cancer Therapeutics
NTRK3_Fusion	Larotrectinib	Molecular Analysis for Therapy Choice (MATCH)	NCT02465060	ECOGEAY131	Phase 2	Meric-Bernstam, Funda	Investigational Cancer Therapeutics
NTRK3_Fusion	LOXO-195	A Phase 1/2 Study of the TRK Inhibitor LOXO-195 in Adult and Pediatric Subjects With Previously Treated NTRK Fusion Cancers	NCT03215511	2017-0418	Phase 1/2	Hong, David S.	Investigational Cancer Therapeutics

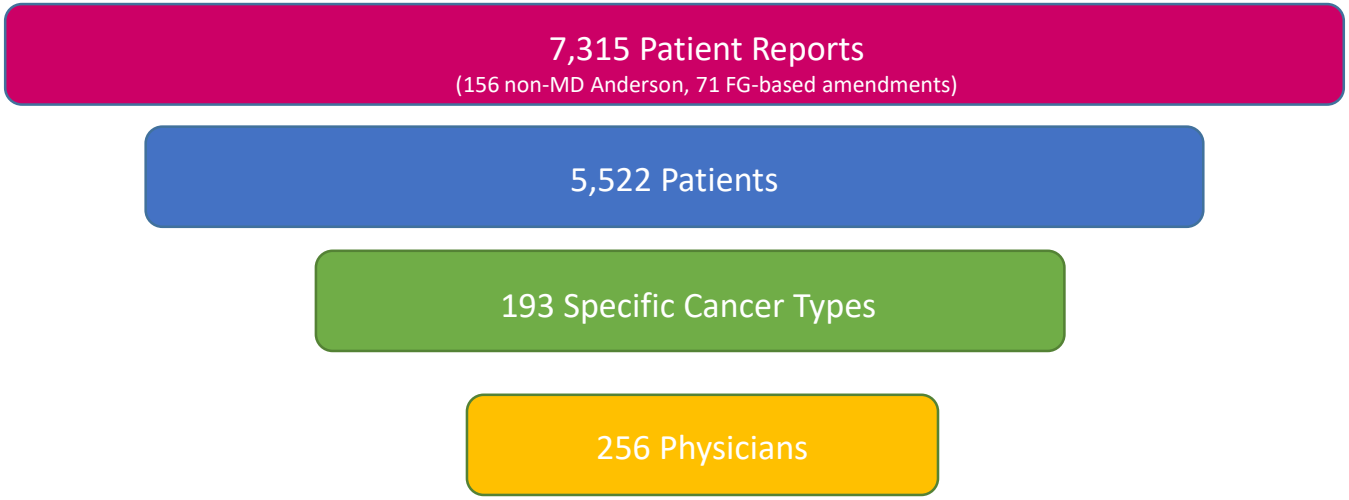
Biomarker-Relevant Trials

Relevant Biomarker(s)*	Drugs**	Title	NCTID	MDACC Protocol ID	Phase	PI	Dept
BRCA2 Any Alteration, ATM Any Alteration	Niraparib	An Open-Label, Randomized-Sequence, Multicenter, Single-Crossover Study to Assess the Relative Bioavailability of Niraparib Tablet Formulation Compared to Niraparib Capsule Formulation in Patients With Advanced Solid Tumors	NCT03329001	2017-0682	Phase 1	Piha-Paul, Sarina A.	Investigational Cancer Therapeutics
BRCA2 Any Alteration	Gemcitabine, Durvalumab, Cisplatin, AZD9150, Nab-paclitaxel, Fluorouracil, Carboplatin	A Phase Ib/II, Open-Label, Multicentre Study to Assess Safety, Tolerability, Pharmacokinetics and Preliminary Anti-tumour Activity of AZD9150 Plus Durvalumab Alone or in Combination With Chemotherapy in Patients With Advanced, Solid Tumours and Subsequently in Patients With Non-Small-Cell Lung Cancer	NCT03421353	2017-1065	Phase 1/2	Hong, David S.	Investigational Cancer Therapeutics
BRCA2 Any Alteration, ATM Any Alteration	Talazoparib	A Phase I Open-label Pharmacokinetics And Safety Study Of Talazoparib (mdv3800) In Patients With Advanced Solid Tumors And Normal Or Varying Degrees Of Hepatic Impairment	NCT02997176	2016-0798	Phase 1	Piha-Paul, Sarina A.	Investigational Cancer Therapeutics

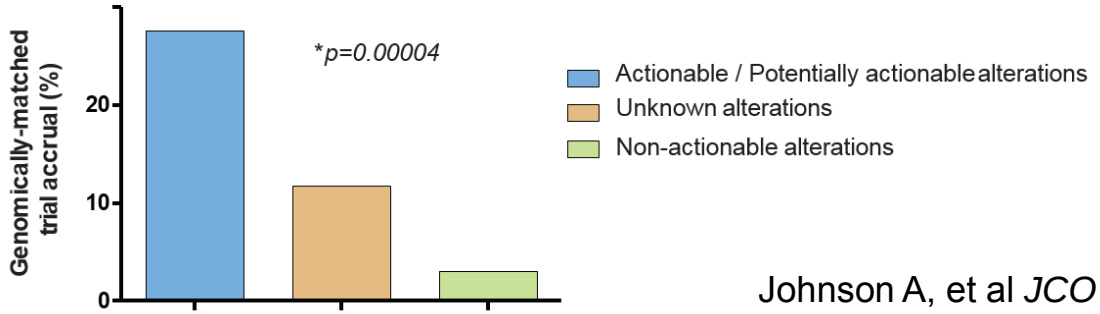
Trials retrieved only if targets a potentially actionable or actionable alteration
Currently, only MD Anderson trials are retrieved

Patient Report Metrics

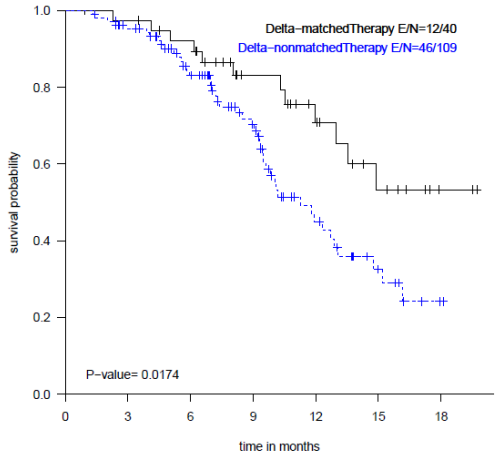
Through June 24, 2019



Impact of Decision Support



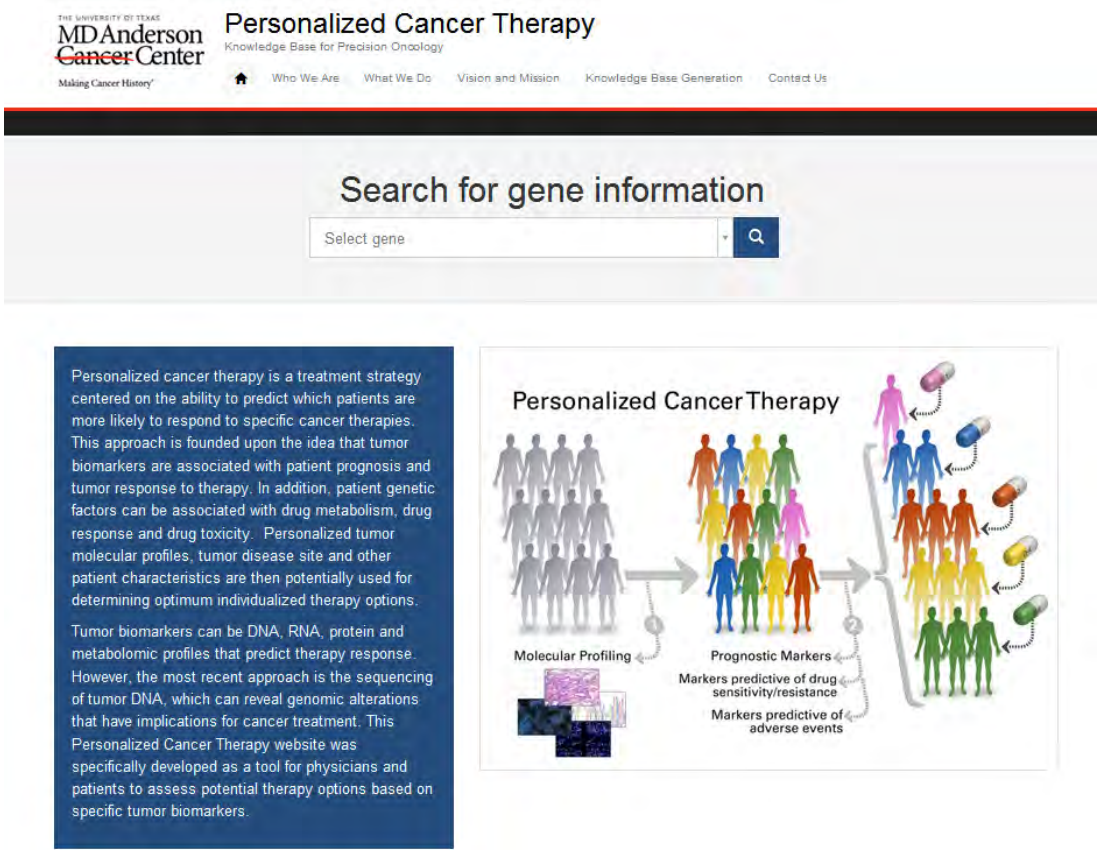
Johnson A, et al *JCO Precis Oncol* 2017



Approval of Genomic Testing
as Orderable for
All Advanced Solid Tumors
At MD Anderson

Kopetz S, et al. *JCO Precis Oncol* 2019

Personalizedcancertherapy.org
PCT.mdanderson.org



- Launched April 2014
- All content publicly accessible with free registration
- First 33 genes with dozens of individual aberrations annotated.
- Therapeutic implications
- Relevant trials
- New genes and respective gene-level variants added continuously

Kurnit K, et al. *Cancer Research*, 2017

Email Alerts – Trial Alert

1st Set

Biomarker	Current Open Trials*
AKT1	4
BRAF	17
FGFR1/2/3/4	12
EGFR	18
ERBB2	21
IDH1/2	8
PTCH1	1
SMO	2
NTRK1/2	5

2nd Set

Biomarker	Current Open Trials*
PIK3CA	7
PIK3R1	1
PTEN	7
MTOR	6
NF1/2	6
KRAS	21
NRAS	14
HRAS	13
ARAF	1
MAP2K1/2	6
MAPK1	3
PDGFRA	7
KIT	9
KDR	4
MET	7

Total # of trial alerts sent: >6300 to 371 Physicians

* As of 6/24/2019

Email Alerts – Patient Alert - example

Dr. Yap,

Below is the list of Patients and Alteration(s). This is based on recent alterations entered in MOCLIP, and curated indirectly from OneConnect.IPCT alerts are not triggered by alterations thought to be common germline variants but may be triggered by uncommon variants as well as mutations. Please check official OneConnect report to confirm presence of mutations as well their classification.

If you need full annotation of the alteration, simply click on "Request Annotation" button and enter the required information, PODS team will annotate.

Patient List

MRN	PT_Name	PtDisease	Panel	ResultDate	Gene	Alterations	FunctionalSignificance	ActionableVariant	Action
			EndCLL	2019-06-21	ATM	ATM_D1853N	Likely Benign	NO	
			EndCLL	2019-06-21	ATM	ATM_D1853N	Likely Benign	NO	
			EndCLL	2019-06-21	ATM	ATM_P1054R	Likely Benign	NO	
		Path Dx:SKIN MAL. MEL. IN JUNCT. NEVUS	STGA-DNA 2018	2019-06-20	ATM	ATM_E2039K	Inactivating	YES: Literature based	
			Liquid Biopsy Panel V1	2019-06-20	BRCA1	BRCA1_E1213D			Request Annotation
		Path Dx:Cancer of Unknown Primary	STGA-DNA 2018	2019-06-20	MRE11A	MRE11A_Q591L			Request Annotation

Total # of patient alerts sent: >8600
to
17 Physicians (43 different alert types)

Variant Annotation Request

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Biomarker Expansion

Currently our infrastructure supports the following for biomarker annotation, clinical trial eligibility annotation, and drug relevance

- Genomic alterations
- Selected Protein alterations
  - Protein expression, over-expression, loss
  - Planned to add: antibody used, scoring system
- Immune markers
  - MSI status (high, low, stable)
  - Tumor mutation burden (high/moderate/low and # mutations/MB by platform
  - Promoter methylation (positive or negative)

Early efforts in RNA expression…

Early efforts in histology specific annotations…

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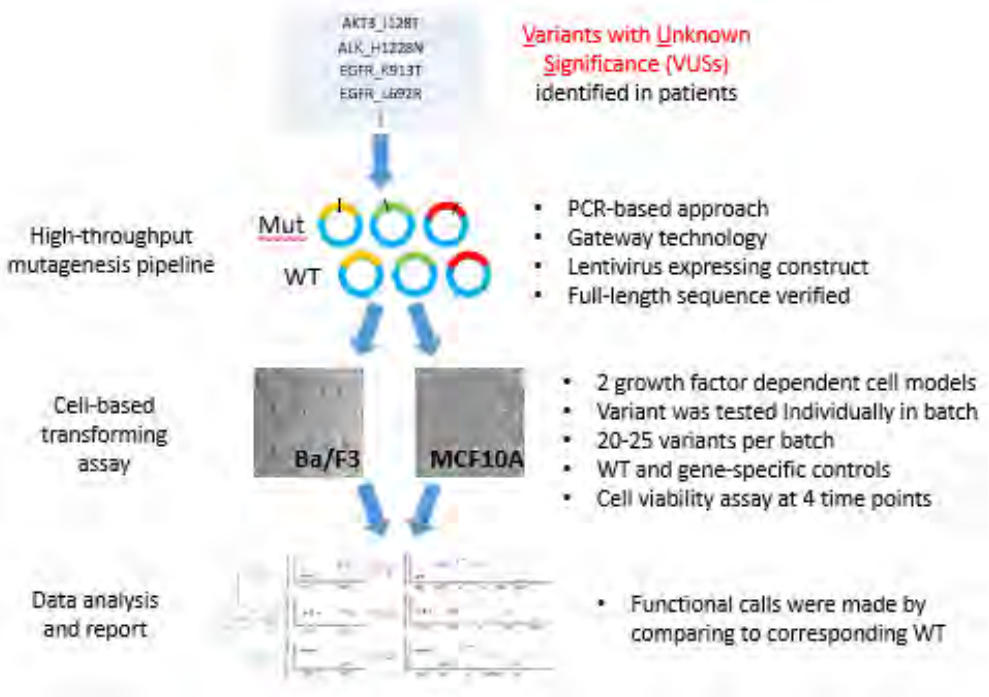
Functional Genomics Overview



- 1736 variants tested in Ba/F3 and MCF10A cell models
- 1583 informative and 153 non-informative
- 71 amendments released with FG results

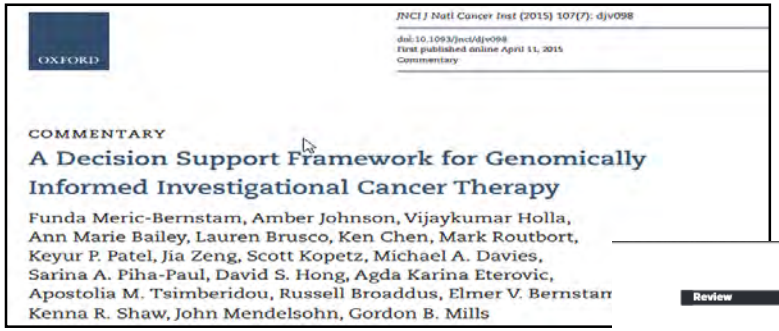
Ongoing Research

- Reverse Phase Protein Arrays (RPPA) on 631 MCF10A lines stably expressing individual WT or variants were done. Analysis in process
- Variant series to determine actionability /differential sensitivity

Shared with Research Community

- Publication of the platform
  - Ng et al., 2018 Cancer Cell
- Public-facing FASMIC website
  - 2191 visitors from >50 countries
- Addgene Deposit
  - 744 variant constructs were submitted to Addgene

Leading Precision Oncology Decision Support



OXFORD

JNCI J Natl Cancer Inst (2015) 107(7): djv098

doi:10.1093/jnci/djv098
First published online April 11, 2015
Commentary

COMMENTARY

A Decision Support Framework for Genomically Informed Investigational Cancer Therapy

Funda Meric-Bernstam, Amber Johnson, Vijaykumar Holla, Ann Marie Bailey, Lauren Brusco, Ken Chen, Mark Routbort, Keyur P. Patel, Jia Zeng, Scott Kopetz, Michael A. Davies, Sarina A. Piha-Paul, David S. Hong, Agda Karina Eterovic, Apostolia M. Tsimberidou, Russell Broaddus, Elmer V. Bernstam, Kenna R. Shaw, John Mendelsohn, Gordon B. Mills

Published OnlineFirst February 2, 2018; DOI: 10.1158/1078-0432.CCR-17-2494

Review

Clinical Cancer Research

Precision Oncology Decision Support: Current Approaches and Strategies for the Future

Katherine C. Kurnit[1], Ecaterina E. Ileana Dumbrava[2], Beate Litzenburger[3,4], Yekaterina B. Khotskaya[3], Amber M. Johnson[3], Timothy A. Yap[2], Jordi Rodon[2], Jia Zeng[3], Md Abu Shufean[3], Ann M. Bailey[3], Nora S. Sánchez[3], Vijaykumar Holla[3], John Mendelsohn[3,5], Kenna Mills Shaw[3], Elmer V. Bernstam[6], Gordon B. Mills[3,7], and Funda Meric-Bernstam[2,3,8]

original report

Clinical Use of Precision Oncology Decision Support

The right drugs at the right time for the right patient: the MD Anderson precision oncology decision support platform

Amber Johnson[1], Jia Zeng[1], Ann M. Bailey[1], Vijaykumar Holla[1], Beate Litzenburger[1], Humberto Lara-Guerra[1], Gordon B. Mills[1,2], John Mendelsohn[1,3], Kenna R. Shaw[1] and Funda Meric-Bernstam[1,4,5,*], fmeric@mdanderson.org

Focus on Computer Resources

Cancer Research

"Personalized Cancer Therapy": A Publicly Available Precision Oncology Resource

Katherine C. Kurnit[1], Ann M. Bailey[2], Jia Zeng[2], Amber M. Johnson[2], Md. Abu Shufean[2], Lauren Brusco[2], Beate C. Litzenburger[2], Nora S. Sánchez[2], Yekaterina B. Khotskaya[2], Vijaykumar Holla[2], Amy Simpson[2], Gordon B. Mills[2,3], John Mendelsohn[2,4], Elmer Bernstam[5], Kenna Shaw[2], and Funda Meric-Bernstam[2,6,7]

special article

OCTANE: Oncology Clinical Trial Annotation Engine

Jia Zeng, PhD[1]; Md Abu Shufean, MS[1]; Yekaterina Khotskaya, PhD[1]; Dong Yang, PhD[1]; Michael Kahle, PhD[1]; Amber Johnson, PhD[1]; Vijaykumar Holla, PhD[1]; Nora Sánchez, PhD[1]; Kenna R. Mills Shaw, PhD[1]; Elmer V. Bernstam, MSE, MD[2,3]; and Funda Meric-Bernstam, MD[1]

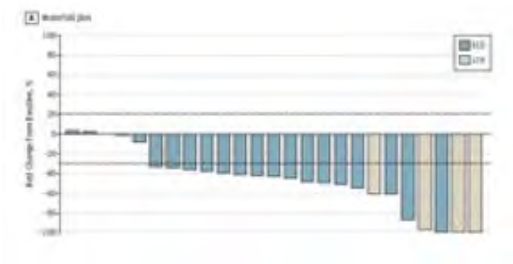
Genomically Matched Trials Leading to FDA Approval

Vivek Subbiah

Maria Cabanillas

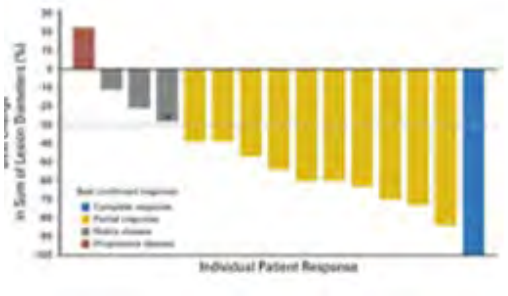
David Hong

BRAF V600E Erdheim-Chester Disease



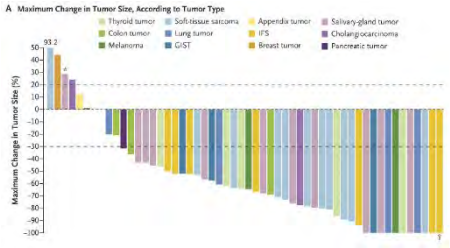
Diamond and Subbiah, JAMA Oncol, 2017

BRAF V600E Anaplastic thyroid carcinoma



Subbiah et al, J Clin Oncol, 2017

Larotrectinib in TRK-fusion cancers



Drillon et al, N Engl J Med, 2018

FDA Approved

PODS Collaborations Within Texas and Beyond

- **UT Southwestern**
  - PODS-trained UTSW-funded annotator based at UTSW
  - Annotator annotates UTSW cases, but all annotations will be captured in the general knowledge base. UTSW generated sequencing data will be uploaded onto MOCLIA too.
- **UT San Antonio**
  - Discussions are ongoing
- **Decision Support for NCI Experimental Therapeutics Clinical Trials Network trials led by MDACC PIs Experimental Therapeutics**
  - **NCI10220 (BeGIN trial):** Basket Trial of Glutaminase Inhibitor CB-839 in Patients with NF1 Aberrations(PI: Subbiah)
  - **NCI10221 (BaCoN trial):** Basket of Copanlisib + Nivolumab +/- Ipilimumab phase I/II trial in solid tumors (PI: Yap)
  - **NCI10217 (COD trial):** Copanlisib + Olaparib +/- Durvalumab phase I/II trial in solid tumors (PI: Yap)
  - Pertuzumab + trastuzumab + copanlisib phase I/II trial in HER2 breast cancer (PI: Murthy)
    - **ET-CTN Grant renewal submitted as a University of Texas-based consortium: MD Anderson, UT Austin, UT San Antonio and UTMB**
- **Baylor**
  - Potential future collaborations in proteogenomics and cfDNA
- **Other:**
  - Contracts with OHSU, “Global PODS”:Molecular Tumor Board Pilot with Hong Kong, pharma

Future Directions

July EAB meeting and August MD Anderson StakeHolders meeting to determine how to optimally meet current and future needs. Priority areas:

Expansion of existing efforts
- Routine PODS annotation at MD Anderson
- Access to PODS more broadly in Texas
- Tools or web-based applications for easy querying
- Collaborations to facilitate curation of site-specific trials

Evolution in molecular profiling
- Transcriptomics - decision support for the actionable transcriptome
- Protemics

Decision support for immunooncology
- TMB, PDL1, relevant genomics (KRAS/STK11)
- Emerging immunooncology markers

Integration of clinical and molecular data
- MD Anderson-wide followed by Texas-wide integration effort? Could also leverage CTSA efforts

THANK YOU!

Questions/comments/collaborations:

fmeric@mdanderson.org

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:	AUGUST 14, 2019

As of this writing the Chief Executive Officer's Report for the August 21, 2019, Oversight Committee meeting will consist of the following:

- Personnel update
- FY 2019 Grant Award Funds Available (attached)

Other topics may be added as warranted.

In addition, for your reference copies of the June 2019 and July 2019 CPRIT Activities Updates previously provided to you are included at the end of this tab. These reports are done in months in which the Oversight Committee does not meet.

*****

CPRIT has awarded **1,380** grants totaling **$2.286 billion**
- 216 prevention awards totaling $235.5 million
- 1,164 academic research and product development research awards totaling $2.050 billion

Of the $2.050 billion in academic research and product development research awards,
- 30.7% of the funding ($630.2 million) supports clinical research projects
- 24.9% of the funding ($510.2 million) supports translational research projects
- 27.2% of funding ($532.0 million) supports recruitment awards
- 14.3% of the funding ($292.7 million) supports discovery stage research projects
- 2.9% of funding ($59.9 million) supports training programs.

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

CPRIT MANAGEMENT DASHBOARD
FISCAL YEAR 2019

	SEPT	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	CUMULATIVE (ANNUAL)	CUMULATIVE (TO DATE)
ACCOUNTABILITY														
Announced Grant Awards			4			54			10				68	
New Grant Contracts Signed	3	29	11	2	9	11	10	20	16	6	3		120	
New Grant Contracts In Negotiation			12			28			8				48	
Grant Reimbursements Processed (#)	215	155	151	117	135	195	186	169	173	144	105		1,745	
Grant Reimbursements Processed ($)	$ 24,200,640	$ 35,131,951	$ 8,541,059	$ 11,659,905	$ 15,228,234	$ 22,212,539	$ 18,347,474	$ 18,652,475	$ 15,377,254	$ 16,388,569	$ 22,527,454		$ 208,267,553	
Revenue Sharing Payments Received	$ -	$ -	$ 158,052	$ -	$ 15,000	$ 32,500	$ 2,020	$ 27,678	$ 13,729	$ 3,806	$ 32,663		$ 285,448	$ 3,707,001
Total Value of Grants Contracted ($)	$ 21,386,494	$ 63,467,857	$35,654,020	$ 2,200,000	$ 18,649,550	$ 38,046,886	$ 24,674,573	$ 22,820,536	$ 32,974,587	$ 9,099,991	$ 4,086,469		$ 273,060,963	
Grants Awarded (#)/ Applications Rec'd (#)	13%	13%	13%	13%	13%	17%	17%	17%	17%	16%	16%			
Debt Issued ($)/Funding Awarded ($)	74%	74%	73%	73%	73%	70%	74%	74%	73%	73%	75%			
Grantee Compliance Trainings	3	1	2	2	1	1	1	2	2	4	1		20	
Grantee Compliance Monitoring Visits	0	3	0	3	2	1	2	1	1	1	1		15	
Awards with Delinquent Reimbursement Submission (FSR)			0			1			0					
Awards with Delinquent Matching Funds Verification			0			3			2					
Awards with Delinquent Progress Report Submission			2			1			0					
IA Agency Operational Recommendations Implemented	0	0	0	0	0	0	0	0	1	1	1			
IA Agency Operational Recommendations In Progress	9	9	9	9	9	9	9	9	8	8	8			
Open RFAs	10	9	12	16	15	7	8	8	8	15	10			
Prevention Applications Received	19	0	0	2	0	28	0	0	0	2	0		51	846
Product Development Applications Received	0	0	0	0	28	0	0	0	0	0	0		28	491
Academic Research Applications Received	7	2	2	5	168	7	9	16	14	397	3		630	7,308
Help Desk Calls/Emails	111	131	83	138	270	202	109	134	203	177	202		1,760	
MISSION														
ACADEMIC RESEARCH PROGRAM														
Number of Research Grants Announced (Annual)	0		4			42			10				56	
Recruited Scientists Announced														242
Recruited Scientists Accepted														181
Recruited Scientists Contracted	`													173
Published Articles on CPRIT-Funded Projects (#)														
Jobs Created & Maintained (#)														
Trainees in CPRIT-Funded Training Programs (#)														
Clinical Studies (#)														109

CPRIT MANAGEMENT DASHBOARD
FISCAL YEAR 2019

	SEPT	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	CUMULATIVE (ANNUAL)	CUMULATIVE (TO DATE)
Number of Patents Resulting from Research														
Number of Patent Applications														
Number of Investigational New Drugs														
PRODUCT DEVELOPMENT RESEARCH PROGRAM														
Number of Product Development Grant Announced (Annual)			0			5			0				5	
Life Science Companies Recruited (in TX)														9
Published Articles on CPRIT-Funded Projects														
Number of Jobs Created & Maintained														515
Clinical Trials (#)														15
Number of Patents Resulting from Research														
Number of Patent Applications														
Number of Investigational New Drugs														
PREVENTION PROGRAM														
Number of Prevention Grants Announced (Annual)			0			7			0				7	
People Served by CPRIT-Funded Prevention and Control Activities			223,464			241,337			234,404				699,205	
People Served through CPRIT-Funded Education and Training			136,707			165,883			177,077				479,667	
People Served through CPRIT-Funded Clinical Services			86,757			75,454			57,327				219,538	
TRANSPARENCY														
Total Website Hits (Sessions)	6,200	6,300	5,300	4,900	8,700	9,100	6,900	7,400	9,722	7,007	7,291		78,820	
Total Unique Visitors to Website (Users)	4,700	4,700	3,900	3,500	6,100	6,200	4,800	5,100	6,608	4,988	5,193		55,789	

FY 2019 GRANT AWARD FUNDS AVAILABLE

General Obligation Bond Proceeds

	Prevention	Academic / Product Development Research	1% Grant Funding Buffer	Operating Budget	Total Appropriations
Available Appropriated Funds	$ 28,022,956	$ 255,297,292		$ 16,679,752	$ 300,000,000
Approved Adjustment to Operating Budget		$ (547,031)		$ 547,031	
Appropriations Transfer to DSHS		$ (2,969,554)		$ 2,969,554	
Adjusted Appropriations	$ 28,022,956	$ 251,780,707		$ 20,196,337	$ 300,000,000
Total Available for All Grants			$ 279,803,663		
1% of Total Available Grant Funding			$ 2,798,037		
Adjusted Grant Award Funding	28,022,956	$ 248,982,670			$ 277,005,626
	Prevention Grants	**Academic Research Grants**	**PD Research Grants**		
Total Available for Grant Awards (Total GO Bond Proceeds Less Operating Budget)	$ 28,022,956	$ 176,246,495	$ 75,534,212		$ 279,803,663
Total Available for Grant Awards Incorporating 1% Grant Funding Buffer	$ 28,022,956	$ 174,287,869	$ 74,694,801		$ 277,005,626
Announced Grant Awards					
11/28/18 AR Recruitment Awards (4)	$ -	$ 16,000,000	$ -		
2/21/19 IIR Awards (23)	$ -	$ 20,623,861	$ -		
2/21/19 IIRA-Childhood and Adolescent Cancer (5)	$ -	$ 5,968,636	$ -		
2/21/19 IIRA-Computational Biology (1)	$ -	$ 885,185	$ -		
2/21/19 IIRA-Clinical Translation (4)	$ -	$ 7,488,820	$ -		
2/21/19 IIRA-Prevention and Early Detection (3)	$ -	$ 3,890,151	$ -		
2/21/19 Recruitment Awards (6)	$ -	$ 14,000,000	$ -		
2/21/19 PDR Relocation Award	$ -	$ -	$ 13,116,095		
2/21/19 PDR SEED Awards (3)	$ -	$ -	$ 8,912,313		
2/21/19 PDR Texas Company Award	$ -	$ -	$ 8,742,509		
2/21/19 Prevention Awards	$ 12,328,462	$ -	$ -		
5/15/19 Recruitment Awards (10)	$ -	$ 31,562,426	$ -		
Announced Grant Award Subtotal	$ 12,328,462	$ 100,419,079	$ 30,770,917	$ -	$ 143,518,458
Grant Award Adjustments					
Declined Recruit Award (BCM-Satpathy) 11/2018 OC	$ -	$ (2,000,000)	$ -		$ (2,000,000)
Declined Recruit Award (UTSW-Alumkal) 2/2019 OC		$ (4,000,000)			$ (4,000,000)
Declined Recruit Award (UTMD-Ben-David) 2/2019 OC		$ (2,000,000)			$ (2,000,000)
Declined Recruit Award (UTHSC-SA-Bao) 11/2018 OC		$ (6,000,000)			$ (6,000,000)
Declined Recruit Award (Rice-Gao) 5/2019 OC		$ (2,000,000)			$ (2,000,000)
Declined Recruit Aware (UTSW-Wang) 11/2018 OC		$ (6,000,000)			$ (6,000,000)
Declined Recruit Award (UTSW-Jin) 5/2019 OC		$ (2,000,000)			$ (2,000,000)
Declined Recruit Award (MDACC-Dieli-Conwright) 5/2019 OC		$ (3,562,426)			$ (3,562,426)
Revised Grant Award Subtotal	$ 12,328,462	$ 72,856,653	$ 30,770,917		$ 115,956,032
Uncommitted Funds as of August 8, 2019	$ 15,694,494	$ 101,431,216	$ 43,923,884		$ 161,049,594
Pending Grants-PIC Recommendations					
Prevention Awards (9)	$ 14,202,528	$ -	$ -		
Prevention Dissemination Award	$ 295,453	$ -	$ -		
PDR Texas Company Awrd	$ -	$ -	$ 15,427,699		
PDR Relocation Award (2)	$ -	$ -	$ 26,134,398		
PDR SEED Award	$ -	$ -	$ 3,000,000		
IIR Awards (6)	$ -	$ 5,397,483	$ -		
IIRA-Childhood and Adolescent Cancers (2)	$ -	$ 1,921,306	$ -		
IIRA-Computational Biology	$ -	$ 1,792,157	$ -		
CAP: Collaborative Action Center	$ -	$ 3,000,000	$ -		
CAP: Investigator-Initiated Research Awards	$ -	$ 2,456,676	$ -		
Core Facility Research Awards	$ -	$ 35,495,696	$ -		
Early Translational Research Awards	$ -	$ 7,599,384	$ -		
High-Impact/High-Risk Awards	$ -	$ 3,597,195	$ -		
Recruitment Awards (16)	$ -	$ 39,669,997	$ -		
Pending Award Subtotal	$ 14,497,981	$ 100,929,894	$ 44,562,097		$ 159,989,972
Revised Uncommitted Grant Funds	$ 1,196,513	$ 501,322	$ (638,213)		
Use of Portion of 1% Buffer for PDR Grant Awards		$ -	$ 638,213		$ 638,213
Total Grant Funding Committed	$ 26,826,443	$ 173,786,547	$ 75,333,014		$ 275,946,004
1% Grant Funding Buffer	$ -	$ 1,958,626	$ 839,411		$ 2,798,037
Adjusted Grant Funding Buffer	$ -	$ 1,958,626	$ 201,198		$ 2,159,824
Total Remaining Uncommitted Funds	$ 1,196,513	$ 2,459,948	$ 201,198		$ 3,857,659

Operating Budget Detail	
Indirect Administration	$ 3,577,683
Grant Review & Award Operations	$ 13,649,100
Subtotal, CPRIT Operating Costs	$ 17,226,783
Cancer Registry Operating Cost Transfer	$ 2,969,554
Total, Operating Costs	20,196,337

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	CPRIT ACTIVITIES UPDATE JUNE 2019
DATE:	JULY 1, 2019

Topics in this memo cover the months of May and June 2019 and include recent milestones in our fight against cancer, a staffing summary, CPRIT outreach efforts – including an opportunity for Oversight Committee members to help and an announcement about the 2020 CPRIT Innovations Conference, as well as updates from Compliance, Programs, and Operations.

Recent Milestones in the Fight Against Cancer

CPRIT Grantees in the News

- *U.S. News & World Report* announced its list of the 2019-2020 Best Children's Hospitals on June 18. It ranked Texas Children's Hospital, affiliated with Baylor College of Medicine, No. 3 for care in pediatric cancer. The top three hospitals for pediatric cancer in the *U.S. News* ranking are: Dana-Farber/Boston Children's Cancer Center, St. Jude Children's Research Hospital and Texas Children's Hospital. Texas Children's Hospital's ranking improved from No. 7 in 2018.

- For a second consecutive year, The University of Texas Southwestern Medical Center is the top institution internationally within the "healthcare institution" category for publishing high-quality scientific research, according to the recently released *Nature* Index 2019 Annual Tables. The University of Texas M. D. Anderson ranked 8th in this category. In the larger academic institution category, which includes research universities in addition to healthcare institutions, UT Southwestern ranked 19th. Other Texas academic institutions among the top 100 listings in the academic institution category include Baylor College of Medicine (29), MD Anderson (35), The University of Texas at Austin (45), and Texas A&M University (84). The rankings are based on contributions to research articles published in 82 high-quality natural science journals. More information about the *Nature* Index can be found at https://www.natureindex.com/faq.

- The National Academy of Medicine recently named CPRIT Scholar, Ning (Jenny) Jiang, Ph.D., an associate professor in The University of Texas at Austin Cockrell School of Engineering and Dell Medical School, an "Emerging Leader in Health and Medicine." Dr. Jiang was among a group of 10 early- to mid-career professionals representing a wide range of health-related fields, from microbiology and surgery to sociology and biomedical

engineering, to receive this recognition. Dr. Jiang's research is focused on the mechanics of the immune system, seeking answers to questions such as how the immune system develops and ages to find better ways of helping the immune system beat cancer. UT-Austin recruited her from Stanford University in 2012 with a CPRIT First-Time Tenure-Track Award.

- The *Vital Record*, a publication of Texas A&M University Health Science Center, featured Drs. Jane Bolin and Anna Lichorad's CPRIT-funded breast and cervical cancer screening project. These projects provide vital services to underserved women in the Brazos Valley while giving future nurses and nurse practitioners the opportunity to gain direct clinical experience. CPRIT originally supported this project, which provided services in nine counties, with a $1.5 million grant in 2013. CPRIT subsequently approved a $1.35 million grant in 2017 to expand the successful project to 17 counties.

- US drug maker Merck & Co. Inc. agreed to buy Peloton Therapeutics for $1.05 billion in cash, gaining access to the company's lead kidney cancer drug candidate. The acquisition, which could total $2.2 billion with additional payments based on drug performance, will strengthen Merck's presence in renal cell carcinoma and its overall cancer drug portfolio.

  Peloton developed a molecular therapy, PT2977, that fights advanced kidney cancer by targeting a protein called hypoxia-inducible factor (HIF)-2alpha. People with mutations of the protein are more likely to develop cancerous cells in the kidney. UT Southwestern researchers were among the first to identify the protein and its link to kidney cancer. In clinical trials, the therapy also has shown promise for Von Hippel-Lindau syndrome, a tumor-causing genetic disease, and glioblastoma. Peloton expects to start a late-stage trial for PT2977 in the second half of this year. The company, founded by UT Southwestern researchers in 2010, received a CPRIT Product Development Research Award in June 2010.

- Houston based AlloVir (formerly known as Viracyte) closed on a Series B financing worth $120 million. Fidelity Management and Research Company led the Series B, which Gilead Sciences, F2 Ventures, Redmile Group, Invus, EcoR1 Capital, Samsara BioCapital, and Leerink Partners Co-Investment Fund joined the Series B round. AlloVir also announced that ElevateBio selected it as its first portfolio company.

  AlloVir is working to develop an allogeneic cell therapy to control infections in patients with weakened immune systems, typically after they undergo stem cell or organ transplants. The company likens its treatment to growing an immune system outside the body to administer to immuno-compromised patients to control infections. Its pipeline, based on technology from the Center for Cell and Gene Therapy at Baylor College of Medicine, comprises two allogeneic T-cell therapies that target multiple viruses.

  The company is developing its lead program, known as Viralym-M, to fight six viruses in immunocompromised people like cancer patients: BK virus, cytomegalovirus, adenovirus, Epstein-Barr virus, human herpesvirus 6 and JC virus. The company published results from its Phase 2 study in the *Journal of Clinical Oncology*, finding that 93 percent of treated patients "demonstrated a clinical response (or met clinical response criteria) following

treatment with Viralym-M." AlloVir received a $9 million CPRIT Product Development Research Award in August 2017.

- Molecular Templates, a clinical-stage oncology company focused on the discovery and development of the company's proprietary engineered toxin bodies (ETBs), announced that the FDA has accepted the company's Investigational New Drug filing for TAK-169, an ETB targeting CD38. ETBs are differentiated, targeted, biologic therapeutics for cancer that may address some of the limitations associated with currently available cancer therapeutics.

  The company is developing TAK-169 to treat multiple myeloma patients and expects to start a Phase 1 trial this year. Molecular Templates also has three Phase 2 studies open for their lead program, MT-3724. The company's ETB targeting HER2-positive breast cancer, MT-5111, has an open IND with Phase 1 dosing expected to begin in the fall. Molecular Templates received a $10.6 million CPRIT Product Development Award in 2011 and a $15.2 million CPRIT Product Development Award in 2016.

