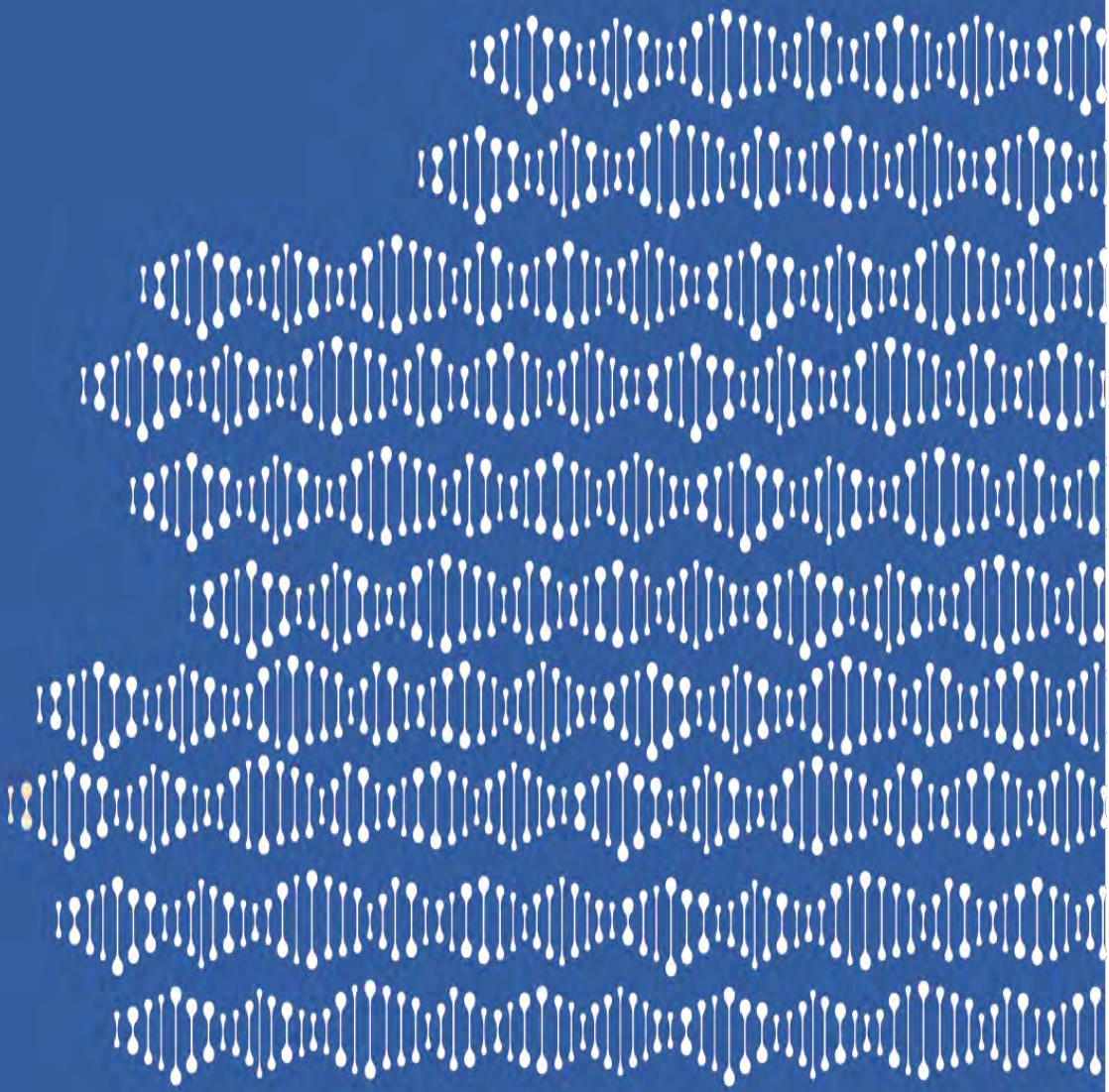
CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Meeting

November 28, 2018



CANCER PREVENTION & RESEARCH
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Summary Overview of the November 28, 2018, Oversight Committee Meeting

This summary provides an overview of major agenda items and background on key issues for Committee consideration at the November 28, 2018, Oversight Committee meeting.

Oath of Office – Dr. David Cummings
Governor Greg Abbott appointed David A. Cummings, M.D., to the Oversight Committee on August 27, 2018. Dr. Cummings' appointment will expire January 31, 2023. CPRIT Presiding Officer Will Montgomery will administer the oath of office.

CEO Report
Wayne Roberts will present the CEO's report and address issues including personnel, available grant funds, pre-filed legislation, 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 proposed requests for applications and timeline for the fiscal year 2020 review cycle. Dr. Willson will also present the Program Integration Committee's (PIC) two award recommendations for Recruitment of First-Time, Tenure-Track Faculty Members and two recommendations for Recruitment of Established Investigators.

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

Chief Prevention and Communications Officer Report and Grant Award Recommendations
Dr. Becky Garcia will update the Oversight Committee on the on the agency's prevention program. She will also report on CPRIT's communications activities.

Chief Product Development Officer Report
CPRIT Interim Chief Product Development Officer Kristen Doyle will provide an update on the Product Development Program.

FY 2020 Program Priorities
Health and Safety Code Chapter 102 requires CPRIT's Oversight Committee to establish program priorities on an annual basis. Mr. Roberts will present the program subcommittees' recommendations for FY 2020 Program Priorities. The Oversight Committee will vote on the final program priorities.

Appointments - Scientific Research and Prevention Programs Committee
Mr. Roberts has provisionally appointed 21 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. The agenda packet includes biographical sketches for the provisional appointees.

Appointments - Advisory Committee on Childhood Cancer
Presiding Officer Will Montgomery has appointed three new members to the Advisory Committee on Childhood Cancer. CPRIT Administrative Rule § 701.13 requires Oversight Committee approval of the presiding officer's ad hoc appointments.

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

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

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

CPRIT's Bylaws Amendment
Ms. Doyle will present a proposed change to CPRIT's Bylaws. The proposed change is necessary to make the Bylaws consistent with CPRIT's administrative rules.

Chief Operating Officer Report
Heidi McConnell will discuss the operating budget, performance measures, and debt issuance history for the fourth quarter of FY 2018.

Subcommittee Business
Dr. Cummings' appointment to the Oversight Committee requires additional subcommittee assignments for fiscal year 2019. The Oversight Committee must vote to approve the changes to subcommittee membership.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Meeting Agenda

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

November 28, 2018
10:00 a.m.

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

1. Call to Order
2. Roll Call/Excused Absences
3. Oath of Office for newly appointed Oversight Committee member
4. Adoption of Minutes from the August 24, 2018, meeting — Tab 1
5. Public Comment
6. Grantee Presentation — Tab 2
7. Chief Executive Officer Report — Tab 3
8. Chief Compliance Officer Report — Tab 4
9. Chief Scientific Officer Report — Tab 5
   - Grant Award Recommendations
   - FY 2020 Cycle 1 Requests for Applications
10. Chief Prevention and Communications Officer Report — Tab 6
11. Chief Product Development Officer Report — Tab 7
12. Scientific Research and Prevention Program Committee Appointments — Tab 8
13. Advisory Committee on Childhood Cancer Appointments — Tab 9
14. FY 2020 Program Priorities — Tab 10
15. Internal Auditor Report — Tab 11
16. Amendments to 25 T.A.C. Chapters 703 — Tab 12
    - Final Orders Approving Amendments to Chapter 703
    - Proposed Amendments to Chapter 703 and Authorization to Publish in *Texas Register*
17. Amendment to Oversight Committee Bylaws — Tab 13
18. Chief Operating Officer Report — Tab 14
19. Subcommittee Business
    - New subcommittee member assignments
20. Compliance Investigation Pursuant to Health & Safety Code § 102.2631
21. Consultation with General Counsel
22. Future Meeting Dates and Agenda Items
23. Adjourn

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Meeting
August 24, 2018

NOTE: Unless the information is confidential, the reports and presentations referenced in the minutes are available at http://www.cprit.state.tx.us/cprit-media/oc_packet_08-24-2018.pdf Information regarding the recommended awards is available at http://www.cprit.state.tx.us/cprit-media/proposed_grant_awards_book_08242018.pdf

Call to Order – Agenda Item 1

A quorum being present, Presiding Officer Will Montgomery called the Oversight Committee to order at 10:05 a.m.

Roll Call/Excused Absences – Agenda Item 2

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

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

Adoption of Minutes from the May 16, 2018, Meeting – Agenda Item 3 – Tab 1

MOTION:
On a motion by Mr. Angelou and seconded by Dr. Rice, the Oversight Committee unanimously voted to approve the minutes of the Oversight Committee meeting of May 16, 2018, as presented.

Public Comment – Agenda Item 4

There were no requests to provide public comment.

Grantee Presentation – Agenda Item 5 – Tab 2

Dr. Garcia introduced Dr. Barbara Turner, Professor of Medicine at UT Health San Antonio and the Founding Director of the Center for Research to Advance Community Health.

Dr. Turner reported on the successful CPRIT-funded Screen, Treat, or Prevent HCC (hepatocellular carcinoma) project, PP150079, and PP180063, the dissemination award for this model.

In response to an Oversight Committee member's question about individuals most at risk for HCC, Dr. Turner explained that those with chronic Hepatitis C are at highest risk. Another member asked about the project's use of telemedicine. Dr. Turner replied that the patient's primary care doctor and the specialist develop a treatment plan together using telemedicine. A member asked how many individuals that program has treated for Hepatitis C infections under this program. Dr. Turner reported that the program treated 84 uninsured patients, with 72 cured. At Parkland Hospital, one-third of the 400-500 patients in that safety-net healthcare system were cured.

Chief Executive Officer Report – Agenda Item 6 – Tab 3

Presiding Officer Montgomery recognized Mr. Roberts for the CEO report.

Mr. Roberts introduced Melanie Cleveland as CPRIT's new Executive Assistant.

Addressing the FY 2018 budget, Mr. Roberts explained that if the Oversight Committee approved all the proposed awards, approximately $3.1 million in agency funds would remain.

Mr. Roberts reported that the American Cancer Society Cancer Action Network held two events in July and August in Austin and Fort Worth.

Mr. Roberts noted that the Oversight Committee will consider the FY 2020 program priorities at its November meeting. He expects that many of the priorities would remain the same as FY 2019 priorities.

Mr. Roberts finished his report with an update about the next CPRIT Conference, which will be held in 2020. He explained that holding the conference in 2020 aligns the timing with the legislative cycle, increases venue choices, and allows staff to repurpose the existing registration system.

There were no questions for Mr. Roberts.

Presiding Officer Montgomery congratulated Mr. Roberts for receiving the "Administrator of the Year" award from the Texas State Agency Business Administrator's Association (TSABAA). The award recognizes state employees who have demonstrated outstanding leadership skills and who have made significant contributions to state agency business administration. Presiding Officer Montgomery thanked Mr. Roberts for his efforts on behalf of CPRIT and his 40-year career dedicated to Texas.

Chief Compliance Officer Report – Agenda Item 7 – Tab 4

Stephen Nance, CPRIT's Compliance Program Manager, presented the Compliance Report in Chief Compliance Officer Vince Burgess's absence. CPRIT included the report in the meeting agenda packet. Mr. Nance informed the Oversight Committee that CPRIT has fully implemented the revised process for submitting the Single Audit Determination forms. Grantees will complete and submit one form to CPRIT on an annual basis.

Mr. Nance reported that CPRIT completed the Annual Grantee Risk Assessment for FY 2019 and explained that the assessment was discussed with the Audit Subcommittee.

The Oversight Committee had no questions for Mr. Nance.

Chief Scientific Officer Report – Agenda Item 8 – Tab 5

Presiding Officer Montgomery recognized CPRIT Chief Scientific Officer James Willson to present the academic research program update and the award slates recommended by the CPRIT Scientific Review Council (SRC) and the Program Integration Committee (PIC).