- Medicenna Therapeutics, a clinical stage immuno-oncology company, announced the results of its recently completed Phase 2b clinical trial of MDNA55 for the treatment of recurrent glioblastoma (rGBM) at two high-profile scientific conferences this month. Dr. Dina Randazzo presented an update at the 2019 Annual Meeting of the American Society of Clinical Oncology held May 31 – June 4 in Chicago. Dr. Farah Merchant presented the top-line preliminary results to the Inaugural Immuno-Oncology Pharma Congress held June 18-20 during World Pharma Week in Boston.

  MDNA55, a first-in-class, fusion cytotoxin specifically targets the interleukin-4 receptor (IL4R), which is over-expressed by 20 different cancers affecting more than a million cancer patients every year. The company is developing a new biomarker test for the IL4R that may enable better selection and treatment for patients with rGBM, an extremely aggressive and uniformly fatal form of brain cancer. In addition, recently published pre-clinical data also shows that MDNA55 effectively targets and kills ovarian cancer cells overexpressing the IL4R. More than half of patients with ovarian cancer overexpress the IL4R.

  The company studied MDNA55 in five clinical trials involving 132 patients, including 112 adults with rGBM. MDNA55 has Fast-Track and Orphan Drug status. CPRIT awarded Medicenna a $14.1 million CPRIT Product Development grant in 2015.

- Synlogic, Inc. a clinical stage company applying synthetic biology to beneficial microbes to develop novel, living medicines, announced May 22 a new clinical collaboration with Roche to explore Synlogic's Synthetic Biotic medicine, SYNB1891, in combination with Roche's PD-L1-blocking checkpoint inhibitor atezolizumab in patients with advanced solid tumors. Synlogic expects to file an Investigational New Drug application in the second half of 2019 to begin an open-label Phase 1 clinical trial to evaluate the candidate as a monotherapy and a combination treatment with atezolizumab. Synlogic is the successor company to Mirna Therapeutics, which received CPRIT Product Development Research Awards in 2010 and 2014 of $10.3 million and $16.8 million, respectively.

- Asuragen, Inc., a molecular diagnostics company delivering easy-to-use products for complex testing in genetics and oncology, announced publication of a study done in collaboration with MD Anderson in the journal *Translational Oncology*. The CPRIT-supported study demonstrates a single next-generation sequencing (NGS) workflow for the sensitive and accurate detection of DNA and RNA variants associated with non-small cell lung cancer (NSCLC).

  Lung cancer is the leading cause of cancer-related death worldwide and NSCLC accounts for approximately 85% of all lung cancer cases. Clinicians have targeted therapies to treat for DNA and RNA variants in NSCLC, but quickly detecting the variants is complicated by current processes that separate NGS methods for DNA versus RNA. Biopsy tissue and nucleic acid quality may be limited and not enough for both processes, which also poses problems for treatment decision-making. To address these challenges, Asuragen and MD Anderson studied a unified DNA/RNA NGS assay that covers hotspot mutations in 20 genes as well as 107 RNA fusion variants recurrent in NSCLC. Ausragen received a $ $6.84 million CPRIT Product Development Research award in 2012.

<u>Notable CPRIT Supported Accomplishments</u>

- Dr. Sally Vernon, Division Director of Health Promotion & Behavioral Sciences at The University of Texas Health Science Center at Houston, leads a successful project that developed, implemented and evaluated the Adolescent Vaccination Program (AVP), a bundled suite of strategies for increasing HPV vaccination in the Texas Children's Hospital network of 51 clinics. Through the CPRIT-supported project, vaccine initiation rates increased from 12.6% to 34.3% and completion rates increased 42%. Based on the success of her original project, Dr. Vernon's team subsequently received a CPRIT grant to implement this program clinic network in San Antonio and a CPRIT Dissemination grant to develop and disseminate a web-based implementation tool to support the adoption, implementation, and maintenance of AVP strategies, regardless of the size and type of pediatric clinic or network.

- CPRIT Scholar Bing Zhang, Ph.D., professor of molecular and human genetics at Baylor College of Medicine, led a multi-institutional study published in the journal *Cell* that has analyzed all the proteins and genes in tissue samples from a group of patients with colon cancer and then applied bioinformatics to create a catalog of the differences in proteins in the colon cancer tumors versus the normal colon. This analysis of both proteins and genomic changes is important because genetic differences between cancer and normal are not always reflected in protein changes. For instance, the FDA has approved the use of a genetic marker called "DNA mismatch repair-deficiency" for identifying patients who are candidates for checkpoint inhibitor-based immunotherapy. However, only a subset of colon cancer patients with this biomarker respond to the therapy. Through bioinformatics analyses, Dr. Zhang and his colleagues identified new clues regarding why immunotherapy does not work for all mismatch repair-deficient colon cancers that may lead to new therapeutic approaches.

- Results from Phase 1 studies in patients with solid tumors were presented at the 2019 meeting of the American Society for Clinical Oncology for an MD Anderson-developed drug

known as IACS-10759, the first therapy to be developed from concept to clinical trial by MD Anderson's Therapeutics Discovery division. IACS-10759 is also in clinical development for acute myeloid leukemia as well as for solid tumors and lymphoma. IACS-10759 was designed to inhibit oxidative phosphorylation (OXPHOS) a prominent energy source supporting growth and survival. A comprehensive translational effort enabled by collaboration across MD Anderson and supported in part by CPRIT Individual Investigator Awards has identified multiple cancers that are highly dependent on OXPHOS and led to these ongoing clinical trials in patients with leukemia, lymphoma, and solid tumors.

Personnel

CPRIT has filled 33 of our 35 full-time equivalent (FTE) positions. We are preparing the Program Manager for Prevention job description for posting later this summer.

CPRIT Outreach

- Rosemary French, Senior Program Manager for Product Development, attended the Texas Health CoLab & Association of British HealthTech Industries Innovation Hub Tradeshow held at the Dell Medical School on April 29.

- Ms. French and Chief Product Development Officer Dr. Cindy WalkerPeach attended the 2019 Texas Life Science CEO Summit, hosted by BioHouston, May 2-3 in Cedar Creek.

- Dr. Cindy WalkerPeach and I attended the Biotechnology Innovation Organization (BIO) conference June 3 – 6 in Philadelphia. BIO is the chief international trade association representing the biotechnology industry. In addition to promoting the biotechnology sector, BIO also endorses public policies favorable to the industry before Congress, federal agencies, and state legislatures. The event brought together biotech and pharma leaders from around the globe for the purposes of partnering, education and networking. The Philadelphia meeting attracted 17,300 attendees.

  We attended BIO to stimulate product development applications and to inform conference attendees of CPRIT activities and funding opportunities. I promoted CPRIT's product development activities to the numerous attendees visiting the Texas pavilion, which the Texas Healthcare and Bioscience Institute hosted. Dr. WalkerPeach focused on one-on-one meetings with 29 companies interested in CPRIT funding. We expect our efforts will result in additional product development applications over the next year.

- Dr. Cindy WalkerPeach and Ms. Rosemary French attended the BioAustin BioBash on June 10.

- CPRIT executive and program staff met with senior officials of the Texas A&M University System on June 19 to discuss ways their components can expand their involvement in all three of CPRIT's grant making programs.

- Deputy Executive Officer and General Counsel Kristen Doyle presented CPRIT's legislative roundup to the Texas Public Health Coalition at its meeting on June 21 in Austin.

- Dr. Cindy WalkerPeach was a jury reviewer (SME: cancer) for the L'Oréal USA For Women in Science Fellowship, American Association for the Advancement of Science.

Upcoming CPRIT Outreach Opportunities

As interest grows over the next four months in the issues on the upcoming November election ballot, I expect numerous opportunities to inform a variety of associations, organizations, and the public about CPRIT's activities. State law prohibits state employees from advocating for the outcome of an election, so all presentations made by CPRIT staff will be informational only. To that end we are preparing new slide decks and educational handouts that highlight CPRIT's benefits to the state and the Texas' economy since 2007. We are also compiling a list of organizations and events that may invite a CPRIT representative to speak.

I welcome your participation in this outreach effort. Please consider any groups that you think may be interested in hearing about CPRIT, as well as any organizations that you belong to that either you or someone from CPRIT could address. Examples include university boards of visitors and alumni organizations, chambers of commerce, social clubs (Kiwanis, Rotary, etc.), independent cancer advocacy organizations and editorial boards.

I will distribute the materials to you in July. We will also post the materials in box.com and on our website.

Compliance Program Update

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

CPRIT typically has 560+ grants that are either active or wrapping up grant activities and receives an average of 560 grantee reports each month. As of June 21, seven entities have not filed 25 Academic Research reports, two Product Development reports, and four Prevention reports. CPRIT's grant accountants and Compliance Specialists review and process incoming reports and reach out to grantees to resolve filing issues. In most cases, CPRIT does not disburse grant funds until the grantee files the required reports. In some instances, grantee institutions may be ineligible to receive a future award if the grantee does not submit the required reports.

<u>Financial Status Report Reviews</u>

CPRIT's Compliance Specialists performed 292 second-level reviews of grantee Financial Status Reports (FSRs) for the months of May and June. Twenty-one FSRs (7%) required resubmission due to insufficient or inaccurate documentation submitted by the grantee. CPRIT's grant accounting staff completes the initial review of the FSRs and supporting documentation before routing them to the Compliance Specialists for final review and disposition.

Single Audit Tracking

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 grantee submits the independent audit report with audit findings to CPRIT within 30 days of receipt, but no later than nine months after the grantee's fiscal year end.

Currently, there is one grantee with a delinquent audit. Grantees are unable to receive reimbursements or advances if they are delinquent in filing the required audit and corrective action plan unless the grantee requested additional time by the due date of the required audit and CPRIT's CEO approved the request. Compliance Specialists are working with the grantee.

Desk Reviews

Compliance Specialists performed 57 desk-based financial monitoring reviews during May and June. Desk reviews verify that grantees expend funds in compliance with specific grant requirements and guidelines and may target an organization's internal controls, current and past fiscal audits, and timeliness of required grantee report submission. Compliance Specialists are working with eight grantees to remediate desk review findings.

On-Site Reviews

Compliance Specialists conducted two on-site reviews during May and June. On-site reviews check the grantee's financial and administrative operations, subcontract monitoring, procurement and contracting procedures, inventory procedures, personnel policies and procedures, payroll and timesheet policies, travel policies and records, and single audit compliance.

Annual Compliance Attestation

CPRIT requires grantees to submit an annual Attestation Form, demonstrating compliance with statutory and administrative grant requirements, CPRIT's policies and procedures, grant contract terms, and the Uniform Grant Management Standards (UGMS). This opportunity to self-report, in the form of a checklist, provides a baseline of grantee compliance and allows Compliance Specialists to proactively work with grantees towards full compliance prior to a desk review or on-site review. As of June 21, Compliance staff are working with two grantees who require additional corrective action related to their attestation.

Training and Support

CPRIT staff conducted a series of Annual Compliance Training webinars on June 5-6. Trainings are specific to each program area (Academic Research, Product Development Research, and Prevention) and allow for an interactive experience and opportunity to focus on topics relevant to each program. The trainings covered grant reporting requirements, administrative rule changes,

grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. This is the second training series offered this year for the annual compliance training requirement, which requires the authorized signing official and at least one other employee from each grantee organization to attend annual compliance training by December 31.

CPRIT staff conducted two new Grantee training webinars on May 28 for Hummingbird Bioscience and Instapath, Inc. The trainings covered grant reporting requirements, administrative rule changes, grant closeout, an overview of the compliance program including fraud, waste, and abuse reporting, and a hands-on navigation of CPRIT's grants management system. Pursuant to Texas Administrative Code §703.22, CPRIT requires new Grantees to complete the initial compliance training program prior to receiving disbursement of Grant Award funds.

Academic Research Program Update

FY 2019 Cycle 2 Academic Research RFAs

CPRIT released the requests for applications (RFAs) for the second award cycle of FY 2019 (19.2) in August 2018. Applicants submitted 161 proposals to CPRIT for five different grant mechanisms by the January 30 deadline. Peer review panels met May 20 - May 24 in Dallas. Dr. Willson will present the Scientific Review Committee's (SRC) award recommendations to the Program Integration Committee (PIC) and the Oversight Committee in August.

FY 19.2 Funding Mechanism	Received	Funding Requested	Recommended	Funding Requested
Core Facilities Support Awards	19	$96,666,954	8	$36,288,629
High Impact/High Risk Research Awards	97	$19,379,981	18	$3,597,195
Early Translational Research Awards	28	$47,527,689	5	$7,599,384
Collaborative Action Program to Reduce Liver Cancer Mortality in Texas: Collaborative Action Center Award	2	$5,999,901	1	$3,000,000
Collaborative Action Program to Reduce Liver Cancer Mortality in Texas: Investigator Initiated Research Awards	15	$36,556,484	1	$2,456,676
TOTAL	**161**	**$206,131,009**	**33**	**$52,941,884**

FY 2019 Recruitment Applications

The SRC reviewed applications for recruitment cycle 19.10 on May 31 and recruitment cycle 19.11 on June 24. Dr. Willson will present the SRC's award recommendations to the PIC and the Oversight Committee at the Oversight Committee meeting in August.

19.10 and 19.11 Mechanisms	Received	Funds Requested	Approved by SRC	Funds Recommended
Recruitment Established Investigators	3	$18,000,000	3	$18,000,000
Recruitment of Rising Stars	4	$15,000,000	1	$4,000,000
Recruitment of First-Time, Tenure Track Faculty Members	16	$31,371,727	12	$23,669,997
TOTAL	**23**	**$64,371,727**	**16**	**$45,669,997**

FY 2020 Cycle 1 RFAs

CPRIT released the FY2020 Cycle 1 (20.1) RFAs in January and received 387 applications by the June 5 deadline. CPRIT has scheduled peer review October 17- 24 in Dallas. Dr. Willson will present the SRC's recommendations to PIC and the Oversight Committee in February 2020.

FY 20.1 Mechanism	Received	Funding Requested
Individual Investigator Research Awards	265	$231,827,224
Individual Investigator Research Awards for Cancer in Children and Adolescents	55	$64,930,190
Individual Investigator Research Awards for Prevention and Early Detection	38	$40,685,739
Individual Investigator Research Awards for Clinical Translation	29	$47,940,124
TOTAL	**387**	**$385,383,277**

The Childhood Brain Cancer Researchers Round-Up January 13, 2020

The Carson Leslie Foundation (CLF) and CPRIT Advisory Committee on Childhood Cancer will convene a meeting of leading brain cancer investigators from across Texas to discuss opportunities to accelerate progress against pediatric brain cancer. CLF will host the meeting in Dallas on January 13, 2020. CLF will provide $500 travel stipends for out-of-towners to attend the meeting. The Carson Leslie Foundation, dedicated to raising funds for research leading to a cure for pediatric cancer and enriching the lives of teens in the battle, was established to honor

the life of Carson Leslie who was diagnosed at age 14 with a medulloblastoma, the most common childhood brain tumor.

Product Development Research Program Update

Product Development Research Applications FY 2019 Cycle 1

During the Due Diligence Evaluation phase of the FY 2019 Cycle 1 review, the CPRIT Product Development Review Council (PDRC) took no action on two applications pending review of additional information requested from each applicant. The PDRC reviewed information provided by one of the applicants in May, declining to recommend the application for an award. The PDRC will review information from the second company at the PDRC meeting July 8. If the PDRC recommends an award, Dr. WalkerPeach will present the recommendation to the PIC and Oversight Committee in August.

Product Development Research Applications FY 2019 Cycle 2

CPRIT released three RFAs for the FY 2019 Cycle 2 (19.2) cycle on December 5, 2018, and accepted applications through January 30. Companies submitted 27 proposals, which CPRIT assigned to peer reviewers for evaluation. The peer review panels met in March for the initial review of applications. Eleven companies presented their applications to the peer review panel meetings held in Dallas April 16-18. The panels selected four companies to move forward to the due diligence review stage. The PDRC will convene July 8 to consider the due diligence reports and make final 19.2 cycle award recommendations. Dr. WalkerPeach will present the PDRC's recommendations to the PIC and the Oversight Committee in August.

19.2 Mechanism	Proposals Received	Funds Requested	In-Person Presentations	Funds Requested	Due Diligence	Funds Requested
Texas Company	4	$63.9M	3	$45.9M	1	$15.4M
Relocation Company	9	$108.8M	3	$23.0M	1	$7.4M
Seed Company	14	$37.8M	5	$15.0M	2	$6.0M
TOTAL	**27**	**$210.5M**	**11**	**$83.9M**	**4**	**$28.8M**

Product Development Research FY 2020 Cycle 1

The application portal for the FY 2020 Product Development Research award cycle (20.1) opened June 27 and will accept applications through August 7. Dr. WalkerPeach and Ms. French hosted a webinar May 23 to provide an overview of available Product Development RFAs. Dr. WalkerPeach will present the PIC award recommendations for the 20.1 cycle to the PIC and Oversight Committee in February 2020.

The Oversight Committee approved three RFAs for the 20.1 cycle at its meeting in February:

- *Texas Company Product Development Research Award*
  Supports early stage "start-up" and established companies in the development of innovative products, services, and infrastructure with significant potential impact on patient care. The proposed project must further the development of new products for the diagnosis, treatment, or prevention of cancer; must establish infrastructure that is critical to the development of a robust industry; or must fill a treatment or research gap. Companies must headquarter in Texas.
  Award: Maximum amount $20 million over 36 months

- *Relocation Company Research Award*
  Supports early stage "start-up" and established companies in the development of innovative products, services, and infrastructure with significant potential impact on patient care. The proposed project must further the development of new products for the diagnosis, treatment, or prevention of cancer; must establish infrastructure that is critical to the development of a robust industry; or must fill a treatment or research gap. Companies must relocate to Texas upon receipt of award.
  Award: Maximum amount $20 million over 36 months

- *Seed Award for Product Development Research*
  Supports projects that are earlier in their development timeline than CPRIT's two other Product Development Awards, the Texas Company Award, and the Company Relocation Award. The proposed project must further the development of new products for the diagnosis, treatment, or prevention of cancer; must establish infrastructure that is critical to the development of a robust industry; or must fill a treatment or research gap. Company applicants must headquarter in Texas or be willing to relocate to Texas upon receipt of award. Award: Maximum amount of $3 million over 36 months.

Unless Texans vote to approve the constitutional amendment authorizing an additional $3 billion in general obligation bond funding, CPRIT's Product Development Research Program will release only one cycle of RFAs for product development grants in FY 2020. If CPRIT secures additional funding, the Product Development Research Program plans to release a second cycle of RFAs for FY 2020.

Prevention Program Update

FY 2019 Cycle 2 Prevention Applications

CPRIT released FY 2019 Cycle 2 (19.2) RFAs in November 2018. CPRIT received 27 proposals requesting $38.1 million by the February 20 deadline. CPRIT held peer review May 21-22 in Dallas. The Prevention Review Council (PRC) will meet July 8 to review the results of the peer review panel as well as two Dissemination of CPRIT-funded Cancer Control Interventions applications. Chief Prevention Officer Ramona Magid will present the PRC's recommendations to the PIC and the Oversight Committee in August.

19.2 Mechanism	Applications Received	Funds Requested
Evidence-based Cancer Prevention Services	7	$ 6,844,590
Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations	13	$24,422,409
Tobacco Control and Lung Cancer Screening	7	$ 6,838,830
TOTAL	**27**	**$38,105,829**

FY 2020 Cycle 1 Prevention RFAs

CPRIT released four RFAs, described below, on June 6 for the first review cycle of FY 2020 (20.1). The 20.1 application deadline is September 4. CPRIT has scheduled peer review for December 9 – 12. Ms. Magid will present the PRC's recommendations to the PIC and the Oversight Committee in February 2020.

- *Evidence-Based Cancer Prevention Services*
  Seeks projects that will deliver evidence-based cancer prevention and control clinical services. CPRIT will give priority to projects that propose to address CPRIT areas of emphasis and serve areas of the state not well addressed by current CPRIT funded projects.
  Award: Maximum of $1 million over 36 months.

- *Tobacco Control and Lung Cancer Screening*
  Seeks programs on tobacco prevention and cessation, as well as screening for early detection of lung cancer. Through release of this RFA, CPRIT's goal is to stimulate more programs across the state, thereby providing greater access for underserved populations and reducing the incidence and mortality rates of tobacco-related cancers. This RFA seeks to promote and deliver evidence-based programming designed to significantly increase tobacco cessation among adults and/or prevent tobacco use by youth.
  Award: Maximum of $1 million over 36 months.

- *Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations*
  Seeks to support coordination and expansion of evidence-based services to prevent cancer in underserved populations who do not have adequate access to cancer prevention interventions and health care, bringing together networks of public health and community partners to carry out programs tailored for their communities. Projects should identify cancers that cause the most burden in the community and use evidence-based models shown to work in similar communities to prevent and control these cancers. Currently funded CPRIT projects should propose to expand their programs to include additional types of prevention clinical services and/or an expansion of current clinical services into additional counties. In either case, the expansion must include delivery of services to nonmetropolitan and medically underserved counties in the state.
  Award: Maximum of $2 million over 36 months.

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

The *2020 CPRIT Innovations VI* Conference

CPRIT sent a "Save the Date" announcement for the *2020 CPRIT Innovations VI Conference*. Communications and IT staff are also updating the conference website with the 2020 conference information, highlighting 2018 Nobel laureate and CPRIT Scholar Dr. Jim Allison as the conference keynote speaker.

Communications Update

Cancer Awareness Month Activities

- In recognition of Cancer Immunotherapy Awareness Month in June, CPRIT highlighted a new video on recent Product Development grantee Hummingbird on our website homepage. We shared a post on social media featuring CPRIT's participation in the BIO 2019 conference that included the embedded Hummingbird video.

- CPRIT also posted Cancer Immunotherapy Awareness Month messages via social media focusing on the work of CPRIT Scholars Dr. Allison and Dr. Qing Yi.

- June is also National Men's Health Month and National Men's Health Week (June 10-16). CPRIT posted general awareness messages focusing on prostate, penile and testicular cancers via social media using ASCO and CDC resources.

- July will be Sarcoma Awareness Month and UV Safety Month. CPRIT is planning social media messages around these events.

Upcoming Special Event - RELLIS Festival and Open House on October 5

The Texas A&M University System has invited CPRIT to participate in the opening celebration for TAMU's RELLIS Campus in Bryan on October 5. TAMU repurposed the Bryan Army Field property for the RELLIS campus, which the system will now dedicate to cutting-edge research, technology development, and workforce training. By tapping the TAMU System's state agencies and multiple universities, along with academic, corporate and government partners, the RELLIS Campus will offer two- and four-year college degrees.

The opening festival is an opportunity for prospective students, families, and the community to tour the RELLIS Campus. The event will feature live entertainment and end with a firework show. There will be family-friendly activities, food trucks, and a beer garden.

TAMU invited CPRIT to participate in the celebration as an opportunity for our agency to inform the public about CPRIT cancer prevention opportunities in the Brazos Valley and to stimulate CPRIT grant proposals from TAMU-component institution attendees.

Ms. Magid and Senior Program Manager for Academic Research Dr. Patty Moore are coordinating CPRIT's activities at the event.

Media Relations

- On June 20 I was interviewed by The University of Texas System's *Texas Health Journal* about UT component participation in CPRIT programs, CPRIT's origins, success and impact, and how the proposed constitutional amendment authorizing an additional $3 billion originated and negotiated through the legislative process. We expect the article to appear by the end of July.

Website/Production

- A brief description of House Joint Resolution 12 has been posted on the CPRIT website homepage that links to the legislation's language and bill analysis as well as my statement on its passage.

- Communications is creating new webpages for Childhood Cancer and Clinical Trials for an expected launch in July.

Social Media

Senior Communications Specialist Chris Cutrone is planning a soft launch of CPRIT's LinkedIn page in July. We plan to use our LinkedIn presence as a centerpiece for outreach to our key stakeholders.

Facebook (last 28 days):
- Reach: 548
- Engagement: 235
- Most popular post: "Today, the Texas Senate unanimously approved HJR 12. 'The Legislature's passage of HJR 12 is a strong endorsement to continue CPRIT's mission to find cures and preventions for cancer," said Wayne Roberts, CPRIT Chief Executive Officer. "The outcome now rests in the hands of Texas voters.'"

Twitter (May):
- 33,100 impressions

- Top tweet: “Today, the Texas Senate approved HJR 12. CPRIT CEO Wayne Roberts: ‘The Legislature’s passage of HJR 12 is a strong endorsement to continue CPRIT’s mission to find cures and preventions for cancer. The outcome now rests in the hands of Texas voters.’” https://cprit.us/2Yi9r0n.

Twitter (June 1-19):
- 12,800 impressions
- Top tweet: “June is #CancerImmunotherapyMonth. What is immunotherapy? Immunotherapy is a type of cancer treatment that boosts the body's natural defenses to fight cancer. Learn more from @CancerDotNet: https://cprit.us/2WfmApl.”

Operations, Audit and Finance Update

The internal audit team from Weaver initiated field work on follow-up procedures for the 2018 information security and communications audits.

Chief Operating Officer Heidi McConnell submitted a request for $54 million in general obligation commercial paper notes to the Texas Public Finance Authority. This is the final tranche of funds that will be issued this year and will bring the total issued for the year to $207.7 million.

August 21 Oversight Committee Meeting and Subcommittee Meetings

The August 21 Oversight Committee meeting is the last meeting of the fiscal year. In addition to grant recommendations for each of the three CPRIT programs, the Oversight Committee will also elect a new chief presiding officer and vice presiding officer for two-year terms as well as consider several other annual issues. We expect the August 21 meeting to last at least three hours and it will include a closed session. We plan to begin the meeting at 10:00, however, we are considering starting the meeting at 9:00 if members’ travel itineraries justify doing so.

Because of the two vacant Oversight Committee positions, any Oversight Committee member’s absence raises potential quorum issues. **Please notify me immediately if you are unable to attend the August 21 meeting or have schedule constraints that require you to arrive late or leave early.**

We will resume meeting in Room E1.012 of the Texas Capitol Extension now that the 2019 legislative session is over.

Listed below are the regularly scheduled subcommittees in advance of the August 21 Oversight Committee meeting.

Board Governance	August 8 at 10:00 a.m.
Audit	August 12 at 10:00 a.m.
Prevention	August 13 at 10:00 a.m.
Academic Research	August 14 at 10:00 a.m.

Product Development	August 15 at 10:00 a.m.
Nominations	August 16 at 10:30 a.m.

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

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CPRIT has awarded **1,380** grants totaling **$2.286 billion**

- 216 prevention awards totaling $235.5 million
- 1,164 academic research and product development research awards totaling $2.050 billion

Of the $2.050 billion in academic research and product development research awards,

- 30.7% of the funding ($630.2 million) supports clinical research projects
- 24.9% of the funding ($510.2 million) supports translational research projects
- 27.2% of funding ($532.0 million) supports recruitment awards
- 14.3% of the funding ($292.7 million) supports discovery stage research projects
- 2.9% of funding ($59.9 million) supports training programs.

CPRIT has 10 open Requests for Applications (RFAs)

- 3 Research Recruitment
- 3 Product Development
- 4 Prevention

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	CPRIT ACTIVITIES UPDATE JULY 2019
DATE:	AUGUST 2, 2019

Topics in this memo cover CPRIT activities in July, including preparations for the upcoming August 21 Oversight Committee meeting, recent milestones in our fight against cancer, a staffing summary, CPRIT outreach efforts, and updates from Compliance, Programs, and Operations.

Planning for the August 21 Oversight Committee Meeting

The Oversight Committee will meet August 21 in Room E1.012 of the Texas Capitol Extension. This meeting is the last meeting of the fiscal year and we have an ambitious agenda. In addition to grant recommendations for each of the three CPRIT programs, end of the fiscal year updates, proposed contract renewals, and audit reports, the Oversight Committee will also elect a new chief presiding officer and vice presiding officer for two-year terms.

We expect the August 21 meeting to last at least three hours and it will include a closed session. We plan to begin the meeting one hour earlier - at 9:00 - to accommodate the full agenda and members' travel schedules. CPRIT will post the final agenda for the Oversight Committee meeting by August 13; I have attached a tentative agenda.

Because of the two vacant Oversight Committee positions, any Oversight Committee member's absence raises potential quorum issues. **Please notify me immediately if you are unable to attend the August 21 meeting or have schedule constraints that require you to arrive after 9:00 a.m. or leave prior to 1:00 p.m.**

You will receive an email from CPRIT by August 9 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 more than 50 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 August 14. Hard copies of the agenda packet will be available at the meeting.

Recent Milestones in the Fight Against Cancer

CPRIT Grantees in the News

- David Johnson, M.D., CPRIT Scholar and chair of the Department of Internal Medicine at The University of Texas Southwestern Medical Center, is one of fifteen world-renowned leaders in hematology and oncology inducted into the 2019 class of "Giants of Cancer Care." *OncLive* sponsors the Giants of Cancer Care program to honor clinicians and investigators who have contributed to advancements in the understanding of cancer and the treatment of patients. Dr. Johnson's induction, in recognition for his clinical investigations that contributed to the current management of lung cancers, was announced at the annual meeting of the American Society of Clinical Oncology.

- The Gray Foundation of New York announced July 23 that Patrick Sung, D.Phil., Department of Biochemistry and Structural Biology Chair at The University of Texas Health Science Center at San Antonio, received a $3.75 million, four-year "team science" grant. Dr. Sung will lead a multi-institution team studying how women who are carriers of harmful mutations in the BRCA1 or BRCA2 gene are at elevated risk for developing breast and ovarian cancer. UTHSC San Antonio recruited Dr. Sung from Yale in early 2019 with the help of a $6 million CPRIT Established Investigator Recruitment Grant.

- Bellicum Pharmaceuticals announced July 8 that the company has achieved primary endpoint of event free survival at 180 days in its BP-004 European registration trial for rivo-cel (rivogenlecleucel). The European study results indicate that adding rivo-cel to stem cell transplants in patients lacking a human leukocyte antigen (HLA)-matched donor delivered comparable outcomes to HLA-matched unrelated donor transplants.

  Oncologists can cure many leukemia patients with a stem cell transplant following intense chemotherapy. However, the 20 – 25% of patients without an HLA-matched donor risk severe, often fatal complications because of the transplant or cannot receive the transplant. Bellicum is developing a new T-cell therapy (BPX-501) to solve the critical problems associated with non-matched transplants in children and adults with leukemia. Bellicum inserts a "safety switch" into donor T-cells, which allows the physician to kill harmful T cells while preserving those helpful T-cells that protect from infection, assist the new stem cells, and kill residual cancer.

  Data from this trial will form the basis of an anticipated submission of European Marketing Authorization Applications for rivo-cel and rimiducid in support of potential regulatory approval. When reporting the results, Bellicum's president and CEO Rick Fair said, "These final results support our belief that rivo-cel, if approved, may be a transformational new treatment option for pediatric patients with leukemias, lymphomas and genetic blood diseases." Bellicum, a Houston based company, received two CPRIT Product Development Awards in 2011 ($5.7 million) and 2016 ($17 million) to support drug development and clinical study.

- OncoNano Medicine, Inc., a clinical stage company, announced July 9 the completion of $23.7 million in a second tranche of Series A financing, bringing the total Series A raise to $35.4 million. Salem Partners arranged the round and participated as a principal investor.

  The company, a Dallas-based UT Southwestern spinout, is developing nanotechnology-enabled fluorescent probes to help cancer surgeons excise tumors. Surgery is a major mode of cancer treatment with over 550,000 cancer resection procedures per year in the U.S. A major surgical challenge is differentiating tumors from healthy tissue. Incomplete tumor removal is a major concern because the remaining tumor could regrow and metastasize to other organs. Conversely, removing healthy tissue can have adverse effects such as the ability to swallow in head and neck surgery, or have severe cosmetic scarring effects, such as in breast cancer surgery.

  OncoNano is the first company to advance product candidates using pH as a biomarker for cancer immunotherapy, therapeutic use and intra-operative imaging based on its pH-sensitive micelle technology. ONM-100 is the first product in a platform based upon OncoNano's library of unique micelles that are ultra-sensitive to changes in pH. The company reports a 100 percent imaging response in its Phase 1 trial for ONM-100. The intravenously administered imaging agent, which detects tumors and metastatic lymph nodes, is entering a Phase 2 clinical trial.

  OncoNano received a $6.0 million CPRIT Product Development Award in 2014 to fund the development of ONM-100 for the detection of breast, head and neck, and skin cancers.

- Hummingbird Bioscience, a biotech company focused on the discovery and development of novel antibody-based therapeutics, announced the successful completion of an extended Series A financing round on July 10. Heritas Capital Management and SEEDS Capital, the investment arm of Enterprise Singapore led the fundraising round.

  The company has developed a new cancer therapy, HMBD-002-V4, for patients who are resistant to cancer immuno-oncology (IO) drugs. FDA-approved IO drugs harness the power of the body's immune system to fight cancer. However, as many as 70% of patients develop resistance to the IO drug treatment and their cancer progresses, leaving them without options. Hummingbird is developing HMBD-002-V4 to treat one of the most important causes of IO treatment resistance – a branch of the immune system called MDSC cells that can switch-off the cancer killing cells turned on by the IO drugs. In preclinical studies, HMBD-002-V4 showed the ability to reverse resistance to IO therapies and completely cure the cancer in some cases.

  Hummingbird received a $13.1 million CPRIT Product Development Award in 2019 to support Phase 1A/B clinical trials in Texas for patients who have become resistant to approved IO therapies and whose cancers have progressed.

- Salarius Pharmaceuticals, Inc., a clinical-stage oncology company targeting the epigenetic causes of cancers, announced July 19 that it closed its merger with Flex Pharma, Inc. The

merged company, operating as Salarius Pharmaceuticals, will focus on the continued development of Salarius' clinical pipeline that targets rare, orphan cancers for which no approved targeted treatments are currently available and cancers with a high unmet need.

As a result of the merger, the company's common stock began trading on the Nasdaq Capital Market July 22 under the new ticker symbol "SLRX." In recognition of this milestone, the Salarius management team rang the opening bell for Nasdaq on July 30. I attended the event on behalf of CPRIT. David Arthur, Salarius CEO credited CPRIT for the company's early success.

Salarius also announced July 22 that the company enrolled the first patient in its Phase 1 clinical study of the company's lead compound, Seclidemstat, in patients with advanced solid tumors resistant to standard-of-care therapies. This is Salarius' second Phase 1 clinical study for Seclidemstat, which is also the subject of an ongoing clinical study focused on Ewing sarcoma, a devastating bone and soft tissue cancer. Seclidemstat has Orphan Drug Designation and Rare Pediatric Disease Designation from the U.S. Food and Drug Administration (FDA). Salarius expects to report early cohort data from both Phase 1 clinical studies in 2020. Salarius received an $18.7 million CPRIT Product Development Award in 2014 to support the Ewing sarcoma clinical trial.

- Aravive, Inc. announced July 31 that preliminary efficacy data from their ongoing clinical trial with AVB-500 showed compelling anti-tumor activity in the 12 patients treated from the first cohort of the ongoing Phase 1b portion of the Phase 1b/2 trial of the company's lead compound, AVB-500, in patients with platinum-resistant recurrent ovarian cancer. The response rate to standard of care chemotherapy alone in platinum-resistant recurrent ovarian cancer patients is typically 10-15 percent. The company reports that it will expand enrollment in the Phase 1b portion of the study to validate the unanticipated early positive efficacy signal.

  More than 22,000 women in the U.S. are diagnosed with ovarian cancer every year. Patients have shown little response to treatment, especially for platinum-resistant ovarian cancer. In fact, on average, only 10-15 percent of patients with platinum-resistant ovarian cancer respond to currently approved therapies.

Aravive, a Houston-based company, received a $20 million CPRIT Product Development Award in November 2015 to develop its lead targeted therapy against acute myeloid lymphoma and certain solid tumor indications including ovarian, pancreatic, and breast cancer.

Notable CPRIT Supported Research and Prevention Accomplishments

- A collaborative team of scientists led by Dr. Philip Lupo, an associate professor of pediatrics at Baylor College of Medicine, reported findings of an important study of cancer risk for children with birth defects in the June 20 issue of *JAMA Oncology*. The study determined that children with chromosomal anomalies were 12 times more likely to receive a cancer diagnosis, and children with nonchromosomal birth defects were 2.5 times more likely to have cancer before turning 18 years old. The research team gathered data from birth, birth defect, and cancer registries in Texas, Arkansas, Michigan, and North Carolina to generate a birth cohort of more than 10 million children born between 1992 and 2013. The investigators looked at diagnoses of cancer for children younger than 18 to determine differences in cancer risk between those with and without birth defects. This important study is the largest of its kind and the data can help to understand differences in outcomes for children with cancer. CPRIT awarded Dr. Lupo an individual investigator research award in August 2014 to support this study.

- CPRIT Scholar Dr. Filippo Giancotti, professor of Cancer Biology at The University of Texas M.D. Anderson Cancer Center, has discovered how an aggressive form of prostate cancer metastasizes by evading the immune system. He found that an epigenetic regulator known as the polycomb repressor complex 1 (PRC1) coordinates the initiation of metastasis by increasing the regenerative capacity of metastatic cells and by suppressing the immune system and spurring tumor blood vessel growth or angiogenesis. Together with other investigators, Dr. Giancotti also developed a novel in-class inhibitor of PRC1 which, when given in combination with existing immunotherapies, appears to stop and even reverse metastasis in mouse models. Dr. Giancotti published these findings in the July 18 online issue of *Cancer Cell*.

- A new molecular mechanism discovered by UT Southwestern researchers indicates that PARP inhibitors, a class of drugs currently used to treat a subset of breast cancer patients, may have broader effectiveness in treating breast cancers and ovarian and prostate cancers. Two CPRIT individual investigator awards to W. L. (Lee) Kraus, Ph.D., a UT Southwestern professor in the Department of Obstetrics and Gynecology, supported the new study reported in the July 24 issue of *Molecular Cell*.

  The FDA approved PARP inhibitors for the treatment of breast and ovarian cancers containing BRCA mutations, rare genetic mutations that disable a DNA repair pathway in cancer cells. Dr. Kraus' lab discovered that while the DNA repair pathway is disabled, PARP inhibitors attack the machinery that makes proteins, called ribosomes. These findings could increase the patient population benefiting from these drugs by two, three, or four-fold. UT Southwestern is planning clinical trials to pursue this new lead.

- Pingwei Li, Ph.D., a professor in the Department of Biochemistry and Biophysics at Texas A&M University's College of Agriculture and Life Sciences, identified the key component of the protein, STING, that signals the immune system to produce interferons to fight against viral infections or cancer. This basic research discovery initially funded by a CPRIT Individual Investigator Research Award led to another $1.8 million in funding from the National Institutes of Health. These findings provide a basis for the development of novel STING binder and blocker drugs for use against viral infection, cancer, and autoimmune disorders.

- Chemists at The University of Texas Dallas, supported by CPRIT High Risk High Impact and Individual Investigator Research awards, are using the natural detoxification process in the liver to improve disease targeting of engineered nanoparticles nanomedicines. Their key discovery, reported in the July 15 edition of the journal *Nature Nanotechnology*, found in a mouse model that the liver's natural toxin-removal processes can be used to enhance the delivery of nanomedicines while also making them safer by eliminating the nanomedicines that miss the target. Scientists have viewed liver uptake as a barrier to nanomedicine delivery; this new strategy utilizes liver behavior, once considered a disadvantage to the clinical translation of nanomedicines, as an advantage.

- Dr. Mamta Jain of The University of Texas Southwestern Medical Center spearheaded the mobilization of a coalition of Texas physicians in support of removing access restrictions for Hepatitis C virus (HCV) treatment. She worked with the Alliance for Patient Access, a national network of physicians dedicated to ensuring patient access to approved therapies and to appropriate clinical care, as well as the National Viral Hepatitis Roundtable, a national coalition of more than 500 members working together to eliminate hepatitis B and C. Dr. Jain's CPRIT project focuses on HCV and Hepatitis B virus screening and access to treatment in Dallas County, El Paso, and four federally qualified health centers in South Texas.

Personnel

CPRIT has filled 33 of our 35 full-time equivalent (FTE) positions. We are preparing the prevention program manager and the system administrator positions for posting later this summer.

Crispin Levi Healy was born on July 3, weighing 8 pounds 7 ounces. Parents Patrick Healy and Rosemary French, Senior Program Manager for Product Development, are happy and excited about their new family addition. So is CPRIT.

CPRIT Outreach

- CPRIT executive and program staff met with senior officials of the Texas A&M University System on July 25 to discuss ways their components can expand their involvement in all three of CPRIT's grant making programs.

- On July 25 Deputy Executive Officer and General Counsel Kristen Doyle and I attended the bill signing ceremony at the Texas Capitol for HB 3147 at the invitation of the bill's author, Representative Tan Parker. Rep. Parker proposed HB 3147 to eliminate patient barriers to participation in cancer clinical trials. CPRIT worked with Representative Parker during the session on the bill. Following the bill signing, Ms. Doyle and I met with Rep. Parker and representatives from the Lazarex Cancer Foundation to discuss opportunities to increase access to clinical trials.

Upcoming CPRIT Outreach Opportunities

Over the next three months interest will grow in the ten proposed constitutional amendments on the upcoming November election ballot. The CPRIT amendment, which we previously referred to as House Joint Resolution 12, is now officially known as Proposition 6. The Office of the Secretary of State randomly selected the resolution numbers on July 23.

We are cultivating opportunities to educate a variety of associations, organizations, ministerial groups, and the public about CPRIT's activities. State law prohibits state employees from advocating for the outcome of an election, so all presentations made by CPRIT staff will be informational only. To that end we have prepared a new slide deck and educational handouts. We prepared the slide deck for a 20-25-minute presentation. If the organization would like a shorter presentation, we designed the overall slide deck so that the presenter can extract high-level slides from the larger deck for two-minute, five-minute and 10-minute talks.

We need your participation in this outreach effort. Please consider any groups that you think may be interested in learning about CPRIT's activities, as well as any organizations that you belong to and report that information to me. Examples include university boards of visitors and alumni organizations, chambers of commerce, church groups, social clubs (Kiwanis, Rotary, etc.), independent cancer advocacy organizations and smaller local paper editorial boards. I may ask you to make the presentation if you have a unique relationship with the organization.

Compliance Program Update

Submission Status of Required Grant Recipient Reports

CPRIT typically has 560+ grants that are either active or wrapping up grant activities and receives an average of 560 grantee reports each month. As of July 23, five entities have not filed 24 Academic Research reports, and three Product Development reports. CPRIT's Grant Accountants and Compliance Specialists review and process incoming reports and reach out to grantees to resolve filing issues. In most cases, CPRIT does not disburse grant funds until the grantee files the required reports. In some instances, grantee institutions may be ineligible to receive a future award if the grantee does not submit the required reports.

Financial Status Report Reviews

CPRIT's Compliance Specialists performed 83 second-level reviews of grantee Financial Status Reports (FSRs) for the month of July. Fifteen FSRs (18%) required resubmission due to insufficient or inaccurate documentation submitted by the grantee. CPRIT's grant accounting

staff completes the initial review of the FSRs and supporting documentation before routing them to the Compliance Specialists for final review and disposition.

Single Audit Tracking

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 grantee submits the independent audit report with findings to CPRIT within 30 days of receipt, but no later than nine months after the grantee's fiscal year end.

Currently, there is one grantee with a delinquent audit. Grantees are unable to receive reimbursements or advances if they are delinquent in filing the required audit and corrective action plan unless the grantee requested additional time by the due date of the required audit and CPRIT's CEO approved the request. Compliance Specialists are working with the grantee.

On-Site Reviews

Compliance Specialists conducted one on-site review during July. On-site reviews examine the grantee's financial and administrative operations, subcontract monitoring, procurement and contracting procedures, inventory procedures, personnel policies and procedures, payroll and timesheet policies, travel policies and records, and single audit compliance.

Desk Reviews

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

Annual Compliance Attestation

CPRIT requires grantees to submit an annual Attestation Form, demonstrating compliance with statutory and administrative grant requirements, CPRIT's policies and procedures, grant contract terms, and the Uniform Grant Management Standards (UGMS). This opportunity to self-report, in the form of a checklist, provides a baseline of grantee compliance and allows Compliance Specialists to proactively work with grantees towards full compliance prior to a desk review or on-site review. As of July 23, Compliance Specialists are working with two grantees who require additional corrective action related to their attestation.

Training and Support

CPRIT staff conducted two new Authorized Signing Official (ASO) training webinars on July 11 for Molecular Templates and Salarius Pharmaceuticals. The trainings covered grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. Pursuant to Texas Administrative Code §703.22, CPRIT requires new ASOs to complete a compliance training within 60 days of the change.

Academic Research Program Update

FY 2019 Cycle 2 Academic Research RFAs

Dr. Willson will present the Scientific Review Committee's (SRC) award recommendations to the Program Integration Committee (PIC) and the Oversight Committee in August. CPRIT released the requests for applications (RFAs) for the second award cycle of FY 2019 (19.2) in August 2018. Applicants submitted 161 proposals to CPRIT for five different grant mechanisms by the January 30 deadline. Peer review panels met May 20 - May 24 in Dallas.

FY 19.2 Funding Mechanism	Received	Funds Requested	Recommended	Funds Recommended
Core Facilities Support Awards	19	$96,666,954	8	$36,288,629
High Impact/High Risk Research Awards	97	$19,379,981	18	$3,597,195
Early Translational Research Awards	28	$47,527,689	5	$7,599,384
Collaborative Action Program to Reduce Liver Cancer Mortality in Texas: Collaborative Action Center Award and Investigator Initiated Research Awards (2 mechanisms)	17	$42,556,385	2	$5,456,676
TOTAL	**161**	**$206,131,009**	**33**	**$52,941,884**

FY 2019 Recruitment Applications

The SRC met on May 31 and June 24 to review 23 applications for recruitment cycles 19.10 and 19.11. Dr. Willson will present the SRC's award recommendations to the PIC and the Oversight Committee at the Oversight Committee meeting in August.

19.10 and 19.11 Mechanisms	Received	Funds Requested	Approved by SRC	Funds Recommended
Recruitment Established Investigators	3	$18,000,000	3	$18,000,000
Recruitment of Rising Stars	4	$15,000,000	1	$4,000,000
Recruitment of First-Time, Tenure Track Faculty Members	16	$31,401,727	11	$21,669,997
TOTAL	**23**	**$64,401,727**	**15**	**$43,669,997**

FY 2020 Cycle 1 RFAs

CPRIT released the FY2020 Cycle 1 (20.1) RFAs in January and received 387 applications by the June 5 deadline. CPRIT has scheduled peer review October 17- 24 in Dallas. Dr. Willson will present the SRC's recommendations to PIC and the Oversight Committee in February 2020.

FY 20.1 Mechanism	Received	Funds Requested
Individual Investigator Research Awards	265	$231,827,224
Individual Investigator Research Awards for Cancer in Children and Adolescents	55	$64,930,190
Individual Investigator Research Awards for Prevention and Early Detection	38	$40,685,739
Individual Investigator Research Awards for Clinical Translation	29	$47,940,124
TOTAL	**387**	**$385,383,277**

Product Development Research Program Update

Product Development Research Applications FY 2019 Cycle 1

During the Due Diligence Evaluation phase of the FY 2019 Cycle 1 review, the CPRIT Product Development Review Council (PDRC) delayed action on two applications pending review of additional information. The PDRC reviewed information from the two applicants in May and July. If the PDRC recommends an award, Dr. WalkerPeach will present the recommendation to the PIC and Oversight Committee in August.

Product Development Research Applications FY 2019 Cycle 2

CPRIT released three RFAs for the FY 2019 Cycle 2 (19.2) cycle on December 5, 2018, and accepted applications through January 30. Companies submitted 27 proposals, which CPRIT assigned to peer reviewers for evaluation. The peer review panels met in March for the initial review of applications. Eleven companies presented their applications to the peer review panels

at meetings held in Dallas April 16-18. The panels selected four companies to move forward to the due diligence review stage. The PDRC convened July 8 to consider the due diligence reports and make final 19.2 cycle award recommendations. Dr. WalkerPeach will present the PDRC's recommendations for three company awards to the PIC and the Oversight Committee in August.

19.2 Mechanism	Proposals Received	Funds Requested	In-Person Presentations	Funds Requested	Due Diligence	Funds Requested
Texas Company	4	$63.9M	3	$45.9M	1	$15.4M
Relocation Company	9	$108.8M	3	$23.0M	1	$7.4M
Seed Company	14	$37.8M	5	$15.0M	2	$6.0M
TOTAL	**27**	**$210.5M**	**11**	**$83.9M**	**4**	**$28.8M**

Product Development Research FY 2020 Cycle 1

The application portal for the FY 2020 Product Development Research award cycle (20.1) opened June 27 and will accept applications through August 7. Dr. WalkerPeach and Ms. French hosted a webinar May 23 to provide an overview of available Product Development RFAs. Dr. WalkerPeach will present the PIC award recommendations for the 20.1 cycle to the PIC and Oversight Committee in February 2020.

Product Development Research FY 2020 Cycle 2

If Texans vote to approve Proposition 6 authorizing an additional $3 billion in general obligation bond funding, CPRIT's Product Development Research Program will release a second cycle of RFAs for product development grants in FY 2020. Dr. WalkerPeach will present the following three RFAs at the August Oversight Committee meeting for approval:

- *Texas Company Product Development Research Award* (TXCO):
  This award supports early-stage and established companies in the development of innovative cancer products, services, and infrastructure with significant potential impact on patient care. The proposed project must further the development of new products for the diagnosis, treatment, or prevention of cancer; must establish ecosystem infrastructure that is critical to the development of a robust life-science industry; or must fill a treatment or research gap with a significant unmet clinical need. Companies must currently headquarter in Texas. Award: Up to $20 million over a maximum timeline of three years.

- *Company Relocation Product Development Award* (RELCO):
  This award supports early-stage and established companies in the development of innovative cancer products, services, and infrastructure with significant potential impact on patient care. The proposed project must further the development of new products for the diagnosis, treatment, or prevention of cancer; must establish ecosystem infrastructure that is critical to the development of a robust life-science industry; or must fill a treatment or research gap

with a significant unmet clinical need. Companies must relocate to Texas upon receipt of award. Award: Up to $20 million over a maximum timeline of three years.

- *Seed Award for Product Development Research* (SEED):
  The award supports early stage "startup" companies that are earlier in their development timeline than CPRIT's two other Product Development Awards, the TXCO and RELCO awards. The proposed project must further the development of new products for the diagnosis, treatment, or prevention of cancer; must establish ecosystem infrastructure that is critical to the development of a robust life-science industry; or must fill a treatment or research gap with a significant unmet clinical need. Company applicants must headquarter in Texas or be willing to relocate to Texas upon receipt of award. Award: Up to $3 million over a maximum timeline of three years.

Prevention Program Update

FY 2019 Cycle 2 Prevention Applications

CPRIT released three FY 2019 Cycle 2 (19.2) RFAs in October 2018 and received 27 proposals requesting $38.1 million by the February 20 deadline. Peer review panels met May 21-22 in Dallas. The Prevention Review Council (PRC) met July 8 to review the results of the peer review panels as well as two Dissemination of CPRIT-funded Cancer Control Interventions applications. Chief Prevention Officer Ramona Magid will present the PRC's recommendations to the PIC and the Oversight Committee in August.

19.2 Mechanism	Applications Received	Funds Requested	Recommended
Evidence-based Cancer Prevention Services	7	$ 6,844,590	1
Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations	13	$24,422,409	6
Tobacco Control and Lung Cancer Screening	7	$ 6,838,830	2
TOTAL	**27**	**$38,105,829**	**$14,497,981**

FY 2020 Cycle 1 Prevention RFAs

CPRIT released four RFAs, described below, on June 6 for the first review cycle of FY 2020 (20.1). The 20.1 application deadline is September 4. CPRIT has scheduled peer review for December 9 – 12. Ms. Magid will present the PRC's recommendations to the PIC and the Oversight Committee in February 2020.

Communications Update

Cancer Awareness Month Activities

July was Sarcoma Awareness Month and UV Safety Month, and August will be National Immunization Awareness Month and Summer Sun Safety Month. August 1 is World Lung Cancer Day. CPRIT plans the core of its social media content around these events.

Media Relations

- On July 26, The San Antonio Business Journal published a positive story focusing on CPRIT's role in supporting local institutions and economic development in the region. https://www.bizjournals.com/sanantonio/news/2019/07/25/cprit-grants-help-bexar-county-with-cancer.html

- An article on CPRIT that featured quotes from an interview with Wayne ran on July 31 in the UT System's Texas Health Journal. https://www.utsystem.edu/sites/texas-health-journal/blog/cprit-reborn-2019-07-29

Website/Production

We plan to travel to San Antonio, Victoria, Houston, Lubbock, and Amarillo to interview prevention grantees by the end of August. We will use the taped interviews to help inform the public about CPRIT's prevention efforts, primarily through our newsroom and social media.

Social Media

CPRIT launched its LinkedIn page this month.

Facebook (July)
- Reach: 435
- Engagement: 177
- Most popular post: Salarius Pharmaceuticals, LLC, a clinical-stage oncology company and CPRIT grantee, today rang the Nasdaq Opening Bell. During the opening bell ceremony David Arthur, Salarius CEO, credited CPRIT for the company's early success. You can watch a video of the event here: https://www.facebook.com/Nasdaq/videos/778531299210732.

Twitter (July):
- 18,700 impressions
- Top tweet: Texans will have a say on CPRIT's continuation Nov. 5: Prop. 6 allows the legislature to increase CPRIT's bond from $3 to $6 billion. We look forward to new opportunities to fulfill our mission to improve the health and lives of fellow Texans. More: cprit.us/32SmaKr.

Operations, Audit and Finance Update

The internal audit team from Weaver initiated field work on follow-up procedures for the 2018 information security and communications audits.

Heidi McConnell submitted a request for $54 million in general obligation commercial paper notes to the Texas Public Finance Authority. This is the final tranche of funds that will be issued this year and will bring the total issued for the year to $207.7 million.

Upcoming Subcommittee Meetings

Listed below are the regularly scheduled subcommittees in advance of the August 21 Oversight Committee meeting.

Board Governance	August 8 at 10:00 a.m.
Audit	August 12 at 10:00 a.m.
Prevention	August 13 at 10:00 a.m.
Academic Research	August 14 at 10:00 a.m.
Product Development	August 15 at 10:00 a.m.
Nominations	August 16 at 10:30 a.m.

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

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CPRIT has awarded **1,380** grants totaling **$2.286 billion**

- 216 prevention awards totaling $235.5 million
- 1,164 academic research and product development research awards totaling $2.050 billion

Of the $2.050 billion in academic research and product development research awards,

- 30.7% of the funding ($630.2 million) supports clinical research projects
- 24.9% of the funding ($510.2 million) supports translational research projects
- 27.2% of funding ($532.0 million) supports recruitment awards
- 14.3% of the funding ($292.7 million) supports discovery stage research projects
- 2.9% of funding ($59.9 million) supports training programs.

CPRIT has 10 open Requests for Applications (RFAs)

- 3 Research Recruitment
- 3 Product Development
- 4 Prevention

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	VINCE BURGESS, CHIEF COMPLIANCE OFFICER
SUBJECT:	COMPLIANCE PROGRAM UPDATE
DATE:	AUGUST 13, 2019

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

Submission Status of Required Grant Recipient Reports

CPRIT typically has 560+ grants that are either active or wrapping up grant activities and receives an average of 560 grantee reports each month. As of August 5, six entities had not filed 15 Academic Research reports and three Product Development reports. CPRIT's grant accountants and Compliance Specialists review and process incoming reports and reach out to grantees to resolve filing issues. In most cases, CPRIT does not disburse grant funds until the grantee files the required reports. In some instances, grantee institutions may be ineligible to receive a future award if the grantee does not submit the required reports.

Financial Status Report Reviews

CPRIT's Compliance Specialists performed 118 second-level reviews of grantee Financial Status Reports (FSRs) for the month of July. Seventeen FSRs (14%) required resubmission due to insufficient or inaccurate documentation submitted by the grantee. CPRIT's grant accounting staff completes the initial review of the FSRs and supporting documentation before routing them to the Compliance Specialists for final review and disposition.

Single Audit Tracking

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 grantee submits the independent audit

report with audit findings to CPRIT within 30 days of receipt, but no later than nine months after the grantee's fiscal year end.

Currently, there is one grantee with a delinquent audit. Grantees are unable to receive reimbursements or advances if they are delinquent in filing the required audit and corrective action plan unless the grantee requested additional time by the due date of the required audit and CPRIT's CEO approved the request. Compliance Specialists are working with the grantee.

On-Site Reviews

Compliance Specialists conducted one on-site review during July. On-site reviews examine the grantee's financial and administrative operations, subcontract monitoring, procurement and contracting procedures, inventory procedures, personnel policies and procedures, payroll and timesheet policies, travel policies and records, and single audit compliance.

Desk Reviews

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

Annual Compliance Attestation

CPRIT requires grantees to submit an annual Attestation Form, demonstrating compliance with statutory and administrative grant requirements, CPRIT's policies and procedures, grant contract terms, and the Uniform Grant Management Standards (UGMS). This opportunity to self-report, in the form of a checklist, provides a baseline of grantee compliance and allows Compliance Specialists to proactively work with grantees towards full compliance prior to a desk review or on-site review. As of August 5, Compliance Specialists are working with one grantee who requires additional corrective action related to their attestation.

Training and Support

CPRIT staff conducted two new Authorized Signing Official (ASO) training webinars on July 11 for Molecular Templates and Salarius Pharmaceuticals. The trainings covered grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. Pursuant to Texas Administrative Code §703.22, CPRIT requires new ASOs to complete a compliance training within 60 days of the change.

Grantee Risk Assessment and FY20 Monitoring Plan

CPRIT's Compliance Program has completed the FY20 Grantee Risk Assessment process. Risk Assessments are performed on a quarterly and annual basis. The Risk Assessment Model considers several factors in determining grantee risk including:

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

Risk Assessments assign a priority ranking (1, 2, or 3) to grant recipients, which is used to determine monitoring and training needs for the coming fiscal year. Based on the results of the Risk Assessment, grantees will receive a desk review, or an on-site monitoring review completed by CPRIT staff. Compliance monitoring reviews are designed to evaluate a grantee's compliance with grant requirements included in the Texas Administrative Code, Texas Health and Safety Code, CPRIT Policies and Procedures, Uniform Grant Management Standards, and terms of the grant contract.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	JAMES WILLSON, MD., CHIEF SCIENTIFIC OFFICER
SUBJECT:	ACADEMIC RESEARCH PROGRAM UPDATE
DATE:	AUGUST 21, 2019

RFA Cycles FY20.1 and Cycle FY20.2

The Academic Research Program RFA release and review schedule is presented in the following figure. The Red bars represent RFAs approved previously by the Oversight Committee and the Blue bars represent RFAs that are proposed for Oversight Committee action at the August 21, 2019 meeting. The descriptions of the approved and proposed RFAs follow the figure.

Academic Research Program RFA Release Schedule

FY2020 Cycles and RFAs			FY2019										FY2020											
20.1/20.2 Propsed RFA Release	FY2020 Budget	Process Steps	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	April	May	June	July	Aug
	$174,287,869																							
Recruitment	**$80,000,000**	OC Approval																						
Established Investigators (5@$6M)	$30,000,000	RFA release																						
Rising Stars (4@$4M)	$16,000,000	Apps due- Mthly																						
First-Time Tenure Track Faculty Members (17@$2M)	$34,000,000	SRC- Monthly																						
		PIC/OC																						
20.1	**$39,287,569**	OC Approval																						
Individual investigator Research Awards (IIRA)	$21,000,000	RFA release																						
IIRA: Childhood and Adolescent Cancers	$7,287,869	Apps due																						
IIRACT: Clinical Translation	$6,000,000	PR/SRC																						
IIRAP: Prevention and Early Detection	$3,000,000	PIC/OC																						
20.2*	**$55,000,000**	OC Approval																						
Collaborative Action Program: RA (4@$2.5M)	$10,000,000	RFA release																						
Core Facility Research Awards (8 @$4M)	$32,000,000	Apps due																						
Early Clinical Investigator Award (6@$1.5M)	$9,000,000	PR/SRC																						
High Impact/High Risk Awards (18@$250K)	$4,500,000	PIC/OC																						

RED: In Process
Blue: Proposed

CAP - Collaborative Action Program to reduce liver cancer mortality in Texas (CAP:RA)

FY 2020 Cycle 1 (20.1) RFAs

CPRIT released FY2020 Cycle 1 RFAs (described below) on January 10, 2019. Applications were due on June 5, 2019. CPRIT has scheduled peer review October 17- 24, 2019 in Dallas. Dr. Willson will present the Scientific Review Council's recommendations to PIC and the Oversight Committee in February 2020.

- **Individual Investigator Research Awards (IIRA)**
  Supports applications for innovative research projects addressing critically important questions that will significantly advance knowledge of the causes, prevention, and/or treatment of cancer. Areas of interest include laboratory research, translational studies, and/or clinical investigations. Competitive renewal applications accepted.
  Award: Up to $300,000 per year. Exceptions permitted if extremely well justified; maximum duration: 3 years.

- **Individual Investigator Research Awards for Cancer in Children and Adolescents (IIRACCA)**
  Supports applications for innovative research projects addressing questions that will advance knowledge of the causes, prevention, progression, detection, or treatment of cancer in children and adolescents. Laboratory, clinical, or population-based studies are all acceptable. CPRIT expects the outcome of the research to reduce the incidence, morbidity, or mortality from cancer in children and/or adolescents in the near or long term. Competitive renewal applications accepted.
  Award: Up to $300,000 per year. Applicants that plan on conducting a clinical trial as part of the project may request up to $500,000 in total costs. Exceptions permitted if extremely well justified; maximum duration: 4 years.

- **Individual Investigator Research Awards for Prevention and Early Detection (IIRAP)**
  Supports applications for innovative research projects addressing questions that will advance knowledge of the causes, prevention, early-stage progression, and/or early detection of cancer. Research may be laboratory-, clinical-, or population- based, and may include behavioral/intervention, dissemination or health services/outcomes research to reduce cancer incidence or promote early detection. Competitive renewal applications accepted.
  Award: Up to of $300,000 per year for laboratory and clinical research; Up to $500,000 per year for population-based research. Exceptions permitted if extremely well justified; maximum duration: 3 years.

- **Individual Investigator Research Awards for Clinical Translation (IIRACT)**
  Supports applications which propose innovative clinical studies that are hypothesis driven and involve patients enrolled prospectively on a clinical trial or involve analyses of biospecimens from patients enrolled on a completed trial for which the outcomes are known. Areas of interest include clinical studies of new or repurposed drugs, hormonal therapies, immune therapies, surgery, radiation therapy, stem cell transplantation, combinations of interventions, or therapeutic devices.

Award: Up to $400,000 per year. Maximum duration: 3 years. Applicants that plan on conducting a clinical trial as part of the project may request up to $600,000 in total costs and a maximum duration of 4 years. Exceptions permitted if extremely well justified.

Proposed
FY 2020 Cycle 2 (20.2) RFAs

Dr. Willson will present the Academic Research Program's RFA proposals for the for FY2020 Cycle 2 at the August 21, 2019 Oversight Committee meeting. If approved, these RFAs will be released on August 26, 2019 with funding recommendations presented to the Oversight Committee at its August 2020 meeting.

- **Collaborative Action Program to reduce liver cancer mortality in Texas: Investigator Initiated Research Awards (RFA-R- 20.2 CAP: RA)**
  Supports investigator-initiated research projects designed to understand the reasons for the increased incidence of hepatocellular cancer (HCC) in Texas, to identify risk factors for cirrhosis and HCC, to identify biomarkers for HCC early detection, and to develop and implement prevention and early detection strategies.
  Award: CPRIT plans to make multiple awards in response to this RFA. Up to $500,000 (total costs); Maximum duration: 5 years.

- **Core Facility Support Awards (RFA R-20.2 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 $4,000,000 (total costs); Maximum duration: 5 years.

- **Early Clinical Investigator Award (ECI R-20.2 ECI)**
  Solicits applications from institutions to provide cancer physicians early in their academic career the opportunity to develop clinical research skills and to gain experience in advanced methods and experimental approaches needed to become clinical investigators; to provide an opportunity to establish a partnership with a laboratory-based collaborator in order to design and conduct correlative studies needed to interpret the outcome of an interventional trial; to provide the protected time from clinical responsibilities required to develop and conduct investigator initiated clinical trials; and to Increase the pool of clinical investigators at Texas academic institutions who are conducting patient-oriented studies, capitalizing on basic discoveries and translating them through conduct of innovative clinical trials involving cancer patients or individuals at risk for cancer.
  Award: Up to $1,5000,000 (total costs) Maximum duration: 5 years

- **High Impact/High Risk Research Awards (RFA R-20.2 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 $250,000 (total costs); Maximum duration: 2 years.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: CINDY R. WALKERPEACH, PH.D.
CHIEF PRODUCT DEVELOPMENT OFFICER

SUBJECT: PRODUCT DEVELOPMENT PROGRAM UPDATE

DATE: JULY 26, 2019

Product Development Research Applications FY 2019 Cycle 1

During the Due Diligence Evaluation phase of the FY 2019 Cycle 1 review cycle, the CPRIT Product Development Review Council (PDRC) voted to take "No Action" on two applications, pending review of additional information requested from each applicant. The PDRC received and reviewed requested information provided by one of the applicants and declined the applicant from further consideration. Requested materials were received from the second "No Action" applicant and reviewed by the PDRC on July 8, 2019. After consideration of the additional diligence materials, the PDRC recommended the RELOC applicant for an award ($18.7 million). For reference, previously awarded 19.1 Review Cycle application data can be found in Table 2.

Table 1: Review Cycle 19.1 Awards Recommended for Funding:

Mechanism	PDRC Recommended	Funds Requested (millions)
Relocation Company	Yes	$18.7

Table 2: Review Cycle 19.1 Application Data by Mechanism (excludes 19.1 recommendation)

Mechanism	Applications Received	Funds Requested (millions)	Invited to In Person	Invited to Due Diligence	Rec'd by PDRC	Funds Requested (millions)
Texas Company	5	$42.4	2	2	1	$8.7
Relocation Company	8	$113.8	4	3	1	$13.1
Seed Company	25	$65.0	11	4	3	$8.9
TOTAL	**38**	**$221.2**	**17**	**9**	**5**	**$30.7**

Product Development Research Applications FY 2019 Cycle 2

CPRIT released three RFAs for the FY 2019 Cycle 2 (19.2) cycle on December 5, 2018, and accepted applications through January 30, 2019. Companies submitted 27 proposals, which were assigned to peer reviewers for evaluation. The peer review screening calls were held on March 18 and 19, 2019 to discuss the applications and reviewers selected 11 companies to make in-person peer review presentations held in Dallas April 16-18, 2019. Four of the 11 applications which presented at the in-person peer review meeting were selected to move forward into the due diligence evaluation phase of the review process.

The PDRC convened on July 8, 2019 to consider the due diligence reports and make final award recommendations for consideration by the PIC and the Oversight Committee. The PDRC recommended one (1) TXCO, one (1) RELOC and one (1) SEED award for the 19.2 cycle. Table 3 details the 19.2 review cycle application data. Dr. WalkerPeach will present the PIC's recommendations for the combined 19.1 "No Action" and 19.2 review cycle awards at the August 2019 Oversight Committee meeting (Table 4).

Table 3: Review Cycle 19.2 Application Data by Mechanism

Mechanism	Applications Received	Funds Requested (millions)	Invited to In Person	Invited to Due Diligence	Rec'd by PDRC	Funds Requested (millions)
Texas Company	4	$63.9	3	1	1	$15.4
Relocation Company	9	$108.8	3	1	1	$7.4
Seed Company	14	$37.8	5	2	1	$3.0
TOTAL	**27**	**$210.4**	**11**	**4**	**3**	**$25.9**

Table 4: Review Cycles 19.1 and 19.2 Awards Recommended for Funding August 21

Mechanism	Application Cycle	Funds Requested (millions)
Relocation Company	19.1	$18.7
Relocation Company	19.2	$7.4
Seed Company	19.2	$3.0
Texas Company	19.2	$15.4
TOTAL	**4 recommended awards**	**$44.6**

Product Development Research Applications FY 2020 Cycle 1

CPRIT released three RFAs on May 16, 2019. The application portal opened June 27 and will be accepting applications through August 7. Initial peer review will take place September 24-25 and applicants that the peer review panel invites to make in-person presentations will do so October 22-25. Following due diligence, the Chief Product Development Officer will present the PDRC's recommendations to the PIC and at the February 2020 Oversight Committee meeting.

Proposed Product Development Research RFAs FY 2020 Cycle 2

Recent activity within the 86th Texas Legislature will allow CPRIT to support a second product development cycle within FY2020. With the Oversight Committee's approval, the Product Development Research Program proposes to release the TXCO, RELCO and SEED RFAs, as described below, for PDR 20.2 cycle. CPRIT plans to release the RFAs on November 20, 2019, with the Chief Product Development Officer presenting award recommendations at the August 2020 Oversight Committee meeting.

- *Texas Company Product Development Research Award* (TXCO)
  Supports early-stage "startup" and established companies in the development of innovative products, services, and infrastructure with significant potential impact on patient care. The proposed project must further the development of new products for the diagnosis, treatment, or prevention of cancer; must establish infrastructure that is critical to the development of a robust industry; or must fill a treatment or research gap. Companies must headquarter in Texas.
  Award: Maximum amount $20 million over 36 months

- *Relocation Company Product Development Research Award* (RELCO)
  Supports early-stage "startup" and established companies in the development of innovative products, services, and infrastructure with significant potential impact on patient care. The proposed project must further the development of new products for the diagnosis, treatment, or prevention of cancer; must establish infrastructure that is critical to the development of a robust industry; or must fill a treatment or research gap. Companies must relocate to Texas upon receipt of award.
  Award: Maximum amount $20 million over 36 months

- *Seed Award for Product Development Research* (SEED)
  Supports projects that are earlier in their development timeline than CPRIT's two other Product Development Awards, the Texas Company Award, and the Company Relocation Award. The proposed project must further the development of new products for the diagnosis, treatment, or prevention of cancer; must establish infrastructure that is critical to the development of a robust industry; or must fill a treatment or research gap. Company applicants must headquarter in Texas or be willing to relocate to Texas upon receipt of award.
  Award: Maximum amount of $3 million over 36 months.

Proposed Product Development Research Program Priorities

The Product Development Research Program priorities were established in 2019 based on the following principles:

- Support commercial development of novel products that address unmet cancer diagnostics and treatment needs;
- Stimulate the Texas life sciences ecosystem by supporting funding gaps that lack enough private investment;
- Invest in projects based on sound scientific research with experienced management and supportable business plans with potential to attached additional private funding necessary to launch cancer healthcare related products and services.

With the Oversight Committee's approval, the Product Development Program recommends continuing with the current program priorities detailed below.

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

Proposed Product Development Advisory Committee (PDAC) Nomination

The CPRIT Product Development Advisory Committee (PDAC) is an *ad hoc* advisory committee that offers guidance to the Oversight Committee on issues related to CPRIT's Product Development Research Program. With the Oversight Committee's approval, the Product Development Program nominates Mr. Greg Hartman, Interim Senior Vice President, Texas A&M University Health Science Center, to join the PDAC.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER
FROM:	CINDY R. WALKERPEACH, PH.D. CHIEF PRODUCT DEVELOPMENT OFFICER
SUBJECT:	NOTIFICATION OF MEMBERSHIP EXPANSION: PRODUCT DEVELOPMENT REVIEW COUNCIL
DATE:	JULY 23, 2019

Background

The CPRIT Product Development Review Council (PDRC) presides over the peer review process for CPRIT's Product Development Research Program. Pre-award, the PDRC critically reviews peer reviewer critiques and makes final award funding recommendations to CPRIT's Program Integration Committee (PIC) and the Oversight Committee (OC). Post-award, the PDRC is responsible for annual progress, tranche and final report reviews, approvals and recommendations for continued project funding. Typically, PDRC members spend approximately 40% on pre-award activities and approximately 60% of their efforts on post-award matters.

Currently the PDRC has six (6) members, each of which is a Subject Matter Expert (SME) in his or her field of drug development. These are highly experienced individuals, with deep biotech and pharmaceutical experience in launching significant products into the drug marketplace. CPRIT funding cycles have historically weighted to drug development with a current awardee company portfolio of 80% drug product development, 10% diagnostic product development and 10% medical device product development. The Product Development Research Program plans to add an additional member to the established PDRC membership for the following reasons.

Workload

As the number of portfolio company awardees continues to increase, the number of annual progress, tranche and final reports also continues to increase. The product development portfolio is currently 20 active company awardees and will expanded to 24 after adding 4 new awards for 19.2 cycle, hence current PDRC members are responsible for 3-4 awardees each. That ratio is not sustainable and the PDRC recently experienced a long-standing member resignation primarily due to workload. Individually the PDRC membership has each been polled by the CPDO and each reported a need to relieve the workload.

Expanded Subject Matter Expertise Outside of Drug Development
CPRIT's Product Development Research awardee portfolio continues to be heavily weighted towards drug development both in applicants and awardees. However, the Program receives, critically reviews and makes funding recommendations for areas outside of drug development. While the current PDRC membership has some limited experience with medical device and diagnostics, the Program believes that by adding an experienced SME in either medical device or diagnostics, will significantly enhance the quality of those applicant reviews and any post-award project matters.

Breaking the Tie
The current membership finds themselves occasionally tied on a significant progress report vote. Adding a 7th member will alleviate the need for the Chair and/or Vice Chair to break the tie.

Notification of PDRC Expansion
Taken together, the Product Development Research Program believes there is significant justification for adding a new (and 7th) member to the PDRC to address workload concerns, industry expertise outside of drug development and having a numerically odd number of members.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: RAMONA MAGID, CHIEF PREVENTION OFFICER

SUBJECT: PREVENTION PROGRAM UPDATE

DATE: AUGUST 6, 2019

FY 2019 Cycle 2 (19.2) Prevention Applications

CPRIT released three FY 2019 Cycle 2 (19.2) RFAs in October 2018 for the second review cycle of FY 2019. Twenty-seven (27) applications underwent peer review in Dallas on May 21 - 22. The Prevention Review Council (PRC) met July 8 to review the results of the peer review panel as well as two Dissemination of CPRIT-Funded Cancer Control Interventions applications that CPRIT received by June 30. The Program Integration Committee (PIC) met August 6 and Ms. Magid presents the PIC's recommendations to the Oversight Committee August 21.

FY 2019.2 (19.2) Application Data by Mechanism

Mechanism	Received	Funds Requested
Evidence-based Cancer Prevention Services	7	$ 6,844,590
Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations	13	$24,422,409
Tobacco Control and Lung Cancer Screening	7	$ 6,838,830
TOTAL	**27**	**$38,105,829**

FY 2020 Cycle 1 Prevention RFAs

CPRIT released four RFAs, described below, on June 6 for the first review cycle of FY 2020 (20.1). The application deadline is September 4. CPRIT has scheduled peer review December 9 - 12. Ms. Magid will present the PRC's recommendations to the PIC and the Oversight Committee in February 2020.

FY 2020 Cycle 2 Prevention RFAs and schedule

The proposed schedule and RFAs to be released for FY 2020 Cycle 2 will be considered at the August 21 Oversight Committee meeting.

Timeline - Cycles 20.1 – 20.2

	20.1 In progress	20.2 For approval
Submission	Sept. 4, 2019	Feb. 19, 2020
Peer Review	Dec. 9 - 12, 2019	May 18 - 21, 2020
PRC	Jan. 17, 2020	Jul. 7, 2020
PIC	Feb. 4, 2020	Aug. 4, 2020
OC	Feb. 19, 2020	Aug. 19, 2020

Proposed RFAs

- *Evidence-Based Cancer Prevention Services*
  Seeks projects that will deliver evidence-based cancer prevention and control clinical services. CPRIT will give priority to projects that propose to address CPRIT areas of emphasis and serve areas of the state not well addressed by current CPRIT funded projects.
  Award: Maximum of $1M over 36 months.

- *Tobacco Control and Lung Cancer Screening*
  Seeks programs on tobacco prevention and cessation, as well as screening for early detection of lung cancer. Through release of this RFA, CPRIT's goal is to stimulate more programs across the state, thereby providing greater access for underserved populations and reducing the incidence and mortality rates of tobacco-related cancers. This RFA seeks to promote and deliver evidence-based programming designed to significantly increase tobacco cessation among adults and/or prevent tobacco use by youth.
  Award: Maximum of $1M over 36 months.

- *Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations*
  Seeks to support coordination and expansion of evidence-based services to prevent cancer in underserved populations who do not have adequate access to cancer prevention interventions and health care, bringing together networks of public health and community partners to carry

out programs tailored for their communities. Projects should identify cancers that cause the most burden in the community and use evidence-based models shown to work in similar communities to prevent and control these cancers. Currently funded CPRIT projects should propose to expand their programs to include additional types of prevention clinical services and/or an expansion of current clinical services into additional counties. In either case, the expansion must include delivery of services to nonmetropolitan and medically underserved counties in the state.
Award: Maximum of $2M over 36 months.

August 2019 Oversight Committee
Internal Audit Status Report
As of August 5, 2019

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 and Daniel Graves, Partner.

2019 Internal Audit Plan and Schedule

The table below reflects the activity to date Weaver has completed for the 2019 Internal Audit Plan. The portions of the plan where the status has been previously provided to the Oversight Committee have been shaded grey.

NEW INTERNAL AUDITS		
Internal Audit	**Description**	**Status**
State Reporting	Fieldwork for the State Reporting audit was completed and an exit meeting was held on January 16, 2019. We issued the report on January 25, 2019. The audit resulted in an overall assessment of "Strong" with two Low findings: • Tracking and communicating report deadlines to CPRIT personnel with responsibility for report completion • Documenting procedures over the expected processes for managing and monitoring state reporting requirements Follow-up procedures on the remediation of the findings will be included in the proposed audit plan for fiscal year 2020.	Complete
Budget and Planning	Fieldwork for the Budget and Planning audit was completed and an exit meeting was held on January 16, 2019. We issued the report on January 25, 2019. The audit resulted in an overall assessment of "Strong" with no findings.	Complete

FOLLOW-UP PROCEDURES		
Follow-Up	**Description**	**Status**
SAO Performance Measures Follow-Up • 3 Findings	Fieldwork for these follow-up procedures was completed on December 5, 2018. The report was issued December 12, 2018. All three findings from the prior audit were remediated.	Complete No open findings

Follow-Up	Description	Status
Post-Award Grant Monitoring Follow-up • 1 Moderate Finding	Fieldwork for these follow-up procedures was completed on April 11, 2019. The report was issued April 26, 2019. The open finding from the prior audit was remediated.	Complete No open findings
Procurement and P-Cards Follow-up • 1 Moderate Finding	Fieldwork for these follow-up procedures was completed on August 1, 2019. The report was issued August 5, 2019. The remaining open finding from the prior audit was remediated.	Complete No open findings
Information Security Follow-Up	Fieldwork for these follow-up procedures was initiated in June 2019. Completion of procedures was postponed due to the implementation of the new CPRIT website. Additional procedures to validate the current data classification and user access review processes will be completed in August 2019.	August 2019
Communications Follow-Up • 1 High Finding • 4 Moderate Findings	Fieldwork for these follow-up procedures was initiated in July 2019. Completion of procedures was postponed due to the implementation of the new CPRIT website. Procedures over CPRIT's social media postings and Momentum Reports have been completed. Additional procedures to validate review and approval of website updates, website compliance and MailChimp user access will be completed in August 2019.	August 2019

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

The annual update of the Internal Audit Risk Assessment was performed on August 1, 2019. Based on the risk assessment results, we prepared proposed Internal Audit Plans for fiscal years 2020, 2021, and 2022. Upon approval from the Oversight Committee, the 2020 Internal Audit Plan will be included in the required Annual Internal Audit Report, due November 1, 2019.

The 2019 fiscal year's guidance for Annual Internal Audit Report which is due November 1, was published on August 2, 2019, and includes no new requirements that affect CPRIT. Based on proposed completion of the follow-up procedures in August 2019 and timing of the November 2019 Oversight Committee Meeting, we have requested an extension to November 22, 2019 for the submittal of the report to the State Auditor's Office. The Annual Internal Audit Report will be presented for approval at the November 2019 Oversight Committee Meeting.