Dr. Willson referred the members to the information on the status of FY 2019 Academic Research RFAs presented in the meeting books on pages 5-3 to 5-4. He noted the recent announcement of two new RFAs, the revised Early Translational Research Award and the Collaborative Action Program to Reduce Liver Cancer Mortality in Texas to reverse the state's liver cancer trajectory.

Dr. Willson presented 51 grant awards from six grant mechanisms recommended by the SRC and the PIC totaling $112,156,309. He summarized each of the award slates. Dr. Willson noted that because the SRC's recommendations exceed the funds available to fund Academic Research Program awards for the final quarter of 2018, the PIC recommended that the Core Facility Support awards be reduced by 8% of the SRC's recommended levels.

Grant Mechanism	**SRC Recommendations**		**PIC Recommendations**	
	Awards	**Funding**	**Awards**	**Funding**
High Impact/High Risk Research Awards	25	$4,998,787	25	$4,998,787
Core Facility Support Awards	10	$49,147,362	10	$45,215,573
Multi-Investigator Research Awards	5	$29,941,949	5	$29,941,949
Recruitment of Established Investigators	2	$12,000,000	2	$12,000,000
Recruitment of Rising Stars	1	$4,000,000	1	$4,000,000
Recruitment of First-Time, Tenure-Track Faculty Members	8	$16,000,000	8	$16,000,000
Total	**51**	**$116,088,098**	**51**	**$112,156,309**

Compliance Certification (Academic Research, Product Development, and Prevention Awards)

Mr. Nance presented Mr. Burgess' certification of the review process for the proposed 51 academic research awards, 3 product development research awards, and 10 prevention awards recommended to the Oversight Committee for consideration. (Mr. Burgess's certification is included in the proposed grant awards packet at pages 187-196.)

Conflict of Interest Notification

Presiding Officer Montgomery noted that Mr. Angelou reported a conflict of interest with grant applications RP180690, RP180880, and RR180042 submitted by The University of Texas at Austin.

Presiding Officer Montgomery suggested that, unless a member objected, the Oversight Committee consider all the academic research award recommendations together in one vote except for the proposed awards to The University of Texas at Austin, which the committee would vote on separately. No member objected.

Academic Research Award Slate

ID	Award Mechanism	Meeting Overall Score	Application Title	PI	PI Organization	Recommended Budget
RP180684	CFSA	**1.1**	Integrated Single Cell Genomics Core Facility	Navin, Nicholas, Ph.D.	The University of Texas M. D. Anderson Cancer Center	$5,323,453
RP180778	MIRA	**1.3**	Metabolic Enablers of Melanoma Progression	Morrison, Sean, Ph.D.	The University of Texas Southwestern Medical Center	$5,998,327
RP180785	CFSA	**1.5**	CARMIT (Children's Access to Regenerative Medicine in Texas)	Gee, Adrian, Ph.D.	Baylor College of Medicine	$5,767,448*
RP180804	CFSA	**1.9**	Protein Array and Analysis Core (PAAC)	Bedford, Mark, Ph.D.	The University of Texas M. D. Anderson Cancer Center	$2,819,682
RP180755	HIHRRA	**1.9**	The Early-Life Exposome and Risk of Pediatric Acute Lymphoblastic Leukemia	Lupo, Philip Ph.D.	Baylor College of Medicine	$199,140
RP180770	CFSA	**1.9**	Preclinical Radiation Core Facility (PCRCF)	Story, Michael, Ph.D.	The University of Texas Southwestern Medical Center	$4,047,022
RP180700	HIHRRA	**2.0**	Mechanisms of Drug Resistance in Lung Cancer	Alto, Neal Ph.D.	The University of Texas Southwestern Medical Center	$200,000
RP180835	HIHRRA	**2.0**	Targeted Proteolysis of Glucocorticoid Receptor as a Therapeutic Strategy in Antiandrogen Treatment–Resistant Prostate Cancer	Lissanu Deribe, Yonathan M.D., Ph.D.	The University of Texas M. D. Anderson Cancer Center	$199,999
RP180805	CFSA	**2.0**	Pediatric Cancer Data Core	Xie, Yang, M.D., Ph.D.	The University of Texas Southwestern Medical Center	$5,863,959***

RP180748	CFSA	**2.1**	GCC Center for Comprehensive PK/PD and Formulation	Liang, Dong Ph.D.	Texas Southern University	$5,550,456
RP180694	HIHRRA	**2.2**	TREX2 Inhibitors to Treat BCR-ABL-Cancers	Hasty, E. Paul DVM	The University of Texas Health Science Center at San Antonio	$200,000
RP180769	HIHRRA	**2.2**	A Novel Anti-BCR-ABL Approach for Leukemia Therapy	Rao, Hai Ph.D.	The University of Texas Health Science Center at San Antonio	$200,000
RP180813	MIRA	**2.2**	BRCA Answers From Cancer Interactome Structures (BACIS)	Tainer, John, Ph.D.	The University of Texas M. D. Anderson Cancer Center	$5,969,140
RP180672	CFSA	**2.2**	Advanced Multiparameter Cytometry and Cell Sorting Core	Beeton, Christine, Ph.D.	Baylor College of Medicine	$5,628,254**
RP180712	MIRA	**2.2**	Rational Combination Treatment Options to Reverse Resistance in Hormone Receptor–Positive Breast Cancer Refractory to Standard Therapy	Hunt, Kelly, M.D.	The University of Texas M. D. Anderson Cancer Center	$5,992,274
RP180819	CFSA	**2.2**	Pediatric Solid Tumors Comprehensive Data Resource Core	Gorlick, Richard, M.D.	The University of Texas M. D. Anderson Cancer Center	$5,440,485***
RP180716	HIHRRA	**2.2**	Noninvasive Diagnostic Imaging of Brain Cancer Using Hyperpolarized 13C-Labeled L-Tryptophan and L-Methionine	Lumata, Lloyd, Ph.D.	The University of Texas at Dallas	$200,000
RP180670	CFSA	**2.3**	Small Animal Imaging Core Facility for Cancer Research at UT Dallas	Hoyt, Kenneth, Ph.D.	The University of Texas at Dallas	$3,892,336
RP180880	HIHRRA	**2.3**	Targeting BRAF- and RAS-Mutant Cancers by Small Molecule–Induced Proteolysis of ERK1/2	Dalby, Kevin N, Ph.D.	The University of Texas at Austin	$200,000
RP180734	CFSA	**2.3**	UTHealth Cancer Genomics Core (UTHealth CGC)	Zhao, Zhongming, Ph.D.	The University of Texas Health Science Center at Houston	$4,814,267

RP180674	MIRA	**2.4**	Predictive Biomarkers and Novel Therapies for High-Risk Pediatric Liver Cancers	Lopez-Terrada, Dolores, M.D., Ph.D.	Baylor College of Medicine	$5,982,208
RP180848	HIHRRA	**2.5**	Autoimmune-Prone Mouse Models for Studying Immune-Related Adverse Events Associated With Cancer Immunotherapy	Yan, Nan Ph.D.	The University of Texas Southwestern Medical Center	$200,000
RP180826	HIHRRA	**2.5**	Integrative Analysis of Structural Variants in Cancer Genomes	Xu, Jian Ph.D.	The University of Texas Southwestern Medical Center	$200,000
RP180690	HIHRRA	**2.6**	Engineering Cancer Immunotherapeutics for Enhanced Activity in the Low pH Tumor Microenvironment	Maynard, Jennifer Ph.D.	The University of Texas at Austin	$200,000
RP180812	HIHRRA	**2.6**	Fluorescently Labeled Somatostatin Analogs for Image-Guided Surgery in Neuroendocrine Tumors	Azhdarinia, Ali Ph.D.	The University of Texas Health Science Center at Houston	$200,000
RP180736	HIHRRA	**2.7**	Nanoparticle-Mediated Hyperthermia to Improve Chemotherapeutic Efficacy in HIPEC	Holder, Ashley Ph.D.	The Methodist Hospital Research Institute	$199,998
RP180751	HIHRRA	**2.8**	Methods for Assessment and Quantification of Imperfect dsDNA Break Repair	Otwinowski, Zbyszek Ph.D.	The University of Texas Southwestern Medical Center	$200,000
RP180801	HIHRRA	**2.8**	Targeting the Menopause Transition to Decrease the Risk for Obesity-Associated Postmenopausal Breast Cancer	Giles, Erin D Ph.D.	Texas A&M University	$200,000
RP180725	MIRA	**2.8**	Targeting Tumor Tissues Increases DNA Sensing to Bridge Innate and Adaptive Immunity	Fu, Yang-Xin, M.D., Ph.D.	The University of Texas Southwestern Medical Center	$6,000,000

RP180863	HIHRRA	**2.9**	Chemoprevention of Colon Cancer Progression in FAP Children	Hu, Ming Ph.D.	University of Houston	$200,000
RP180771	HIHRRA	**2.9**	Small Molecule for Selective Targeting of Epithelial-Mesenchymal Transition–Induced Cancer Stem Cells	Taube, Joe Ph.D.	Baylor University	$199,951
RP180810	HIHRRA	**2.9**	Controlling the Activity of Anticancer T Cells by Inducing Replicative Senescence	Mamonkin, Maksim Ph.D.	Baylor College of Medicine	$200,000
RP180875	HIHRRA	**2.9**	Cyanine-Conjugated Kinase Inhibitors (Cy-KIs) as Potential Glioblastoma Theranostics	Sitcheran, Raquel Ph.D.	Texas A&M University System Health Science Center	$200,000
RP180882	HIHRRA	**3.0**	Developing a Clinically Relevant Drug Testing Platform	Yun, Kyuson Ph.D.	The Methodist Hospital Research Institute	$199,700
RP180846	HIHRRA	**3.0**	Molecular Opening of the Blood-Brain Barrier by Molecular Hyperthermia	Qin, Zhenpeng Ph.D.	The University of Texas at Dallas	$200,000
RP180827	HIHRRA	**3.1**	Polymer Nanodiscs: Novel Lipoprotein-Mimicking Nanocarriers With High Stability and Long Circulation Time for Enhanced Anticancer Drug Delivery	Liang, Hongjie Ph.D.	Texas Tech University Health Sciences Center	$200,000
RP180844	HIHRRA	**3.2**	Regulating Androgen Receptor as a Corepressor by Neurofibromin (NF1)	Chang, Eric C. Ph.D.	Baylor College of Medicine	$200,000
RP180873	HIHRRA	**3.2**	Molecular Targeted Magnetic Resonance Reporter for Cancer Detection	Carson, Daniel Ph.D.	Rice University	$200,000
RP180862	HIHRRA	**3.3**	Microfluidic Cancer Assay for Liquid Biopsies and Early Detection	Pappas, Dimitri Ph.D.	Texas Tech University	$199,999
RP180851	HIHRRA	**3.4**	Targeting MYCN-Driven Metabolism in Neuroblastoma	Barbieri, Eveline M.D., Ph.D.	Baylor College of Medicine	$200,000

*RP180785 reflects the budget as reduced by the SRC. SRC recommended the removal of 2nd Prodigy Cell Processor
**RP180672 reflects the recommended budget as reduced by the SRC. SRC recommended the elimination of salary support for Bioinformatician
***RP180805 and RP180819 - The SRC notes that Core Facility Support Award applications from UT Southwestern (RP180805) and MD Anderson (RP180819) propose separate comprehensive data cores to support pediatric cancer research in Texas. The goals of the individual applications complement each other and together represent a unique opportunity to build a statewide resource that will accelerate pediatric cancer research in Texas. To realize the full potential of the CPRIT investment in these cores, the SRC recommended that prior to finalizing a funding plan for each core that the PIs and their respective institutions develop a plan that maximizes opportunities for the two cores to work together and to incorporate that plan into their core's goals and budget.