Alyssa G. Martin, CPA, MBA, Internal Auditor
Executive Partner
Weaver and Tidwell L.L.P

Cancer Prevention and Research Institute of Texas
Schedule of Audits, Status, and Findings Summary
As of August 5, 2019

Audit	Fiscal Year	Status/Timing	Report Date	Report Rating	Open Findings				Closed Findings				Total Findings			
					High	Mod	Low	Total	High	Mod	Low	Total	High	Mod	Low	Total
Fiscal Year 2015																
Grant Management	2015	Complete	July 27, 2015	Satisfactory	-	8	1	9	-	-	-	-	-	8	1	9
Expenditures Internal Audit	2015	Complete	August 24, 2015	Strong	-	-	2	2	-	-	-	-	-	-	2	2
2014 Governance and IT Follow-Up	2015	Complete	August 14, 2015	Satisfactory	-	-	-	9	-	-	-	7	-	1	1	2
2014 Grantee Monitoring Follow-Up	2015	Complete	July 31, 2015	Satisfactory	-	-	-	14	-	-	-	11	1	-	2	3
Fiscal Year 2015 Subtotal					-	8	3	34	-	-	-	18	1	9	6	16
Fiscal Year 2016																
Commodity and Service Contracts Internal Audit	2016	Complete	May 13, 2016	Satisfactory	-	3	2	5	-	-	-	-	-	3	2	5
Revenue Internal Audit	2016	Complete	July 8, 2016	Strong	-	-	2	2	-	-	-	-	-	-	2	2
Information Security Internal Audit	2016	Complete	August 3, 2016													
Cash Management Internal Audit	2016	Complete	August 12, 2016	Strong	-	1	-	1	-	-	-	-	-	1	-	1
2015 Grant Management Follow-Up	2016	Complete	June 9, 2016	Strong	-	8	1	9	-	8	1	9	-	-	-	-
2015 Information Technology Follow-Up	2016	Complete	N/A	N/A	-	1	1	2	-	1	1	2	-	-	-	-
Fiscal Year 2016 Subtotal					-	13	6	19	-	9	2	11	-	4	4	8
Fiscal Year 2017																
Training Program Internal Audit	2017	Complete	March 10, 2017	Strong	-	2	-	2	-	-	-	-	-	2	-	2
Internal Agency Compliance	2017	Complete	April 17, 2017	Strong	-	1	-	1	-	-	-	-	-	1	-	1
Pre-Award Grant Management	2017	Complete	May 30, 2017	Satisfactory	1	2	-	3	-	-	-	-	1	2	-	3
Procurement and P-Card Internal Audit	2017	Complete	August 4, 2017	Satisfactory	-	7	2	9	-	-	-	-	-	7	2	9
2016 Information Security Follow-Up	2017	Complete	May 30, 2017													
2016 Commodity and Service Contracts Follow-Up	2017	Complete	July 13, 2017	Strong	-	3	2	5	-	3	2	5	-	-	-	-
2016 Revenue Follow-Up	2017	Complete	July 8, 2017	Strong	-	-	2	2	-	-	2	2	-	-	-	-
2016 Cash Management Follow-Up	2017	Complete	July 13, 2017	Strong	-	1	-	1	-	1	-	1	-	-	-	-
Fiscal Year 2017 Subtotal					1	16	6	23	-	4	4	8	1	12	2	15
Fiscal Year 2018																
Post Award Grant Monitoring Internal Audit	2018	Complete	February 1, 2018	Strong	-	1	-	1	-	-	-	-	-	1	-	1
Grant Contracting Internal Audit																
Communication Internal Audit	2018	Complete	April 30, 2018	Satisfactory	1	4	-	5	-	-	-	-	1	4	-	5
2016 Information Security Follow-Up	2018	Complete	July 17, 2018													
2017 Training Program Follow-Up	2018	Complete	January 19, 2018	Strong	-	2	-	2	-	2	-	2	-	-	-	-
2017 Internal Agency Compliance Follow-Up	2018	Complete	January 19, 2018	Strong	-	1	-	1	-	1	-	1	-	-	-	-
2017 Pre-Award Grant Management Follow-Up	2018	Complete	April 24, 2018	Strong	1	2	-	3	1	2	-	3	-	-	-	-
2017 Procurement and P-Card Follow-Up	2018	Complete	April 30, 2018	Strong	-	7	2	9	-	6	2	8	-	1	-	1
Fiscal Year 2018 Subtotal					2	17	2	21	1	11	2	14	1	6	-	7
Fiscal Year 2019																
State Reporting Internal Audit	2019	December 2018	January 25, 2019	Strong	-	-	2	2	-	-	-	-	-	-	2	2
Budget and Planning	2019	December 2018	January 25, 2019	Strong	-	-	-	-	-	-	-	-	-	-	-	-
2017 SAO Performance Measures Follow-up	2019	November 2018	December 6, 2018	Strong	-	-	3	3	-	-	3	3	-	-	-	-
2016 Information Security Follow-Up	2019	August 2019	TBD													
2018 Communication Follow-Up	2019	August 2019	TBD	TBD	1	4	-	5	-	1	-	1	1	3	-	4
2018 Post Award Grant Monitoring Follow-Up	2019	February 2019	April 11, 2019	Strong	-	1	-	1	-	1	-	1	-	-	-	-
2018 Grant Contracting Follow-Up																
2017 Procurement and P-Card Follow-Up	2019	July 2019	August 1, 2019	Strong	-	7	2	9	-	7	2	9	-	-	-	-
Fiscal Year 2019 Subtotal					1	12	7	20	-	9	5	14	1	3	2	6

FISCAL YEAR 2019 SUMMARY

Audit	Fiscal Year	Status/Timing	Report Date	Report Rating	Findings				Closed Findings				Total Open Findings				Timing of Follow-Up Procedures by IA
					High	Mod	Low	Total	High	Mod	Low	Total	High	Mod	Low	Total	
State Reporting Internal Audit	2019	December 2018	January 25, 2019	Strong	-	-	2	2	-	-	-	-	-	-	2	2	FY 2020
Budget and Planning	2019	December 2018	January 25, 2019	Strong	-	-	-	-	-	-	-	-	-	-	-	-	
Post Award Grant Monitoring Internal Audit	2018	February 2019	April 11, 2019	Strong	-	1	-	1	-	1	-	1	-	-	-	-	
Grant Contracting Internal Audit																	
Communication Internal Audit	2018	August 2019	TBD	TBD	1	4	-	5	-	1	-	1	1	3	-	4	August 2019
SAO Performance Measures	2017	November 2018	December 6, 2018	Strong	-	-	3	3		-	3	3	-	-	-	-	
Procurement and P-Cards	2017	July 2019	August 1, 2019	Strong	-	7	2	9	-	7	2	9	-	-	-	-	
Information Security Internal Audit	2016	August 2019	TBD														August 2019
Total Findings For Internal Audit Follow-Up					1	12	7	20	-	9	5	14	1	3	2	6	

Cancer Prevention and Research Institute of Texas

IA #05-2019 Internal Audit Follow-Up Procedures Report over Procurement and P-Cards

Report Date: August 1, 2019

Issued: August 5, 2019

weaver

Assurance • Tax • Advisory

CONTENTS

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

This report presents the results of the internal audit follow-up procedures performed for the Cancer Prevention and Research Institute of Texas (CPRIT) during the period February 19, 2019 through August 1, 2019 related to the findings from the Internal Audit Report over Procurement and P-Cards dated June 21, 2017.

The objective of these follow-up procedures was to validate that adequate corrective action has been taken in order to remediate the remaining open issue identified in the 2017 Internal Audit Report over Procurement and P-Cards.

To accomplish this objective, we conducted interviews with key Finance personnel. We also reviewed documentation and performed specific testing procedures to validate actions taken. Procedures were performed at the Cancer Prevention and Research Institute and completed on August 1, 2019.

The following report summarizes the results of our procedures.

Weaver and Tidwell, L.L.P.

WEAVER AND TIDWELL, L.L.P.

Austin, Texas
August 5, 2019

Cancer Prevention and Research Institute of Texas

IA #05-2019 Internal Audit Follow-Up Procedures Report
over Procurement and P-Cards
August 1, 2019
Issued: August 5, 2019

Background

In fiscal year 2017, an internal audit over CPRIT's procurement and P-Card processes was completed. The internal audit report identified nine areas of improvement. In fiscal year 2018, follow-up procedures were performed to evaluate the corrective action taken by CPRIT management to remediate internal audit findings. As a result of those follow-up procedures, seven findings were determined to be remediated while one was determined to be partially remediated, and one was closed by management.

The 2019 Internal Audit Plan included performing follow-up procedures to validate that CPRIT management has taken steps to address the one remaining open internal audit finding.

Follow-Up Objective and Scope

The follow-up procedures focused on the remediation efforts taken by CPRIT management to address the open finding included in the 2017 Internal Audit Report over Procurement and P-Cards, and to validate that appropriate corrective action had been taken.

We evaluated the corrective action of the one remaining open internal audit finding identified in the 2017 Internal Audit Report over Procurement and P-Cards. In addition, we evaluated corrective action taken by management to address the open observation identified in the 2017 Internal Audit over Procurement and P-Cards that was provided separately.

Executive Summary

The findings from the 2017 Internal Audit Report over Procurement and P-Cards include those items that were identified and are considered to be non-compliance issues with CPRIT's policies and procedures, rules and regulations required by law, or where there is a lack of procedures or internal controls in place to cover risks to CPRIT. These issues could have significant financial or operational implications.

Through our interviews, review of documentation, observations and testing we determined that the one open finding where corrective action was evaluated was remediated.

A summary of our results is provided in the table below.

Risk Rating	Total Findings	Previously Closed	Remediated	Open
High	-	-	-	-
Moderate	7	6	1	-
Low	2	2	-	-
Total	**9**	**8**	**1**	**-**

Cancer Prevention and Research Institute of Texas
IA #05-2019 Internal Audit Follow-Up Procedures Report
over Procurement and P-Cards
August 1, 2019
Issued: August 5, 2019

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

OVERALL ASSESSMENT	STRONG

SCOPE AREA	RESULT	RATING
Procurement and P-Cards: Validate that adequate corrective action has been taken in order to remediate the remaining open issue identified in the 2017 Internal Audit Report over Procurement and P-Cards.	We identified that remediation efforts were made by CPRIT management for the one remaining finding from the 2017 Internal Audit Report over Procurement and P-Cards.	**STRONG**

Conclusion

Based on our evaluation, CPRIT has made satisfactory progress to remediate the remaining open finding from the 2017 Internal Audit Report over Procurement and P-Cards. Management should continue to focus on maintaining and strengthening internal controls over Procurement and P-Cards processes.

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

Cancer Prevention and Research Institute of Texas

IA #05-18 Internal Audit Follow-Up Procedures Report
over Procurement and P-Cards
August 1, 2019
Issued: August 5, 2019

Detailed Follow-Up Results, Recommendations and Management Response

Our procedures included interviewing key personnel in Procurement and Finance to gain an understanding of the corrective actions taken in order to address the open finding identified in the 2017 Internal Audit Report over Procurement and P-Cards, as well as examining existing documentation and communications and performing testing in order to validate those corrective actions. We evaluated the existing policies, procedures, and processes in their current state.

Finding 9 – MODERATE – Timeliness of P-Card and Travel Card Reconciliations: CPRIT does not have procedures in place to ensure that P-Card and Travel Card reconciliations are performed timely. P-Card and Travel Card reconciliations are performed prior to submitting the transactions for payment. The monthly statements must be reconciled and submitted within 30 days to meet the payment requirement of the Texas Prompt Payment Act.

Of the 6 monthly P-Card reconciliations tested, 1 was not completed and reviewed in a timely manner. The reconciliation was completed and reviewed 45 days after receipt of the statement resulting in a delayed payment of the P-Card.

Of the 6 monthly Travel Card reconciliations tested, 4 were not completed and reviewed in a timely manner. Reconciliations were completed between 34 and 70 days after receipt of the statement resulting in a delayed payment of the Travel Card.

In April 2018, we reviewed the 4 Travel Card statement reconciliations for the period of December 2017 through March 2018 and determined that 3 of the 4 reconciliations were not completed timely, within 30 days from the receipt of the statement. Reconciliations were completed 48, 59, and 66 days after receipt of the statement.

Results: Finding remediated

We reviewed the four Travel Card statement reconciliations for the period of April 2018 through July 2018 and determined that all reconciliations were completed timely, within 30 days from the receipt of the statement. In addition, we examined each Travel Card statement and supporting receipt documentation and verified the reconciliation had adequate supporting documentation.

Appendix

Cancer Prevention and Research Institute of Texas
IA #05-18 Internal Audit Follow-Up Procedures Report
over Procurement and P-Cards
August 1, 2019
Issued: August 5, 2019

The appendix defines the approach and classifications utilized by Internal Audit to assess the residual risk of the area under review, the priority of the findings identified, and the overall assessment of the procedures performed.

Report Ratings

The report rating encompasses the entire scope of the engagement and expresses the aggregate impact of the exceptions identified during our test work on one or more of the following objectives:

- Operating or program objectives and goals conform with those of the agency
- Agency objectives and goals are being met
- The activity under review is functioning in a manner which ensures:
    - Reliability and integrity of financial and operational information
    - Effectiveness and efficiency of operations and programs
    - Safeguarding of assets
    - Compliance with laws, regulations, policies, procedures and contracts

The following ratings are used to articulate the overall magnitude of the impact on the established criteria:

Strong — The area under review meets the expected level. No high risk rated findings and only a few moderate or low findings were identified.

Satisfactory — The area under review does not consistently meet the expected level. Several findings were identified and require routine efforts to correct, but do not significantly impair the control environment.

Unsatisfactory — The area under review is weak and frequently falls below expected levels. Numerous findings were identified that require substantial effort to correct.

The appendix defines the approach and classifications utilized by Internal Audit to assess the residual risk of the area under review, the priority of the findings identified, and the overall assessment of the procedures performed.

Cancer Prevention and Research Institute of Texas
IA #05-18 Internal Audit Follow-Up Procedures Report
over Procurement and P-Cards
August 1, 2019
Issued: August 5, 2019

Risk Ratings

Residual risk is the risk derived from the environment after considering the mitigating effect of internal controls. The area under audit has been assessed from a residual risk level utilizing the following risk management classification system.

High

High risk findings have qualitative factors that include, but are not limited to:

- Events that threaten the agency's achievement of strategic objectives or continued existence
- Impact of the finding could be felt outside of the agency or beyond a single function or department
- Potential material impact to operations or the agency's finances
- Remediation requires significant involvement from senior agency management

Moderate

Moderate risk findings have qualitative factors that include, but are not limited to:

- Events that could threaten financial or operational objectives of the agency
- Impact could be felt outside of the agency or across more than one function of the agency
- Noticeable and possibly material impact to the operations or finances of the agency
- Remediation efforts that will require the direct involvement of functional leader(s)
- May require senior agency management to be updated

Low

Low risk findings have qualitative factors that include, but are not limited to:

- Events that do not directly threaten the agency's strategic priorities
- Impact is limited to a single function within the agency
- Minimal financial or operational impact to the organization
- Require functional leader(s) to be kept updated, or have other controls that help to mitigate the related risk

Cancer Research and Prevention Institute of Texas
Proposed Internal Audit Plan
Draft - For Discussion Purposes Only

Audit Area	Risk Rating	Summary Procedures	Audit Focus	Timing
2020 Planned New Internal Audits				
Governance	High	Internal Audit will evaluate risks and internal controls in place related to CPRIT's governance practices. Activities to be evaluated will include board Oversight and Responsibilities, Management Leadership, Institute Communications, Internal Audit, Risk Management, Administrative Rules, and Legislative Communications.	Internal Audit	TBD
Disaster Recovery	High	Internal Audit will evaluate risks and internal controls in place for CPRIT's Disaster Recovery plan and Business Continuity Plan. Disaster recovery activities to be evaluated will include IT backup and recovery systems, disaster recovery plan and procedures, IT hardware recovery, data recovery, and disaster recovery testing. Business continuity planning activities to be evaluated will include business resumption plan and procedures, scenario determination and criticality, business impact analysis, and continuity plan testing.	Internal Audit	TBD
Business Continuity Planning	High			
2020 Planned Internal Audit Consulting and Follow-up				
Information Security	High	Internal Audit will perform follow-up procedures on the open findings from the 2016 internal audit to ensure corrective action has been taken.	Follow-up	TBD
Communications	Moderate	Internal Audit will perform follow-up procedures on the open findings from the 2018 internal audit to ensure corrective action has been taken.	Follow-up	TBD
State Reporting	Moderate	Internal Audit will perform follow-up procedures on the open findings from the 2019 internal audit to ensure corrective action has been taken.	Follow-up	TBD
2020 Planned Annual Requirements				
Project Management	NA	Track overall internal audit procedures, coordinate audit activities, and reporting to management.	Project Management	Ongoing
Update Risk Assessment	NA	Perform required annual update of risk assessment	Policy Compliance	Ongoing
Annual and Quarterly Board Reports	NA	Prepare and submit required Annual Internal Audit Report and quarterly reports to the Audit Committee of internal audit activities.	Policy Compliance	Ongoing

Cancer Research and Prevention Institute of Texas
Proposed Internal Audit Plan
Draft - For Discussion Purposes Only

Audit Area	Risk Rating	Summary Procedures	Audit Focus	Timing
2021 Planned New Internal Audits				
Information Technology General Computer Controls	High	Internal Audit will evaluate the risks and internal controls in place related to CPRIT's Information Technology practices. Activities to be evaluated will include Network Operations, Help Desk, Change Management, Website Maintenance, Back-Up and Recovery.	Internal Audit	TBD
Commodity and Services Contracts	High	Internal Audit will evaluate the commodity and services contracting practices as well as perform an analysis of critical and material CPRIT contracts. The audit will include an evaluation of vendor performance and compliance on key contracts.	Internal Audit	TBD
2021 Planned Internal Audit Consulting and Follow-up				
Records Management - Grantee Compliance Records	High	Internal Audit will provide consulting services to evaluate the planning process for the grantee compliance record migration from a third-party designed system to the integrated CPRIT system. Evaluation of the designed process will include the validation of the system architecture design and data mapping of the file migration plan. Consulting services will also include the validation of the system configuration upon implementation, verification of the completeness of the data migration and testing the accuracy of data classification and mapping.	Consulting	TBD
Governance	High	Internal Audit will perform possible follow-up procedures on the findings from the 2020 internal audit to ensure corrective action has been taken.	Follow-up	TBD
Disaster Recovery	High	Internal Audit will perform possible follow-up procedures on the findings from the 2020 internal audit to ensure corrective action has been taken.	Follow-up	TBD
Business Continuity Planning	High			
2021 Planned Annual Requirements				
Project Management	NA	Track overall internal audit procedures, coordinate audit activities, and reporting to management.	Project Management	Ongoing
Update Risk Assessment	NA	Perform required annual update of risk assessment	Policy Compliance	Ongoing
Annual and Quarterly Board Reports	NA	Prepare and submit required Annual Internal Audit Report and quarterly reports to the Audit Committee of internal audit activities.	Policy Compliance	Ongoing

Cancer Research and Prevention Institute of Texas
Proposed Internal Audit Plan
Draft - For Discussion Purposes Only

Audit Area	Risk Rating	Summary Procedures	Audit Focus	Timing
2022 Planned New Internal Audits				
Post-Award Grant Management	High	Internal Audit will evaluate the risks and internal controls in place related to CPRIT's post-award grant management practices. Activities to be evaluated will include grantee monitoring, sub-recipient monitoring, grantee reporting, and project progress review.	Internal Audit	TBD
Procurement and P-Cards	High	Internal Audit will evaluate the risks and internal controls in place related to CPRIT's procurement and P-Cards practices. Activities to be evaluated will include purchase orders, bidding process and proposal evaluation, contract negotiation and approval, vendor management (selection, vendor acceptance and set-up), P-Card use, and central travel card use.	Internal Audit	TBD
Application Development and Management	Moderate	Internal Audit will evaluate the risks and internal controls in place related to CPRIT's software application development and management practices. Activities to be evaluated will include application management, monitoring third party providers, new systems implementation, application configuration, database administration, data integrity, and vendor SOC Reports monitoring.	Internal Audit	TBD
2022 Planned Internal Audit Consulting and Follow-up				
Information Technology General Computer Controls	High	Internal Audit will perform possible follow-up procedures on the findings from the 2021 Internal Audit to ensure corrective action has been taken.	Follow-up	TBD
Commodity and Services Contracts	High	Internal Audit will perform possible follow-up procedures on the findings from the 2021 Internal Audit to ensure corrective action has been taken.	Follow-up	TBD
2022 Planned Annual Requirements				
Project Management	NA	Track overall internal audit procedures, coordinate audit activities, and reporting to management.	Project Management	Ongoing
Update Risk Assessment	NA	Perform required annual update of risk assessment	Policy Compliance	Ongoing
Annual and Quarterly Board Reports	NA	Prepare and submit required Annual Internal Audit Report and quarterly reports to the Audit Committee of internal audit activities.	Policy Compliance	Ongoing

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	CAMERON ECKEL, STAFF ATTORNEY
SUBJECT:	APPOINTMENTS TO THE SCIENTIFIC RESEARCH AND PREVENTION PROGRAMS COMMITTEE
DATE:	AUGUST 13, 2019

Summary and Recommendation

The Chief Executive Officer has appointed eight experts to CPRIT's Scientific Research and Prevention Programs Committee. CPRIT's statute requires the appointments be approved by the Oversight Committee. The Nominations Subcommittee will discuss the appointments at its meeting on August 16th and vote on whether to recommend that the Oversight Committee vote to approve the appointments.

Discussion

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

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

The nominations subcommittee will review the peer reviewer appointments at its August 16th meeting.

Academic Research Peer Review Panels

- Myles Brown, M.D. (to assist SRC with recruitment review)
- Paul Northcott, Ph.D.

BIOGRAPHICAL SKETCH

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

NAME: Myles Brown, M.D.

eRA COMMONS USER NAME (credential, e.g., agency login): MBROWN01

POSITION TITLE: Emil Frei III Professor of Medicine

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

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Yale University	B.S.	05/1978	Biology
Johns Hopkins University School of Medicine	M.D.	05/1982	Medicine
Brigham and Women's Hospital	Residency	07/1986	Internal Medicine
Dana-Farber Cancer Institute	Fellowship	07/1989	Medical Oncology
Massachusetts Institute of Technology	Postdoctoral	07/1990	Cancer Biology

A. Personal Statement

The primarily focus of the work in my laboratory has been the molecular understanding of the hormone dependence of cancer and the identification of improved therapies targeting steroid hormone receptors. My lab identified the p160 class of nuclear receptor interacting proteins and showed that these coregulators play an important role in the tissue and promoter selective action of steroid receptors and their ligands. Working with Shirley Liu, we were the first to define androgen and estrogen receptor binding sites on a genomic scale. This led to the concept of the cistrome, the set of cis-acting targets of a trans-acting factor across the genome. Together with Shirley Liu, I direct the Center for Functional Cancer Epigenetics with the goals of defining the epigenetic and cistromic changes in cancer including those that influence response to immunotherapy and of training the next generation of cancer researchers.

1. Halachmi S, Marden E, Martin G, MacKay H, Abbondanza C, Brown M. Estrogen receptor associated proteins: possible mediators of hormone-induced transcription. Science 1994; 264:1455–8.
2. Shang Y, Hu X, Lazar MA, DiRenzo, J, Brown M. Cofactor dynamics and sufficiency in estrogen receptor regulated transcription. Cell 2000;103:843-52.
3. Shang Y, Brown M. Molecular determinants for the tissue specificity of SERMs. Science 2002; 295(5564):2465-8.
4. Carroll JS, Liu XS, Brodsky AS, Meyer CA, Li W, Szary AJ, Eeckhoute J, Shao W, Hestermann EV, Geistlinger TR, Fox EA, Silver PA, Brown M. Chromosome-wide mapping of estrogen receptor binding reveals long-range regulation requiring the forkhead protein FoxA1. Cell 2005; 15;122:33-43.

B. Positions and Honors

Positions and Employment

1983-1986 Research Fellow, Laboratory of David Livingston, Dana-Farber Cancer Institute
1987-1990 Post-doctoral Fellow, Laboratory of Phillip Sharp, Massachusetts Institute of Technology
1989-1991 Instructor in Medicine, Dana-Farber Cancer Institute and Harvard Medical School
1991-1998 Assistant Professor of Medicine, Dana-Farber Cancer Institute and Harvard Medical School
1998-2006 Associate Professor of Medicine, Dana-Farber Cancer Institute and Harvard Medical School
2002-2010 Chief, Division of Molecular and Cellular Oncology, Dana-Farber Cancer Institute
2006-2017 Professor of Medicine, Dana-Farber Cancer Institute and Harvard Medical School
2010- Director, Center for Functional Cancer Epigenetics, Dana-Farber Cancer Institute
2017- Emil Frei III Professor of Medicine, Dana-Farber Cancer Institute and Harvard Medical School

Other Experience and Professional Membership

2008-2014 Member, ACS Council for Extramural Grants

2013-2014 Chair, ACS Council for Extramural Grants
2011-2015 NIH Tumor Cell Biology Study Section, member

Awards and Honors

1997 American Society for Clinical Investigation
2003 Association of American Physicians
2005 NAMS/Wyeth Pharmaceuticals SERM Research Award
2006 Tisch Family Outstanding Achievement Award, Dana-Farber Cancer Institute
2009 D. Wayne Calloway Visiting Lectureship in Prostate Cancer, MSKCC
2010 Edwin B. Astwood Award, The Endocrine Society
2014 Fellow, American Association for the Advancement of Science
2015 Brinker Award for Scientific Distinction in Basic Science, Susan G. Komen
2016 Member, National Academy of Sciences
2017 Fellow, American Academy of Arts and Sciences

C. Contribution to Science

1. Identification and characterization of steroid receptor cistromes

a. Carroll, J.S., Meyer, C.A., Song, J., Li, W., Geistlinger, T.R., Eeckhoute, J., Brodsky, A.S., Keeton, E.K., Fertuck, K.C., Hall, G.F., Wang, Q., Berkiranov, S., Sementchenko, V., Fox, E.A., Silver, P.A., Gingeras, T.R., Liu, X.,S., Brown, M. Genome wide analysis of estrogen receptor binding sites. Nat Genet, 2006 Nov;38(11):1289-97.

b. Lupien, M., Eeckhoute, J., Meyer, C.A., Wang, Q., Zhang, Y., Li, W., Carroll, J.S., Liu, X.S. and Brown, M. FoxA1 translates epigenetic signatures into enhancer driven lineage-specific transcription. Cell 2008, 132 (6): 958-70. PMCID: PMC2323438

c. Wang Q, Li W, Zhang Y, Yuan X, Xu K, Yu J, Chen Z, Beroukhim R, Wang H, Lupien M, Wu T, Regan MM, Meyer CA, Carroll JS, Manrai AK, Jänne OA, Balk SP, Mehra R, Han B, Chinnaiyan AM, Rubin MA, True L, Fiorentino M, Fiore C, Loda M, Kantoff, PW, Liu XS, Brown M. Androgen receptor regulates a distinct transcription program in androgen-independent prostate cancer. Cell. 2009 Jul 23;138(2):245-56. PMCID: PMC2726827.

d. Lupien M, Eeckhoute J, Meyer CA, Krum SA, Rhodes DR, Liu XS, Brown M. Coactivator function defines the active estrogen receptor-α cistrome. Mol Cell Biol. 2009 Jun;29(12):3413-23. PMCID: PMC2698732.

2. Defined steroid receptor coregulator complexes and their functions

a. Hanstein B, Eckner R, DiRenzo J, Halachmi S, Liu H, Searcy B, Brown M. p300 is a component of an estrogen receptor co-activator complex. Proc Natl Acad Sci 1996;93:11540-5.

b. Font de Mora, J, Brown, M. AIB1 is a conduit for kinase-mediated growth factor signaling to the estrogen receptor. Mol Cell Biol 2000;20:5041-47.

c. Shao W, Halachmi S, Brown M. ERAP140, a conserved tissue-specific nuclear receptor coactivator. Mol Cell Biol 2002;22:3358-72.

d. Torres-Arzayus MI, Font de Mora J, Yuan J, Vazquez F, Bronson R, Rue M, Sellers WR, Brown M. High tumor incidence and activation of the PI3K/AKT pathway in transgenic mice define AIB1 as an oncogene. Cancer Cell 2004;6:263-74.

3. Defined mechanisms of hormone independence in breast and prostate cancer

a. Xu K, Wu ZJ, Groner AC, He HH, Cai C, Lis RT, Wu X, Stack EC, Loda M, Liu T, Xu H, Cato L, Thornton JE, Gregory RI, Morrissey C, Vessella RL, Montironi R, Magi-Galluzzi C, Kantoff PW, Balk SP, Liu XS, Brown M. EZH2 oncogenic activity in castration resistant prostate cancer cells is polycomb-independent. Science 2012 Dec 14;338(6113):1465-9. PMCID: PMC3625962

b. Jeselsohn R, Bergholz JS, Pun M, Cornwell M, Liu W, Nardone A, Xiao T, Li W, Qiu X, Buchwalter G, Feiglin A, Abell-Hart K, Fei T, Rao P, Long H, Kwiatkowski N, Zhang T, Gray N, Melchers D, Houtman R, Liu XS, Cohen O, Wagle N, Winer EP, Zhao J, Brown M. Allele-Specific Chromatin Recruitment and Therapeutic Vulnerabilities of ESR1 Activating Mutations. Cancer Cell. 2018 Feb 12;33(2):173-186.PMCID: PMC5813700.

c. Xiao T, Li W, Wang X, Xu H, Yang J, Wu Q, Huang Y, Geradts J, Jiang P, Fei T, Chi D, Zang C, Liao Q, Rennhack J, Andrechek E, Li N, Detre S, Dowsett M, Jeselsohn RM, Liu XS, Brown M. Estrogen-regulated feedback loop limits the efficacy of estrogen receptor-targeted breast cancer therapy. Proc Natl Acad Sci U S A. 2018 Jul 9. pii: 201722617. doi: 10.1073/pnas.1722617115. [Epub ahead of print] PubMed PMID: 29987050.

d. Cato L, de Tribolet-Hardy J, Lee I, Rottenberg JT, Coleman I, Melchers D, Houtman R, Xiao T, Li W, Uo T, Sun S, Kuznik NC, Göppert B, Ozgun F, van Royen ME, Houtsmuller AB, Vadhi R, Rao PK, Li L, Balk SP, Den RB, Trock BJ, Karnes RJ, Jenkins RB, Klein EA, Davicioni E, Gruhl FJ, Long HW, Liu XS, Cato ACB, Lack NA, Nelson PS, Plymate SR, Groner AC, Brown M. ARv7 Represses Tumor-Suppressor Genes in Castration-Resistant Prostate Cancer. Cancer Cell. 2019 Mar 18;35(3):401-413.

4. Development of new approaches for epigenomic analysis in collaboration with Shirley Liu

a. He HH, Meyer C, Shin H, Bailey S, Wei G, Wang Q, Zhang Y, Xu K, Ni M, Lupien M, Mieczkowski P, Lieb JD, Zhao K, Brown M, Liu XS (2010). Nucleosome dynamics defines transcriptional enhancers. Nat Genet. 42(4):343-7. PMCID:PMC2932437.

b. He HH, Meyer CA, Hu SS, Chen MW, Zang C, Liu Y, Rao PK, Fei T, Xu H, Long H, Liu XS, Brown M. Refined DNase-seq protocol and data analysis reveals intrinsic bias in transcription factor footprint identification. Nat Methods. 2014 Jan;11(1):73-8. PMCID: PMC4018771

c. Li W, Xu H, Xiao T, Cong L, Love MI, Zhang F, Irizarry RA, Liu JS, Brown M, Liu XS. MAGeCK enables robust identification of essential genes from genome-scale CRISPR/Cas9 knockout screens. Genome Biol. 2014 Dec 5;15(12):554. PubMed PMID: 25476604.

d. Li W, Köster J, Xu H, Chen CH, Xiao T, Liu JS, Brown M, Liu XS. Quality control, modeling, and visualization of CRISPR screens with MAGeCK-VISPR. Genome Biol. 2015 Dec 16;16(1):281. doi: 10.1186/s13059-015-0843-6. PubMed PMID: 26673418; PubMed Central PMCID: PMC4699372.

5. Collaborate to identify factors influencing response to immunotherapy

a. Pan D, Kobayashi A, Jiang P, Ferrari de Andrade L, Tay RE, Luoma AM, Tsoucas D, Qiu X, Lim K, Rao P, Long HW, Yuan GC, Doench J, Brown M, Liu XS, Wucherpfennig KW. A major chromatin regulator determines resistance of tumor cells to T cell-mediated killing. Science. 2018 Feb 16;359(6377):770-775. doi: 10.1126/science.aao1710. Epub 2018 Jan 4. PubMed PMID: 29301958; PubMed Central PMCID: PMC5953516.

b. Jiang P, Lee W, Li X, Johnson C, Liu JS, Brown M, Aster JC, Liu XS. Genome-Scale Signatures of Gene Interaction from Compound Screens Predict Clinical Efficacy of Targeted Cancer Therapies. Cell Syst. 2018 Mar 28;6(3):343-354.e5. doi: 10.1016/j.cels.2018.01.009. Epub 2018 Feb 7. PubMed PMID: 29428415; PubMed Central PMCID: PMC5876130.

c. Jiang P, Gu S, Pan D, Fu J, Sahu A, Hu X, Li Z, Traugh N, Bu X, Li B, Liu J, Freeman GJ, Brown MA, Wucherpfennig KW, Liu XS. Signatures of T cell dysfunction and exclusion predict cancer immunotherapy response. Nat Med. 2018 Oct;24(10):1550-1558. doi: 10.1038/s41591-018-0136-1. Epub 2018 Aug 20. PubMed PMID: 30127393.

Complete List of Published Work in MyBibliography:
https://www.ncbi.nlm.nih.gov/sites/myncbi/myles.brown.2/bibliography/40800002/public/?sort=date&direction=descending

D. Research Support

Ongoing Research Support

Novartis 15003 (Brown) 01/01/18 – 12/31/20

Combination Therapies to Overcome Endocrine Resistance in ER + Breast Cancer

The goal of this project is to validate results of shRNA and CRISPR screens performed at Novartis and in Brown lab that have identified potential vulnerabilities in ER+ breast cancers and to develop combination therapies to treat and ultimately prevent the emergence of endocrine resistant breast cancers. Role: PI

The Breast Cancer Research Foundation (Brown) 10/01/2012 – 09/30/18

Breast Cancer Subtype Specific Functions of the Androgen Receptor

Specific Aims:1. Determine AR target genes in ER+ and ER–/HER2+ breast cancer cells.

2. Perform gene expression profiling to identify the differentially regulated transcriptome in response to hormone stimulation. 3. Validate the biological function of AR and AR targets in ER+ and ER–/HER2+ breast cancers. In our previous study of ER–/HER2+ breast cancers, we identified WNT7B and HER3 as two crucial AR targets in ER–/HER2+ tumors. Role: PI

Komen Leadership Grant (Brown, M) 04/01/2012 – 03/31/2019

Elucidating the ER Transcriptional Network Associated with Endocrine Resistance

The central hypothesis of this proposal is that aberrant ER binding to DNA, and the resulting alteration of its transcriptional program, constitute a fundamental mechanism of endocrine resistance. Our preliminary studies in pre-clinical models suggest that non-canonical binding of ER to RUNX motifs is one such alteration in ER chromatin binding and is responsible for tamoxifen resistance. Role: PI

5P50 CA168504 (Winer/Brown) 07/01/2013 – 07/31/2018
Dana-Farber/Harvard SPORE in Breast Cancer (Project 1)
The goal of this project is to seek to gain a better understanding of the role of the androgen receptor (AR) in cancer risk and progression. Role: Project Leader

P50 CA090381 (Loda/Balk) 09/23/2007 – 06/30/2018
DF/HCC SPORE in Prostate Cancer - Project 5 (Brown/Balk)
The Androgen Receptor in Hormone Refractory Disease
The overall aims of this proposal are to identify mechanisms mediating AR activity in advanced CRPC, and in particular CRPC that has become resistant to abiraterone. Role: Project Leader

P01 CA080111 (Weinberg, R) 02/01/2014 – 01/31/2019
NIH/NCI/Whitehead Institute
Mechanisms of breast development and carcinogenesis – Project 2 (Brown)
The major goal of this project is to characterize the expression of the estrogen signaling machinery during normal breast development and in breast cancer. Role: Project Leader

R01CA193910(Brown, Freedman & Pomerantz) 03/01/2015 – 02/29/2020
Defining the epigenetic landscape in human prostate cancer
The overall objectives of the present proposal are to characterize the mechanisms underlying AR reprogramming during tumorigenesis and - for the first time - to characterize the AR program in human tissue during progression from localized prostate cancer to metastatic, drug-resistant disease. Role: PI

W81XWH-15-1-0593 (Brown & Liu) 07/01/15-06/30/18
Mechanism of Hormone Independence and Drug Resistance in Prostate Cancer
The major goals of this project are to identify key genes and pathways underlying hormone independence and drug resistance to AR antagonist and EZH2 inhibitors in CRPC, and understand the mechanism of function for of the identified key genes. Role: PI

R01 HG008728 (Brown & Liu) 09/01/2015 – 08/31/2018
Large-Scale In Vivo Functional Characterization of the Human Cistrome
Specifically, we propose to 1) use CRISPR/Cas9 knockout screens to identify transcription factors and chromatin regulators in eight human cell lines that have strong effect on cell growth; 2) conduct CRISPR/Cas9 knockout screens on putative cis-regulatory elements to identify elements with strong effects on gene expression and cell growth or survival; 3) computationally model in vivo cistrome function, experimentally validate the model and create a Cistrome annotation web server. Role: PI

P50 CA127003-06A1 (Fuchs) 09/01/2013 - 08/31/2018
Specialized Program for Research Excellence (SPORE) in Gastrointestinal Cancers
The overarching goal of the Program is to translate biological and technological advances in prevention, diagnosis and outcome prediction into improved detection and treatment of gastrointestinal malignancies. The Applicant has two roles: (1) Administrative and scientific oversight of the Program on Developmental Projects; and (2) Co-Leader on Project 2, which aims to dissect the transcriptional and genetic basis for the protective effect of Vitamin D in colorectal cancer risk and disease progression. Role: Co-Investigator

Prostate Cancer Foundation Challenge Award (Brown, Cato, and DeBono) 08/22/2016-08/21/2018
Prostate Cancer Foundation Challenge Award Targeting the Druggable Interaction Between the NH2-Terminal Domain of The Androgen Receptor and BAG-1L, A Key Regulator of AR Function.
Specific aims: (1) Define BAG-1L as a critical mediator of AR-FL and AR-V7 activity and a key driver for the development and progression of CRPC. (2) Characterize the interaction between BAG-1L and AR-FL (and AR-S7) in novel cancer models and patient biopsies. Define the essential domains required for this interaction to fully describe the BAG-1L druggable cavity (utilizing functionally significant mutational analysis). (3) Evaluate small molecule compounds, previously identified through a low-throughput screen, that abrogate BAG-1L-mediated AR AF-1 transactivation, while simultaneously developing a high-throughput assay to support the identification of drug-like BAG-1L anticancer drugs. Role: PI

5P01 CA163227 (Balk/Brown) 05/01/2013 – 04/31/2019
Androgen Receptor Action in Castration Resistant Prostate Cancer
The goal is to test the hypothesis that the epigenetic regulator EZH2 reprograms AR function in CRPC to stimulate the induction of a set of cell cycle regulatory genes required for the AR-dependent growth of CRPC.
Role: Project Leader

<u>Completed Research Support</u>

Prostate Cancer Foundation Challenge Award (**Freedman/Brown**) 08/01/2014 – 7/31/2017

Characterization of the Prostate Epigenome
The overall objectives of this proposal are to characterize: 1) the super-enhancer landscape during prostate cancer progression to metastatic disease, 2) if AR mutations influence AR localization in advanced prostate disease, and 3) the FOXA1 and HOXB13 cistromes during prostate cancer progression to metastatic disease. Role: Co-PI

U24DK097748-01 (O'Malley/Brown) 09/17/2012 – 08/31/2015
Epigenetics of Diet and Menopause in Nonhuman Primates
This proposal will address how estrogen replacement and diet influence the ER cistrome and the epigenetic state of liver and subcutaneous and visceral adipose tissues in nonhuman primates. It will also involve the development of methods for cross-species comparison to allow the integration of data obtained in model organisms with the existing human ENCODE data. Role: Project Leader

R01GM099409-01 (Liu, Shirley) 09/10/2011 - 08/31/2015
Inferring Mammalian Transcriptional Regulatory Networks from Epigenomics
Major goals of this project are to develop effective computational algorithms to TF binding from nucleosome-resolution histone mark dynamics, identify target genes from TF binding, histone marks and gene expression profiles, and infer the TRN over a time course. Role: Co-Investigator

R01 HG004069 (Liu, X) 09/27/2006 – 08/31/2015
Computational Models of Mechanisms of Global Transcription Regulation
The goal of the project is to develop computational algorithms to analyze and annotate ChIP-chip experiments on genome tiling microarrays, identify the variability introduced in ChIP protocol, array platforms and analysis methods, and model the global transcriptional regulatory mechanism. Role: Co-Investigator

R01 CA166666 (Hankinson) 09/01/2012 - 07/31/2016
Assessing the role of androgens in breast cancer risk
In this study, we propose to investigate the role of androgens in the etiology of breast cancer to help elucidate whether androgen acts directly or indirectly in breast tumor tissue. Role: Co-Investigator

W81XWH-13-01-0142 (Liu) 08/15/2013-08/14/2015
Therapeutic Mechanism of BET Bromodomain Inhibitor in Breast Cancer
The major goals of this project are to identify the cistrome, transcriptome and chromatin dynamics in breast cancer cell line MCF-7 treated with BET domain inhibitor JQ1 or BRD4 knockout, computationally infer and experimentally validate the JQ1 induced transcriptional regulatory network and pathway in MCF-7, and apply the above approaches to test JQ1 on different breast cancer cell lines. Role: Co-PI

U01 CA180980 (Liu, X.S.) 09/17/2013-08/31/2016
Developing Informatics Technologies to Model Cancer Gene Regulation
We propose to develop bioinformatics tools to help integrate TCGA data with ChIP-seq data to interpret cancer gene regulation. Role: Co-PI

NOVARTIS 15003 (Brown) 01/01/2015 – 12/31/2017
Combination Epigenetic Therapy for Prostate and Breast Cancer
The major goal of our program is to develop EZH2 inhibitors in combination with AR, PI3K/AKT and WNT pathway inhibitors for the treatment of CRPC and will test whether EZH2 is a valid therapeutic target in different breast cancer subtypes. Role: PI

BIOGRAPHICAL SKETCH

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

NAME: **NORTHCOTT, Paul Andrew**

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

POSITION TITLE: **Assistant Member**

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

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YY	FIELD OF STUDY
Palm Beach Atlantic University, FL, USA	B.Sc.	04/2000	Biology
McMaster University, ON, Canada	M.Sc.	11/2004	Medical Genetics
University of Toronto, ON, Canada	Ph.D.	11/2010	Cancer Genetics
The Hospital for Sick Children, ON, Canada	Postdoctoral	02/2012	Cancer Genomics
German Cancer Research Center, B-W, DE	Postdoctoral	02/2015	Cancer Genomics

A. Personal Statement

My research is focused on resolving the molecular mechanisms underlying the pathogenesis of My research is focused on resolving the molecular and cellular mechanisms underlying the pathogenesis of medulloblastoma (MB), the most common malignant pediatric brain tumor. Throughout my PhD studies, postdoctoral training, and early independent career, I have devoted considerable efforts towards the molecular characterization of MB, contributing a multitude of seminal publications that have been transformative in both the research and clinical settings. Genomic analyses performed during my PhD thesis led to the current definition of biologically and clinically distinct molecular subgroups of MB, which are now recognized by the WHO as part of the routine diagnosis of the disease and constitute the basis of modern clinical protocols. Subsequently, using a variety of next-generation sequencing methods, I have led several large consortia-level studies that have defined the genomic and epigenomic landscapes of MB, led to the discovery and characterization of novel *driver* genes, delineated novel genetic mechanisms contributing to oncogenesis, and implicated distinct developmental origins of MB subgroups. My current research efforts involve implementation of a variety of innovative and integrative genomic approaches that build on previous work, with the goal of continuing to dissect intertumoral and intratumoral heterogeneity across MB subgroups and subtypes. My lab is using single-cell genomics to resolve the cellular composition and cellular hierarchies of MB according to molecular subgroup, linking malignant cellular programs to normal developmental populations to define cellular origins. Findings from these studies are being experimentally validated and used to inform the generation of faithful preclinical models recapitulating the biological and clinical heterogeneity seen in MB patients.

B. Positions and Honors

Positions and Employment

2000-03 Teaching Assistant – Biochemistry I & II, McMaster University, Hamilton, ON
2004-05 Research Technologist, Pathol. & Molecular Medicine, Juravinski Cancer Centre, Hamilton, ON
2005-06 Research Technologist II, Developmental & Stem Cell Biology, SickKids, Toronto, ON
2010-12 Postdoctoral Fellow, Developmental & Stem Cell Biology, SickKids, Toronto, ON
2012-15 Senior Researcher and Subgroup Leader, Division of Pediatric Neurooncology, German Cancer Research Center (DKFZ), Heidelberg, Germany
2015-present Assistant Member, Developmental Neurobiology, St. Jude Children's Research Hospital, Memphis, TN, USA

Other Experience and Professional Memberships

2006-Present: Member, American Association for Cancer Research (AACR)
2007-Present: Member, Society for Neuro-Oncology (SNO)
2016-Present: Member, Children's Oncology Group (COG)
2017-Present: CNS Steering Committee, Children's Oncology Group (COG)
2017-Present: CNS Biology Committee, Children's Oncology Group (COG)
2016-Present: Scientific Advisory Board Member, The Brain Tumor Charity (UK)

Honors

1996-99	Provost's Scholarship (PBA)
1997-99	Mary Sisler Pre-Medical Scholarship (PBA)
1997-98	Provost's List (PBA)
1998-99	President's List (PBA)
1999-2000	President's Scholarship (PBA)
2000	Graduate Entrance Scholarship (McMaster University)
2000-03	Graduate Scholarship (McMaster University)
2006	University of Toronto Fellowship (U of T)
2008	AACR-Aflac Scholar-in-Training Award (AACR)
2008	McMurrich Research Award (U of T)
2008	Dr. Rajalakshmi S. Dittakavi and Dr. Prema M. Rao Graduate Award (U of T)
2009	University of Toronto Fellowship (U of T)
2009	AACR-Bristol-Myers Squibb Oncology Scholar-in-Training Award (AACR)
2009	Hoshino Award, World Federation of Neuro-Oncology (WFNO) Quadrennial Meeting
2009	CIHR National Poster Competition – Gold Award
2010	AACR-Bristol-Myers Squibb Oncology Scholar-in-Training Award (AACR)
2010	Young Investigator Award, Basic Science, Canadian Neuro-Oncology (CNO) Meeting
2011	Keystone Symposia Future of Science Fund Scholarship
2011	Stuart Alan Hoffman Memorial Prize (U of T)
2012	Roman Herzog PostDoctoral Fellowship (Hertie Foundation)
2013	Lap-Chee Tsui Publication Award for 2012 (CIHR Institute of Genetics)
2014	DKFZ Alumni Award (German Cancer Research Center, DKFZ)
2014	Pediatric Basic Science Award (Society for Neuro-Oncology Annual Meeting)
2015	2015 V Foundation V Scholar Award
2016	Inaugural AACR NextGen Grant for Transformative Cancer Research
2016	Pew-Stewart Scholar for Cancer Research
2016	Sontag Foundation Distinguished Scientist Award

C. Contributions to Science

1. Medulloblastoma comprises four distinct diseases

As a PhD student, my thesis focused on the genomic analysis of MB. Using a combination of high-resolution DNA copy-number and gene expression array platforms, I analyzed unprecedented cohorts of primary patient samples in order to discover the molecular mechanisms underlying MB development. In addition to identifying previously undisclosed recurrent copy-number alterations and implicating new driver genes, these efforts helped to reveal the extent of intertumoral molecular heterogeneity among MBs, identifying four distinct molecular subgroups of the disease – WNT, SHH, Group 3, and Group 4. This work was the first to demonstrate a clear correlation between molecular subgroup affiliation and patient outcome, carrying significant implications from both biological and clinical perspectives. These findings precipitated the subsequent consensus recognition that the disease consists of four distinct molecular subgroups, changing the way MB is studied in the laboratory and how it is treated in the clinical setting.

a. **Northcott, P. A.**, et al. J Clin Oncol 29, 1408-1414, doi:10.1200/JCO.2009.27.4324 (2011).
b. Taylor, M. D., **Northcott, P. A.**, et al. Molecular subgroups of medulloblastoma: the current consensus. Acta Neuropathol 123, 465-472, doi:10.1007/s00401-011-0922-z (2012).
c. Shih, D. J.*, **Northcott, P. A.***, Remke, M.*, et al. Cytogenetic prognostication within medulloblastoma subgroups. J Clin Oncol 32, 886-896, doi:10.1200/JCO.2013.50.9539 (2014).

d. Robinson, G. W.*, Rudneva, V. A.*…Gajjar, A.# & **Northcott, P., A.#** Risk-adapted therapy for young children with medulloblastoma (SJYC07): therapeutic and molecular outcomes from a multicentre, phase 2 trial. Lancet Oncol, 19, 768-784, doi:10.1016/S1470-2045(18)30204-3 (2018).

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[*]denotes shared first-author
[#]denotes shared senior author

Complete List of Published Work in My Bibliography:
https://www.ncbi.nlm.nih.gov/myncbi/collections/bibliography/43769088/

D. Research Support

Ongoing Research Support

AACR NextGen Grant for Transformative Cancer Research — Northcott (PI) — 07/01/2016-06/30/2019
Title: Integrative Functional Genomics of Recurrent Childhood Medulloblastoma
Role: PI

Pew-Stewart Scholar for Cancer Research — Northcott (PI) — 08/01/2016-07/31/2020
Title: Molecular Dissection of Intratumoral Heterogeneity Driving Medulloblastoma Relapse
Role: PI

Sontag Foundation Distinguished Scientist Award — Northcott (PI) — 10/01/2016-09/30/2020
Title: Molecular and Functional Dissection of Group 4 Medulloblastoma Origins
Role: PI

St. Jude Collaborative Research Consortium — Northcott (co-PI) — 12/01/2017-11/30/2022
Title: Chromatin Regulation in Pediatric Cancer
Role: Co-PI

The Brain Tumor Charity Quest for Cures — Northcott (co-PI) — 07/01/2018-06/30/2023
Title: MERIT – Medulloblastoma Epigenome Regulation in Treatment
Role: Co-PI

The Brain Tumor Charity Clinical Biomarkers — Northcott (PI) — 01/01/2019-12/31/2023
Title: Refining the definition and clinical significance of medulloblastoma subtypes
Role: PI

National Cancer Institute (PA-18-484, R01) — Northcott (PI) — 10/01/2018-09/30/2023
Title: Dissecting the Spectrum, Prevalence, and Molecular Mechanisms of Enhancer Hijacking in Medulloblastoma
Role: PI

National Cancer Institute (R01) — Olson (PI) — 01/01/2019-12/31/2021
Title: Targeted therapy in ex vivo medulloblastoma/PNET
Role: Co-Investigator

Completed Research Support

5 P30CA021765-36 — Roberts (PI) — 04/01/1997-02/29/2019
Cancer Center Support Grant (NCI) 07/01/2015-06/30/2017
Developmental Funds (Northcott)
Title: Functional Characterization of Recurrently Mutated Neuronal Transcription Factors in Medulloblastoma

V Foundation V Scholar Award — Northcott (PI) — 11/01/2015-11/01/2017
Title: Functional Characterization of Hotspot *KBTBD4* Mutations in High-Risk Medulloblastoma

BIOGRAPHICAL SKETCH

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

NAME: **NORTHCOTT, Paul Andrew**

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

POSITION TITLE: **Assistant Member**

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

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YY	FIELD OF STUDY
Palm Beach Atlantic University, FL, USA	B.Sc.	04/2000	Biology
McMaster University, ON, Canada	M.Sc.	11/2004	Medical Genetics
University of Toronto, ON, Canada	Ph.D.	11/2010	Cancer Genetics
The Hospital for Sick Children, ON, Canada	Postdoctoral	02/2012	Cancer Genomics
German Cancer Research Center, B-W, DE	Postdoctoral	02/2015	Cancer Genomics

A. Personal Statement

My research is focused on resolving the molecular mechanisms underlying the pathogenesis of My research is focused on resolving the molecular and cellular mechanisms underlying the pathogenesis of medulloblastoma (MB), the most common malignant pediatric brain tumor. Throughout my PhD studies, postdoctoral training, and early independent career, I have devoted considerable efforts towards the molecular characterization of MB, contributing a multitude of seminal publications that have been transformative in both the research and clinical settings. Genomic analyses performed during my PhD thesis led to the current definition of biologically and clinically distinct molecular subgroups of MB, which are now recognized by the WHO as part of the routine diagnosis of the disease and constitute the basis of modern clinical protocols. Subsequently, using a variety of next-generation sequencing methods, I have led several large consortia-level studies that have defined the genomic and epigenomic landscapes of MB, led to the discovery and characterization of novel *driver* genes, delineated novel genetic mechanisms contributing to oncogenesis, and implicated distinct developmental origins of MB subgroups. My current research efforts involve implementation of a variety of innovative and integrative genomic approaches that build on previous work, with the goal of continuing to dissect intertumoral and intratumoral heterogeneity across MB subgroups and subtypes. My lab is using single-cell genomics to resolve the cellular composition and cellular hierarchies of MB according to molecular subgroup, linking malignant cellular programs to normal developmental populations to define cellular origins. Findings from these studies are being experimentally validated and used to inform the generation of faithful preclinical models recapitulating the biological and clinical heterogeneity seen in MB patients.

B. Positions and Honors

Positions and Employment

2000-03 Teaching Assistant – Biochemistry I & II, McMaster University, Hamilton, ON
2004-05 Research Technologist, Pathol. & Molecular Medicine, Juravinski Cancer Centre, Hamilton, ON
2005-06 Research Technologist II, Developmental & Stem Cell Biology, SickKids, Toronto, ON
2010-12 Postdoctoral Fellow, Developmental & Stem Cell Biology, SickKids, Toronto, ON
2012-15 Senior Researcher and Subgroup Leader, Division of Pediatric Neurooncology, German Cancer Research Center (DKFZ), Heidelberg, Germany
2015-present Assistant Member, Developmental Neurobiology, St. Jude Children's Research Hospital, Memphis, TN, USA

Other Experience and Professional Memberships

2006-Present: Member, American Association for Cancer Research (AACR)
2007-Present: Member, Society for Neuro-Oncology (SNO)
2016-Present: Member, Children's Oncology Group (COG)
2017-Present: CNS Steering Committee, Children's Oncology Group (COG)
2017-Present: CNS Biology Committee, Children's Oncology Group (COG)
2016-Present: Scientific Advisory Board Member, The Brain Tumor Charity (UK)

Honors

1996-99	Provost's Scholarship (PBA)
1997-99	Mary Sisler Pre-Medical Scholarship (PBA)
1997-98	Provost's List (PBA)
1998-99	President's List (PBA)
1999-2000	President's Scholarship (PBA)
2000	Graduate Entrance Scholarship (McMaster University)
2000-03	Graduate Scholarship (McMaster University)
2006	University of Toronto Fellowship (U of T)
2008	AACR-Aflac Scholar-in-Training Award (AACR)
2008	McMurrich Research Award (U of T)
2008	Dr. Rajalakshmi S. Dittakavi and Dr. Prema M. Rao Graduate Award (U of T)
2009	University of Toronto Fellowship (U of T)
2009	AACR-Bristol-Myers Squibb Oncology Scholar-in-Training Award (AACR)
2009	Hoshino Award, World Federation of Neuro-Oncology (WFNO) Quadrennial Meeting
2009	CIHR National Poster Competition – Gold Award
2010	AACR-Bristol-Myers Squibb Oncology Scholar-in-Training Award (AACR)
2010	Young Investigator Award, Basic Science, Canadian Neuro-Oncology (CNO) Meeting
2011	Keystone Symposia Future of Science Fund Scholarship
2011	Stuart Alan Hoffman Memorial Prize (U of T)
2012	Roman Herzog PostDoctoral Fellowship (Hertie Foundation)
2013	Lap-Chee Tsui Publication Award for 2012 (CIHR Institute of Genetics)
2014	DKFZ Alumni Award (German Cancer Research Center, DKFZ)
2014	Pediatric Basic Science Award (Society for Neuro-Oncology Annual Meeting)
2015	2015 V Foundation V Scholar Award
2016	Inaugural AACR NextGen Grant for Transformative Cancer Research
2016	Pew-Stewart Scholar for Cancer Research
2016	Sontag Foundation Distinguished Scientist Award

C. Contributions to Science

1. Medulloblastoma comprises four distinct diseases

As a PhD student, my thesis focused on the genomic analysis of MB. Using a combination of high-resolution DNA copy-number and gene expression array platforms, I analyzed unprecedented cohorts of primary patient samples in order to discover the molecular mechanisms underlying MB development. In addition to identifying previously undisclosed recurrent copy-number alterations and implicating new driver genes, these efforts helped to reveal the extent of intertumoral molecular heterogeneity among MBs, identifying four distinct molecular subgroups of the disease – WNT, SHH, Group 3, and Group 4. This work was the first to demonstrate a clear correlation between molecular subgroup affiliation and patient outcome, carrying significant implications from both biological and clinical perspectives. These findings precipitated the subsequent consensus recognition that the disease consists of four distinct molecular subgroups, changing the way MB is studied in the laboratory and how it is treated in the clinical setting.

a. **Northcott, P. A.**, et al. J Clin Oncol 29, 1408-1414, doi:10.1200/JCO.2009.27.4324 (2011).
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Title: Functional Characterization of Hotspot *KBTBD4* Mutations in High-Risk Medulloblastoma

Prevention Peer Review Panels

- Elva M. Arredondo, PhD.
- Nikki Nollen, Ph.D.

Dr. Arredondo is a tenured Professor in the Graduate School of Public Health, and Core Investigator in the Institute for Behavioral and Community Health (IBACH) at San Diego State University. She is a bilingual/bicultural native of Mexico with over 18 years of research experience in developing, implementing, and evaluating multi-level community-based programs that improve the health of ethnic minority and socially/economically disadvantaged communities. To date, She has have served as PI, Co-PI or subcontract PI of 19 grants, from sources ranging from the American Cancer Society, the Centers for Disease Control and Prevention, the Robert Wood Johnson Foundation's, and other agencies, and have received continued funding from the National Institutes of Health to support my research. Her research has resulted in over 120 manuscripts, book chapters, and scientific entries. Currently, she is also the Principal Investigator of the SDSU/UCSD Cancer Center Partnership which aims to identify effective, sustainable, and disseminable methods to prevent and control cancer in the U.S. Latino/Hispanic population (U54CA132384).

Nikki Nollen, PhD

Dr. Nollen is an associate professor in the Department of Preventive Medicine and Public Health at the University of Kansas School of Medicine. Her research focuses on understanding determinants of health and health behaviors, both at the individual- and systems-level, among high risk groups. Specific research interests are in evaluating promising behavioral and pharmacotherapy treatments for nicotine addiction, as well as examining psychosocial and biological mechanisms underlying tobacco use and treatment outcomes. Dr. Nollen is PI of two NIH funded R01s to examine disparities in quitting between African American and White smokers (R01DA031815), to improve short-term treatment outcomes in African American smokers through a novel optimized pharmacotherapy approach (R01DA046576), and an ongoing PCORI-funded study that is the first treatment study for African American non-daily smokers (AD-1310-08709). Dr. Nollen has mentored over 10 junior faculty, pre- and postdoctoral fellows, and undergraduate students, the majority of whom are from diverse backgrounds underrepresented in biomedical research. Her current mentees hold a diversity supplement to her R01, two NIH K01 awards, and an NIH SC3 award for junior faculty in non-research institutions.

Product Development Research Peer Review Panels

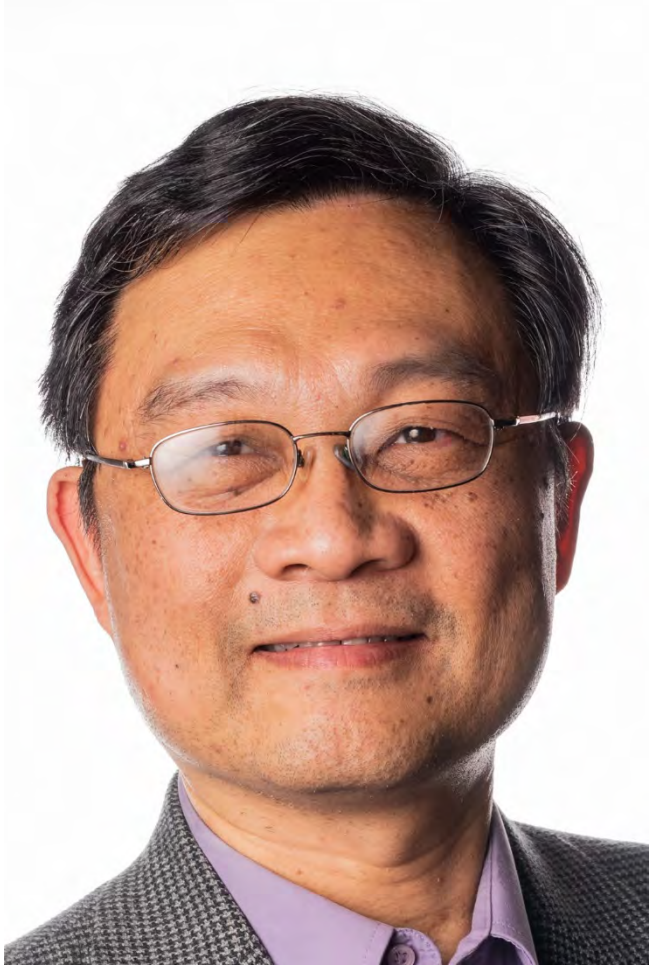
- Judith A. Britz, Ph.D.
- George Lee
- Dr. Feng Tao
- Alan I. West

Britz Bio

Dr. Judith Britz' 40+ year career has spanned academia, industry and government. Her academic credentials include a PhD in Immunology and Microbiology from Stanford University and postdoctoral positions at Johns Hopkins and Yale. Dr. Britz spent more than 25 years in industry in which she held management positions at Becton Dickinson, Johnson and Johnson (Ortho Diagnostics Systems, Inc.) where she focused on vitro diagnostic instrumented and manual systems for infectious diseases and hormone assays. As an entrepreneur of two startup companies, Dr. Britz raised more than $50M from investors for the development of an instrumented system the for detection of multiple analytes simultaneously in blood and one of the first FDA-cleared living cell assays for immune function. Most recently, she was the Executive Director of the BioMaryland Center, a division of Maryland's Economic Development Group.

George Lee

George Lee is a Senior Research Investigator at Bristol-Myers Squibb with over 10 years of expertise in the areas of digital pathology, machine learning, and clinical oncology. He is partnering with image analysis vendors to develop and validate pathology image-based pipelines to provide biomarkers for patient stratification and mechanistic insights of immunotherapy response. Previously, George served as Research Assistant Professor in the Biomedical Engineering Department at Case Western Reserve University. He was awarded a K01 award in Biomedical Big Data Science by the National Institute of Health to develop machine learning and image-analysis methodologies for modeling the progression of prostate cancer. George received his PhD in Biomedical Engineering at Rutgers University and has authored over 30 peer-reviewed manuscripts and abstracts and holds several patents for image-based companion diagnostics.



Dr. Feng Tao has a BS degree in medicinal chemistry and a PhD degree in molecular biology, biochemistry and biophysics. He is an entrepreneur with broad experience in developing and commercialization of life science and medical products. He was a principal investigator of many research grant awards, and commercialized products from concepts to distributions worldwide. He was the founder and CEO of multiple companies, including Omic Biosystems and Kanri Technologies. Dr. Tao served the National Institutes of Health as a Scientific Review Officer responsible for reviewing over 1,000 proposals in 2014-15. Since 2016, as an independent consultant, he has helped others receive research grants with a combined budget over $12 million on a variety topics, including oncological vaccines, stem cell therapies, imaging technologies, surgical products, drugs and drug deliveries, biopharmaceutical manufacturing, as well as health informatics solutions. Dr. Tao frequently serves as a reviewer for study sections at the NIH and NSF.

Alan I. West

Prior to becoming Resident Entrepreneur at the Pittsburgh Life Sciences Greenhouse in 2016, Mr. West was the founding CEO and President of Carmell Therapeutics, Inc. and moved the Company from inception through its first clinical trial. He was previously employed by the Pittsburgh Life Sciences Greenhouse (PLSG) as an Executive in Residence from 2005-2009. In that role he worked with over 40 entrepreneurs and start-up companies in the Life Sciences, providing business planning and strategic assistance while making investment recommendations to the Greenhouse. In 2003, he founded one of the Michigan SmartZones, a program similar to the Pennsylvania Greenhouses that provides business assistance and incubator space to entrepreneurs and start-up companies. Prior to that experience, Mr. West had over 25 years of experience in founding and managing medical device start-up companies in Massachusetts for which he raised more than $50M through private and public offerings. He was the VP of R&D for Boston Scientific prior to their IPO. He holds numerous patents and publications, most recently authored a book on Civil War Medicine. Mr. West received a Bachelor's degree in Mechanical Engineering from Brown University and a Masters in Design from Tufts University.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	CAMERON ECKEL, STAFF ATTORNEY
SUBJECT:	APPOINTMENTS TO ADVISORY COMMITTEES
DATE:	AUGUST 13, 2019

Summary and Recommendation

At its August 16th meeting, the Nominations subcommittee will discuss Presiding Officer Will Montgomery's proposed appointments to the Clinical Trials Advisory Committee (CTAC) and the Product Development Advisory Committee (PDAC) and vote on whether to recommend that the Oversight Committee vote to approve the appointments.

Discussion

Texas Health and Safety Code Section 102.155 allows the Oversight Committee to create ad hoc committees of experts to advise the Oversight Committee. The CTAC advises the Oversight Committee on important issues of clinical trials and provides expert opinions on the impact of current CPRIT mechanisms supporting clinical trials; gives advice on opportunities to increase CPRIT's impact on translating basic discoveries to clinical trials; and advises on mechanisms that would address barriers to patient enrollment in therapeutic clinical trials.

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

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

The Nominations subcommittee will consider the pending CTAC and PDAC appointments at its August 16th meeting.

BIOGRAPHICAL SKETCH

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

NAME: Ronan J. Kelly

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

POSITION TITLE: Director of the Charles A. Sammons Cancer at Baylor University Medical Center, Dallas Texas; Chief of Oncology Baylor Scott and White Health (NTX); Clinical Professor Texas A&M University College of Medicine; Adjunct Associate Professor of Oncology Johns Hopkins Univeristy

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

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
The Royal College of Surgeons, Ireland	MB, BCh, BOA, LRCP & SI, (NUI)	1992 -1998	Medicine
The Royal College of Physicians, Ireland	Intern & 1st yr Residency	1998 - 2000	Internal Medicine
The Michael Smurfit Business School, University College Dublin	MBA	2000 - 2001	Business Administration
The Royal College of Physicians, Ireland	2nd yr Residency	2003 - 2004	Internal Medicine
The Royal College of Physicians, Ireland	Fellowship	2004 - 2007	Medical Oncology
The National Cancer Institute, Bethesda MD	Fellowship	2007 - 2009	Medical Oncology
The National Cancer Institute, Bethesda MD		2009 - 2011	Clinical Investigator

A. Personal Statement

Dr. Kelly is the Director of the Charles A. Sammons Cancer Center at Baylor University Medical Center in Dallas Texas and the Chief of Oncology for the Baylor Scott & White Health System (NTx). As the largest not-for-profit healthcare system in Texas, Baylor Scott & White and their affiliated physicians treat tens of thousands of cancer patients across the state each year. Baylor Scott and White Health's integrated network of cancer centers is the 3rd largest collection of Commission on Cancer-accredited centers in the United States and the largest network of hospital-based cancer programs in Texas. Dr. Kelly is a clinical professor at Texas A&M University and remains an adjunct associate professor at the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins. He previously served as the director of the gastroesophageal cancer therapeutics program at Johns Hopkins and as the director of global oncology for John Hopkins International. In the latter role, he was responsible for improving the quality of cancer care in all John Hopkins-affiliated hospitals across four continents. He performs translational and clinical research encompassing the discovery and the development of new targeted and immunotherapeutic approaches in the prevention and treatment of gastroesophageal cancer and lung cancer. He is the national and international principal investigator on numerous ongoing phase II and phase III studies investigating single agent and combination checkpoint inhibitors in locally advanced and metastatic gastroesophageal cancer. All of these studies involve extensive laboratory correlative studies and as such, he collaborates with numerous immunologists, pathologists, and basic scientists across the United States. He is the chair of the International Association for the Study of Lung Cancer (IASLC) quality and value taskforce and sits on the ASCO measures taskforce (lung cancer chair), quality of cancer care taskforce, international quality taskforce and the clinical practice committee. He is currently leading a new initiative between ASCO and the IASLC to improve lung cancer care in Brazil. He is a taskforce member of the gastroesophageal cancer committee of ECOG and the National Cancer Institute.

B. Positions and Honors

Positions and Employment

09/2011 – 02/2016	Assistant Professor, Medical Oncology, The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins
03/2016 – 11/2018	Associate Professor, Medical Oncology, The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins
01/2013 – 11/2018	Medical Director of Global Oncology Johns Hopkins Medicine International
11/2018 – Present	Director of the Charles A. Sammons Cancer at Baylor University Medical Center Dallas Texas Chief of Oncology Baylor Scott and White Health (NTX) Clinical Professor at Texas A&M University College of Medicine Adjunct Associate Professor of Oncology at Johns Hopkins

Other Experience and Professional Memberships

2012	Invited Grant Reviewer and Member of the Scientific Review Panel, Prevent Cancer Foundation
2013 – 2016	Member, Membership Committee, International Thymic Malignancies Interest Group (ITMIG)
2014 – 2018	Taskforce member, ASCO Quality of Cancer Care Committee
2015	Invited Grant Reviewer and Member of the Scientific Review Panel: California Healthcare Foundation
2015 – Present	Co-Chair, quality and value taskforce at the International Association for the Study of Lung Cancer (IASLC)
2015 – Present	Taskforce member, ASCO Quality Measures Committee
2015 – Present	Invited Grant Reviewer: ASCO – Improving the delivery of cancer care in medically underserved communities
2015 – Present	Taskforce member, ASCO International Quality Oncology Practice Initiative
2015	Invited Grant Reviewer and Expert Scientific Panel Member: Newton Fund - United Kingdom and South African Medical Research Councils Non-Communicable Diseases in Africa (esophageal cancer)
2016	Invited Grant Reviewer and Expert Scientific Panel Member of the Dutch Organization for Health Research and Development (ZonMw). Blood-based prediction of response to immune-checkpoint inhibitors in advanced non-small cell lung cancer.
2017 – Present	Taskforce member of the National Quality Forum (NQF) expert panel on lung cancer survivorship

Honors

2011	Travel award, 11th Annual Targeted Therapies of the Treatment of Lung Cancer, Santa Monica, CA
2012	National Comprehensive Cancer Network (NCCN) Young Investigator Award
2013	Lilly USA Research Award in Cancer Prevention and Early Detection
2014	Specialized Program of Research Excellence (SPORE) in GI Cancer Career Development Award
2016	Specialized Program of Research Excellence (SPORE) in GI Cancer Career Concept Award
2016	Esophageal Cancer Action Network (ECAN) award for clinical research in esophageal cancer

C. Contributions to Science

1. Gastroesophageal and lung cancers are heterogeneous tumors dominated by copy number alterations and frequent large-scale rearrangements. Exome sequencing and whole genome sequencing have failed to identify potential driver mutations in gastroesophageal cancer. As a result, I have been focusing on developing novel immunotherapeutic strategies that are currently being investigated in numerous phase I through III clinical trials.

   A. **Kelly RJ**, Shepherd F, Krivoshik A et al. A Phase III, Randomized, Open-label Study of ASP8273 Versus Erlotinib or Gefitinib in Patients With Advanced Stage IIIB/IV Non-Small Cell Lung Cancer. *Ann Oncol* 2019 May 9th.

B. **Kelly RJ**, Lee J, Bang YJ et al. Safety and Efficacy of Durvalumab and Tremelimumab Alone or in Combination in Advanced Gastric and Gastroesophageal Junction Adenocarcinoma: A Randomized Clinical Trial (In Press 2019).
C. Thompson E, Zahurak M, Murphy A, Cornish T, Cuka N, Abdelfatah E, Yang S, Duncan M, Ahuja N, Taube M, Anders R, **Kelly RJ.** Patterns of PD-L1 expression and CD8 T cell infiltration in gastric adenocarcinomas and associated immune stroma. *GUT* 2017 May:66(5):794-801. PMID: 26801886.
D. Gerber DE, Socinski MA, Neal JW, Wakelee HA, Shirai K, Sequist LV, Rosovsky RP, Lilenbaum RC, Bastos BR, Huang C, Johnson ML, Hesketh PJ, Subramaniam DS, Dietrich MF, Chai F, Wang Y, Kazakin J, Schwartz B, Schiller JH, Brahmer JR, **Kelly RJ**. Randomized phase 2 study of tivantinib plus erlotinib versus single-agent chemotherapy in previously treated KRAS mutant advanced non-small cell lung cancer. *Lung Cancer.* 2018 Mar;117:44-49. PMID: 29496255.
E. **Kelly RJ**, Zaidi AH, Smith MA, Omstead AN, Kosovec JE, Matsui D, Martin SA, DiCarlo C, Werts ED, Silverman JF, Wang DH, Jobe BA. The Dynamic and Transient Immune Microenvironment in Locally Advanced Esophageal Adenocarcinoma Post Chemoradiation. *Ann Surg.* 2018 Dec;268(6):992-999. PMID: 28806299.

2. In addition to clinical trials, my collaborators and I have been utilizing the Levrat esophagojejunostomy rat model to study esophageal cancer. The changes observed in this model closely mirrors the physiological progression of esophageal cancer seen in humans. Use of this model allows us to study changes in the immune microenvironment post chemo-radiation or checkpoint inhibition in esophageal cancer at set points in time, something very difficult to study in humans.

A. **Kelly RJ**, Ansari A, Miyashita T et al. Targeting the Hedgehog Pathway Using Itraconazole to Prevent Progression of Barrett's Esophagus to Invasive Esophageal Adenocarcinoma. (In Press) *Ann Surg* 2019
B. Zaidi AH, Kosovec JE, Matsui D, Omstead AN, Raj M, Rao RR, Biederman RWW, Finley GG, Landreneau RJ, **Kelly RJ**, Jobe BA. PI3K/mTOR Dual Inhibitor, LY3023414, Demonstrates Potent Antitumor Efficacy Against Esophageal Adenocarcinoma in a Rat Model. *Ann Surg.* 2017 Jul;266(1):91-98. PMID: 27471841.
C. Matsui D, Omstead AN, Kosovec JE, Komatsu Y, Lloyd EJ, Raphael H, **Kelly RJ**, Zaidi AH, Jobe BA. High yield reproducible rat model recapitulating human Barrett's carcinogenesis. *World J Gastroenterol.* 2017 Sep 7;23(33):6077-6087. PMID: 28970723.
D. Omstead AN, Kosovec JE, Matsui D, Martin SA, Smith MA, Aaron Guel D, Kolano J, Komatsu Y, Habib F, Lai C, Christopher K, **Kelly RJ**, Zaidi AH, Jobe BA. Serial Endoscopic Evaluation of Esophageal Disease in a Cancer Model: A Paradigm Shift for Esophageal Adenocarcinoma (EAC) Drug Discovery and Development. *Cancer Invest.* 2018;36(7):363-370. PMID: 30142016.

Besides GI cancers, I am also a recognized expert in the management of lung cancer. I am leading international efforts to improve the quality of care delivered to patients with thoracic tumors and to bend the cost curve to deliver care at lower costs for patients here in the US and globally.

1. **Kelly RJ**, Turner R, Chen YW et al. Complications and Economic Burden Associated With Obtaining Tissue for Diagnosis and Molecular Analysis in Patients With Non-Small-Cell Lung Cancer in the United States. *J Oncol Pract*. 2019 June 25th.
2. **Kelly RJ**, Smith TJ. Delivering maximum clinical benefit at an affordable price: engaging stakeholders in cancer care. *Lancet Oncol.* 2014 Mar;15(3):e112-8. PMID: 24534294.
3. **Kelly RJ**, Hillner BE, Smith TJ. Cost effectiveness of crizotinib for anaplastic lymphoma kinase-positive, non-small-cell lung cancer: who is going to blink at the cost? *J Clin Oncol.* 2014 Apr 1;32(10):983-5. PMID: 24567437.
4. Shih YC, Smieliauskas F, Geynisman DM, **Kelly RJ**, Smith TJ. Trends in the Cost and Use of Targeted Cancer Therapies for the Privately Insured Nonelderly: 2001 to 2011. *J Clin Oncol.* 2015 Jul 1;33(19):2190-6. PMID: 25987701.
5. **Kelly RJ**, Smith TJ. Checkpoint Inhibitors in Lung Cancer Are Not Immune from Cost-Effectiveness Analysis. *J Thorac Oncol.* 2016 Nov;11(11):1814-1816. PMID: 27770973.

Complete List of Published Work on Pubmed:
https://www.ncbi.nlm.nih.gov/pubmed/?term=kelly+rj

D. Additional Information: Research Support

06/2015 **Role: International PI** NCT02340975
"A Phase 1b/2 Study of Durvalumab in combination with Tremelimumab, Durvalumab monotherapy, and Tremelimumab monotherapy in subjects with metastatic or recurrent gastric or gastroesophageal junction adenocarcinoma."
Sponsor: Medimmune LLC

04/2016 **Role: Site PI** NCT02572687
"An open-label, multicenter, phase 1 study of Ramucirumab plus Durvalumab in patients with locally advanced and unresectable or metastatic gastrointestinal or thoracic malignancies."
Sponsor: Eli Lilly and Company

6/2016 **Role: Site PI** NCT02689284
"A phase 1b/2, open label, dose escalation study of Margetuximab in combination with Pembrolizumab in patients with relapsed/refractory advanced HER2+ gastroesophageal junction or gastric cancer."
Sponsor: MacroGenics

12/2016 **Role: International PI** NCT02743494
"A randomized, multicenter, double blind, phase III study of nivolumab or placebo in subjects with resected lower esophageal, or gastroesophageal junction cancer (CheckMate 577)."
Sponsor: Bristol Myers Squibb

02/2017 **Role: Site PI** NCT02872116
"A Randomized, Multicenter, Open-Label, Phase III Study of Nivolumab Plus Ipilimumab versus Oxaliplatin plus Fluoropyrimidine in Subjects with Previously Untreated Advanced or Metastatic Gastric or Gastroesophageal Junction Cancer (CheckMate 649)."
Sponsor: Bristol Myers Squibb

07/2017 **Role: SITE PI** NCT02935634
"A Phase 2, Fast Real-time Assessment of Combination Therapies in Immuno-Oncology Study in Participants with Advanced Gastric Cancer (FRACTION-gastric cancer)."
Sponsor: Bristol Myers Squibb

07/2017 **Role: Award Recipient and National PI** NCT03044613
"A Phase IB trial of neoadjuvant Nivolumab in patients with locally advanced esophageal and gastroesophageal Junction Cancer."
Sponsor: Investigator Sponsored Research; Bristol Myers Squibb; $2.3 million

7/2017 **Role: Co-PI (5%)**
"PD-L1 inhibition alone (FAZ053) and in combination with epigenetic therapy and/or radiation for the treatment of esophageal adenocarcinoma in a rat model."
Sponsor: Beigene**;** $174,502

10/2017 **Role: Co-PI**
"STING agonist alone and in combination with radiation for the treatment of esophageal adenocarcinoma in a rat model."
Sponsor: Aduro Biotech/Novartis; $163,752

10/2017 **Role: Award Recipient and National PI** NCT03610711
"REACTION (Radiation Enhanced Assessment of Combination Therapies in Immuno-ONcology) – Nivolumab or Nivolumab in combination with other Immuno-oncology (IO) agents after Targeted Systemic Radiation in patients with advanced Esophagogastric cancer."
Sponsor: Investigator Sponsored Research/Bristol Myers Squibb; $2.3 million

6/2018 **Role: International PI** UTRN# U1111-1206-3033
"A Randomized, Active-Controlled, Blinded, Phase II Clinical Trial of BMS-986213 (Fixed Dose Combination of Relatlimab [anti-LAG-3] and Nivolumab) in Combination with Chemotherapy versus Placebo in Combination with Chemotherapy as First-Line Treatment in Participants with Unresectable, Locally Advanced or Metastatic LAG-3 Positive Gastric or Gastroesophageal Junction Adenocarcinoma."
Sponsor: Bristol Myers Squibb

GREG HARTMAN

Interim Senior Vice President, Texas A&M University Health Science Center

Greg Hartman serves as interim senior vice president of the Texas A&M University Health Science Center.