Recruitment Slate

App ID	Candidate	Mechanism	Organization	Budget	Overall Score
RR180061	Chao Cheng, Ph.D.	RRS	Baylor College of Medicine	$4,000,000	1.0
RR180066	Xuebing Wu, Ph.D.	RFTFM	Baylor College of Medicine	$2,000,000	1.2
RR180060	Yejing Ge, Ph.D.	RFTFM	The University of Texas M. D. Anderson Cancer Center	$2,000,000	1.2
RR180072	Tao Wu, Ph.D.	RFTFM	Baylor College of Medicine	$2,000,000	1.4
RR180032	Peng (George) Wang, Ph.D.	REI	Baylor College of Medicine	$6,000,000	1.5
RR180051	Glen P. Liszczak, Ph.D.	RFTFM	The University of Texas Southwestern Medical Center	$2,000,000	1.8
RR180050	Peter Ly, Ph.D.	RFTFM	The University of Texas Southwestern Medical Center	$2,000,000	1.8
RR180056	Anke Henning, Ph.D.	REI	The University of Texas Southwestern Medical Center	$6,000,000	2.0
RR180067	Fuguo Jiang, Ph.D.	RFTFM	The University of Texas M. D. Anderson Cancer Center	$2,000,000	2.0
RR180042	Can Cenik, Ph.D.	RFTFM	The University of Texas at Austin	$2,000,000	2.0
RR180071	Sung-Man (Kenneth) Chen, M.D.	RFTFM	The University of Texas Southwestern Medical Center	$2,000,000	2.4

Responding to an Oversight Committee member's question about the Academic Research Program priorities represented in the six slates, Dr. Willson explained that the grant award recommendations

incorporated many of the program priorities. He referred the members to table 2 on page 13 of the Proposed Grant Awards book.

MOTION:
On a motion made by Dr. Rice and seconded by Mr. Margo, the Oversight Committee unanimously voted to approve the PIC's recommendations for The University of Texas at Austin grant applications RP180690, RP180880, and RR180042.

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

MOTION:
On a motion made by Mr. Angelou and seconded by Mr. Rice, the Oversight Committee unanimously voted to approve the PIC's recommendations for the remaining Academic Research and Recruitment Awards.

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

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

Presiding Officer Montgomery recognized Chief Product Development Research Officer Michael Lang to present the Product Development Review Council's (PDRC) and the PIC's recommendations for product development awards and to provide an update on the product development program.

Mr. Lang updated the Oversight Committee on the progress of the first funding cycle for FY 2019, referring members to his report in the meeting books. He noted that the 19.1 review cycle represents the first time that the Product Development program has offered the Seed Award funding mechanism. He reported that CPRIT received 27 applications for the new Seed Award.

Mr. Lang responded to an Oversight Committee member's question regarding whether CPRIT can accelerate the review process for the Seed Award in comparison to the review process for the other product development awards. Mr. Lang explained that although the Seed Award applications will include less information since the projects will be at an earlier development stage, the applications will undergo the same process and sequence for review as the other awards to comply with CPRIT policy and minimize budget impact.

Mr. Lang presented three product development awards recommended by the PDRC and the PIC totaling $50,587,540. He explained that all the recommended applications address one or more of the Product Development Program priorities. Mr. Lang reported that Magnolia Neurosciences acquired Korysso Therapeutics and renamed it Magnolia Tejas. He also noted that the PDRC and PIC award recommendation for Korysso included several contract contingencies the company must resolve before CPRIT and the company can execute the award contract.

Application ID	Mech	Company Name	Project	Maximum Recommended Budget
DP180040	TXCO	Formation Biologics Corp.	Clinical Evaluation of AVID100, a Highly Potent Antibody-Drug Conjugate, Focusing on Cancer Indications With High Unmet Medical Need	$18,850,000
DP180048	TXCO	Korysso Therapeutics, Inc.	Development of KOR-8287 for the Prevention of Chemotherapy-Induced Peripheral Neuropathy and Chemo Brain	$19,953,624
DP180042	TXCO	CerRx, Inc.	Combination Drug Therapy for Cutaneous T-Cell Lymphoma	$11,783,916

Compliance Certification

Presiding Officer Montgomery reminded members that Mr. Burgess previously certified compliance of the product development award process, as reported by Mr. Nance.

Conflict of Interest Notification

Presiding Officer Montgomery confirmed that no members reported a conflict of interest with any of the product development award recommendations.

MOTION:
On a motion made by Dr. Rice and seconded by Mr. Angelou, the Oversight Committee unanimously voted to approve the PIC's recommendation for the three product development research awards.

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

MOTION:
On a motion made by Dr. Rice and seconded by Mr. Margo, the Oversight Committee unanimously voted to authorize CPRIT to disburse grant funds via advance payments to DP180040, DP180042, and DP180048 upon execution of the award contracts and the successful completion of tranches pursuant to the General Appropriations Act, Article IX, Section 4.03(a).

Chief Prevention and Communications Officer Report – Agenda Item 10 – Tab 7

Presiding Officer Montgomery recognized Dr. Garcia to present the Prevention Review Council's (PRC) and the PIC's recommendations for prevention awards and to provide an update on the prevention program.

Dr. Garcia reported that CPRIT will post the 2018 Texas Cancer Plan on CPRIT's website by the end of August and printed copies sent to the Oversight Committee in September.

Dr. Garcia presented ten projects, representing three grant mechanisms, recommended by the PRC and PIC, totaling $14,322,379. The PIC agreed with the PRC's recommendation to reduce the budgets of all recommended projects by 10.02% to assure that enough funds are available. She reported that all the recommended awards address one or more of the Prevention Program priorities.

App. ID	Mech	Application Title	PD	Organization	Score	Rank Order	Budget
PP180080	EBP	HPV Vaccination in a Pediatric Minority-Based Community Oncology Network	Grimes, Allison	The University of Texas Health Science Center at San Antonio	1.6	1	$1,010,690
PP180091	EPS	STOP-HCC Expansion Grant	Jain, Mamta	The University of Texas Southwestern Medical Center	1.9	2	$2,592,731
PP180026	EBP	Pasos Para Prevenir Cancer: Obesity-related Cancer Prevention in El Paso	Salinas, Jennifer J	Texas Tech University Health Sciences Center at El Paso	2.0	3	$1,244,512
PP180086	EBP	Liver Cancer Prevention am those with Experiences of Homelessness	Schick, Vanessa R	The University of Texas Health Science Center at Houston	2.3	4	$1,159,751
PP180082	EBP	West Texas HCV Screening and Linkage to Care Program	Gallegos, Patricia	Centro San Vicente	2.4	5	$1,349,700
PP180018	EBP	BSPAN4: Optimizing Spatial Access to High-Quality Breast Screening & Patient Navigation for Rural Underserved Women across North Texas	Craddick Lee, Simon	The University of Texas Southwestern Medical Center	2.5	6	$1,349,700

PP180077	TCL	Increasing Access to Smoking Cessation and Smoke Free Home Services for Low-Income Pregnant Women in Northeast Texas	Blalock, Janice A	The University of Texas M. D. Anderson Cancer Center	2.6	7	$1,346,919
PP180092	TCL	Tobacco Services for Primary Care & Cancer Patients at UT Health San Antonio	Ramirez, Amelie G	The University of Texas Health Science Center at San Antonio	2.6	8	$1,324,982
PP180012	EBP	Vaccinating medically underserved women against HPV	Berenson, Abbey B	The University of Texas Medical Branch at Galveston	2.7	9	$1,344,926
PP180089	EPS	Adolescent Vaccination Program (AVP): Expanding a Successful Clinic-based Multicomponent HPV Vaccination Program to the San Antonio Area	Vernon, Sally W	The University of Texas Health Science Center at Houston	2.8	10	$1,598,468

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

Dr. Garcia responded to Oversight Committee members' questions, explaining that the work of PP180091 is similar to Dr. Turner's STOP-HCC project. She noted that projects often target specific populations, for example the homeless population served by PP180086. When the Prevention program staff see opportunities for collaboration between projects serving the same counties, staff coordinates and encourages communication. Maps with the number of projects by county are on the CPRIT website and applicants use these to apply to cover counties not well represented in the prevention program portfolio. Dr. Garcia directed the Oversight Committee members to the "Counties of Residence Served by the 10 Recommended Prevention Projects" (page 101 of the Proposed Grants Awards book).

Compliance Certification

Presiding Officer Montgomery reminded members that Mr. Burgess previously certified compliance of the prevention awards process, as reported by Mr. Nance.

Conflict of Interest Notification

Presiding Officer Montgomery noted that Mr. Margo reported a conflict of interest with one of the applications under consideration, PP180091.

Presiding Officer Montgomery suggested that, unless a member objected, the Oversight Committee consider all the prevention award recommendations together in one vote except for the proposed award to PP180091, which the committee would vote on separately. No member objected.

MOTION:
On a motion made by Dr. Patel and seconded by Mr. Angelou, the Oversight Committee unanimously voted to approve the PIC's recommendation for the grant application PP180091.

Presiding Officer Montgomery noted for the record that Mr. Margo did not vote on this recommendation.

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

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

Proposed Plan for RFAs for FY 2019 Cycle 2

Dr. Garcia presented the FY 2019 Cycle 2 RFA release schedule and timeline (page 7-2) for consideration. The proposed RFAs in the schedule include Evidence-Based Cancer Prevention Services, Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations, and Tobacco Control and Lung Cancer Screening.

MOTION:
On a motion made by Dr. Rice and seconded by Mr. Angelou, the Oversight Committee unanimously voted to approve the Prevention Program's plan for proposed RFAs for the second cycle of FY 2019.

Communications Report

Dr. Garcia referred to her report in the meeting packet. She presented a redesigned Achievements Report, now called the Momentum Report. In addition to updated program statistics, the new document features a grant story from each program. She noted that the communication staff are working with IT on the new website roll-out tentatively scheduled for release in late November.

There were no questions for Dr. Garcia.

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

Presiding Officer Montgomery recognized Mr. Roberts to present four appointees to CPRIT's Scientific Research Program Committees. Mr. Roberts recommended the peer review appointments for Oversight Committee approval. He noted that CPRIT provided the appointee's biographical information in the meeting packet (pages 8-3 – 8-22) and that the Nominations Subcommittee recommended approval of the appointments.

There were no questions for Mr. Roberts.

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

Advisory Committee on Clinical Trials Appointments – Agenda Item 12 – Tab 9

Mr. Roberts presented two appointees to CPRIT's Advisory Committee on Clinical Trials. He recommended the two appointees to join the six members appointed in May 2018 by the Oversight Committee. Mr. Roberts referred members to the appointees' biographical information CPRIT provided in the meeting packet (pages 9-3 – 9-22).

There were no questions for Mr. Roberts.

MOTION:
On a motion by Dr. Rice and seconded by Mr. Angelou, the Oversight Committee unanimously voted to approve the two Clinical Trials Advisory Committee appointments.

FY 2019 Honoraria Policy - Agenda Item 13 – Tab 10

Mr. Roberts presented the FY 2019 honoraria policy, noting there are no substantive changes to the policy adopted for FY 2018.

There were no questions for Mr. Roberts.

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

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

Mr. Roberts presented conflict of interest waivers for Don Brandy, Dr. Becky Garcia, Dr. John Hellerstedt, Presiding Officer Will Montgomery, and a general waiver for review council members in exceptional circumstances. He referred members to pages *** in the meeting packet.

There were no questions for Mr. Roberts.

MOTION:
On a motion made by Dr. Rice and seconded by Mr. Margo, the Oversight Committee unanimously voted to approve the proposed Health & Safety Code Section 102.1062 waivers.

Presiding Officer Montgomery abstained from voting.

Amendments to 25 T.A.C. Chapters 701 - 703 – Agenda Item 16 – Tab 13

CPRIT Staff Attorney Cameron Eckel presented the final order approving amendments to Chapters 701 and 703. She reported that the Board Governance subcommittee recommended final approval for amendments to Texas Administrative Code Chapter 701 and 703, preliminarily approved by the

Oversight Committee at its May meeting. In addition, Ms. Eckel presented new proposed amendments to Chapter 703. She reported that the Board Governance subcommittee recommended that the Oversight Committee approve publication in the *Texas Register* of five proposed rule changes to Texas Administrative Code Chapter 703. She also noted that CPRIT followed the new process put in place by the Office of the Governor to submit the proposed rule changes to the Governor before publishing the proposal in the *Texas Register*.

MOTION:
On a motion by Dr. Rice and seconded by Mr. Margo, the Oversight Committee unanimously voted to approve the final orders adopting rules changes to the Texas Administrative Code Chapters 701 and 703.

There were no questions for Ms. Eckel.

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

Amendments to the Oversight Committee Bylaws and Code of Conduct – Agenda Item 17 – Tab 14

CPRIT General Counsel Kristen Doyle explained a proposed revision to the Oversight Committee bylaws necessary to align the bylaws with a change made to CPRIT's statute during the 2017 legislative session. The proposed change removes a requirement that Oversight Committee members disclose and post political contributions on CPRIT's website. The legislature repealed the requirement from CPRIT's statue in 2017.

There were no questions for Ms. Doyle.

MOTION:
On a motion by Dr. Rice and seconded by Mr. Margo, the Oversight Committee unanimously voted to approve the change to the Oversight Committee Bylaws and Code of Conduct.

Chief Operating Officer Report – Agenda Item 18 – Tab 15

Ms. McConnell presented the Chief Operating Officer's report. She reported that CPRIT submitted its legislative appropriations request (LAR) on August 3. She noted that prior to the LAR's submission, the audit subcommittee confirmed it was consistent with the Oversight Committee's discussion at the May meeting. Ms. McConnell reminded members that the LAR includes two exceptional items related to general revenue and additional IT staff. She reported that the Legislative Budget Board and Governor Office have scheduled a September 4 hearing on the LAR.

Ms. McConnell discussed the FY 2019 operating budget, which CPRIT has adjusted for additional IT needs identified by the IT security audit. Ms. McConnell explained CPRIT's request to transfer funds form the Award Cancer Research Grants to Indirect Administration line.

There were no questions for Ms. McConnell.

Contract Approvals – Agenda Item 19 – Tab 16

Ms. McConnell summarized the three recommended contracts presented for approval: Hahn Public Communications for strategic communications, The Perryman Group for the economic assessment for cost of cancer (contract renewal), and Weaver and Tidwell for internal audit services (contract renewal).

There were no questions for Ms. McConnell.

MOTION:
On a motion by Dr. Rice and seconded by Mr. Margo, the Oversight Committee unanimously voted to approve contract and contract renewals with Hahn Public Communications, The Perryman Group, and Weaver and Tidwell.

Subcommittee Business – Agenda Item 20

Presiding Officer Montgomery announced the Board Governance Subcommittee's recommendation that Dr. Mahendra Patel fill the Board Governance chair position, which is vacant following the resignation of Amy Mitchell from the Oversight Committee.

MOTION:
On a motion by Dr. Rice and seconded by Mr. Angelou, the Oversight Committee unanimously voted to approve Dr. Patel as chair of the Board Governance Subcommittee.

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

Presiding Officer Montgomery noted that the Oversight Committee would not take up Item 21.

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

Presiding Officer Montgomery noted that the Oversight Committee will meet November 28, 2018. He also directed members to the FY 2019 meeting dates in the meeting packet behind Tab 17.

Mr. Margo reported that he had scheduling conflicts with some of the proposed meeting dates.

Internal Audit – Agenda Item 15 – Tab 12
Consultation with General Counsel – Agenda Item 22

Alyssa Martin, Internal Auditor, with Weaver and Tidwell presented her report, which included the FY 2018 Annual Internal Audit, the FY 2019 Audit Plan, the Audit Status report, the Internal Audit over Communications as well as the Follow-Up Procedures Reports over Procurement and P-Cards and Pre-Award Grant Management. She indicated that she would discuss the Follow-Up Procedures Report over IT Security with members in closed session.

Ms. Martin reported that it was a satisfactory Internal Audit Report with five findings, with only one that was high risk. Ms. Martin noted that CPRIT staff had already identified the issue and were

in the process of remedying it. She explained that she had presented all reports to the audit subcommittee and updated members on the two new audits, State Reporting and Budget and Planning, noting that the IT General Controls Audit has been deferred.

There were no questions for Ms. Martin.

Presiding Officer Montgomery announced that the Oversight Committee would go into closed session pursuant to Texas Open Meetings Act section 551.076 to discuss the security audit. He explained that to minimize the number of times the Oversight Committee would go into closed session, it would also take up Item No. 22 while in closed session to receive advice from counsel pursuant to Texas Open Meetings Act § 551.071. Presiding Officer Montgomery asked Ms. Martin and Dan Graves (Internal Auditors), Ms. McConnell, Ms. Doyle, Therry Simien, Ms. Eckel, and Mr. Roberts to join the Oversight Committee in the closed session.

Presiding Officer Montgomery convened the closed session at 11:57 a.m. and reconvened the open meeting at 12:23 p.m. He reported that the Oversight Committee would not take action on Agenda Item 22.

MOTION:
On a motion by Dr. Rice and seconded by Mr. Margo, the Oversight Committee unanimously voted to approve the Communications internal audit report and the three follow-up reports.

MOTION:
On a motion by Dr. Rice and seconded by Mr. Margo, the Oversight Committee unanimously voted to approve the FY 2019 Audit Plan.

MOTION:
On a motion by Dr. Rice and seconded by Mr. Margo, the Oversight Committee unanimously voted to approve the FY 2018 Internal Audit Annual Report.

Presiding Officer Montgomery reminded members that the next meeting will be November 28.

Adjourn – Agenda Item 27

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

Meeting adjourned at 12:26 p.m.

_____ _____

Signature Date

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: Schiavinato Eberlin, Livia

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

POSITION TITLE: Assistant Professor

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
State University of Campinas, UNICAMP, Campinas, São Paulo, Brazil	B.S.	12/07	Chemistry
Purdue University, West Lafayette, IN, USA	Ph.D.	07/12	Analytical Chemistry
Stanford University	Postdoctoral	12/15	Chemistry

A. Personal Statement

I am a chemist passionate about research at the interface of chemistry and medicine. Molecular analysis by ambient ionization mass spectrometry (MS) is powerful for biomedical research. I have broad background in analytical chemistry with specific training and expertise in MS. I have experience designing and leading basic and translational research projects through which I have managed collaborative teams of surgeons, pathologists, oncologists, biologists, and statisticians to develop new chemical methods for tissue imaging and cancer diagnosis. I have successfully competed for research funding from several sources including the NIH. Through my career, I contributed to advancing the emerging ambient ionization MS field to its current state: pioneering ambient ionization MS for the diagnosis of human cancer, developing novel methods for histologically compatible MS imaging, multimodal MS imaging, drug distribution imaging and 3D ambient molecular imaging, identifying diagnostic metabolic patterns of cancer related to oncogene expression, adapting refined statistical tools to build classification models from MS imaging data, and pioneering the intrasurgical use of ambient ionization for surgical margins evaluation. My career goal is to develop novel technology to improve human health. In particular, I am very enthusiastic about the research proposed in this R33. The MasSpec Pen technology has incredible potential to be used in the operating room for near real time cancer diagnosis and surgical margin evaluation. Here, we propose to rigorously test and validate this technology for clinical use. Our team is poised and enthusiastic to pursue this validation study aiming at implementing the MasSpec Pen in clinical practice in breast and pancreatic cancer surgeries.

Key publications that exemplify my work:

1. Zhang J., Rector J., Lin J., Young J.H., Sans M., Katta N., Giese N., Yu W., Nagi C., Suliburk J., Liu J., Bensussan A., DeHoog R.J., Garza K.Y., Ludolph B., Sorace A.G., Syed A., Zahedivash A., Milner T.E., and **Eberlin L.S.** (2017). Nondestructive Tissue Analysis for Ex Vivo and In Vivo Cancer Diagnosis using a Handheld Mass Spectrometry System, *Science Translational Medicine*, 9, eaan3968.
2. Zhang J., Yu W., Ryu S., Lin J., Buentello G., Tibshirani R., Suliburk J., **Eberlin L.S.** (2016). Cardiolipins are biomarkers of mitochondria-rich thyroid oncocytic tumors. *Cancer Research*, 76, 6588-6597.
3. Porcari A.M., Zhang J., Garza K.Y., Rodrigues-Peres R.M., Lin J.Q., Young J.H., Tibshirani R., Nagi C., Paiva G.R., Carter S.A., Sarian L.O., Eberlin M.N., and **Eberlin L.S.**, (2018) A Multi-Center Study Using Desorption Electrospray Ionization Mass Spectrometry Imaging for Breast Cancer Diagnosis. *Analytical Chemistry*, 90, 11324-11332.
4. **Eberlin L.S.**, Margulis K., Planell-Mendez I., Zare R.N., Tibshirani R., Longacre T.A., Jalali M., Norton J.A., Poultsides G.A. (2016). Pancreatic Cancer Surgical Resection Margins: Molecular Assessment by Mass Spectrometry Imaging. *Plos Medicine*, 13, e1002108.

B. Research and/or Professional Experience:

i. Employment

2005-2007	Undergraduate Research Assistant, Thomson Laboratory for Mass Spectrometry (Prof. Marcos Eberlin), Department of Chemistry, State University of Campinas, São Paulo, Brazil
2005-2007	Undergraduate Research Assistant (summers), Aston Laboratory for Mass Spectrometry (Prof. R. Graham Cooks), Department of Chemistry, Purdue University, IN, USA
2008	Analytical Chemist, Spectrum Inc., Campinas, São Paulo, Brazil
2008-2009	Graduate Teaching Assistant, Department of Chemistry, Purdue University, IN
2009-2012	Graduate Research Assistant, Aston Laboratory for Mass Spectrometry (Prof. R. Graham Cooks), Department of Chemistry, Purdue University, IN
2012-2015	Postdoctoral Researcher, Prof. Richard N. Zare's Laboratory, Department of Chemistry, Stanford University, CA
2016-current	Assistant Professor, Department of Chemistry, The University of Texas at Austin
2016-current	Adjunct Assistant Professor, Department of Surgery, Baylor College of Medicine

ii. Honors

2005	Brazilian Research Development National Council (CNPq) Undergraduate Fellowship, Brazil
2008	Lavoisier Award, Best Undergraduate Student in Chemistry Class of 2007, São Paulo, Brazil
2009	Women in Science Program Travel Award, Purdue University, IN, USA
2011	Eastman Chemical Company Travel Award in Analytical Chemistry, USA
2011	American Chemical Society (ACS) Summer Fellowship, USA
2011	Amy Travel Award, Purdue University, IN, USA
2012	Alice Watson Kramer Research Scholar, Purdue University, IN, USA
2012	M.G. Mellon Award in Analytical Chemistry, Purdue University, IN, USA
2012	Stanford Cancer Institute Innovation Award, Stanford University, Stanford, CA, USA
2013	Center for Molecular Analysis and Design Postdoctoral Fellowship, Stanford University, CA,USA
2013	Helena Anna Henzl-Gabor Young Women in Science Fund Travel Fellowship, Stanford University, CA, USA
2014	Nobel Laureate Signature Award for Graduate Education in Chemistry from the American Chemical Society (ACS), USA
2014	L'Oréal USA for Women in Science Fellowship, USA
2014	Named among The Analytical Scientist's Top 40 under 40 Power List
2015	Named among "Forbes' 30 under 30" list in Healthcare, USA
2015	K99 Pathway to Independence Award (NCI/NIH), USA
2016	AAAS Marion Milligan Mason Award for Women in the Chemical Sciences, USA
2017	Named a "Science Super Hero" by Discovery Channel
2018	Named among "2018's Incredible Women" list by Porter Magazine
2018	Sloan Research Fellow
2018	MacArthur Fellow

iii. Professional Societies and Public Advisory Committees

2005-*present*	Member of the Brazilian Society for Mass Spectrometry (BrMASS)
2008-*present*	Member of the American Society for Mass Spectrometry (ASMS)
2012-*present*	Member of the American Chemical Society (ACS)
2013-*present*	Reviewer for journals *Analytical Chemistry*, *Journal of Mass Spectrometry*, *Rapid Communications in Mass Spectrometry,International Journal for Mass Spectrometry*, *PNAS*.