A former health care executive with more than 30 years of experience and responsibility in executive management, strategy, health policy, marketing, communications, government relations and philanthropy, Hartman joined The Texas A&M University System as vice chancellor of strategic initiatives in January 2019. His focus has been to foster collaborations among institutions and agencies within the system on key priorities, with a special focus on health care initiatives such as Engineering Medicine and Healthy Texas.

Hartman served in a number of executive roles with Seton Healthcare, a $2 billion hospital system in Central Texas, including as CEO of the system's two largest hospitals, overseeing academic and research programs affiliated with the University of Texas System and responsibility for public partnerships and the system's foundations. He was heavily involved in the creation of a unique collaboration between Seton, the University of Texas at Austin and the UT System to bring translational medical research and academic medicine to Austin.

Before joining Seton, Hartman worked around the nation as a consultant on management and operations, strategic planning, public affairs, communications, marketing and advertising. He was a managing director for Public Strategies, Inc., a corporate strategy firm, and a senior partner with MGT of America, a national management consulting and research firm. He also served as an executive in the Texas State Comptroller's office and has worked for legislators in both the Texas Senate and House.

BIOGRAPHICAL SKETCH

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

NAME: Wood, John

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

POSITION TITLE: Robert A. Welch Distinguished Professor

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

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of Colorado, Boulder	B.A.	05/1985	Chemistry
University of Pennsylvania	Ph.D.	05/1991	Organic Chemistry
Harvard University	Postdoctoral	07/1993	Organic Chemistry

A. Personal Statement

After completing Doctoral and Postdoctoral studies in the laboratories of Amos B. Smith, III and Stuart L. Schreiber, respectively, I began my independent career at Yale University in 1993. In 1998 I was promoted to full professor with tenure and in 2006 I moved from Yale to join the faculty at Colorado State University as the A. I. Meyers Professor of chemistry. In 2013, I moved to my current position at Baylor University as the Robert A. Welch Distinguished Professor and Cancer Prevention Research Institute of Texas (CPRIT) Scholar. This latest move has given my laboratory unfettered access to state-of-the-art equipment in newly renovated facilities and opportunities to interact and collaborate with prominent researchers across the state of Texas (as part of CPRIT and the Baylor network of institutions) and beyond.

Throughout my independent research career, my laboratory has engaged in the pursuit of complex natural products driven by novel synthetic disconnections. Though historically the laboratory has not set out to develop synthetic methods, we have repeatedly, if inadvertently, developed novel methodology to surmount various synthetic challenges encountered en route to a natural product. This approach to natural products synthesis has produced numerous successful total syntheses, and has provided a robust education for 35 Ph.D. students and an equal number of postdoctoral and undergraduate researechers. My group has accrued considerable expertise in small molecule synthesis, and former students have utilized the knowledge and skills acquired under my tutelage to rise to prominent positions in academia (e.g., Caltech, Yale, U of Arizona, Waterloo) and industry (Merck, Pfizer, Lilly, etc.). In addition to our synthetic work, my laboratory has been involved in several collaborations to explore the biological activity of small molecules through the synthesis of their analogues. These experiences have led my laboratory to be well suited for the studies proposed in the accompanying application.

Representative publications:

1. “Total Synthesis of Caesalpinnone A and Caesalpinflavan B: Evolution of a Concise Strategy” Timmerman, Jacob C.; Sims, Noah J.; Wood, John L. *J. Am. Chem. Soc.* **2019**, (In Press).
2. “Total Synthesis of Herqulines B and C” Cox, J. B.; Kimishima, A.; Wood, J. L. *J. Am. Chem. Soc.* **2019**, *141*, 25. DOI: 10.1021/jacs.8b10212, PMID: 30561198
3. “Total Synthesis of (±)-Aspergilline A” Nakhla, M. C.; Wood, J. L. *J. Am. Chem. Soc.* **2017**, *139*, 18504. DOI: 10.1021/jacs.7b12570, PMID: 29235866.

4. “Total Syntheses of (+)-and (-)-Tetrapetalones A and C” Dhanjee H. H.; Kobayashi, Y.; Buergler, J. F.; McMahon, T. C.; Haley, M. W.; Howell, J. M.; Fujiwara, K.; Wood, J. L. *J. Am. Chem. Soc.* **2017,** 139, 14901. DOI: 10.1021/jacs.7b09358, PMID: 28991468
5. “Total Synthesis of (±)-Phomoidride D” Leung, J. C.; Bedermann, A. B.; Njardarson, J. T.; Spiegel, D. A.; Murphy, G. K.; Hama, N.; Twenter, B. M.; Dong, P.; Shirahata, T.; McDonald. I M.; Inoue, M.; Taniguchi, N.; McMahon, T. C.; Schneider, C. M.; Tao, N.; Stoltz, B. M.; Wood, J. L. *Angewandte Chemie International Edition* **2018**, *57,* 1991. DOI: 10.1002/anie.201712369, PMID: 29286556
6. “An Enantioselective Total Synthesis and Stereochemical Revision of (+)-Citrinadin B” Kong, K.; Enquist, Jr., J.A.; McCallum, M.; Smith, G. M.; Matsumaru, T.; Menhaji-Klotz, E.; Wood, J. L. *J. Am. Chem. Soc.* **2013**, *135*, 10890-10893.
7. “Total Synthesis of Ingenol” Nickel, A. Maruyama, T.; Tang, H.; Murphy, P.; Greene, B.; Yusuff, N.; Wood, J. L. *J. Am. Chem. Soc*. **2004**, *126*, 16300.
8. "Design and Implementation of an Efficient Synthetic Approach to Pyranosylated Indolocarbazoles: Total Synthesis of (+)-RK286c, (+)-MLR-52, (+)-Staurosporine, and (-)-TAN-1030a" Wood, J. L.; Stoltz, B. M.; Goodman, S. N.; Onwueme, K. *J. Am. Chem. Soc.* **1997**, *119*, 9652.

B. Positions and Honors

Positions and Employment

1991-1993	American Cancer Society Postdoctoral Fellow, Harvard University
1993-1997	Assistant Professor of Chemistry, Yale University
1997-1998	Associate Professor of Chemistry (non tenured), Yale University
1998-2006	Professor of Chemistry with Tenure, Yale University
2006-2013	A. I. Meyers Professor of Chemistry, Colorado State University
2013-	Robert A. Welch Distinguished Professor of Chemistry and Cancer Prevention and Research Institute of Texas Scholar, Baylor University

Selected Honors and Awards

2019	Outstanding Faculty Scholar, Baylor University
2018	Fellowship of the Royal Society of Chemistry (FRSC)
2013	Invited Overseas Lecturer, Universities of Switzerland Summer School
2009	Katritzky Award in Heterocyclic Chemistry (ISHC)
2009	3éme Cycle Lectureship, University of Basel
2009	Distinguished Behringer Simon Lecturer, ETH Zurich
2005-2009	Amgen Faculty Award
2008	Japanese Society for the Promotion of Science Fellow
2004	American Chemical Society Arthur C. Cope Scholar Award
1998-2003	Yamanouchi USA Faculty Award
2000-2002	Merck Faculty Award
2001	Kitasato Microbial Chemistry Medal
1998-2001	Bristol-Myers Squibb Foundation Research Award
1997-2001	Pfizer Research Award
1998	Zeneca Excellence in Chemistry Award
1998	Dreyfus Teacher Scholar Award
1997-1998	Novartis Chemistry Lectureship
1997	Alfred P. Sloan Foundation Fellow
1997	Bristol-Myers Squibb Research Award
1996-1998	Glaxo-Wellcome Young Chemistry Scholar Award
1995-1997	Eli Lilly Young Faculty Award
1989-1990	University of Pennsylvania Dean's Dissertation Fellowship
1993	Camille and Henry Dreyfus New Faculty Award
1994	American Cancer Society, Junior Faculty Award
1996-2000	NSF CAREER award

C. Contribution to Science

1. **Total syntheses of complex natural products.** Since the beginning of my independent career, my laboratory has pursued the total synthesis of complex natural products. Our successful syntheses have employed a wide variety of techniques and synthetic methodologies to execute novel routes. These efforts have resulted in access of twenty different natural products in as many years, a representative sample of which are cited above and below.
    a. "Collaborative Total Synthesis: An Approach to (±)-Hippolachnin A Enable by Quadricyclane Cycloaddition and Late-Stage C-H Oxidation" McCallum, M. E.; Rasik, C. M.; Wood, J. L.; Brown, M. K. *J. Am. Chem. Soc*. **2016**, *138*, 2437.
    b. "Toward the Synthesis of Phomoidride D" Murphy, G. K.; Shirahata, T.; Hama, N.; Bedermann, A.; Dong, P.; McMahon, T. C.; Twenter, B. M.; Spiegel D. A.; McDonald, I. M.; Taniguchi, N.; Inoue, M.; Wood, J. L. *J. Org. Chem.* **2013**, *78*, 447.
    c. "Evolution of a Synthetic Strategy: Total Synthesis of (±)-Welwitindolinone A Isonitrile" Reisman, S.E.; Ready, J. M.; Weiss, M. M.; Hasuoka, A.; Hirata, M.; Tamaki, K.; Ovaska, T. V.; Smith, C. J.; Wood, J. L. *J. Am. Chem. Soc.* **2008**, *129*, 2087.
    d. "Design and Implementation of an Efficient Synthetic Approach to Furanosylated Indolocarbazoles: Total Synthesis of (+)- and (-)-K252a" Wood, J. L.; Stoltz, B. M.; Dietrich, H. -J.; Pflum, D. A.; Petsch, D. T. *J. Am. Chem. Soc.* **1997**, *119*, 9641.
2. **Development of synthetic methodologies and studies of the reaction mechanisms.** During our investigations into the synthesis of complex natural products, we have developed a number of novel synthetic methodologies. In several cases, these have led to the study of complex reaction mechanisms and the publications of methodology papers, as cited below.
    a. "Chemoselective Intramolecular Carbonyl Ylide Formation through Electronically Differentiated Molonate Diesters" Nakhla, M. C.; Lee, C.-W.; Wood, J. L. *Org. Lett.* **2015**, *17*, 5760.
    b. "Deoxygenation of Alcohols Employing Water as the Hydrogen Atom Source" Spiegel, D. A.; Wiberg, K. B.; Schacherer, L. N.; Medeiros, M. R.; Wood, J. L. *J. Am. Chem. Soc.* **2005**, *127*, 12513.
    c. "Reactive Dienes: Intramolecular Aromatic Oxidation of 3-(2-Hydroxyphenyl)-propionic Acids" Drutu, I.; Njardarson, J. T.; Wood, J. L. *Org. Lett.*, **2002**, *4*, 493.
    d. "Development of a Rhodium Carbenoid-Initiated Claisen Rearrangement for the Enantioselective Synthesis of a-Hydroxy Carbonyl Compounds" Wood, J. I.; Moniz, G. A.; Pflum, D. A.; Stoltz, B. M.; Holubec, A. A.; Dietrich, H. -J. *J. Am. Chem. Soc.* **1999**, *121* 1748.
3. **Synthesis of analogues of biologically active small molecules and their studies of modes of action.** Many of the molecules my laboratory has targeted over the years have exhibited biological activity of some kind. Consequently, we have been involved in collaborations with other laboratories to test the biological activity of these small molecules and have been called upon to synthesize analogues for further testing. By providing these analogues, these collaborations were able to answer fundamental questions about how these compounds function in biological systems.
    a. "Synthesis and Biological Evaluation of Hippolachnin A Analogs" Timmerman, J. C.; Wood, J. L. *Org. Lett.* **2018**, *20*, 3788. DOI: 10.1021/acs.orglett.8b01381, PMID: 29916256
    b. "Metformin Suppresses Gluconeogenesis by Inhibiting Mitochondrial Glycerophosphate Dehydrogenase" Madiraju, A. K.; Erion, D. M.; Rahimi, Y.; Zhang, X.-M.; Braddock, D. T.; Albright, R. A.; Prigaro, B. J.; Wood, J. L.; Bhanot, S.; MacDonald, M. J.; Jurczak, M. J.; Camporez, J.-P.; Lee, H.-Y.; Cline, G. W.; Samuel, V. T.; Kibbey R. G.; Shulman, G. I. *Nature* **2014**, *510*, 542.
    c. "An Aminooacyl-tRNA Synthetase that Specifically Activates Pyrrolysin" Polycarpo, C.; Ambrogelly, A.; Bérubé, A.; Winbush, S. M.; McCloskey, J. A.; Crain, P. F.; Wood, J. L.; Söll, D. *Proc. Nat. Acad. Sci.* **2004**, *101* (34), 12450.
    d. "The K252a Derivatives, Inhibitors for the PAK/MLK Kinase Family, Selectively Block the Growth of RAS Transformants" Nheu, T. V.; He, H.; Hirokawa, Y.; Tamaki, K.; Florin, L.; Schmitz, M. L.; Suzuki-Takahashi, I.; Jorissen, R. N.; Burgess, A. W.; Nishimura, S.; Wood, J.; Maruta, H. *The Cancer Journal* **2002**, *8*, 328.
    e. "A Chemical Switch for Inhibitor-Sensitive Alleles of Any Protein Kinase" Bishop, A. C.; Ubersax, J. A.; Petsch, D. T.; Matheos, D. P.; Gray, N. S.; Blethrow, J.; Shimizu, E.; Tsien, J. Z.; Schultz, P. G.; Rose, M. D.; Wood, J. L.; Morgan, D. O.; Shokat, K. M. *Nature* **2000**, *407*, 395.

For a Complete List of my Published Work, Please See:
http://www.johnwoodgroup.com/publications.html

D. Additional Information: Research Support
Ongoing Research Support

Cancer Prevention Research Institute of Texas (R1309) Wood (PI) 3/1/13-2/28/19
Recruitment of investigators grant. Total Award: $4,215,750
Current No Cost Extension to 2/28/19 pending.

Robert A. Welch Foundation, Baylor University Welch Chair (AA-0006) Wood(PI) 8/1/2013-
This is an indefinite grant that provides funds based on endowment return (±) 3 $200,000/year

National Science Foundation (CHE-1764240) Wood (PI) 7/1/18-6/30/21
"Development of New Strategies for Complex Molecule Synthesis" Total Award: $450,000
This grant focuses on syntheses of tetrapetalone and aspergilline (no overlap with current application)

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	FY 2020 HONORARIA POLICY
DATE:	AUGUST 5, 2019

Summary and Recommendation:

CPRIT's enabling legislation requires the Chief Executive Officer, in consultation with the Oversight Committee, to adopt a policy regarding honoraria paid by CPRIT for peer review services. The Oversight Committee approved the FY 2019 honoraria policy at the August 2018 meeting. CPRIT has revised the FY 2020 honoraria policy to reflect the growing workload for Academic Research, Prevention, and Product Development Program peer reviewers. The proposed changes increase the FY 2020 honoraria budget by $165,200. I recommend approval of the FY 2020 honoraria policy.

Discussion:

CPRIT's Scientific Research and Prevention Programs committee members (also referred to as "peer reviewers") review grant applications and recommend grant awards for meritorious projects addressing cancer prevention and research (including product development) in Texas. State law authorizes CPRIT to pay honoraria to individuals appointed to CPRIT's Scientific Research and Prevention Programs committees (Health and Safety Code § 102.151(d)). The ability to pay honoraria is essential to retaining individuals with the expertise and experience to carry out the complex review process required by CPRIT's statute and administrative rules.

In its January 2013 report, the State Auditor's Office recommended CPRIT implement a process supporting the honorarium it pays, to justify any changes, and to ensure that the honoraria are reasonable and competitive for the value CPRIT receives. The State Auditor also advised CPRIT to adopt documentation and process requirements for honoraria payments. CPRIT's statute reflects the State Auditor's guidance at Texas Health and Safety Code § 102.151(e).

CPRIT's program staff relied upon historical information as well as anticipated workload projections to perform a detailed analysis of the activities, hours, and units for peer reviewer workload. The FY 2020 policy incorporates the roles and responsibilities assigned to Review Council chairs, Peer Review committee chairs, and peer review committee members and justifies the FY 2020 honorarium amount paid for each role. When honoraria rates are not standard across the prevention, academic research, and product development programs, the policy justifies the reasons for paying different amounts. CPRIT's FY 2020 honoraria policy fully implements the statutory mandate and audit recommendations.

This memo explains the changes to the proposed FY 2020 honoraria amounts from those approved by the Oversight Committee for FY 2019. The FY 2020 honoraria budget will increase by $165,200 if the Oversight Committee approves all proposed changes.

Academic Research Program Honoraria Changes

Academic Research Program peer review activities have increased since the honoraria policy was last modified in FY 2017, due mostly to the surging number of recruitment nominations, which have risen by one-third, as well as the number of new RFAs for expanding research opportunities. The table below shows the proposed changes to the FY 2020 honoraria policy (activities and corresponding units not listed on the table remain the same as FY 2019). As noted on the table, the Scientific Review Council (SRC) Chair recommends adding two additional recruitment reviewers to provide subject matter expertise not fully covered by the SRC members. CPRIT has benchmarked the unit cost for recruitment reviewer position between the unit cost for SRC members ($875) and the academic research peer reviewers ($250). The projected unit cost reflects the expertise and experience necessary for the review of CPRIT's recruitment applications.

The proposed changes indicated below increase the FY 2020 honoraria paid to academic research reviewers by $64,600.

Proposed Changes to Academic Research Activities for FY 2020 Honoraria Policy					
	Unit Cost	Activity (Units)		Annual Honoraria	
		2019	2020	2019	2020
SRC Chair	$1200	57	62.5	$68,400	$75,000
Review recruitment nominations		20	24		
Lead SRC evaluation of recruitment applications		5	5.5		
Review draft RFAs		4	5		
SRC Committee Chair	$875	52	57.5	$46,000	$50,000
Review recruitment nominations		20	24		
Participate in SRC evaluation of recruitment applications		3	4.5		
Recruitment Reviewer (new position for FY 2020)	$525		28.5		$15,000
Review recruitment nominations			24		
Participate in SRC evaluation of recruitment applications			4.5		

Prevention Program Changes

Prevention peer review activities have increased for the Prevention Review Council (PRC) Chair and PRC Committee Chairs, primarily because of the additional work created with the review of applications for the *Dissemination of CPRIT-Funded Cancer Control Interventions* awards. Although the Prevention Program introduced the mechanism in FY 2017, CPRIT has not updated the honoraria policy to recognize the substantial amount of work that PRC members undertake due to the new initiative. In addition, the increase in honoraria proposed for the two PRC

Committee Chairs reflects more work done in selecting and recruiting committee members, reviewing RFAs, and reading abstracts for all applications assigned to their review panels.

The proposed changes indicated below will increase the FY 2020 honoraria paid to prevention reviewers by $26,000.

Proposed Changes to Prevention Activities for FY 2020 Honoraria Policy					
	Unit Cost	Activity (Units)		Annual Honoraria	
		2019	2020	2019	2020
PRC Chair	$1200	53	60	$64,000	$72,000
Prepare for programmatic review meetings		2	4		
Lead programmatic review		6	4		
Review dissemination applications (new in FY 2020)			4		
Participate in PRC evaluation of dissemination applications (new in FY 2020)			2		
Review annual and final progress reports		4	5		
PRC Committee Chair	$875	32	42	$28,000	$37,000
Select/recruit committee members		1	2		
Review draft RFAs		1	2		
Read abstracts assigned to their committee, review panel assignments		10	12		
Review dissemination applications (new in FY 2020)			4		
Participate in PRC evaluation of dissemination applications (new in FY 2020)			2		

Product Development Program Changes

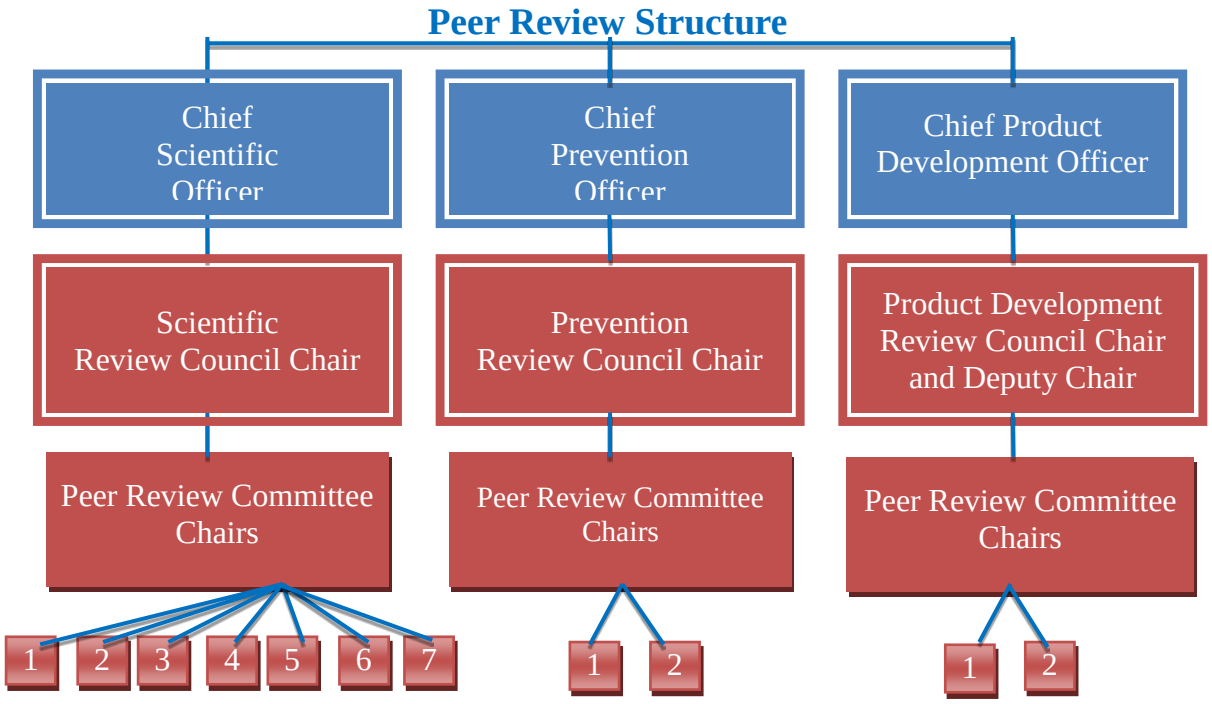
The proposed changes to the Product Development Program peer review activities in FY 2020 acknowledge the increased workload for the members of the Product Development Review Council (PDRC). The additional work is related to the rising number of applications reviewed as well as an increase in annual progress report reviews for active product development projects. In a separate memo, Chief Product Development Officer Dr. Cindy WalkerPeach has requested approval to add an additional PDRC committee chair to also address the growing workload.

The proposed changes indicated below will increase the FY 2020 honoraria policy paid to product development reviewers by $75,600. This amount includes honoraria for the new member CPRIT will add to the PDRC.

Proposed Changes to Product Development Activities for FY 2020 Honoraria Policy					
	Unit Cost	Activity (Units)		Annual Honoraria	
		2019	2020	2019	2020
Product Development Review Council Chair	$1200	62.5	69.5	$75,000	$83,400
Advise on peer review and programmatic processes		2	4		
Review draft RFAs		6	7		
Lead programmatic review panels, facilitate diligence review meetings		5	7		
Review progress reports		12.5	14.5		
Product Development Review Council Deputy	$1200	48.5	54.5	$58,200	$65,400
Advise on peer review and programmatic processes		2	4		
Lead programmatic review panels, facilitate diligence review meetings		5	7		
Review progress reports		12.5	14.5		
Product Development Review Committee Chairs	$875	45	50	$40,000	$44,000
Review draft RFAs and advise on programmatic process improvements		1	3		
Review progress reports		11	15		

CPRIT PEER REVIEW FY 2020 HONORARIA POLICY[1]

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



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

CPRIT's expert peer reviewers live and work outside Texas, which is an uncommon requirement among grant-making organizations. CPRIT implemented this peer reviewer qualification to ensure an impartial review, minimize conflicts of interest, and provide the opportunity to select the best projects without regard for self-interest.

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

Honoraria

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

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

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

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

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

Honoraria Payment Process and Documentation

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

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

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

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

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

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

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

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

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

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

Peer Review Responsibilities

Review Council Chairs

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

- advising on the selection of committee chairs
- recruiting specialized peer reviewers and assisting with peer reviewer selection
- reviewing all abstracts of projects that discussed at Prevention, Scientific, and Product Development Review Council meetings
- chairing Review Council meetings
- chairing a peer review panel meeting if a chair has an unexpected conflict[5]
- finalizing grant award recommendations to the Chief Executive Officer
- providing ongoing advice to CPRIT staff on programs, review processes, and future funding opportunities

Estimated Annual Time Commitment: CPRIT expects Council Chairs to commit approximately 300 hours to CPRIT-related activities in FY 2020. This equates to 11.5% of a standard 2080-hour work year. **Table 1** provides a detailed analysis of the activities, hours, and units used to project the Council Chair workload. The information in Table 1 reflects 2018 – 2019 review cycle information and the projected workload for FY 2020.

NOTE: In addition to the regular Council Chair duties in FY 2020, CPRIT anticipates that the Product Development Review Council Chair will perform services totaling 60 additional hours. Examples of the additional activities include coordinating the review of annual progress reports and milestone funding decisions and providing expert advice and assistance related to CPRIT's product development portfolio and substantive grant contract amendment requests. In FY 2016, CPRIT created the Product Development Review Council Deputy Chair position. This position is equivalent to the Council Chair position except that the Deputy Chair will not prepare slate recommendation for the Chief Executive Officer. CPRIT will continue to use a Deputy Chair position for FY 2020.

Hourly Rate Proxy: CPRIT pays honorarium for the annual service of the Review Council chair and is not based on an hourly wage structure. However, for comparison, the honoraria paid to Review Council chairs equate to a $250/hour rate. This is in line with hourly rates paid for skilled professional services in other industries and less than the $500/hour rate paid for medical experts in malpractice cases.[6] The hourly rate used by CPRIT is also likely to be less than rates

[5] The Product Development Committee Chair regularly chairs review committee meetings.

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

used to calculate consultant fees for physicians and scientists who advise pharmaceutical companies. Although there is no standard rate for consulting fees, one Texas institution of higher education limits the amount of consulting fees a professor may accept to 25% of their base salary. The capped amount is greater than the $72,000 - $83,400 honoraria paid to CPRIT Review Council Chairs.

Review Committee Chairs

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

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

Estimated Annual Time Commitment: The amount of time spent on committee chair activities varies depending on the program. CPRIT expects Review Committee chairs to commit between 190 and 250 hours to CPRIT-related activities in FY 2020. **Table 2** provides a detailed analysis of the activities, hours, and units used to project the committee chair workload. The information in Table 2 reflects 2009 – 2019 review cycle information and the projected workload for FY 2020. Note: For the purposes of the honoraria policy, CPRIT refers to Product Development Review Council members to as "committee chairs" and perform all activities listed in Table 2.

Hourly Rate Proxy: CPRIT pays honorarium for the annual service of the Review Committee chair and is not based on an hourly wage structure. However, for comparison, the honoraria paid to Committee chairs equates to a $200/hour fee. This is in line with hourly rates paid for skilled professional services in other industries and less than the $500/hour rate paid for medical experts

in malpractice cases.[7] The hourly rate used by CPRIT is also likely to be less than rates used to calculate consultant fees for physicians and scientists who advise pharmaceutical companies. Although there is no standard rate for consulting fees, one Texas institution of higher education limits the amount of consulting fees a professor may accept to 25% of their base salary. The capped amount is more than the $37,000 - $50,000 honoraria paid to CPRIT Review Committee Chairs.

Review Committee Members

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

Estimated Time Commitment per Review Cycle: Peer reviewer activity varies by program and number of applications assigned. academic research peer reviewers are expected to commit approximately 85 hours per review cycle. Prevention peer reviewers will commit 55-70 hours per cycle. Product Development peer reviewers will commit 100+ hours per cycle. **Table 3** provides a detailed analysis of the activities, hours, and units used to project the peer review workload. The information in Table 3 reflects 2009–2019 review cycle information and the projected workload for FY 2020.

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

Comparison to other Grant Making Organizations

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

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

CPRIT reviewers because of CPRIT's policy to use highly qualified, experienced, out-of-state reviewers.

- International Cancer Research Partners (ICRP) surveyed 31 of its partner organizations and 21 responded. The report found that organizations paid different honoraria depending on the role of the reviewer. Chairs often received more than committee members did, and teleconference or online reviewers typically received less compensation than those members who participated in-person. The report did not compute an average based on the supplied data.[8]

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

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

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

Table 1. Council Chair Activities (See Table 4 for an explanation of the correlation between units and hours.)

Table 1 - Review Council Chair Activities, Hours, Units						
Academic Research Review		**Prevention Review**		**Product Development Review**		
Units	Activity	Units	Activity	Units Chair	Units Deputy	Activity
5	Consult with staff on vision and direction for the program; bi-weekly calls with staff	5	Consult with staff on vision and direction for the program; bi-weekly calls with staff	5	5	Consult with staff on vision and direction for the program; bi-weekly conference calls with staff
2	Help select and recruit Committee Chairs	2	Help select and recruit Committee Chairs	2	2	Assist in selecting and recruiting review council members and peer reviewers
2	Advise on peer review and other processes as needed	2	Advise on peer review and other processes as needed	4	4	Advise on peer review and other programmatic processes as needed
5	Review draft RFAs, propose new ones, etc.	4	Review draft RFAs, propose new ones, etc.	7	0	Review draft RFAs, propose new RFA concepts, etc.
5	Communicate with Committee Chairs prior to peer review & programmatic mtg	1	Communicate with Committee Chairs prior to peer review & programmatic mtg	6	6	Communicate with Review Council members prior to peer review & programmatic mtg
4	Prepare for Programmatic meetings; review materials	4	Prepare for Programmatic meetings; review materials	4	4	Prepare for Programmatic meetings; review materials
2	Lead programmatic review	4	Lead programmatic review	7	7	Lead programmatic review panels; facilitate diligence teleconference calls
4	Prepare slate recommendations for CEO and Oversight Committee Chair	1	Prepare slate recommendations for CEO and Oversight Committee Chair	4	0	Prepare slate recommendations for CEO and Oversight Committee Chair
24	Review recruitment applications, become familiar with applications to be discussed	15	Review abstracts, attend portions of panel meetings, back up for panel Chair	12	12	Review applications, facilitate panel meetings
5.5	Lead quarterly discussion on recruitment awards	4	Collaborate on articles for publication	4	0	Analyze data for Product Development program
4	Analyze data for Research program	4 3 6 5	Analyze data for Prevention program Participate in quarterly teleconference Review dissemination applications Review Annual and Final progress reports	14.5	14.5	Review annual, tranche, and final progress reports, advise on activities of funded product development grants and recommend continued funding.
62.5		60		69.5	54.5	
$ 1,200	Unit cost	$1,200	Unit cost		$1,200	Unit cost
$ 250	Hourly rate	$250	Hourly rate		$250	Hourly rate
$75,000	Annual honoraria	**$72,000**	Annual honoraria		**$83,400** **$65,400**	Annual honoraria Chair Annual honoraria Deputy Chair

Table 2. Committee Chair* Activities (See Table 4 for an explanation of the correlation between units and hours.)

Table 2 - Committee Chair Activities, Hours, Units					
Academic Research Review		**Prevention Review**		**Product Development Review**	
Units	Activity	Units	Activity	Units	Activity
2	Select/recruit committee members	2	Select/recruit committee members	2	Select/recruit committee members
2	Review draft RFAs and provide input (as needed)	2	Review draft RFAs and provide input (as needed)	3	Review draft RFAs and provide input (as needed); advise on Programmatic process improvements
12	Read abstracts; assign grants to reviewers	12	Read abstracts assigned to their committee; review panel assignments	15	Read applications assigned to their panel
1	Assist with follow up of delinquent reviewers	1	Assist with follow up of delinquent reviewers	3	Participate on assigned Screening Teleconference committee via conference call
6	Chair the assigned committee review process via conference call or in person meeting	6	Chair the assigned committee review process via conference call or in person meeting	10	Participation in-person peer review meeting
2	Prepare for Programmatic meetings; review materials	2	Prepare for Programmatic meetings; review materials	2	Participate in debriefing sessions, discussion of future direction of program, development of new RFAs
2	Participate in Chair's programmatic review meetings	6	Participate in Chair's programmatic review & debriefing meetings	15	Review annual, tranche, and final progress reports; advise on activities of funded product development grants and recommend continued funding.
2	Participate in debriefing sessions, discussion of future direction of program, development of new RFAs	2	Participate in debriefing sessions, discussion of future direction of program, development of new RFAs		
		3	Prepare and participate in quarterly Review Council teleconferences		
24	Review recruitment applications	4	Review dissemination applications		
4.5	Participate in quarterly review of recruitment applications	2	Participate in review of dissemination applications		
57.5		42		50	
$875	Unit cost	$875	Unit cost	$875	Unit cost
$200	Hourly	$200	Hourly	$200	Hourly
$50,000	**$50,000** Annual honoraria	$36,750	**$37,000** Annual honoraria	$43,750	**$44,000** Annual honoraria

See Table 4 for an explanation of the correlation between units and hours.

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

Table 3. Peer Reviewer Activities per Cycle (See Table 4 for an explanation of the correlation between units and hours.)

Table 3 - Peer Reviewers Activity by Program					
Product Development Review: ~60 reviewers		**Prevention Review: ~20 reviewers**		**Academic Research Review: ~ 130 reviewers**	
Units	**Activity**	**Units**	**Activity**	**Units**	**Activity**
1	Declaration of expertise and conflicts	1	Declaration of expertise and conflicts	1	Declaration of expertise and conflicts
7	Preparation of full critiques	8	Preparation of full critiques	9	Preparation of critiques*
2	Participation in screening teleconference	3	Travel to/from meetings	3	Travel to/from on-site meeting
3	Travel to/from on-site meeting	4	Participation at meeting	3	Participation at meeting
4	Participation at in-person meeting	1	Post-meeting discussion**	1	Post-meeting discussion**
1	Post-meeting discussion**				
1	Review of due diligence and intellectual property evaluations				
1	Teleconference discussion of due diligence and intellectual property evaluation				
20	$325 Unit cost $65 avg. hourly rate $6,500 per cycle	17	$250 Unit cost $50 avg. hourly rate $4,250 in person per cycle	17	$250 Unit cost $50 avg. hourly rate $4,250 per cycle

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

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

Table 4. Hours and Units Calculation

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

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE CHAIR WILL MONTGOMERY
FROM:	WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	SECTION 102.1062 WAIVER—BRANDY FY 2020
DATE:	AUGUST 1, 2019

Waiver Request and Recommendation

I request that the Oversight Committee approve a conflict of interest waiver for FY 2020 for Mr. Donald Brandy, CPRIT's Purchaser and HUB Coordinator, pursuant to Health & Safety Code Section 102.1062 "Exceptional Circumstances Requiring Participation." The Oversight Committee approved the same waiver for Mr. Brandy since FY 2015.

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

Background

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

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

department pays Mr. Brandy for his services as an independent contractor when he referees collegiate matches.

CPRIT employees may engage in outside employment so long as the employment does not detract from the employee's ability to fulfill his or her responsibilities to CPRIT. Employees must receive written approval from the CEO to engage in outside employment and I notify the Audit Subcommittee regarding any approvals. I also annually report to the Oversight Committee all approved outside employment. I notified the Audit Subcommittee regarding my approval for Mr. Brandy's outside employment and the subcommittee first discussed it at the December18, 2014, subcommittee meeting.

Exceptional Circumstances Requiring Mr. Brandy's Participation

To approve a conflict of interest waiver, the Oversight Committee must find that there are exceptional circumstances justifying the conflicted individual's participation in the review process or other expenditure of CPRIT funds.[1]

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

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

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

Proposed Waiver and Limitations

In granting the waiver of the conflict of interest set forth in Health & Safety Code Section 102.106(c)(3), I recommend that the Oversight Committee permit Mr. Brandy to perform all duties assigned as purchaser, subject to the limitations stated below:

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

Important Information Regarding this Waiver and the Waiver Process

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

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	SECTION 102.1062 WAIVER – DR. JOHN HELLERSTEDT
DATE:	AUGUST 1, 2019

Waiver Request and Recommendation

I request that the Oversight Committee approve a conflict of interest waiver for FY 2020 for Program Integration Committee (PIC) member DSHS Commissioner Dr. John Hellerstedt, pursuant to Health & Safety Code Section 102.1062 "Exceptional Circumstances Requiring Participation." The waiver is necessary for Commissioner Hellerstedt to participate in CPRIT's review process as a PIC member. Together with the waiver's proposed limitations, adequate protections are in place to mitigate factors other than merit and the established grant criteria affecting the award of grant funds. The waiver is the same as approved by the Oversight Committee for FY 2019.

Background

Governor Abbott appointed Dr. Hellerstedt as Commissioner of the Department of State Health Services (DSHS) on January 1, 2016. The DSHS Commissioner is a statutorily designated member of the PIC. As a PIC member, Commissioner Hellerstedt must exercise discretion related to whether to recommend applications proposed for grant awards to the Oversight Committee for final approval.

DSHS is a CPRIT grant recipient, which implicates conflict of interest concerns. Health & Safety Code Section 102.106(c)(3) mandates that a professional conflict of interest exists if a PIC member is an employee of an entity applying to receive or receiving CPRIT funds. Furthermore, CPRIT's administrative rule 702.13(c) categorizes this type of professional conflict of interest as one that raises the presumption that the existence of the conflict may affect the impartial review of all other grant applications submitted pursuant to the same grant mechanism in the grant review cycle. A person involved in the review process that holds one of the conflicts included in the Section 702.13(c) "super conflict" category must be recused from participating in the "review, discussion, scoring, deliberation and vote on all grant applications competing for the same grant mechanism in the entire grant review cycle, unless a waiver has been granted..."

CPRIT's administrative rule Section 702.17(3) authorizes the Oversight Committee to approve a waiver that applies for all activities affected by the conflict during the fiscal year.

Exceptional Circumstances Requiring Commissioner Hellerstedt's Participation

To approve a conflict of interest waiver, the Oversight Committee must find that there are exceptional circumstances justifying the conflicted individual's participation in the review process. The statute compels Commissioner Hellerstedt's participation in the review process. The Oversight Committee should grant the proposed waiver so that CPRIT may fulfill legislative intent that the DSHS Commissioner serve as a PIC member. The proposed limitations will substantially mitigate any potential for bias.

Proposed Waiver and Limitations

In granting the waiver of the conflict of interest set forth in Section 102.106(c)(3), I recommend that the Oversight Committee permit Commissioner Hellerstedt to continue to perform the following activities and duties associated with CPRIT's review process subject to the stated limitations:

1. Attend and participate fully in the PIC meetings except that Commissioner Hellerstedt shall not participate in the PIC's discussion or vote on grant award recommendations to DSHS;
2. Have access to grant application information developed during the grant review process, except for information related to DSHS applicants, if any; and
3. Provide information to the Oversight Committee or CPRIT personnel about the grant review process and applications recommended by the PIC for grant awards, including answering questions raised by the Oversight Committee or CPRIT personnel. To the extent that Commissioner Hellerstedt provides information on his own initiative in a review cycle in which DSHS is a grant applicant, the information provided by Commissioner Hellerstedt should be general information related to the overall grant application process and not advocate specifically for a grant application submitted by DSHS.

CPRIT's statute requires the Chief Compliance Officer to attend PIC meetings to document compliance with CPRIT's rules and processes, including adherence to this limitation. The Chief Compliance Officer shall report to the Oversight Committee any violation of this waiver prior to the Oversight Committee's action on the PIC recommendations.

Important Information Regarding this Waiver and the Waiver Process

- The Oversight Committee may amend, revoke, or revise this waiver, including but not limited to the list of approved activities and duties and the limitations on duties

and activities. Approval for any change to the waiver granted shall be by a vote of the Oversight Committee in an open meeting.