C. Contribution to Science (*Listed below the key manuscripts from a total of 60 manuscripts*)

1. **Developed Ambient Ionization Mass Spectrometry Technology for Biological Tissue Imaging:** I have developed approaches using desorption electrospray ionization mass spectrometry imaging (DESI-MSI) in order to make the technology broadly applicable and compatible with other imaging techniques for tissue analysis, as well as to enable 3D molecular imaging. Ambient ionization is an exciting field in MS that allows in situ analysis of samples with minimal pretreatment, in the open air. DESI-MSI, the first ambient MS

technique developed, is particularly powerful for imaging the distribution of small molecules from biological samples. I have applied DESI-MSI to image human cancerous tissue and examine their molecular patterns through the development of histologically compatible solvent systems. Using this approach, DESI-MSI is performed while preserving tissue integrity. The same tissue section is sequentially subjected to histochemistry for unambiguous correlation between molecular information and tissue morphology. I further integrated DESI-MSI, MALDI-MSI, and, more recently, ion mobility mass spectrometry, to image lipids and proteins of a single mouse brain tissue section, and correlated their distributions with tissue morphology. These advances allow DESI-MSI to be inserted into an analytical workflow dealing with tissue analysis for comprehensive evaluation of tissue molecular composition and have been used by many research groups.

a. **Eberlin LS**, et al. (2011) Desorption Electrospray Ionization then MALDI Mass Spectrometry Imaging of Lipid and Protein Distributions in Single Tissue Sections. Anal. Chem. 83(22):8366-8371.
b. **Eberlin LS**, et al. (2011) Non-Destructive, Histologically Compatible Tissue Imaging by Desorption Electrospray Ionization Mass Spectrometry. ChemBioChem 12(14):2129-2132.
c. **Eberlin LS**, Ifa DR, Wu C, & Cooks RG (2010) Three-Dimensional Vizualization of Mouse Brain by Lipid Analysis Using Ambient Ionization Mass Spectrometry. Angew. Chem.-Int. Edit. 49(5):873-876.
d. **Eberlin LS**, Ferreira CR, Dill AL, Ifa DR, & Cooks RG (2011) Desorption electrospray ionization mass spectrometry for lipid characterization and biological tissue imaging. Biochim. Biophys. Acta Mol. Cell Biol. Lipids 1811:946-960.

2. **Developed DESI-MSI for molecular characterization of brain cancers and surgical margin evaluation:** In collaboration with researchers from the Brigham and Women's Hospital (BWH) at Harvard Medical School, I have demonstrated that DESI-MSI can make a significant contribution to brain cancer diagnosis and to guide surgical resection. We developed a system to rapidly analyze and classify ex-vivo brain tumor tissue based on lipid information acquired by DESI-MSI. Using multivariate statistical analysis, classification models were built to distinguish human meningioma and glioma samples, including glioma subtypes, histologic grades and tumor cell concentration. The results revealed a robust capacity to provide diagnostic information from banked glioma samples. We then pioneered the use of the technology for tumor margin assessment. DESI-MSI results of stereotactically registered samples were correlated to pre-operative MRI, and visualized over segmented 3D MRI tumor volume reconstruction. In addition, we used DESI-MSI to detect the oncometabolite 2-hydroxygluterate (2HG) from glioma tissue. Remarkably, detection of 2HG by DESI-MSI allowed accurate determination of IDH1 status in gliomas, even when immunohistochemistry was not useful. This innovative research powerfully demonstrated DESI-MSI's potential for brain tumor diagnosis, and laid the groundwork for the studies I and other scientists have pursued in oncology.

a. **Eberlin LS**, et al. (2010). Discrimination of Human Astrocytoma Subtypes by Lipid Analysis Using Desorption Electrospray Ionization Imaging Mass Spectrometry. Angew. Chem. Int. Ed. 49(34):5953-5956.
b. **Eberlin LS**, et al. (2012). Classifying human brain tumors by lipid imaging with mass spectrometry. Cancer Res. 72(3):645-654.
c. **Eberlin LS**, et al. (2013). Ambient mass spectrometry for the intraoperative molecular diagnosis of human brain tumors. Proc. Natl. Acad. Sci. USA 110(5):1611-1616.
d. Santagata S*, **Eberlin LS***, et al. (2014). Intraoperative mass spectrometry mapping of an onco-metabolite to guide brain tumor surgery. Proc. Natl. Acad. Sci. USA 111(30): 11121-11126. (*equal contribution)

3. **Developed DESI-MSI and machine learning algorithms for gastrointestinal cancers diagnosis and surgical margin evaluation:** At Stanford University, I developed an approach using DESI-MSI and the Lasso statistical technique to analyze and classify tissue as cancerous or normal. The novel use of the Lasso technique provided key advantages in selecting molecular features that are indicative of disease state, and in building sparse classification models. Our method showed an overall accuracy values higher than 97% for gastric and pancreatic cancers. It also selected 120 m/z species as statistically significant, many of which were identified as phospholipids and metabolites. I then tested our method on the margin samples prospectively collected from gastric and pancreatic cancer operations. The results showed that our molecular approach was powerful for assessing margin status even when histopathologic evaluation was unclear.

These groundbreaking studies successfully demonstrate that the technology I have developed has immediate application in the operating room for better treating human cancers.

a. **Eberlin LS**, et al. (2014). Molecular assessment of surgical-resection margins of gastric cancer by mass-spectrometric imaging. Proc. Natl. Acad. Sci. USA 111(7):2436-2441.
b. **Eberlin LS**, et al. (2015). Pancreatic Cancer Surgical Resection Margins: Molecular Assessment by Mass Spectrometry Imaging. Plos Medicine, 13, e1002108.
c. Ifa DR, **Eberlin LS** (2016). Ambient Ionization Mass Spectrometry for Cancer Diagnosis and Surgical Margin Evaluation, Clin. Chem., 62(1), 111-123.
d. Zhang J., Yu W., Suliburk J., and **Eberlin L.S.** (2016). Will ambient ionization mass spectrometry become an integral technology in the operating room of the future?, Clin. Chem., 62 (9), 1172-1174.

4. **Identified distinct lipid signatures in MYC-induced cancers:** In collaboration with scientists at Stanford University, I have demonstrated that gene-specific lipid signatures can be directly detected from cancer tissue by DESI-MSI. Using conditional transgenic mouse models, high mass resolution/mass accuracy DESI-MSI, statistical analysis, and molecular biology approaches, a relationship between lipid metabolism and the overexpression of the MYC oncogene was observed in MYC-induced lymphomas, hepatocellular carcinomas, and renal cell carcinomas. MYC functions as a global regulator of transcription involving cellular programs, such as cellular growth, metabolism, and lipid synthesis. Detection of aberrant metabolic signatures should be a useful approach to diagnose MYC-associated tumors. To test this idea, I analyzed transgenic mouse models that conditionally expressed the MYC oncogene. Using DESI-MSI, I identified a lipid signature characteristic of MYC-induced cancers, characterized by overexpression of complex phospholipids, in particular, glycerophospholipids. Our results suggest that there is a relationship between lipid metabolism and MYC expression. Through this approach, I identified 86 molecules as glycerophospholipids not previously associated with lymphomas. These molecules have potential value as diagnostic and prognostic markers.

   a. **Eberlin LS**, et al. (2014) Alteration of the Lipid Profile in Lymphomas Induced by MYC Overexpression. Proc. Natl. Acad. Sci. USA 111(29): 10450-10455.
   b. Shroff EH, **Eberlin LS**, et al. (2015) Oncogene overexpression drives renal cell carcinoma in a mouse model through glutamine metabolism. Proc. Natl. Acad. Sci. USA 112(21):6539-44.

5. **Developed high-performance mass spectrometry approaches for cancer diagnosis and surgical margin evaluation.** As an independent investigator, my laboratory has been developing refined ambient ionization mass spectrometry techniques for cancer diagnosis and clinical use. We are combining mass spectrometry imaging with high-performance mass spectrometers that allow high mass-resolution and high mass-accuracy measurements from tissues. We have used this approach to molecularly characterize oncocytic thyroid cancer, and have discovered a unique molecular signature characterized by the overexpression of multiply-charged cardiolipins and oxidized cardiolipins. These novel molecules had not yet been described in any human tissue. We combined ambient ionization mass spectrometry to ion mobility mass spectrometry which has enables us to image cardiolipins in thyroid cancers with higher analytical performance. Concomitantly, we have used this technology to image proteins and lipids in ovarian cancers. Lastly, we have recently developed the MasSpec Pen technology for *ex vivo* and *in vivo* cancer diagnosis.

   a. Zhang J., Rector J., Lin J., Young J.H., Sans M., Katta N., Giese N., Yu W., Nagi C., Suliburk J., Liu J., Bensussan A., DeHoog R.J., Garza K.Y., Ludolph B., Sorace A.G., Syed A., Zahedivash A., Milner T., and **Eberlin L.S.** (2017). Nondestructive Tissue Analysis for Ex Vivo and In Vivo Cancer Diagnosis using a Handheld Mass Spectrometry System, *Science Translational Medicine*, 9, eaan3968.
   b. Sans M., Gharpure K., Tibshirani R., Zhang J., Liang L., Liu J., Sood A.K., **Eberlin L. S.** (2017). Metabolic Markers and Statistical Prediction of Serous Ovarian Cancer Aggressiveness by Ambient Ionization Mass Spectrometry Imaging. Cancer Research, 77, 2903-2913.
   c. Zhang J., Feider C. L., Nagi C., Yu W., Carter S. A., Suliburk J., Cao H. T. S., **Eberlin L.S.** (2017) Detection of Metastatic Breast and Thyroid Cancer in Lymph Nodes by Desorption Electrospray Ionization Mass Spectrometry Imaging. Journal of The American Society for Mass Spectrometry, 28, 1166-1174.

d. Zhang J., Yu W., Ryu S., Lin J., Buentello G., Tibshirani R., Suliburk J., **Eberlin L.S.** (2016). Cardiolipins are biomarkers of mitochondria-rich thyroid oncocytic tumors. Cancer Research, 76, 6588-6597.
e. Feider C.L., Elizondo N., **Eberlin L.S.** (2016) Ambient Ionization and FAIMS Mass Spectrometry for Enhanced Imaging of Multiply Charged Molecular Ions in Biological Tissues. Analytical Chemistry, 88, 11533-11541.