- CPRIT limits this waiver to the conflict of interest specified in this request. To the extent that Commissioner Hellerstedt has a conflict of interest with an application that is not the conflict identified in Section 102.106(c)(3), then Commissioner Hellerstedt will follow the required notification and recusal process.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	SECTION 102.1062 WAIVER—MONTGOMERY FY 2020
DATE:	AUGUST 1, 2019

Waiver Request and Recommendation

I request that the Oversight Committee approve a conflict of interest waiver for FY 2020 for Mr. Will Montgomery, presiding officer of the CPRIT Oversight Committee, pursuant to Health & Safety Code Section 102.1062 "Exceptional Circumstances Requiring Participation." Mr. Montgomery's waiver is the same as the one approved by the Oversight Committee for FY 2019. The waiver is necessary for Mr. Montgomery to fully participate in the grant award approval process. Together with the waiver's proposed limitations, adequate protections are in place to mitigate the opportunity for factors other than merit and established criteria to affect the award of grant funds.

Background

Mr. Montgomery is a partner at Jackson Walker L.L.P., a long-time, Texas-based law firm that employs more than 350 attorneys. Mr. Montgomery's legal practice focuses on disputes related to the financial services industry, including regulatory investigations, enforcement proceedings, and internal investigations relating to securities, options, derivatives, commodities, and futures. Mr. Montgomery does not personally represent CPRIT grant recipients; however, some lawyers employed by Jackson Walker provide legal services to the following grant applicants and grant recipients:

- Rice University
- Texas A & M University System
- Texas A & M System Technology Commercialization
- Texas A & M Institute for Biosciences & Technology
- Methodist Hospital System (Houston)
- The University of Texas Southwestern Medical Center
- The University of Texas School of Public Health
- The University of Texas Medical Branch, Galveston
- Children's Medical Center Research Institute

- The University of Texas San Antonio
- The University of Texas at Austin
- The University of Texas Health Science Center at Houston
- The University of Texas M.D. Anderson Cancer Center
- Texas Association of Nurse Anesthetists
- University General Health system
- MHMR Tarrant County
- Texas Tech University
- Texas Tech University Health Science Center
- UNT Health Science Center
- Baylor University
- Baylor College of Medicine

Health & Safety Code Section 102.106(c)(4) mandates that a professional conflict of interest exists if an Oversight Committee member represents an entity applying to receive or receiving CPRIT funds. Similarly, Texas Administrative Code Section 702.11(d) finds that there is a professional conflict of interest if an Oversight Committee member "represents in business or law an entity receiving or applying to receive money from the Institute…"

The entities listed above were clients of the law firm prior to Mr. Montgomery's appointment to the Oversight Committee. Although Mr. Montgomery does not perform legal work for these entities or supervise anyone who does so, he has previously recused himself from participating in the grant award process related to these entities out of an abundance of caution. He does not have an economic interest in the revenues paid to Jackson Walker by these entities, aside from his position as a partner of the firm. However, Mr. Montgomery's percentage of ownership interest in the law firm is not impacted whether these entities are clients of the firm.

It is reasonable to expect that the same conflict will affect Mr. Montgomery's participation in more than one grant review cycle in the 2020 fiscal year as well. CPRIT's administrative rule Section 702.17(3) authorizes the Oversight Committee to approve a waiver that applies for all activities affected by the conflict during the fiscal year.

Exceptional Circumstances Requiring Mr. Montgomery's Participation

To approve a waiver, the Oversight Committee must find that there are exceptional circumstances justifying the conflicted individual's participation in the review process. There are compelling reasons warranting Mr. Montgomery's participation in the review process when he would otherwise recuse himself because of the conflict. One of the principal duties for an Oversight Committee member is to approve grant award recommendations submitted by the Program Integration Committee. The statute requires a two-thirds vote of the Oversight Committee to approve a grant

award. The significant majority of CPRIT's grant applicants and grant recipients are academic institutions, including many of the entities listed above. Excluding Mr. Montgomery from participation in the decision-making process related to grant awards reduces the number of Oversight Committee members able to perform the critical task of reviewing information about potential grantees and the review process associated with the grant recommendations.

The proposed limitations and CPRIT's existing process and procedures will mitigate substantially any potential for bias.

Proposed Waiver and Limitations

In granting the waiver of the conflict of interest set forth in Health & Safety Code Section 102.106(c)(4), I recommend that the Oversight Committee permit Mr. Montgomery to participate in the review process for applications submitted by the following entities, subject to the limitations stated below:

- Rice University
- Texas A & M University System
- Texas A & M System Technology Commercialization
- Texas A & M Institute for Biosciences & Technology
- Methodist Hospital System (Houston)
- UT Southwestern
- UT School of Public Health
- UT Medical Branch, Galveston
- Children's Medical Center Research Institute
- UT San Antonio
- UT Austin
- UT Health Science Center at Houston
- UT M.D. Anderson Cancer Center
- Texas Association of Nurse Anesthetists
- University General Health system
- MHMR Tarrant County
- Texas Tech University
- Texas Tech University Health Science Center
- UNT Health Science Center
- Baylor University
- Baylor College of Medicine

Important Information Regarding this Waiver and the Waiver Process

- The Oversight Committee may amend, revoke, or revise this waiver. Approval for any change to the waiver granted shall be by a vote of the Oversight Committee in an open meeting.
- CPRIT limits this waiver to the conflict of interest specified in this request, Health & Safety Code Section 102.106(c)(4). To the extent that Mr. Montgomery has a conflict of interest with an application submitted by an entity listed herein that is not the conflict identified in Section 102.106(c)(4), then Mr. Montgomery will follow the required notification and recusal process.
- CPRIT limits the waiver to the entities specified in the request and based upon the circumstances stated herein. If circumstances change such that Mr. Montgomery personally represents one of the entities listed herein or supervises the work of someone representing the entity, he will notify the Chief Executive Officer and the presiding officer of the Oversight Committee.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE CHAIR WILL MONTGOMERY
FROM:	WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	SECTION 102.1062 WAIVER—REVIEW COUNCILS FY 2020
DATE:	AUGUST 1, 2019

Waiver Request and Recommendation

I request that the Oversight Committee approve a fiscal year 2020 conflict of interest waiver for review council members pursuant to Health & Safety Code § 102.1062 "Exceptional Circumstances Requiring Participation." Unlike other conflict of interest waivers that the Oversight Committee has approved previously, this waiver is not granted for a specific conflict of interest or person. Instead, CPRIT intends to invoke this waiver as necessary to address the unusual scenario when a review council member has a conflict with a grant application that is part of the larger group of proposals that the review panel or review council must act upon (usually to recommend for awards). The waiver is necessary for a review council member to participate in the overall discussion and vote on the slate of award recommendations. This waiver is the same waiver the Oversight Committee approved for FY 2019.

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

Background

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

house of representatives, the governor, and the standing committees of each house of the legislature with primary jurisdiction over CPRIT matters.

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

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

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

Exceptional Circumstances Requiring the Review Council Member's Participation

In order to approve a conflict of interest waiver, the Oversight Committee must find that there are exceptional circumstances justifying the conflicted individual's participation in the review process. In this case, exceptional circumstances exist due to the necessity of the review council member's participation in the process to develop the overall award recommendation slates and the Oversight Committee should grant the proposed waiver. The limitations mitigate the potential for bias.

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

Proposed Waiver and Limitations

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

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

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

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

Important Information Regarding this Waiver and the Waiver Process

- The Oversight Committee may amend, revoke, or revise this waiver, including but not limited to the list of approved activities and duties and the limitations on duties and activities. Approval for any change to the waiver granted shall be by a vote of the Oversight Committee in an open meeting.
- CPRIT limits this waiver to review council members operating under the circumstances specified in this request.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: KRISTEN DOYLE, DEPUTY EXECUTIVE OFFICER AND GENERAL COUNSEL

SUBJECT: TRANSFER OF ASSET MANAGEMENT AUTHORITY TO THE TEXAS TREASURY SAFEKEEPING TRUST COMPANY

DATE: AUGUST 12, 2019

Summary and Recommendation

The Texas Legislature amended CPRIT's statute in 2017 to permit the Oversight Committee to transfer the management and final disposition authority for assets generated by CPRIT's grant award projects to the Texas Treasury Safekeeping Trust Company (Trust Company). CPRIT staff propose to transfer the management and final disposition authority for assets generated by CPRIT's grant contract with AlloVir, formerly ViraCyte. The proposed resolution approves the transfer of AlloVir and delegates authority to the Chief Executive Officer to take all actions necessary to complete the transfer, including negotiating a fee for the Trust Company's reasonable and necessary expenses involved with managing the transferred assets. The Oversight Committee approved a similar resolution in August 2017 for assets associated with four companies. The Board Governance Subcommittee met August 9 to discuss this issue and recommends that the Oversight Committee vote to approve the AlloVir resolution.

Background

CPRIT's statute requires all grant award contracts to include a revenue sharing provision allowing the state to collect royalties, income, and other benefits, including interest or proceeds resulting from securities and equity ownership realized because of CPRIT grant projects. CPRIT has more than 1,100 award contracts. Most CPRIT-funded grant projects that generate revenue will fulfill the contractual revenue sharing requirements through royalty payments to CPRIT.

The Legislature created the Trust Company as a special purpose entity to manage, invest, and safeguard funds for the state and its political subdivisions efficiently and economically. According to the Trust Company, it is first and foremost a fiduciary organization, and as such, it is held to the highest standard of care imposed in either law or equity and is obligated to subordinate its own interests to those of its beneficiaries. The Trust Company's 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, separately managed portfolios for

various Texas state agency clients, and endowment monies invested across a broad spectrum of asset classes, including hedge, private equity, and real estate funds.

The Trust Company Provides Asset Management Expertise

Cancer research projects in CPRIT's growing portfolio are progressing through the phases of research and development, with some early investments generating revenue through licensing and market sales. In its fiduciary role, the Oversight Committee will need to make decisions regarding the management and disposition of CPRIT-controlled assets as the portfolio continues to mature. There are near term and longer-term issues that CPRIT must address to ensure the state also benefits monetarily from its investment in cancer research. These include decisions on whether to convert royalty obligations to equity holdings, when to sell equity, and the bundling and sale of potential royalty obligations.

CPRIT staff identified the need for investment expertise to assist the Oversight Committee and the agency in making decisions associated with asset management. Investment management is a specialized field. The Trust Company investment staff are skilled in statistical analysis, economics, portfolio management, trading, portfolio transition management, risk management, and accounting. Additionally, the Trust Company has experience managing assets like those generated by CPRIT grants. The Trust Company took over the management and control of the state's equity positions and other investments in the Emerging Technology Fund's ("ETF") portfolio in 2015. The ETF is comprised of approximately 100 investments in early stage companies, about two-thirds of which are life sciences ventures. The Trust Company will leverage its experience managing the ETF's equity investments and draw from the relationships it has developed investing in private equity for over a decade to provide additional resources to aid in the successful completion of projects and grant awards.

The Oversight Committee approved transfer of four assets to the Trust Company in August 2017: Cell Medica; Mirna Therapeutics (now Synlogic Therapeutics); Codiak Biosciences; and Coregon, Inc.

Process for Transferring Management and Disposition Authority to the Trust Company

The decision to transfer asset management and disposition authority to the Trust Company is at the discretion of the Oversight Committee. Accordingly, initiating the transfer requires an affirmative vote of the Oversight Committee. In August 2017, the Oversight Committee agreed to consider transfers on an asset-by-asset basis, as opposed to a blanket transfer.

The resolution proposed for the Oversight Committee's consideration memorializes the intent of the Oversight Committee to transfer management and disposition authority for the specific assets named in the resolution. The resolution also authorizes CPRIT's CEO to act on the Oversight Committee's behalf for all activities necessary to complete the full transfer of authority for the assets, including the execution of required legal documents and approval of a negotiated fee CPRIT will pay to the Trust Company. The statutory amendment permits the Trust Company to charge CPRIT to recover the costs associated with managing any transferred assets. CPRIT staff and Trust Company representatives are negotiating an appropriate fee and payment structure,

which we will memorialize through an inter-agency agreement. Mr. Roberts will report the final fee agreement to the Oversight Committee.

Another outstanding issue CPRIT and Trust Company representatives are discussing is how the Trust Company will update the Oversight Committee regarding CPRIT assets under its management, as well as the frequency of those updates. At this time, we anticipate that the Trust Company will update the Oversight Committee annually, but the update may occur more frequently at the Oversight Committee's request or as circumstances dictate.

Recommendation:

CPRIT staff discussed this issue with the Board Governance Subcommittee at its meeting on August 9. The subcommittee recommends that the Oversight Committee approve the proposed resolution for AlloVir.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

A RESOLUTION
AUTHORIZING THE TRANSFER OF
MANAGEMENT AND DISPOSITION AUTHORITY FOR ALLOVIR TO
THE TEXAS TREASURY SAFEKEEPING TRUST COMPANY
AND THE PAYMENT OF A FEE
FOR MANAGEMENT OF THE ASSETS

Whereas, Texas Health & Safety Code § 102.256 authorizes the Cancer Prevention and Research Institute of Texas ("CPRIT") to collect royalties, income, and other benefits, including interest or proceeds resulting from securities or equity, realized because of projects undertaken with CPRIT grant awards;

Whereas, CPRIT holds revenue sharing obligations that provide for the state's interest in securities, equities, royalties, income, and other benefits realized because of projects undertaken with CPRIT grant awards pursuant to contractual agreements authorized by Texas Health & Safety Code § 102.256;

Whereas, Texas Health & Safety Code § 102.256 ("Authorizing Law") permits CPRIT to transfer to the Texas Treasury Safekeeping Trust Company ("Trust Company") CPRIT's management and disposition authority over the state's interest in securities, equities, royalties, income, and other benefits realized because of projects undertaken with CPRIT grant awards;

Whereas, in managing the assets transferred by CPRIT through procedures and subject to restrictions that the Trust Company considers appropriate, the Trust Company may acquire, exchange, sell, supervise, manage, or retain any kind of investment that a prudent investor, exercising reasonable care, skill, and caution, would acquire, exchange, sell, or retain in light of the purposes, terms, distribution requirements, and other circumstances then prevailing pertinent to each investment, including the requirements prescribed by Texas Health & Safety Code § 102.256(b) and the purposes described by Texas Health & Safety Code § 102.002;

Whereas, the CPRIT Oversight Committee desires and intends to transfer its management and disposition authority over specific revenue sharing interests realized because of certain CPRIT grant awards as permitted by Authorizing Law; and

Whereas, Authorizing Law permits the Trust Company to charge CPRIT a fee to recover the reasonable and necessary costs incurred in managing the assets transferred by CPRIT.

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

Section 1. The CPRIT Oversight Committee intends to transfer its management and disposition authority of AlloVir's (formerly ViraCyte) contractual revenue sharing obligation to the Trust Company effective on or after August 21, 2019, in accordance with applicable local law and relevant constitutional documents of the company. Accordingly, and pursuant to the Authorizing Law, the CPRIT Oversight Committee hereby ratifies, approves, and confirms the transfer of the AlloVir revenue sharing obligation.

Section 2. The CPRIT Oversight Committee hereby delegates authority to CPRIT's Chief Executive Officer, and any designee of the Chief Executive Officer, to take all action in conformity with the Authorizing Law necessary to effect the transfer of CPRIT's management and disposition authority for AlloVir's contractual revenue sharing obligation to the Trust Company on or after August 21, 2019. CPRIT's Chief Executive Officer, and any designee of the Chief Executive Officer, may take all action necessary or desirable in conformity with the Authorizing Law for carrying out, giving effect to, and consummating the transactions required to complete the transfer. Such authority includes, without limitation, the execution and delivery of any documents in connection with the transfer and the negotiation and payment of a fee paid by CPRIT to the Trust Company for the reasonable and necessary costs incurred in managing the transferred assets.

Section 3. The CPRIT Oversight Committee hereby empowers, authorizes, and directs CPRIT's Chief Executive Officer to:

a. sign and deliver any and all documents necessary or desirable to complete the transfer of authority to the Trust Company. Such documents may include but not limited to a Memorandum of Understanding and Fee Agreement between CPRIT and the Trust Company;
b. cooperate with AlloVir, including their successors, the Trust Company and its consultants to effectuate the transfer; and
c. to take any other action necessary to assist in such transfer.

Section 4. The CPRIT Oversight Committee hereby ratifies, approves, and confirms all actions consistent with provisions of this Resolution heretofore taken by CPRIT and its Chief Executive Officer or designee thereof and the other officers of, or consultants to CPRIT, directed toward the transfer of the specific assets named herein.

Section 6. The CPRIT Oversight Committee adopts this Resolution at a meeting open to the public, and CPRIT provided public notice of the time, place, and purpose of said meeting, all as required by Ch. 551, Texas Government Code.

Adopted by the affirmative vote of a majority of the CPRIT Oversight Committee present and voting on August 21, 2019.

Cancer Prevention and Research Institute
of Texas Oversight Committee

Attested:

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Presiding Officer

Secretary

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	KRISTEN PAULING DOYLE, GENERAL COUNSEL CAMERON L. ECKEL, STAFF ATTORNEY
SUBJECT:	CHAPTER 703 RULE CHANGES PROPOSED FOR FINAL ADOPTION
DATE:	AUGUST 12, 2019

Summary and Recommendation

The Board Governance Subcommittee recommends that the Oversight Committee adopt the proposed administrative rule changes to Chapter 703 as originally considered at the May meeting. Once the Oversight Committee approves the final order adopting the rule changes, CPRIT will submit the amendments to the Secretary of State and the changes will be effective 20 days later.

Discussion

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

The Oversight Committee approved publication of the following proposed rule amendments to §§ 703.3, 703.10, 703.14, and 703.25 at the May meeting.

- The proposed amendment to § 703.3(b) clarifies how CPRIT will make any modifications to a published Request for Applications (RFA) available to the public. The proposed amendment explains that CPRIT will post the modified RFA (with a revision history in the document) on CPRIT's public website.

- The proposed rule amendment to § 703.10(c)(22) requires that a grantee request approval if a Principal Investigator, Program Director, or Company Representative takes a temporary leave of absence. CPRIT requires the grantee to notify the agency and seek approval of changes in effort of senior members or key personnel of a grant, but the rule is silent regarding a leave of absence. This proposed amendment makes it clear that the grantee must seek CPRIT approval for a proposed leave of absence. This is like NIH and NSF policies.

- The proposed change to § 703.14(c)(3) eliminates automatic approval for a grantee's first no cost extension. Under the current rule, CPRIT automatically approves a grantee's first no cost extension if the proposed contract extension is six months or less and the grantee is in

good fiscal and programmatic standings. However, there may be extenuating circumstances weighing against extending the contract term, even for an initial request.

- The proposed amendment to § 703.25(e) clarifies when a grantee may make a budget transfer or change without prior approval from CPRIT. The amendment provides for automatic approval when the total dollar amount of the proposed change within the budget category is 10% or less of the total budget for the grant year. While the grantee may make the transfer or change without prior approval, the proposed amendment provides that CPRIT may review the frequency of budget change requests for a grant project and reverse approval of one or more budget changes or transfers, if necessary.

The Board Governance Subcommittee met on August 9 to review the final order with CPRIT's General Counsel. The Subcommittee recommends the Oversight Committee approve the final order 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.

The Cancer Prevention and Research Institute of Texas ("CPRIT" or "the Institute") adopts the amendments to 25 Tex. Admin. Code §§703.3, 703.10, 703.14, and 703.25 without changes to the proposed amendments as published in the May 31, 2019, issue of the Texas Register (44 TexReg 2698), therefore, the rules will not be republished. The amendments are related to Request for Applications modifications on the Institute's website, leave of absences, no cost extension requests review and approval, and approval of grantee budget changes and transfers.

Reasoned Justification

In § 703.3(b), the proposed change clarifies that modifications to Request for Applications (RFAs) will be available on CPRIT's website. The amendment to § 703.10(c)(22) requires a grant recipient to request approval for a Principal Investigator, Program Director, or Company Representative's temporary leave of absence. Proposed changes to § 703.14(c)(3) eliminate automatic approval of a grant recipient's first no cost extension request. Finally, the amendment to § 703.25(e) clarifies when a grant recipient's budget change or transfer is automatically approved and explains that CPRIT may review and reverse approval, depending on certain circumstances.

Summary of Public Comments and Staff Recommendation

CPRIT received no public comments regarding the proposed amendments to §§703.3, 703.10, 703.14, and 703.25.

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

Certification

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

To be filed with the Office of Secretary of State on August 22, 2019.

<rule>

§703.3.Grant Applications.

(a) The Institute shall accept Grant Applications for Cancer Research and Cancer Prevention programs to be funded by the Cancer Prevention and Research Fund or the proceeds of general obligation bonds issued on behalf of the Institute in response to standard format Requests for Applications issued by the Institute.

(b) Each Request for Applications shall be publicly available through the Institute's Internet website. The Institute reserves the right to modify the format and content requirements for the Requests for Applications from time to time. Any modifications will be available through the Institute's Internet website. The Request for Applications shall:

(1) Include guidelines for the proposed projects and may be accompanied by instructions provided by the Institute.

(2) State the criteria to be used during the Grant Review Process to evaluate the merit of the Grant Application, including guidance regarding the range of possible scores.

(A) The specific criteria and scoring guidance shall be developed by the Chief Program Officer in consultation with the Review Council.

(B) When the Institute will use a preliminary evaluation process as described in §703.6 of this chapter (relating to Grant Review Process) for the Grant Applications submitted pursuant to a particular Grant Mechanism, the Request for Applications shall state the criteria and Grant Application components to be included in the preliminary evaluation.

(3) Specify limits, if any, on the number of Grant Applications that may be submitted by an entity for a particular Grant Mechanism to ensure timely and high-quality review when a large number of Grant Applications are anticipated.

(c) Requests for Applications for Cancer Research and Cancer Prevention projects issued by the Institute may address, but are not limited to, the following areas:

(1) Basic research;

(2) Translational research, including proof of concept, preclinical, and Product Development activities;

(3) Clinical research;

(4) Population based research;

(5) Training;

(6) Recruitment to the state of researchers and clinicians with innovative Cancer Research approaches;

(7) Infrastructure, including centers, core facilities, and shared instrumentation;

(8) Implementation of the Texas Cancer Plan; and

(9) Evidence based Cancer Prevention education, outreach, and training, and clinical programs and services.

(d) An otherwise qualified applicant is eligible solely for the Grant Mechanism specified by the Request for Applications under which the Grant Application was submitted.

(e) The Institute may limit the number of times a Grant Application not recommended for a Grant Award during a previous Grant Review Cycle may be resubmitted in a subsequent Grant Review Cycle. The Request for Applications will state the resubmission guidelines, including specific instructions for resubmissions.

(f) Failure to comply with the material and substantive requirements set forth in the Request for Applications may serve as grounds for disqualification from further consideration of the Grant Application by the Institute. A Grant Application determined by the Institute to be incomplete or otherwise noncompliant with the terms or instructions set forth by the Request for Applications shall not be eligible for consideration of a Grant Award.

(g) Only those Grant Applications submitted via the designated electronic portal designated by the Institute by the deadline, if any, stated in the Request for Applications shall be eligible for consideration of a Grant Award.

(1) Nothing herein shall prohibit the Institute from extending the submission deadline for one or more Grant Applications upon a showing of good cause, as determined by the Chief Program Officer.

(2) A request to extend the Grant Application submission deadline must be in writing and sent to the CPRIT Helpdesk via electronic mail, within 24 hours of the submission deadline.

(3) The Institute shall document any deadline extension granted, including the good cause for extending the deadline and will cause the documentation to be maintained as part of the Grant Review Process records.

(h) The Grant Applicant shall certify that it has not made and will not make a donation to the Institute or any foundation created to benefit the Institute.

(1) Grant Applicants that make a donation to the Institute or any foundation created to benefit the Institute on or after June 14, 2013, are ineligible to be considered for a Grant Award.

(2) For purposes of the required certification, the Grant Applicant includes the following individuals or the spouse or dependent child(ren) of the following individuals:

(A) the Principal Investigator, Program Director, or Company Representative;

(B) a Senior Member or Key Personnel listed on the Grant Application; and

(C) an officer or director of the Grant Applicant.

(3) Notwithstanding the foregoing, one or more donations exceeding $500 by an employee of a Grant Applicant not described by paragraph (2) of this subsection shall be considered to be made on behalf of the Grant Applicant for purposes of the certification.

(4)The certification shall be made at the time the Grant Application is submitted.

(5) The Chief Compliance Officer shall compare the list of Grant Applicants to a current list of donors to the Institute and any foundation created to benefit the Institute.

(6) To the extent that the Chief Compliance Officer has reason to believe that a Grant Applicant has made a donation to the Institute or any foundation created to benefit the Institute, the Chief Compliance Officer shall seek information from the Grant Applicant to resolve any issue. The Grant Application may continue in the Grant Review Process during the time the additional information is sought and under review by the Institute.

(7) If the Chief Compliance Officer determines that the Grant Applicant has made a donation to the Institute or any foundation created to benefit the Institute, then the Institute shall take appropriate action. Appropriate action may entail:

(A) Withdrawal of the Grant Application from further consideration; or

(B) Return of the donation, if the return of the donation is possible without impairing Institute operations.

(8) If the donation is returned to the Applicant, then the Grant Application is eligible to be considered for a Grant Award.

(i) Grant Applicants shall identify by name all sources of funding contributing to the project proposed for a Grant Award. A Grant Applicant for a Product Development Research Grant Award must provide a capitalization table that includes those individuals or entities that have an investment, stock or rights in the company. The Institute shall make the information provided by the Grant Applicant available to Scientific Research and Prevention Programs Committee members, Institute employees, independent contractors participating in the Grant Review Process, Program Integration Committee Members and Oversight Committee Members for purposes of identifying potential Conflicts of Interest prior to reviewing or taking action on the Grant Application. The information shall be maintained in the Institute's Grant Review Process records.

(j) A Grant Applicant shall indicate if the Grant Applicant is currently ineligible to receive Federal or State grant funds due to debarment or suspension or if the Grant Applicant has had a grant terminated for cause within five years prior to the submission date of the Grant Application. For purposes of the provision, the term Grant Applicant includes the personnel, including collaborators or contractors, who will be working on the Grant Award. A Grant Applicant is not eligible to receive a Grant Award if the Grant Applicant is debarred, suspended, ineligible or otherwise excluded from participation in a federal or state grant award.

(k) The Institute may require each Grant Applicant for a Cancer Research Grant Award for Product Development to submit an application fee.

(1) The Chief Executive Officer shall adopt a policy regarding the application fee amount.

(2) The Institute shall use the application fee amounts to defray the Institute's costs associated with the Product Development review processes, including due diligence and intellectual property reviews, as specified in the Request for Application.

(3) Unless a request to submit the fee after the deadline has been approved by the Institute, the Institute may administratively withdraw a Grant Application if the application review fee is not received by the Institute within seven business days of the Grant Application submission deadline.

(4) Upon a written request from the Grant Applicant, the Institute may refund the application fee to the Grant Applicant if the Grant Applicant withdraws the Grant Application or the Grant Application is otherwise removed from the Grant Review Process prior to the review of the Grant Application by the Scientific Research and Prevention Programs Committees. The Institute's decision regarding return of the application fee is final.

(l) During the course of administrative review of the Grant Application, the Institute may contact the Grant Applicant to seek clarification on information provided in the Grant Application or to request additional information if such information clarifies the Grant Application. The Institute shall keep a record of requests made under this subsection for review by the Chief Compliance Officer.

§703.10.Awarding Grants by Contract.

(a) The Oversight Committee shall negotiate on behalf of the state regarding the awarding of grant funds and enter into a written contract with the Grant Recipient.

(b) The Oversight Committee may delegate Grant Contract negotiation duties to the Chief Executive Officer and the General Counsel for the Institute. The Chief Executive Officer may enter into a written contract with the Grant Recipient on behalf of the Oversight Committee.

(c) The Grant Contract shall include the following provisions:

(1) If any portion of the Grant Contract has been approved by the Oversight Committee to be used to build a capital improvement, the Grant Contract shall specify that:

(A) The state retains a lien or other interest in the capital improvement in proportion to the percentage of the Grant Award amount used to pay for the capital improvement; and

(B) If the capital improvement is sold, then the Grant Recipient agrees to repay to the state the Grant Award used to pay for the capital improvement, with interest, and share with the state a proportionate amount of any profit realized from the sale;

(2) Terms relating to Intellectual Property Rights and the sharing with the Institute of revenues generated by the sale, license, or other conveyance of such Project Results consistent with the standards established by this chapter;

(3) Terms relating to publication of materials created with Grant Award funds or related to the Cancer Research or Cancer Prevention project that is the subject of the Grant Award, including an acknowledgement of Institute funding and copyright ownership, if applicable;

(4) Repayment terms, including interest rates, to be enforced if the Grant Recipient has not used Grant Award funds for the purposes for which the Grant Award was intended;

(5) A statement that the Institute does not assume responsibility for the conduct of the Cancer Research or Cancer Prevention project, and that the conduct of the project and activities of all investigators are under the scope and direction of the Grant Recipient;

(6) A statement that the Cancer Research or Cancer Prevention project is conducted with full consideration for the ethical and medical implications of the project and that the project will comply with all federal and state laws regarding the conduct of the Cancer Research or Prevention project;

(7) Terms related to the Standards established by the Oversight Committee in Chapter 701 of this title (relating to Policies and Procedures) to ensure that Grant Recipients, to the extent reasonably possible, demonstrate good faith effort to purchase goods and services for the Grant Award project from suppliers in this state and from historically underutilized businesses as defined by Chapter 2161, Texas Government Code, and any other state law;

(8) An agreement by the Grant Recipient to submit to regular inspection reviews of the Grant Award project by Institute staff during normal business hours and upon reasonable notice to ensure compliance with the terms of the Grant Contract and continued merit of the project;

(9) An agreement by the Grant Recipient to submit Grant Progress Reports to the Institute on a schedule specified by the Grant Contract that include information on a grant-by-grant basis quantifying the amount of additional research funding, if any, secured as a result of Institute funding;

(10) An agreement that, to the extent possible, the Grant Recipient will evaluate whether any new or expanded preclinical testing, clinical trials, Product Development, or manufacturing of any real or intellectual property resulting from the award can be conducted in this state, including the establishment of facilities to meet this purpose;

(11) An agreement that the Grant Recipient will abide by the Uniform Grant Management Standards (UGMS) adopted by the Governor's Office, if applicable unless one or more standards conflicts with a provision of the Grant Contract, Chapter 102, Texas Health and Safety Code, or the Institute's administrative rules. Such interpretation of the Institute rules and UGMS shall be made by the Institute;

(12) An agreement that the Grant Recipient is under a continuing obligation to notify the Institute of any adverse conditions that materially impact milestones and objectives included in the Grant Contract;

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

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

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

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

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

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

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

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

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

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

(20) A certification of dedicated Matching Funds equal to one-half of the amount of the Research Grant Award that includes the name of the Research Grant Award to which the matching funds

are to be dedicated, as specified in Section §703.11 of this chapter (relating to Requirement to Demonstrate Available Funds for Cancer Research Grants);

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

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

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

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

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

§703.14.Termination, Extension, Close Out of Grant Contracts, and De-Obligation of Grant Award Funds.

(a) The termination date of a Grant Contract shall be the date stated in the Grant Contract, except:

(1) The Chief Executive Officer may elect to terminate the Grant Contract earlier because the Grant Recipient has failed to fulfill contractual obligations, including timely submission of required reports or certifications;

(2) The Institute terminates the Grant Contract because funds allocated to the Grant Award are reduced, depleted, or unavailable during the award period, and the Institute is unable to obtain additional funds for such purposes; or

(3) The Institute and the Grant Recipient mutually agree to terminate the Grant Contract earlier.

(b) If the Institute elects to terminate the Grant Contract pursuant to subsection (a)(1) or (2) of this section, then the Chief Executive Officer shall notify the Grant Recipient in writing of the intent to terminate funding at least thirty (30) days before the intended termination date. The notice shall state the reasons for termination, and the procedure and time period for seeking reconsideration of the decision to terminate. Nothing herein restricts the Institute's ability to

terminate the Grant Contract immediately or to seek additional remedies if justified by the circumstances of the event leading to early termination.

(c) The Institute may approve the Grant Recipient's written request to extend the termination date of the Grant Contract to permit the Grant Recipient additional time to complete the work of the project.

(1) A no cost extension may be granted if the Grant Recipient is in good fiscal and programmatic standing. The Institute's decision to approve or deny a no cost extension request is final.

(2) The Grant Recipient may request a no cost extension no earlier than 180 days and no later than thirty (30) days prior to the termination date of the Grant Contract.

(A) If a Grant Recipient fails to request a no cost extension within the required timeframe, the Grant Recipient may petition the Chief Executive Officer in writing to consider the no cost extension. The Grant Recipient's petition must show good cause for failing to submit the request within the timeframe specified in subsection (c) of this section.

(B) Upon a finding of good cause, the Chief Executive Officer may consider the request. If a no cost extension request is approved under this subsection, the Chief Executive Officer must notify the Oversight Committee in writing and provide justification for the approval.

(3) The Institute may approve one or more no cost extensions. The duration of each no cost extension may be no longer than six months from the termination date of the Grant Contract, unless the Institute finds that special circumstances justify authorizing additional time to complete the work of the project. If a grant recipient requests a second no cost extension or requests a no cost extension greater than six months, the grantee must provide good cause for approving the request.

(4) If the Institute approves the request to extend the termination date of the Grant Contract, then the termination date shall be amended to reflect the change.

(5) Nothing herein prohibits the Institute and the Grant Recipient from taking action more than 180 days prior to the termination date of the Grant contract to extend the termination date of the Grant Contract. Approval of an extension must be supported by a finding of good cause and the Grant Contract shall be amended to reflect the change.

(d) The Grant Recipient must submit a final Financial Status Report and final Grant Progress Report as well as any other required reports as specified in the Grant Contract. For purposes of this rule, the final Grant Progress Report and other required reports shall be collectively referred to as "close out documents."

(1) The final Financial Status Report shall be submitted to the Institute within ninety (90) days of the end of the state fiscal quarter that includes the termination date of the Grant Contract. The Grant Recipient's failure to submit the Financial Status report within thirty (30) days following the due date specified in this subsection will waive reimbursement of project costs incurred

during the reporting period. The Institute may approve additional time to submit the final Financial Status Report if the Grant Recipient can show good cause for failing to timely submit the final Financial Status Report.

(2) Close out documents must be submitted within ninety (90) days of the termination date of the Grant Contract. The final reimbursement payment shall not be made until all close out documents have been submitted and approved by the Institute. Failure to submit one or more close out documents within 180 days of the Grant Contract termination date shall result in the Grant Recipient being ineligible to receive new Grant Awards or continuation Grant Awards until such time that the close out documents are submitted unless the Institute waives the final submission of close out documents by the Grant Recipient.

(A) Approval of the Grant Recipient's request to waive the submission of close out documents is at the discretion of the Institute. Such approval must be granted by the Chief Executive Officer.

(B) The Oversight Committee shall be notified in writing of the Grant Recipient's waiver request and the Chief Executive Officer's decision to approve or reject the waiver request.

(C) Unless the Oversight Committee votes by a simple majority of members present and able to vote to overturn the Chief Executive Officer's decision regarding the waiver, the Chief Executive Officer's decision shall be considered final.

(e) The Institute may make upward or downward adjustments to the Allowable Costs requested by the Grant Recipient within ninety (90) days following the approval of the close out reports or the final Financial Status Report, whichever is later.

(f) Nothing herein shall affect the Institute's right to disallow costs and recover Grant Award funds on the basis of a later audit or other review or the Grant Recipient's obligation to return Grant Award funds owed as a result of a later refund, correction, or other transaction.

(g) Any Grant Award funds paid to the Grant Recipient in excess of the amount to which the Grant Recipient is finally determined to be entitled under the terms of the Grant Contract constitute a debt to the state. If not paid within a reasonable period after demand, the Institute may reduce the debt owed by:

(1) Making an administrative offset against other requests for reimbursements;

(2) Withholding advance payments otherwise due to the Grant Recipient; or

(3) Other action permitted by law.

(h) Grant Award funds approved by the Oversight Committee and specified in the Grant Contract but not spent by the Grant Recipient at the time that the Grant Contract is terminated are considered de-obligated for the purposes of calculating the maximum amount of annual Grant Awards and the total amount authorized by Section 67, Article III, Texas Constitution. Such de-obligated funds are available for all purposes authorized by the statute.

(i) If a deadline set by this rule falls on a Saturday, Sunday, or federal holiday as designated by the U.S. Office of Personnel Management, the required filing may be submitted on the next business day. The Institute will not consider a required filing delinquent if the Grant Recipient complies with this subsection.

§703.25.Grant Award Budget.

(a) The Grant Contract shall include an Approved Budget that reflects the amount of the Grant Award funds to be spent for each Project Year.

(b) All expenses charged to a Grant Award must be budgeted and reported in the appropriate budget category.

(c) Actual expenditures under each category should not exceed budgeted amounts authorized by the Grant Contract as reflected on the Approved Budget for each Grant Award.

(d) Recipients may make transfers between or among lines within budget categories listed on the Approved Budget so long as the transfer fits within the scope of 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) Except as provided herein, all budget changes or transfers require Institute approval.

(1) The Grant Recipient may make budget changes or transfers without prior approval from the Institute for expenses not specified in the equipment category if:

(A) The total dollar amount of all changes of any single line item (individually and in the aggregate) within budget categories other than equipment is 10% or less of the total budget for the applicant grant year;

(B) The transfer will not increase or decrease the total grant budget; and

(C) The transfer will not materially change the nature, performance level, or scope of the project.

(2) The Institute may reverse one or more budget changes or transfers under subsection (1) if the Institute determines that the Grant Recipient made multiple individual budget changes or transfers within the same category that, if considered together, would require Institute approval.

(f) A Grant Recipient awarded a Grant Award for a multiyear project that fails to expend the total Project Year budget may carry forward the unexpended budget balance to the next Project Year.

(1) If the amount of the unexpended balance for a budget line item in a Project Year exceeds twenty-five percent (25%) or more of the total budget line item amount for that year, Institute approval is required before the Grant Recipient may carry forward the unexpended balance to the next Project Year.

(2) For a budget carry forward requiring Institute approval, the Grant Recipient must provide justification for why the total Grant Award amount should not be reduced by the unexpended balance.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	KRISTEN PAULING DOYLE, GENERAL COUNSEL CAMERON L. ECKEL, STAFF ATTORNEY
SUBJECT:	CHAPTER 703 PROPOSED RULE CHANGES
DATE:	AUGUST 12, 2019

Summary and Recommendation

The Board Governance Subcommittee recommends that the Oversight Committee approve the proposed administrative rule changes for publication in the *Texas Register* for public comment. The proposed changes affect Texas Administrative Code Chapter 703.

Discussion

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

The Board Governance subcommittee met on August 9 to discuss the proposed rule changes to §§ 703.14 and 703.24 with legal staff.

- The proposed change to § 703.14 provides a process for CPRIT to review and approve a grantee's request to extend the grant contract termination date even if the grantee has fiscal or programmatic reports pending approval by CPRIT. Currently, Texas Administrative Code § 703.14 requires the grantee to be in "good fiscal and programmatic standing" before CPRIT may approve a request to extend the contract term. (Since the approval provides only additional time to complete the grant project and does not provide any additional funds, CPRIT refers to these requests as "no cost extensions.") Grantees must submit regular fiscal and programmatic reports to CPRIT at specified times during their grant contract. Report due dates are set in Texas Administrative Code Chapters 701-703. In some instances, CPRIT may not have approved one or more fiscal or programmatic reports at the time that the grantee requests an extension of the grant contract. The proposed change allows CPRIT to consider and approve a grantee's no cost extension request while other reports are pending approval. Approval of a no cost extension remains at CPRIT's discretion. CPRIT will retain documentation of the request and approval as part of the grant record.

- The proposed change to § 703.24(a) clarifies the process for CPRIT to consider and approve a grantee's reimbursement request for an otherwise allowable cost paid by the grant recipient prior to the current reporting period. The proposed change provides that CPRIT may consider and approve reimbursement after the grantee provides a written explanation for failing to timely seek reimbursement during the fiscal quarter it paid the expense. CPRIT will retain documentation of the request and approval as part of the grant record.