Complete List of Published Work in MyBibliography:
http://www.ncbi.nlm.nih.gov/sites/myncbi/1HoJjhI3kPvk4/bibliography/48238357/public/?sort=date&direction=ascending

D. Research Support

Ongoing Research Support

4R00CA190783-02 (NIH/NCI) Schiavinato Eberlin (PI) 04/2016-03/2019
Mass Spectrometry Imaging for Clinical Diagnosis and Prognosis of Human Cancers
The major goal of this project is to develop a handheld mass spectrometry tool for diagnosis and prognosis of human ovarian and breast cancer tissues and surgical margins.
Role: PI

F-1895 (Welch Foundation) Schiavinato Eberlin (PI) 06/2016-05/2019
Development of Ambient Ionization Ion Mobility Mass Spectrometry Imaging for Spatial and Chemical Lipids Analysis in Biological Samples
The major goal of this project is to develop an ion mobility approach integrated to ambient ionization mass spectrometry imaging technologies for comprehensive imaging of lipid species.
Role: PI

RP160776 (CPRIT) Schiavinato Eberlin (PI) 06/2016-11/2018
Rapid Molecular Diagnosis of Lung Cancer Biopsies by Ambient Ionization Mass Spectrometry
The goal of this project is to use ambient ionization mass spectrometry for analysis and diagnosis of lung biopsies.
Role: PI

Marion Mason Award (AAAS) Schiavinato Eberlin (PI) 01/2017-12/2018
Mass Spectrometry Imaging for Lipid-Based Diagnosis of Ovarian Cancers
The goal of this project is to developed ion mobility coupled to mass spectrometry imaging for lipid analysis and diagnosis of ovarian cancers.
Role: PI

RP170427 (CPRIT) Schiavinato Eberlin (PI) 01/2017-12/2020
Ambient Mass Spectrometry for Preoperative Molecular Diagnosis of Thyroid Fine Needle Aspirate Biopsies
The goal of this project is to use ambient ionization mass spectrometry for analysis and diagnosis of thyroid biopsies.
Role: PI

L'Oréal USA For Women in Science Schiavinato Eberlin (PI) 07/2018-12/2018
My Science ↔ My Life
Role: PI

FG-2018-10608 (Sloan Fellowship) Schiavinato Eberlin (PI) 09/2018-09/2020
Sloan Research Fellowship
Role: PI

UTA17-001327 LH (Merck) Schiavinato Eberlin (PI) 08/2018-02/2019
Discovery of Metabolomics Markers of Treatment with Immunotherapies in Syngeneic Tumor Models

Role: PI

Gordon & Betty Moore Foundation Schiavinato Eberlin (PI) 10/2018-9/20201
Advanced Development of the MasSpec Pen Technology for Open and Minimally Invasive Surgical Applications
Role: PI

Completed Research Support

Dell Medical School – THC Schiavinato Eberlin (PI) 01/2017-09/2018
Low-cost smart intraoperative imaging system for laparoscopic endometriosis surgery
Role: Co-PI

1K99CA190783-01 Schiavinato Eberlin (PI) 09/2015-12/2015
Mass Spectrometry Imaging for Clinical Diagnosis and Prognosis of Human Cancers
The major goal of this project was to use ambient ionization mass spectrometry for diagnosis of hepatocellular carcinomas in MYC-induced models and human tissues, and its use for surgical margin evaluation.
Role: PI

L'Oréal USA for Women in Science Fellowship Schiavinato Eberlin (PI) 11/01/14-06/30/15
"Mass Spectrometry Imaging for Clinical Diagnosis of Pancreatic Cancer"
The goal of this project are to develop mass spectrometry imaging as a clinical tool for rapid diagnosis and prognosis of human pancreatic cancer.
Role: PI

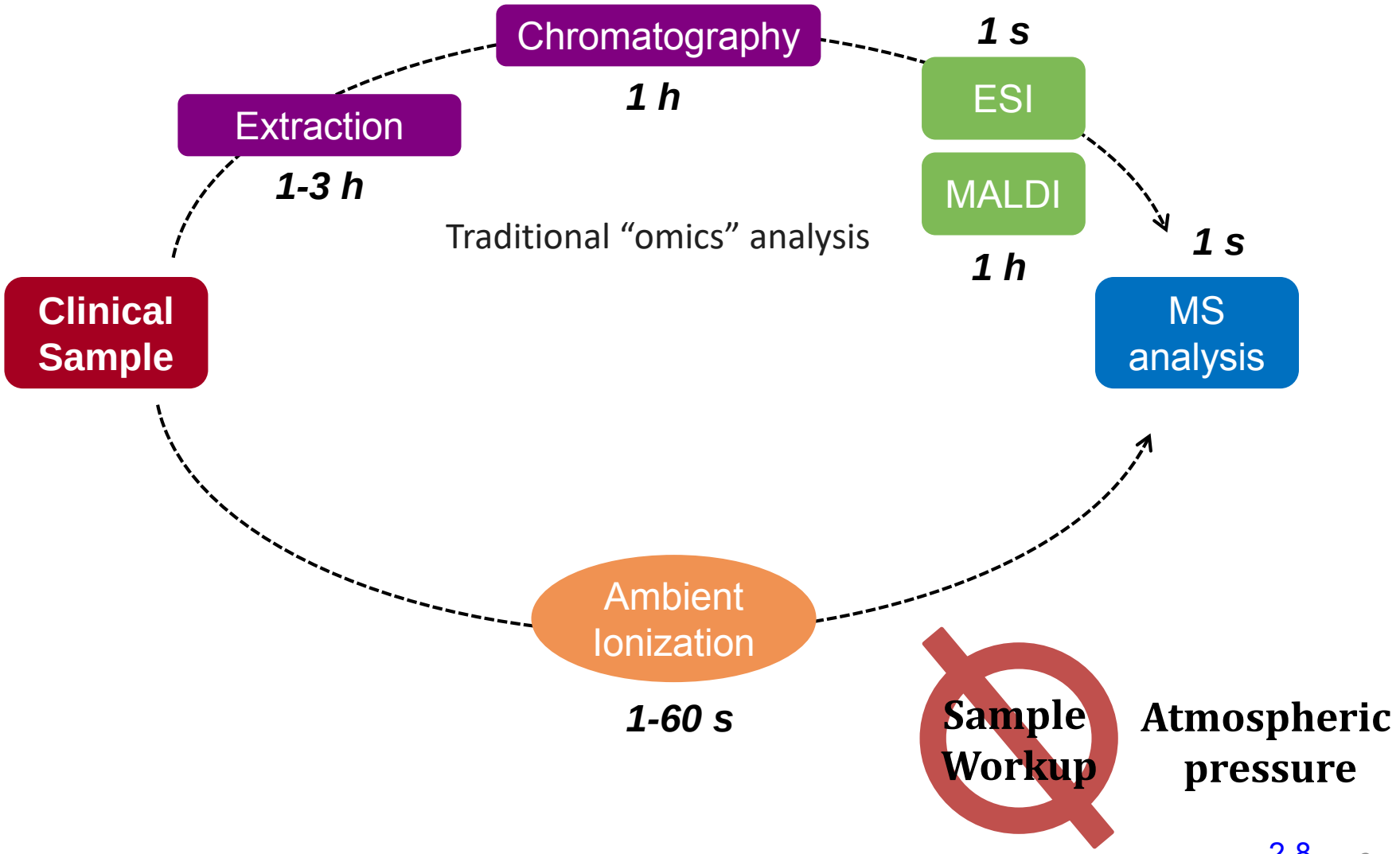
Ambient Ionization Mass Spectrometry for Cancer Research & Clinical Use

Livia Schiavinato Eberlin

Assistant Professor, Department of Chemistry - UT Austin
Adjunct Assistant Professor, Department of Surgery - Baylor College of Medicine

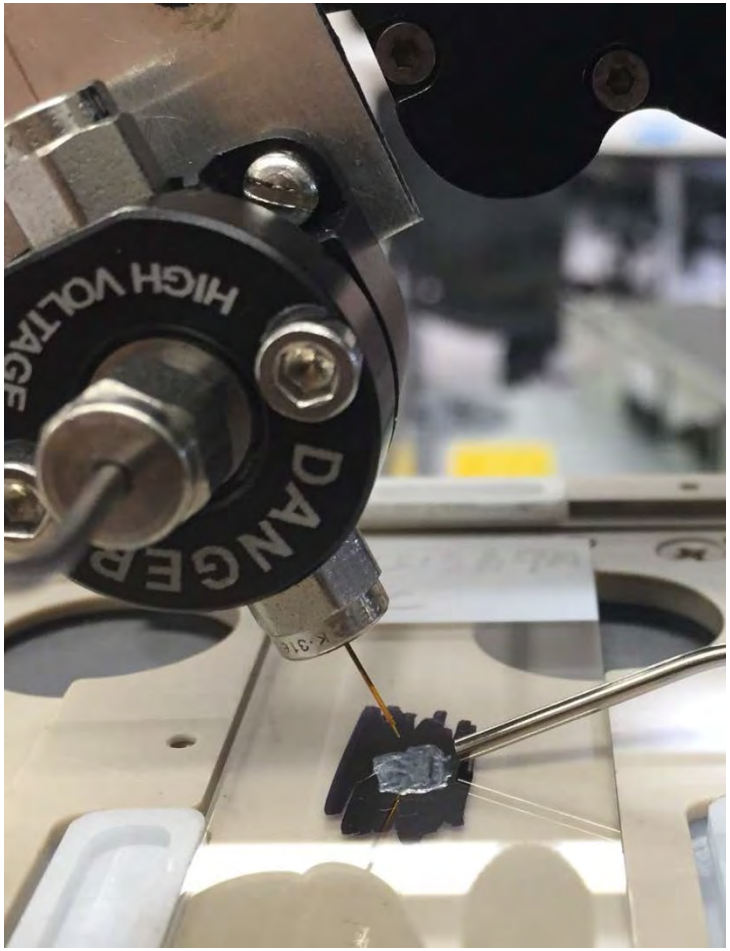
Ambient Ionization Mass Spectrometry

Analysis of complex, condensed-phase samples



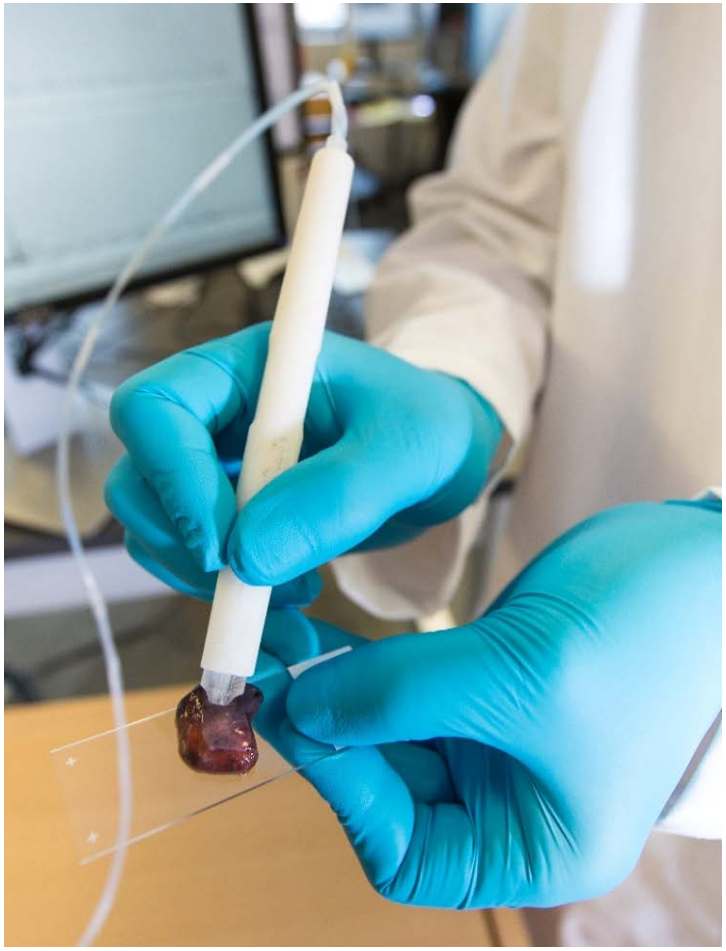
Ambient Ionization MS: Chemical Extraction

DESI-MS Imaging



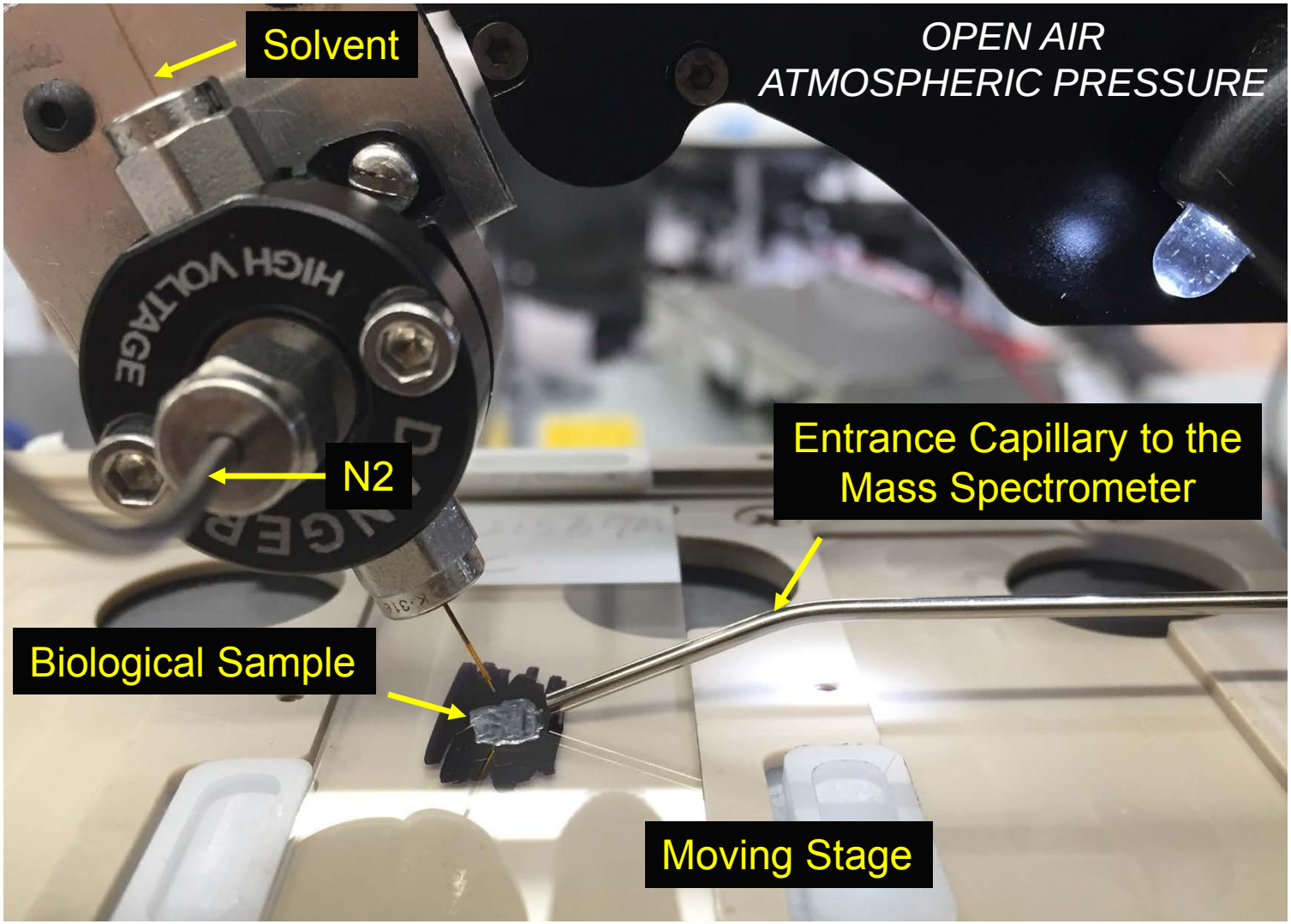
- Higher spatial resolution (100 µm)
- Ideal for Imaging/Analysis of planar samples
- Experimental optimization/expertise needed

MasSpec Pen



- Spot-by-spot analysis (2.7 mm)
- Ideal for in vivo, soft sample analysis
- Easy to use, no optimization

Desorption Electrospray Ionization (DESI-MS)

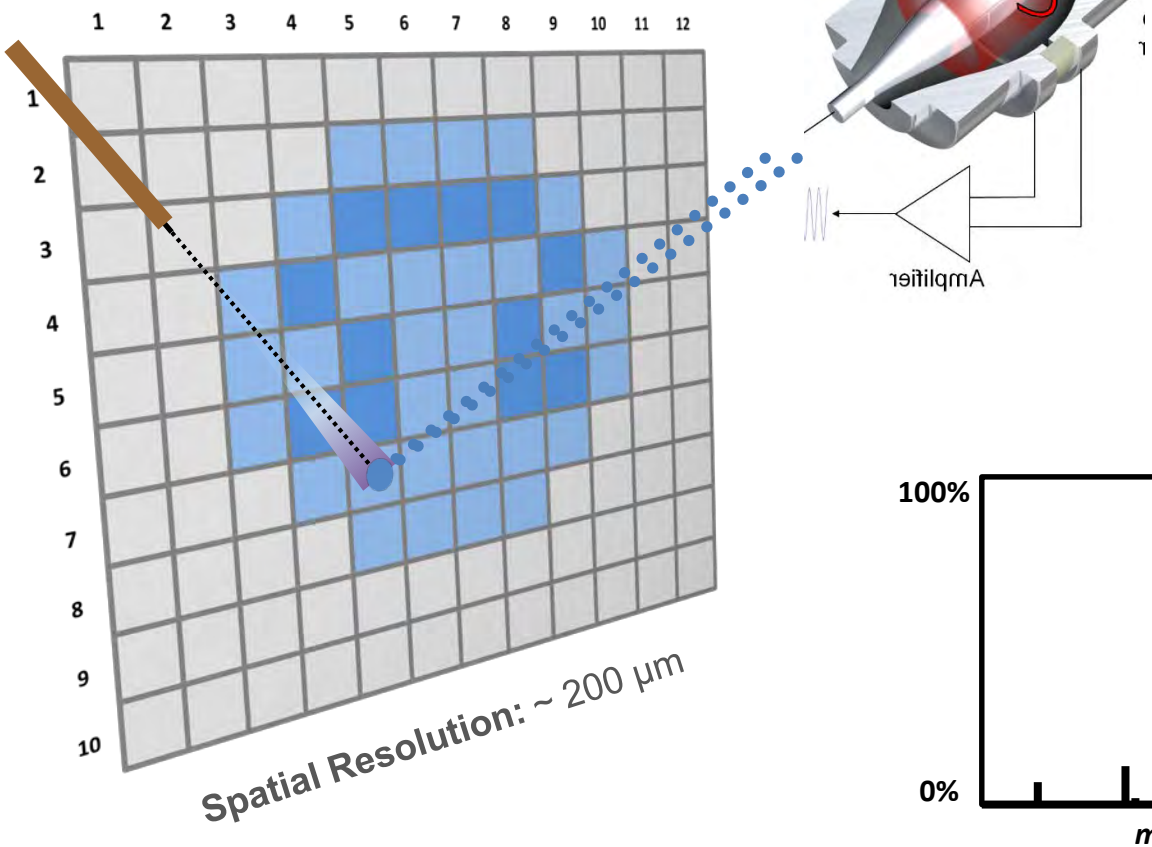


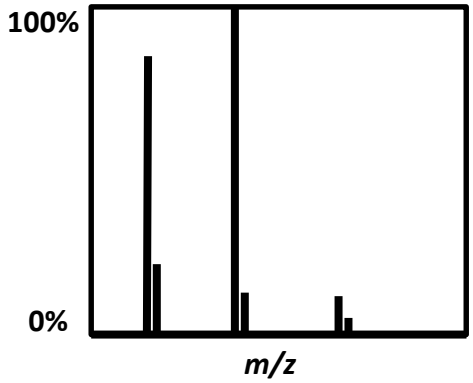
Takats Z, Wiseman JM, Gologan B, Cooks RG. Science. 2004;306(5695):471-34
Wiseman JM, Ifa DR, Song QY, Cooks RG. Angew Chem-Int Ed 2006;45(43):7188-92.

DESI-MS Imaging

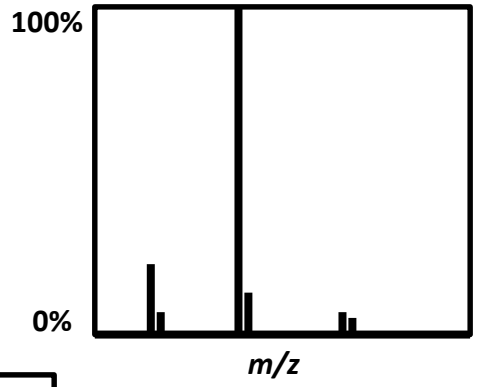
Mass spectra linked to spatial coordinates (x,y)

Orbitrap





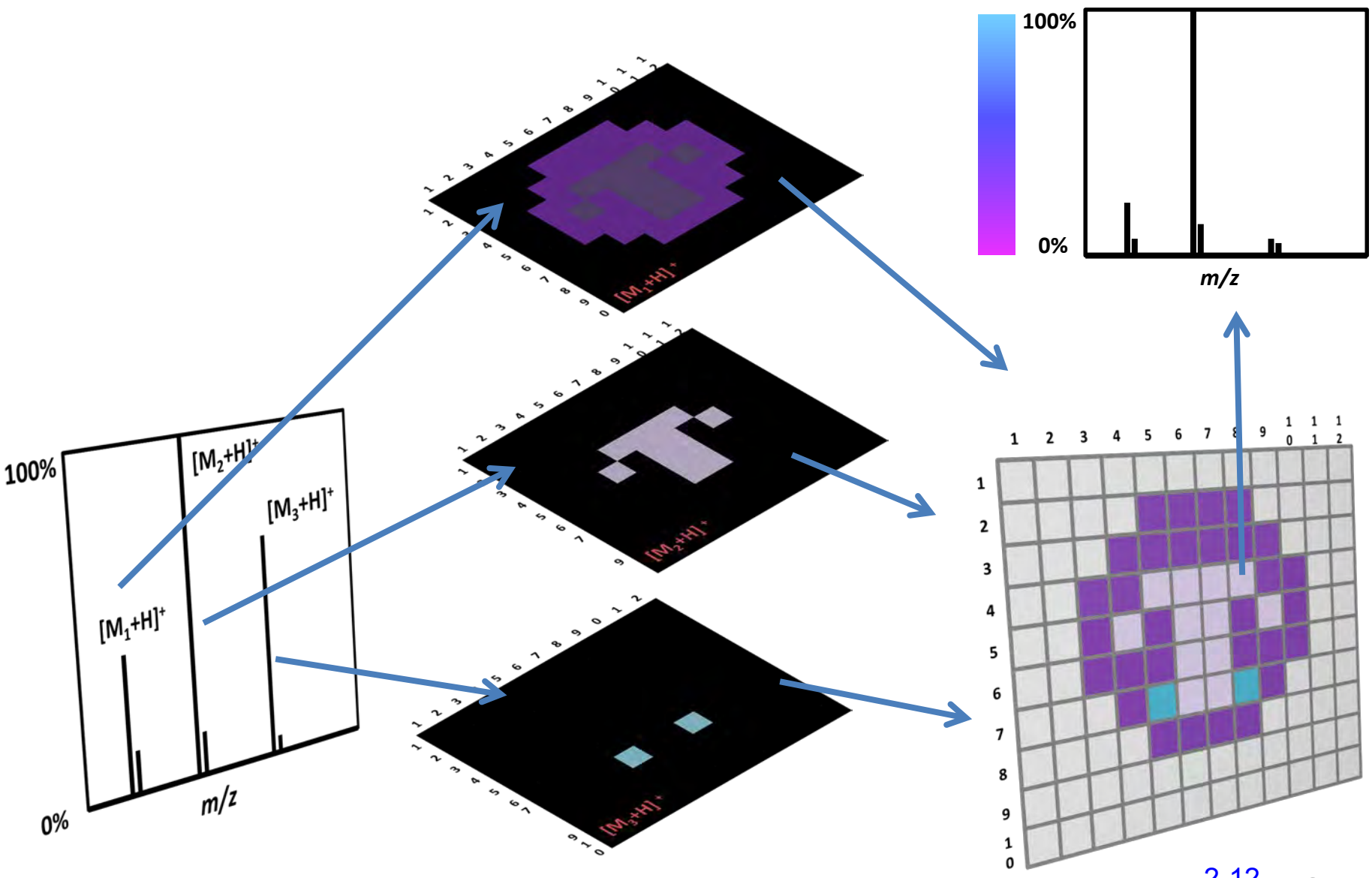
Pixel(4,4)