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

Next Steps

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

The Cancer Prevention and Research Institute of Texas ("CPRIT" or "the Institute") proposes amendments to 25 Tex. Admin. Code §§ 703.14(c) and 703.24(a) relating to the Institute's consideration and approval of a grant recipient's request to extend its grant contract and the process for a grant recipient to report and receive reimbursement for expenses the grant recipient paid prior to the current financial status reporting period.

Background and Justification

The proposed change to § 703.14(c) provides a process for the Institute to review and approve a grant recipient's request to extend the grant recipient's grant contract termination date even if the grant recipient has fiscal or programmatic reports pending approval by the Institute. Currently, Texas Administrative Code § 703.14 requires a grant recipient to be in "good fiscal and programmatic standing" before the Institute may approve a request to extend the contract term. (Since the approval provides only additional time to complete the grant project and does not provide any additional funds, CPRIT refers to these requests as "no cost extensions.") Grant recipients must submit regular fiscal and programmatic reports to the Institute at specified times during their grant contract. Report due dates are set in Texas Administrative Code Chapters 701-703. In some instances, the Institute may not have approved one or more fiscal or programmatic reports at the time that the grant recipient requests an extension of the grant contract. The proposed change allows the Institute to consider and approve a no cost extension request while other reports are pending approval. Approval of a no cost extension remains at the discretion of the Institute. The Institute will retain documentation of the request and approval as part of the grant record.

The proposed change to § 703.24(a) clarifies the process for the Institute to consider and approve a grant recipient's reimbursement request for an otherwise allowable cost paid by the grant recipient prior to the current reporting period. The proposed change clarifies that the Institute may consider and approve reimbursement after the grant recipient provides a written explanation for failing to timely seek reimbursement during the fiscal quarter it paid the expense. The Institute will retain documentation of the request and approval as part of the grant record.

Fiscal Note

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

Public Benefit and Costs

Ms. Doyle has determined that for each year of the first five years the rule changes are in effect the public benefit anticipated due to enforcing the rule will be clarifying processes regarding extending the grant contract termination deadline and submitting requests for reimbursement of costs incurred and paid by the grant recipient.

Small Business, Micro-Business, and Rural Communities Impact Analysis

Ms. Doyle has determined that the rule changes will not affect small businesses, micro businesses, or rural communities.

Government Growth Impact Statement

The Institute, in accordance with 34 Texas Administrative Code §11.1, has determined that during the first five years that the proposed rule changes will be in effect:

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

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

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

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

(5) the proposed rule changes will not create new rules;

(6) the proposed rule changes will not expand existing rules;

(7) the proposed rule changes will not change the number of individuals subject to the rules; and

(8) The rule changes are unlikely to have a significant impact on the state's economy. Although these changes are likely to have neutral impact on the state's economy, the Institute lacks enough data to predict the impact with certainty.

Submit written comments on the proposed rule changes to Ms. Kristen Pauling Doyle, General Counsel, Cancer Prevention and Research Institute of Texas, P. O. Box 12097, Austin, Texas 78711, no later than October 28, 2019. The Institute asks parties filing comments to indicate whether 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 Institute proposes the rule changes under the authority of the Texas Health and Safety Code Annotated, §102.108, which provides the Institute with broad rule-making authority to administer the chapter. Ms. Doyle has reviewed the proposed amendments and certifies the proposal to be within the Institute’s authority to adopt.

There is no other statute, article, or code affected by these rules.

<rule>

§ 703.14. Termination, Extension, Close Out of Grant Contracts, and De-Obligation of Grant Award Funds

(a) The termination date of a Grant Contract shall be the date stated in the Grant Contract, except:

(1) The Chief Executive Officer may elect to terminate the Grant Contract earlier because the Grant Recipient has failed to fulfill contractual obligations, including timely submission of required reports or certifications;

(2) The Institute terminates the Grant Contract because funds allocated to the Grant Award are reduced, depleted, or unavailable during the award period, and the Institute is unable to obtain additional funds for such purposes; or

(3) The Institute and the Grant Recipient mutually agree to terminate the Grant Contract earlier.

(b) If the Institute elects to terminate the Grant Contract pursuant to subsection (a)(1) or (2) of this section, then the Chief Executive Officer shall notify the Grant Recipient in writing of the intent to terminate funding at least thirty (30) days before the intended termination date. The notice shall state the reasons for termination, and the procedure and time period for seeking reconsideration of the decision to terminate. Nothing herein restricts the Institute's ability to terminate the Grant Contract immediately or to seek additional remedies if justified by the circumstances of the event leading to early termination.

(c) The Institute may approve the Grant Recipient's written request to extend the termination date of the Grant Contract to permit the Grant Recipient additional time to complete the work of the project.

(1) A no cost extension may be granted if the Grant Recipient is in good fiscal and programmatic standing. [~~The Institute's decision to approve or deny a no cost extension request is final.~~]

(A) If a Grant Recipient is not in good fiscal and programmatic standing, the Grant Recipient may petition the Chief Executive Officer in writing to consider the no cost extension. The Grant Recipient’s petition must show good cause for failing to be in good fiscal and programmatic standing.

(B) Upon a finding of good cause, the Chief Executive Officer may consider the request. If a no cost extension is approved under this subsection, the Chief Executive Officer must notify the Oversight Committee in writing and provide justification for the approval.

(2) The Grant Recipient may request a no cost extension no earlier than 180 days and no later than thirty (30) days prior to the termination date of the Grant Contract.

(A) If a Grant Recipient fails to request a no cost extension within the required timeframe, the Grant Recipient may petition the Chief Executive Officer in writing to consider the no cost extension. The Grant Recipient's petition must show good cause for failing to submit the request within the timeframe specified in subsection (c) of this section.

(B) Upon a finding of good cause, the Chief Executive Officer may consider the request. If a no cost extension request is approved under this subsection, the Chief Executive Officer must notify the Oversight Committee in writing and provide justification for the approval.

(3) The Institute may approve one or more no cost extensions. The duration of each no cost extension may be no longer than six months from the termination date of the Grant Contract, unless the Institute finds that special circumstances justify authorizing additional time to complete the work of the project. If a grant recipient requests a second no cost extension or requests a no cost extension greater than six months, the grantee must provide good cause for approving the request.

(4) If the Institute approves the request to extend the termination date of the Grant Contract, then the termination date shall be amended to reflect the change.

(5) Nothing herein prohibits the Institute and the Grant Recipient from taking action more than 180 days prior to the termination date of the Grant contract to extend the termination date of the Grant Contract. Approval of an extension must be supported by a finding of good cause and the Grant Contract shall be amended to reflect the change.

(6) The Institute's decision to approve or deny a no cost extension request is final.

(d) The Grant Recipient must submit a final Financial Status Report and final Grant Progress Report as well as any other required reports as specified in the Grant Contract. For purposes of this rule, the final Grant Progress Report and other required reports shall be collectively referred to as "close out documents."

(1) The final Financial Status Report shall be submitted to the Institute within ninety (90) days of the end of the state fiscal quarter that includes the termination date of the Grant Contract. The Grant Recipient's failure to submit the Financial Status report within thirty (30) days following the due date specified in this subsection will waive reimbursement of project costs incurred during the reporting period. The Institute may approve additional time to submit the final Financial Status Report if the Grant Recipient can show good cause for failing to timely submit the final Financial Status Report.

(2) Close out documents must be submitted within ninety (90) days of the termination date of the Grant Contract. The final reimbursement payment shall not be made until all close out documents have been submitted and approved by the Institute. Failure to submit one or more close out documents within 180 days of the Grant Contract termination date shall result in the Grant Recipient being ineligible to receive new Grant Awards or continuation Grant Awards until such time that the close out documents are submitted unless the Institute waives the final submission of close out documents by the Grant Recipient.

(A) Approval of the Grant Recipient's request to waive the submission of close out documents is at the discretion of the Institute. Such approval must be granted by the Chief Executive Officer.

(B) The Oversight Committee shall be notified in writing of the Grant Recipient's waiver request and the Chief Executive Officer's decision to approve or reject the waiver request.

(C) Unless the Oversight Committee votes by a simple majority of members present and able to vote to overturn the Chief Executive Officer's decision regarding the waiver, the Chief Executive Officer's decision shall be considered final.

(e) The Institute may make upward or downward adjustments to the Allowable Costs requested by the Grant Recipient within ninety (90) days following the approval of the close out reports or the final Financial Status Report, whichever is later.

(f) Nothing herein shall affect the Institute's right to disallow costs and recover Grant Award funds on the basis of a later audit or other review or the Grant Recipient's obligation to return Grant Award funds owed as a result of a later refund, correction, or other transaction.

(g) Any Grant Award funds paid to the Grant Recipient in excess of the amount to which the Grant Recipient is finally determined to be entitled under the terms of the Grant Contract constitute a debt to the state. If not paid within a reasonable period after demand, the Institute may reduce the debt owed by:

(1) Making an administrative offset against other requests for reimbursements;

(2) Withholding advance payments otherwise due to the Grant Recipient; or

(3) Other action permitted by law.

(h) Grant Award funds approved by the Oversight Committee and specified in the Grant Contract but not spent by the Grant Recipient at the time that the Grant Contract is terminated are considered de-obligated for the purposes of calculating the maximum amount of annual Grant Awards and the total amount authorized by Section 67, Article III, Texas Constitution. Such de-obligated funds are available for all purposes authorized by the statute.

(i) If a deadline set by this rule falls on a Saturday, Sunday, or federal holiday as designated by the U.S. Office of Personnel Management, the required filing may be submitted on the next business day. The Institute will not consider a required filing delinquent if the Grant Recipient complies with this subsection.

§ 703.24 Financial Status Reports

(a) The Grant Recipient[s] shall report expenditures to be reimbursed with Grant Award funds on the quarterly Financial Status Report form. The Grant Recipient must report all expenses for which it seeks reimbursement that the Grant Recipient paid during the fiscal quarter indicated on the quarterly Financial Status Report form.

(1) Expenditures shall be reported by budget category consistent with the Grant Recipient's Approved Budget.

(2) If the Grant Recipient seeks reimbursement for an expense it paid prior to the period covered by the current quarterly Financial Status Report but did not previously report to the

Institute, the Grant Recipient must provide a written explanation for failing to claim the prior payment in the appropriate period.

(A) The Grant Recipient must submit the written explanation with any supporting documentation at the time that the Grant Recipient files its current Financial Status Report.

(B) The Institute shall consider the explanation and may approve reimbursement for the otherwise eligible expense. The Institute's decision whether to reimburse the expense is final.

(3) [(~~2~~)] All expenditures must be supported with appropriate documentation showing that the costs were incurred and paid. A Grant Recipient that is a public or private institution of higher education as defined by §61.003, Texas Education Code is not required to submit supporting documentation for an individual expense totaling less than $750 in the "supplies" or "other" budget categories.

(4) [(~~3~~)] The Financial Status Report and supporting documentation must be submitted via the Grant Management System, unless the Grant Recipient is specifically directed in writing by the Institute to submit or provide it in another manner.

(5) [(~~4~~)] The Institute may request in writing that a Grant Recipient provide more information or correct a deficiency in the supporting documentation for a Financial Status Report. If a Grant Recipient does not submit the requested information within 21 days after the request is submitted, the Financial Status Report will be disapproved by the Institute.

(A) Nothing herein restricts the Institute from disapproving the FSR without asking for additional information or prior to the submission of additional information.

(B) Nothing herein extends the FSR due date.

(6) [(~~5~~)] The requirement to report and timely submit quarterly Financial Status Reports applies to all Grant Recipients, regardless of whether Grant Award funds are disbursed by reimbursement or in advance of incurring costs.

(b) Quarterly Financial Status Reports shall be submitted to the Institute within ninety (90) days of the end of the state fiscal quarter (based upon a September 1 - August 31 fiscal year). The Institute shall review expenditures and supporting documents to determine whether expenses charged to the Grant Award are:

(1) Allowable, allocable, reasonable, necessary, and consistently applied regardless of the source of funds; and

(2) Adequately supported with documentation such as cost reports, receipts, third party invoices for expenses, or payroll information.

(c) A Grant Award with a Grant Contract effective date within the last quarter of a state fiscal year (June 1 - August 31) will have an initial financial reporting period beginning September 1 of the following state fiscal year.

(1) A Grant Recipient that incurs Authorized Expenses after the Grant Contract effective date but before the beginning of the next state fiscal year may request reimbursement for those Authorized Expenses.

(2) The Authorized Expenses described in paragraph (1) of this subsection must be reported in the Financial Status Report reflecting Authorized Expenses for the initial financial reporting period beginning September 1.

(d) Except as provided herein, the Grant Recipient waives the right to reimbursement of project costs incurred during the reporting period if the Financial Status Report for that quarter is not submitted to the Institute within thirty (30) days of the Financial Status Report due date. Waiver of reimbursement of project costs incurred during the reporting period also applies to Grant Recipients that have received advancement of Grant Award funds.

(1) For purposes of this rule, the "Financial Status Report due date" is ninety (90) days following the end of the state fiscal quarter.

(2) The Chief Executive Officer may approve a Grant Recipient's request to defer submission of the reimbursement request for the current fiscal quarter until the next fiscal quarter if, on or before the original Financial Status Report due date, the Grant Recipient submits a written explanation for the Grant Recipient's inability to complete a timely submission of the Financial Status Report.

(3) A Grant Recipient may appeal the waiver of its right to reimbursement of project costs.

(A) The appeal shall be in writing, provide good cause for failing to submit the Financial Status Report within thirty (30) days of the Financial Status Report due date, and be submitted via the Grant Management System.

(B) The Chief Executive Officer may approve the appeal for good cause. The decision by the Chief Executive Officer to approve or deny the grant recipient's appeal shall be in writing and available to the Grant Recipient via the Grant Management System.

(C) The Chief Executive Officer's decision to approve or deny the Grant Recipient's appeal is final, unless the Grant Recipient timely seeks reconsideration of the Chief Executive Officer's decision by the Oversight Committee.

(D) The Grant Recipient may request that the Oversight Committee reconsider the Chief Executive Officer's decision regarding the Grant Recipient's appeal. The request for reconsideration shall be in writing and submitted to the Chief Executive Officer within 10 days of the date that the Chief Executive Officer notifies the Grant Recipient of the decision regarding the appeal as noted in subparagraph (C) of this paragraph.

(E) The Chief Executive Officer shall notify the Oversight Committee in writing of the decision to approve or deny the Grant Recipient's appeal. The notice should provide justification for the Chief Executive Officer's decision. In the event that the Grant Recipient timely seeks reconsideration of the Chief Executive Officer's decision, the Chief Executive Officer shall provide the Grant Recipient's written request to the Oversight Committee at the same time.

(F) The Grant Recipient's request for reconsideration is deemed denied unless three or more Oversight Committee members request that the Chief Executive Officer add the Grant Recipient's request for reconsideration to the agenda for action at the next regular Oversight Committee meeting. The decision made by the Oversight Committee is final.

(G) If the Grant Recipient's appeal is approved by the Chief Executive Officer or the Oversight Committee, the Grant Recipient shall report the project costs and provide supporting documentation for the costs incurred during the reporting period covered by the appeal on the next available financial status report to be filed by the Grant Recipient.

(H) Approval of the waiver appeal does not connote approval of the expenditures; the expenditures and supporting documentation shall be reviewed according to subsection (b) of this section.

(I) This subsection applies to any waivers of the Grant Recipient's reimbursement decided by the Institute on or after September 1, 2015.

(4) Notwithstanding subsection (c) of this section, in the event that the Grant Recipient and Institute execute the Grant Contract after the effective date of the Grant Contract, the Chief Program Officer may approve additional time for the Grant Recipient to prepare and submit the outstanding Financial Status Report(s). The approval shall be in writing and maintained in the Grants Management System. The Chief Program Officer's approval may cover more than one Financial Status Report and more than one fiscal quarter.

(5) In order to receive disbursement of grant funds, the most recently due Financial Status Report must be approved by the Institute.

(e) If a deadline set by this rule falls on a Saturday, Sunday, or federal holiday as designated by the U.S. Office of Personnel Management, the required filing may be submitted on the next business day. The Institute will not consider a required filing delinquent if the Grant Recipient complies with this subsection.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	HEIDI MCCONNELL, CHIEF OPERATING OFFICER
SUBJECT:	CHIEF OPERATING OFFICER REPORT
DATE:	AUGUST 12, 2019

CPRIT Financial Overview for FY 2019, Quarter 3

FY 2019, Quarter 3 Operating Budget

CPRIT expended or obligated approximately $2.6 million in Indirect Administration and approximately $12.9 million in Grant Review and Award Operations, or approximately 85% of the overall $18.0 million administrative budget for the fiscal year. The majority of the budget expenditures and obligations fall into two categories, employee salaries and service contracts.

During the second quarter, the agency received $43,426.16 in revenue sharing payments, totaling $248,978 received through the end of May 2019 for the fiscal year. The total revenue sharing payments received to date is approaching $3.7 million.

FY 2019, Quarter 3 Performance Measure Report

CPRIT reported third quarter performance to the Legislative Budget Board on the two output measures with quarterly reporting requirements:

1) Number of Cancer Prevention and Control Services Provided, and
2) Number of Entities Relocating to Texas for Cancer Research Related Projects.

Debt Issuance History

In March 2019, CPRIT requested Texas Public Finance Authority (TPFA) issue $77,725,000 in general obligation commercial paper notes to cover grant reimbursement expenses and the remaining half of the agency's operating budget. This was the first tranche of commercial paper debt issued for the agency because the general obligation bonds TPFA issued in September 2018 covered grant reimbursement expenses and the agency's operating budget for the first half of the year. Between the General Obligation Bonds and Commercial Paper Notes, TPFA issued $148.7 million in debt on CPRIT's behalf through the end of May 2019.

2020 CPRIT Innovations Conference Update

Arrangements for the 2020 conference are moving forward with the confirmation of several high-profile speakers including Dr. James Allison, 2018 Nobel Laureate and CPRIT Scholar, Dr. Nancy Chang, co-founder of Tanox and presently President and CEO of Apex Enterprise, Inc.,

and Dr. Robert Croyle, Director of the Division of Cancer Control and Population Services at NCI, to anchor keynote and plenary sessions at the conference. CPRIT program staff are developing additional sessions for the one and one-half day conference, which will conclude at 1 pm on Friday, July 31, 2020.

The conference will be held on July 30-31, 2020, at the Austin Convention Center (ACC) with hotel accommodations at the Fairmont Austin, which is connected by a skybridge to the ACC. In addition to the contracts with the ACC and Fairmont Austin, CPRIT is also finalizing contracts with Freeman for audiovisual equipment and support services and Austin Convention Center Catering for food and beverage banquet services during the conference. Both are preferred ACC vendors for their respective services.

The initial conference save-the-date notice was emailed to CPRIT's listserv on June 24, 2019.

2020 Budget

CPRIT plans to submit a request to the Legislative Budget Board to transfer $2,421,300 out of the Award Cancer Research Grants budget line item and into the Grant Review and Award Operations budget line item.

Of the $2.4 million to be transferred into the Grant Review and Award Operations line item, $2,105,100 will cover service contract increases for grant management support services with SRA International, Inc., a CSRA Company, product development grant application business due diligence evaluations with ICON Clinical Research Limited, and peer review meeting monitoring services with Business and Financial Management Solutions.

CPRIT anticipates negotiating a new interagency contract for a not-to-exceed amount of $150,000 with the Texas Treasury Safekeeping Trust Company for grant revenue asset management services.

The remaining $165,600 of the transfer will address increases for Review Council honoraria expenses in line with the changes to the FY 2020 Honoraria Policy which increases annual honoraria amounts for the membership of all three Review Councils based on grant application review workload increases as well as increases the number of members of the Scientific Review Council and the Product Development Review Council.

The details on the referenced service contracts and the peer review honoraria policy changes are addressed in other agenda items in the meeting packet

Cancer Prevention and Research Institute of Texas
Quarterly Financial Report
As of May 31, 2019

Indirect Administration (B.1.1.)

		2019 Appropriated	2019 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
1001	Salaries and Wages	$ 1,617,425	$ 1,525,975		$ 1,012,189	513,786	66%	$ 1,012,189	$ 513,786
1002	Other Personnel Costs	38,785	135,816		14,673	121,143	11%	14,673	121,143
2001	Professional Fees and Services	961,664	1,504,614		1,111,807	392,807	74%	1,111,807	392,807
2003	Consumable Supplies	24,000	24,000		12,921	11,079	54%	12,921	11,079
2004	Utilities	58,600	58,600		42,772	15,828	73%	42,772	15,828
2005	Travel	45,000	45,000		29,642	15,358	66%	29,642	15,358
2006	Rent-Building	13,700	22,093		22,092	1	0%	22,092	1
2007	Rent-Machine and Other	32,172	32,172		13,709	18,463	43%	13,709	18,463
2009	Other Operating Expenses	473,815	406,447		317,565	88,882	78%	317,565	88,882
	Subtotal - Indirect Administration (B.1.1.)	**$ 3,265,161**	**$ 3,754,717**	**1.26%**	**$ 2,577,370**	**$ 1,177,347**	**69%**	**$ 2,577,370**	**$ 1,177,347**

Grant Review and Award Operations (A.1.3.)

		2019 Appropriated	2019 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
1001	Salaries and Wages	$ 3,078,084	3,069,855		$ 2,455,520	$ 614,335	80%	$ 2,455,520	$ 614,335
1002	Other Personnel Costs	45,500	53,729		53,729	-	0%	53,729	-
2001	Professional Fees and Services	10,151,277	10,961,839		10,298,344	663,496	94%	10,298,344	663,496
2003	Consumable Supplies	-	-		-	-	0%	-	-
2004	Utilities	12,000	12,000		9,659	2,341	80%	9,659	2,341
2005	Travel	65,000	65,000		31,123	33,877	48%	31,123	33,877
2009	Other Operating Expenses	102,730	96,680		30,086	66,594	31%	30,086	66,594
	Subtotal - Grant Operations (A.1.3.)	**$ 13,454,591**	**$ 14,259,103**	**4.79%**	**$ 12,878,460**	**$ 1,380,643**	**90%**	**$ 12,878,460**	**$ 1,380,643**

Grants

		2019 Appropriated	2019 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
4000	Grants - Prevention (A.1.2)	$ 28,037,956	$ 28,037,956		$ 12,328,462	$ 15,709,494	44%	$ 12,328,462	$ 15,709,494
4000	Grants - Research (A.1.1.)	252,327,738	$ 251,780,707		115,189,996	$ 136,590,711	46%	115,189,996	136,590,711
	Subtotal - Grants	**$ 280,365,694**	**$ 279,818,663**	**93.95%**	**$ 127,518,458**	**$ 152,300,205**	**46%**	**$ 127,518,458**	**$ 152,300,205**
	Grand Totals	**$ 297,085,446**	**$ 297,832,483**	**100.00%**	**$ 142,974,289**	**$ 154,858,194**	**48%**	**$ 142,974,289**	**$ 154,858,194**

Cancer Prevention and Research Institute of Texas
Cancer Prevention and Research Institute Fund Account - 5136
As of May 31, 2019

	05/01/2019-05/31/2019	AY 19 Year to Date as of 05/31/2019
Beginning Balance : 05/01/2019		**$ 600,506**
Increases:		
(1)	$ -	$ -
(2)	-	
Total Increases	**$ -**	**$ 600,506.00**
Reductions:		
Expenditures - Appropriated	$ -	$ -
	$ -	$ -
	$ -	$ -
Total Reductions	**$ -**	**$ -**
Ending Balance, 05/31/2019		**$ 600,506.00**

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

Cancer Prevention and Research Institute of Texas

License Plate Trust Fund Account - 0802

As of May 31, 2019

	05/01/2019-05/31/2019	AY 19 Year to Date as of 05/31/2019
Beginning Balance : 05/01/2019		**$ 7,933.16**
Increases:		
(1) License Plate Revenue Received	$ 940.48	$ 6,851.16
Total Increases	**$ 940.48**	**$ 14,784.32**
Reductions:		
Expenditures - Appropriated	$ -	$ -
	-	-
Total Reductions	**$ -**	**$ -**
Ending Balance, 05/31/2019		**$ 14,784.32**

Note:

Cancer Prevention and Research Institute of Texas

Appropriated Receipts - 666

As of May 31, 2019

		05/01/2019-05/31/2019	AY 19 Year to Date as of 05/31/2019
Beginning Balance : 05/01/2019			**$ 24,449.98**
Increases:			
(1)	Product Development Application Fees Received	$ -	$ 26,000.00
(2)	Appropriated Receipts applied to payments	$ -	$ -
(3)	Conference Registration Fees	$ -	$ -
(4)	Conference Registration Fees-Credit Card	$ -	$ -
Total Increases		**$ -**	**$ 26,000.00**
Reductions:			
	Conference Expenditures - Appropriated	$ -	$ -
	Credit Card Fees Expended	$ -	$ -
	Legal Services Expenses (Application Fees)	$ -	$ -
Total Reductions		**$ -**	**$ -**
Ending Balance, 05/31/2019			**$ 50,449.98**

Begin balance is $24,449.98
Application Fees

Cancer Prevention and Research Institute of Texas

Interest & Sinking Fund Account - 5168

As of May 31, 2019

		05/01/2019-05/31/2019	AY 19 Year to Date as of 05/31/2019
Beginning Balance : 05/01/2019			**$ 226,766.25**
Increases:			
(1)	Revenue Sharing / Royalties	$ 14,659.10	$ 255,217.51
Total Increases		**$ 14,659.10**	**$ 481,983.76**
Reductions:			
	Expenditures - Appropriated	$ -	$ -
		$ -	
		$ -	$ -
Total Reductions		**$ -**	**$ -**
Ending Balance, 05/31/2019			**$ 481,983.76**

Cancer Prevention and Research Institute of Texas
FY 2019, Quarter 2 Performance Measure Report

Measure	Targeted Performance	QTR 1	QTR 2	QTR 3	QTR 4	Sum of QTRs	% of Mandate Attained
Number of People Served by Institute Funded Prevention and Control Activities	500,000	223,464	241,337	234,404		699,205	139.84%
Number of Entities Relocating to TX for Cancer Research Related Projects	2	0	0	0		0	0.00%
Annual Age-adjusted Cancer Mortality Rate	156.8	N/A	N/A	N/A	N/A		0.00%
Number of Published Articles on CPRIT-Funded Research Projects	900	N/A	N/A	N/A	N/A		0.00%
Number of New Jobs Created and Maintained	1,335	N/A	N/A	N/A	N/A		0.00%

Variance Explanations

Number of People Served by Institute Funded Prevention and Control Activities
CPRIT grantees deliver education and clinical services throughout the year, so the reported number of people served is not allocated evenly for each fiscal quarter.
Number of Entities Relocating to TX for Cancer Research Related Projects
This output is dependent on the number of companies applying for CPRIT Company Awards that can successfully advance through CPRIT's rigorous review and evaluation process, receive an award and actually relocate operations to Texas.

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	$ 51,000,000		G.O. Bonds	Taxable Series 2011	Par amount of new money	Fixed Rate Bonds All-In-True Interest Cost 4.0144%
2011		August 10, 2011	$ 232,045,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2011	Par amount of refunding; Refunded $233.2M of GOCP CPRIT Series A (9/9/09, 3/12/09, 8/26/09, 9/7/10)	Fixed Rate Bonds All-In-True Interest Cost 4.0144%
				$ 62,800,000				
2012	$ 300,000,000	September 7, 2011	$ 3,200,000		Commercial Paper Notes	Series A, Taxable		
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	Par amount of new money: Disbursed to CPRIT January 2016	Fixed Rate Bonds All-In-True Interest Cost 3.299867%
2016		May 16, 2016	$ 92,100,000		Commercial Paper Notes	Series A, Taxable		
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		
2017		January 5, 2017	$ 58,900,000		Commercial Paper Notes	Series A, Taxable		
2017		February 8, 2017	$ 269,000,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2017	Par amount of refunding: Refunded $269M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 3.4622%
2017		February 8, 2017	$ 106,000,000		G.O. Bonds	Taxable Series 2017	Par amount of new money	Fixed Rate Bonds All-In-True Interest Cost 3.4622 %
				$ 222,900,000				
2018	$300,000,000	September 29, 2017	$ 68,200,000		Commercial Paper Notes	Series A, Taxable		
2018		March 8, 2018	$ 99,000,000		Commercial Paper Notes	Series A, Taxable		
2018		July 11, 2018	$ 55,000,000		Commercial Paper Notes	Series A, Taxable		
				$ 222,200,000				
2019		September 21, 2018	$ 222,200,000		G.O. Bond (Refunding Bonds)	Taxable Series 2018	Par amount of refunding: Refunded $222.2M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 3.720632%
2019	$300,000,000	September 21, 2018	$ 75,975,000		G.O. Bonds	Taxable Series 2018	Par amount of new money	Fixed Rate Bonds All-In-True Interest Cost 3.720544%
2019		March 28, 2019	$ 72,725,000		Commercial Paper Notes	Series A, Taxable		
				$ 148,700,000				
TOTAL ISSUED TO DATE				**$ 1,664,700,000**				

Cancer Prevention and Research Institute of Texas
2020 Operating Budget

	2020 GAA Budget	Adjustments	Adjusted 2020 GAA Budget	2020 Projected Budget	Net Increase/ (Decrease)
Institute Operations (Indirect)					
Salaries and Wages	**1,702,425**		**1,702,425**	1,702,425	-
Other Personnel Costs	**38,785**		**38,785**	38,785	-
Professional Fees and Services:	**1,936,041**		**1,936,041**	1,936,041	-
Consumable Supplies	**24,000**		**24,000**	24,000	-
Utilities	**58,600**		**58,600**	58,600	-
Travel	**45,000**		**45,000**	45,000	-
Rent-Building	**11,000**		**11,000**	11,000	-
Rent-Machine and Other	**32,172**		**32,172**	32,172	-
Other Operating Expenses	**554,030**		**554,030**	554,030	-
Subtotal - Institution Operations	**$ 4,402,053**		**$ 4,402,053**	**$ 4,402,053**	$ -
Grant Review and Award Operations					
Salaries and Wages	**3,078,084**		**3,078,084**	3,078,084	-
Other Personnel Costs	**45,000**		**45,000**	45,000	-
Professional Fees and Services:	**9,351,363**	**272,750**	**9,624,113**	12,045,413	2,421,300
Utilities	**12,000**		**12,000**	12,000	-
Travel	**65,000**		**65,000**	65,000	-
Other Operating Expenses	**313,283**	**(272,750)**	**40,533**	40,533	-
Subtotal - Grant Operations	**$ 12,864,730**		**$ 12,864,730**	**$ 15,286,030**	**$ 2,421,300**
Total Operating Budget Adjustments	**$ 17,266,783**			**$ 19,688,083**	**$ 2,421,300**
Grants					
Grant Awards - Prevention	**$ 28,050,081**		**$ 28,050,081**	$ 28,050,081	-
Grant Awards - Research	**254,738,136**	**(3,118,032)**	**251,620,104**	249,198,804	(2,421,300)
Subtotal - Grants	**$ 282,788,217**		**$ 279,670,185**	**$ 277,248,885**	(2,421,300)
Grand Total	**$ 300,055,000**		**$ 296,936,968**	**$ 296,936,968**	

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

To:	OVERSIGHT COMMITTEE MEMBERS
From:	HEIDI MCCONNELL, CHIEF OPERATING OFFICER
Subject:	FY 2020 SERVICE CONTRACT APPROVALS
Date:	AUGUST 12, 2019

Recommendation

CPRIT staff recommends the Oversight Committee approve the following contracts for FY 2020:

- Contract amendment with SRA International, Inc., a CSRA Company, for an additional $1,813,665, bringing the contract amount up to $9,771,475 from $7,957,810 to provide grant management support services,
- Contract renewal with ICON Clinical Research Limited for $438,640 to perform diligence reviews of product development research grant applications,
- Contract renewal with Hahn Public Communications for $149,975 to provide strategic communications services,
- Contract renewals with Vinson & Elkins, LLP, Baker Botts, LLP, and Yudell Isidore, PLLC for $125,000 each to provide legal advice and evaluation services regarding the intellectual property and revenue sharing agreements associated with CPRIT grants,
- Contract with The Perryman Group for $165,000 to perform an economic assessment of the cost of cancer in Texas,
- Contract with Weaver and Tidwell for $186,000 to provide internal audit services, and
- Interagency contract with the Texas Treasury Safekeeping Trust Company up to $150,000 authority to provide CPRIT grant asset management services.

The contract costs for consideration are not-to-exceed amounts, and payment is based on the delivery of actual services through time and materials expended by the vendor or as a fee for service based on the delivery of a report.

The contract amendment with SRA International, Inc., a CSRA Company, will require approval by the Legislative Budget Board (LBB) prior to finalizing the amendment. CPRIT has received LBB approval of the FY 2020 SRA International contract renewal for $7,957,810, so there will be a contract in effect on September 1st.

The Office of the Attorney General must approve the outside legal services contract renewals prior to contract execution.

The contract with Weaver and Tidwell will require the State Auditor's Office to provide audit delegation authority to CPRIT prior to contract execution.

Background

Grant Management Support Services Contract Amendment

The contract pricing provided to the Oversight Committee at its May 15th meeting included only one major grant application review cycle in fall 2019 for all of CPRIT's grant programs during FY 2020 because the House and Senate were considering different versions of the 2020-21 biennial state budget at the time this contract needed to be considered by the Oversight Committee to allow sufficient time for the contract approval request to make it through the LBB review required for a contract of this dollar amount to be effective on September 1st.

As noted in the contract approval memo provided to the Oversight Committee for the May meeting, when the final 2020-21 biennial budget was passed at the end of May by the 86th Texas Legislature with $300 million in general obligation bond proceeds appropriated in FY 2020, CPRIT staff requested pricing for a second grant application review cycle from SRA International.

The amended contract amount of $9,771,475 is $1,371,032 higher than the FY 2019 contract for $8,400,443 because in the initial pricing request for the contract renewal we included assumptions for several extensive security enhancements to both the grants management module and the program and peer review module of the Grants Management Platform software to increase protections over the data in those systems.

Due Diligence Review Services Contract Renewal

ICON Clinical Research provides due diligence review reports which are an evaluation of a product development research grant applicant's business operations and management that covers discovery science capability, preclinical and clinical research capabilities, manufacturing facilities, regulatory approval pathway, management capability, financial viability, and commercial viability. ICON performs the diligence evaluation on a select subset of product development grant applications following the completion of peer review evaluation of the Texas Company, Company Relocation and SEED grant applications submitted during any given product development program grant award cycle.

The pricing is based on ICON performing up to 15 company and two SEED project diligence reviews in FY 2020. However, CPRIT can adjust the types of reviews if actual results warrant within the total contract amount. CPRIT would be exercising the first of three renewal options.

Strategic Communications Services Contract Renewal

Hahn Public Communications provides strategic communication program services including communications strategy, media relations support, digital media relations advisory services, and communication program evaluation and assessment. CPRIT would be exercising the first of three renewal options.

Outside Legal Counsel Service Contract Renewals

Vinson & Elkins, Baker Botts, and Yudell Isidore possess the intellectual property (IP) expertise to perform a due diligence review of the IP estate of a company CPRIT is considering for a grant award in the product development research program. The IP counsel performs diligence review on a select

subset of product development grant applications. The review 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.

Contracting with multiple legal firms allows CPRIT to balance the workload and avoid potential conflicts of interest between the firms and the companies under review. CPRIT would be exercising the third renewal option on all three contracts.

Economic Assessment of the Cost of Cancer in Texas Contract

CPRIT conducted a competitive solicitation for economic assessment services during late spring 2019. CPRIT received five proposals by the bid period close on May 29, 2019. In the evaluation of the proposals, CPRIT staff determined that The Perryman Group (TPG) is the best value because of its ability to deliver a final report with the necessary metrics by the beginning of December when CPRIT requires the information for inclusion in the agency's statutorily required annual report. TPG is the incumbent vendor.

The report produced by The Perryman Group provides CPRIT with the:

- statutorily required cost of cancer in Texas measurement;
- measurement of key economic performance indicators based on CPRIT funding and program impact; and
- estimates of the economic impact to Texas if CPRIT were not to exist and no additional funding is provided beyond the $3 billion in general obligation debt authorized by the Texas Constitution.

Internal Audit Services Contract

CPRIT conducted a competitive solicitation for internal audit services during late spring 2019. CPRIT received three proposals by the bid period close on June 14, 2019. CPRIT staff evaluated the proposals and determined that Weaver and Tidwell is the best value in terms of having an experienced public sector audit team in Texas with in-depth experience adhering to the state's internal audit requirements and serving as an internal auditor to a state agency. Weaver and Tidwell is the incumbent vendor.

In FY 2020, the proposed internal audit plan includes audits over governance, disaster recovery, and business continuity planning processes and follow-up audits on communications, information security, and state reporting audits.

Texas Treasury Safekeeping Trust Company Interagency Contract

The Texas Legislature amended CPRIT's statute in 2017 to permit the Oversight Committee to transfer the management and final disposition authority for assets generated by CPRIT's grant award projects to the Texas Treasury Safekeeping Trust Company (Trust Company). In FY 2020 CPRIT plans to transfer management authority for the assets generated by its revenue sharing agreements with at least two companies, and potentially many more. CPRIT's statute permits the Trust Company to charge CPRIT to recover the costs associated with managing any transferred assets. CPRIT staff and Trust Company representatives are negotiating an

appropriate fee and payment structure, which will be memorialized through an interagency contract. CPRIT would like authorization for a not-to-exceed amount of $150,000 to ensure there is adequate capacity to manage the assets that need to be transferred.

FY 2018 – 2019 Subcommittee Membership

	Audit	Brd Gov	Nom	Prev	Aca Res	Prod Dev	Contract*	Special Issues*
Montgomery		X			X		X	X
Margo	X		X	X		X		X
Patel		X		X	X			
Angelou			X			X		
Cummings	X			X				
Rice	X	X			X	X		X
Rosenfeld			X			X	X	

X = Chair

* The subcommittee meets on an as-needed basis

FY 2020 – 2021 Proposed Subcommittee Membership

	Audit	Brd Gov	Nom	Prev	Aca Res	Prod Dev	Contract*	Special Issues*
Montgomery				X	X	X	X	X
Margo	X			X				X
Patel		X	X		X			
Angelou			X			X	X	
Cummings	X	X		X				X
Rice	X	X			X	X		X
Rosenfeld		X	X			X		

X = Chair

* The subcommittee meets on an as-needed basis

Placeholder for

Agenda Item 22

Tab 18

Election of Board Officers

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

Oversight Committee Meetings and Standing Subcommittees Meetings 2020

November 2019						
Sun	**Monday**	**Tuesday**	**Wednesday**	**Thursday**	**Friday**	**Sat**
3	4	5 PIC Meeting CPRIT Staff Only	6 Portal Opens	7 Board Governance	8	9
10	11 Audit	12 Prevention	13 Academic Research	14 Product Development	15 Nominations	16
17	18	19	20 Oversight Committee Meeting	21	22	23

February 2020						
Sun	**Monday**	**Tuesday**	**Wednesday**	**Thursday**	**Friday**	**Sat**
2	3	4 PIC Meeting CPRIT Staff Only	5 Portal Opens	6 Board Governance	7	8
9	10 Audit	11 Prevention	12 Academic Research	13 Product Development	14 Nominations	15
16	17	18	19 Oversight Committee Meeting	20	21	22

May 2020						
Sun	**Monday**	**Tuesday**	**Wednesday**	**Thursday**	**Friday**	**Sat**
3	4	5 PIC Meeting CPRIT Staff Only	6 Portal Opens	7 Board Governance	8	9
10	11 Audit	12 Prevention	13 Academic Research	14 Product Development	15 Nominations	16
17	18	19	20 Oversight Committee Meeting	21	22	23

August 2020						
Sun	**Monday**	**Tuesday**	**Wednesday**	**Thursday**	**Friday**	**Sat**
2	3	4 PIC Meeting CPRIT Staff Only	5 Portal Opens	6 Board Governance	7	8
9	10 Audit	11 Prevention	12 Academic Research	13 Product Development	14 Nominations	15
16	17	18	19 Oversight Committee Meeting	20	21	22

Note: Unless the subcommittee members agree to a different time, all subcommittee meetings will begin at 10:00 a.m. with the exception of Nominations which will begin at 10:30 a.m. Members of the Audit and Program subcommittees should allocate 1.5 hours for a meeting. All others subcommittee meetings require one hour.