Pixel(5,4)

Pixel(5,7)

DESI-MS Imaging



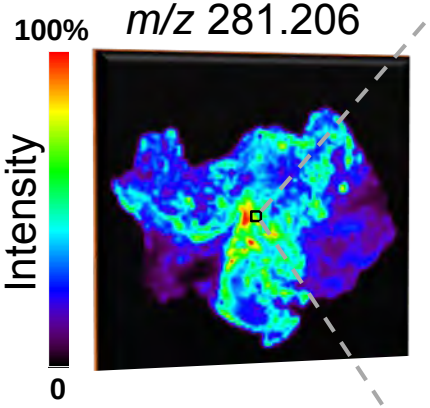
Molecular Data from Biological Tissues

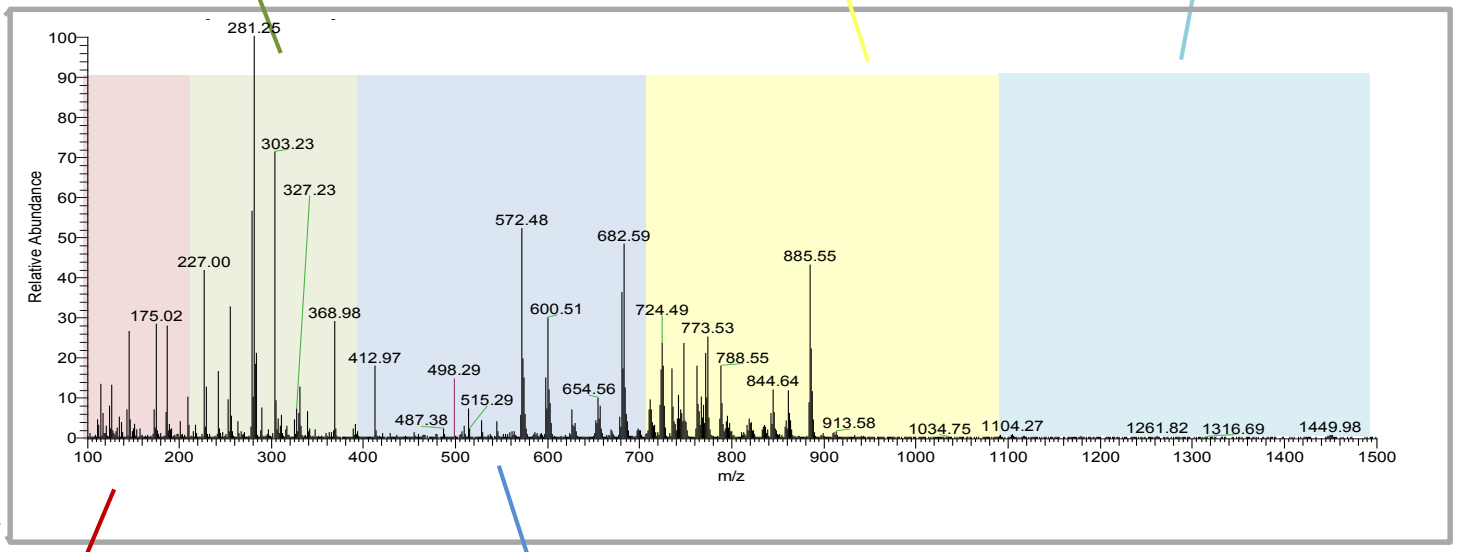
***m/z* 200-400**
- Free fatty acids
- Prostaglandins

***m/z* 700-1300**
- Phospholipids
- Glycerolipids
- Sphingolipids

***m/z* 1000-2000**
- Cardiolipins
- Gangliosides
- Proteins (<~15kDa)

2D ion image
m/z 281.206



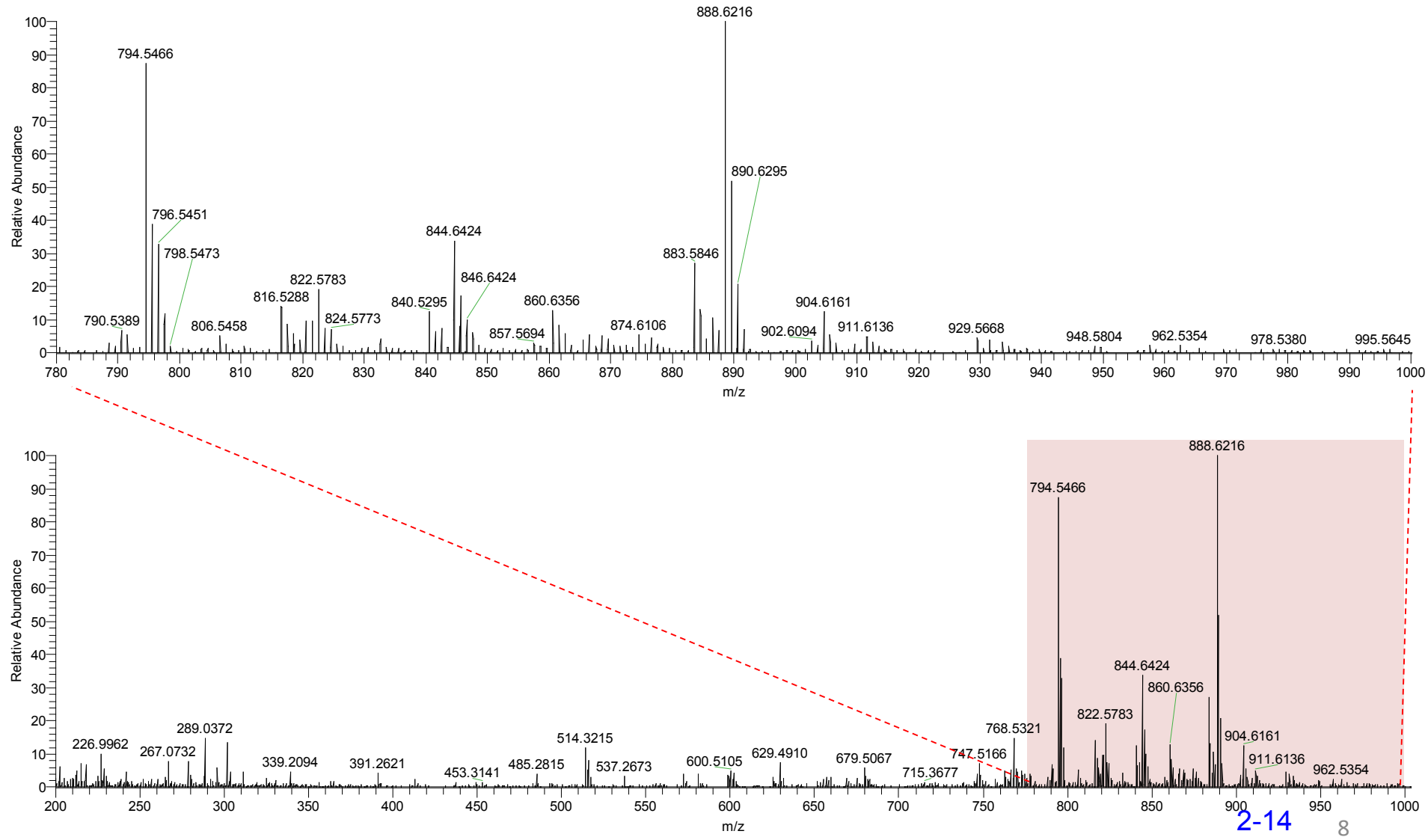


***m/z* 50-200**
- Primary and secondary metabolites
- Glutaminolysis
- Aerobic glycolysis
- Krebs cycle
- Amino acids

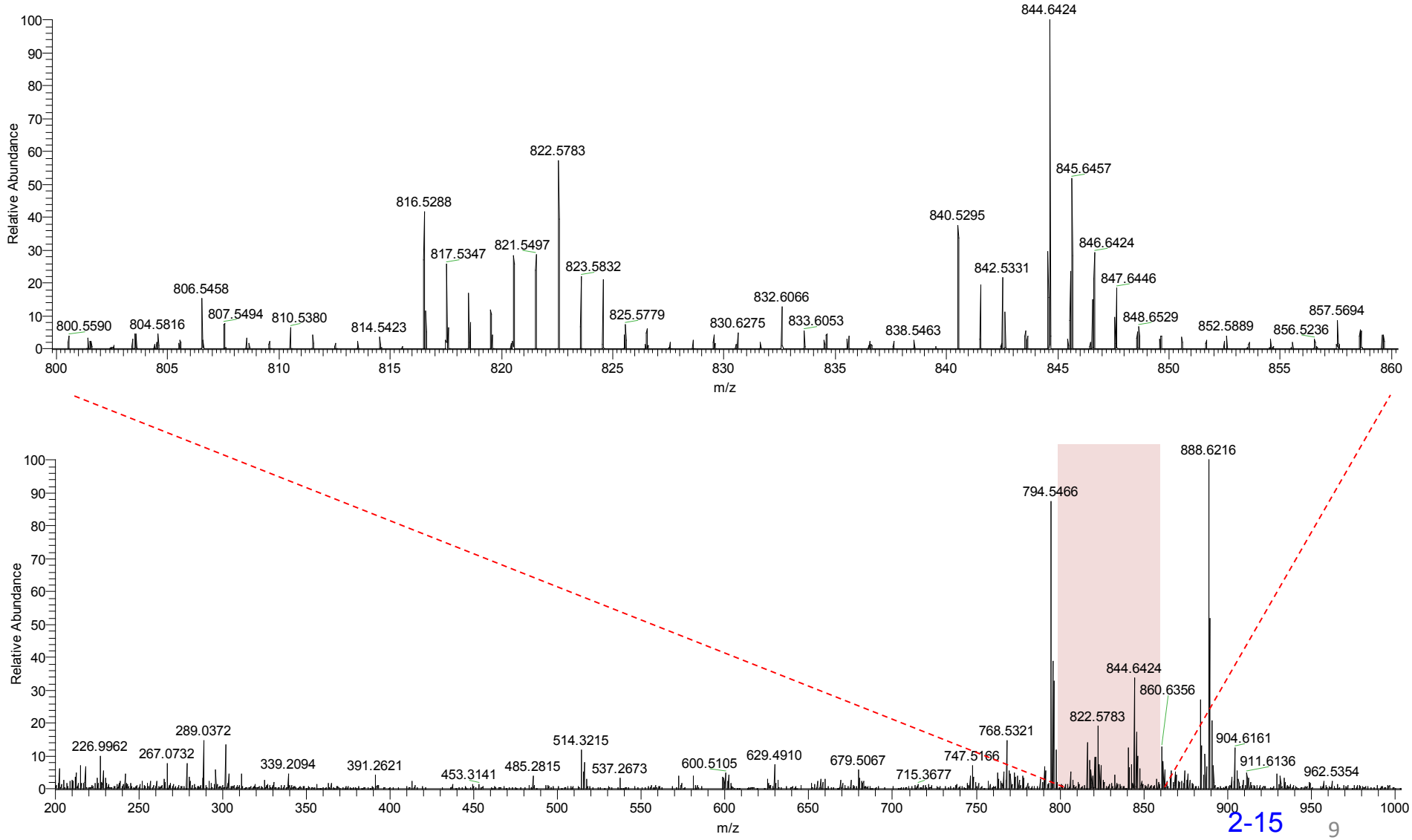
***m/z* 400-700**
- Fatty acid dimers
- Sterol lipids and derivatives
- Lyso-lipids
- Ceramides

Molecular Data from Biological Tissues

- How much molecular information do we get? Modest 60,000 resolving power

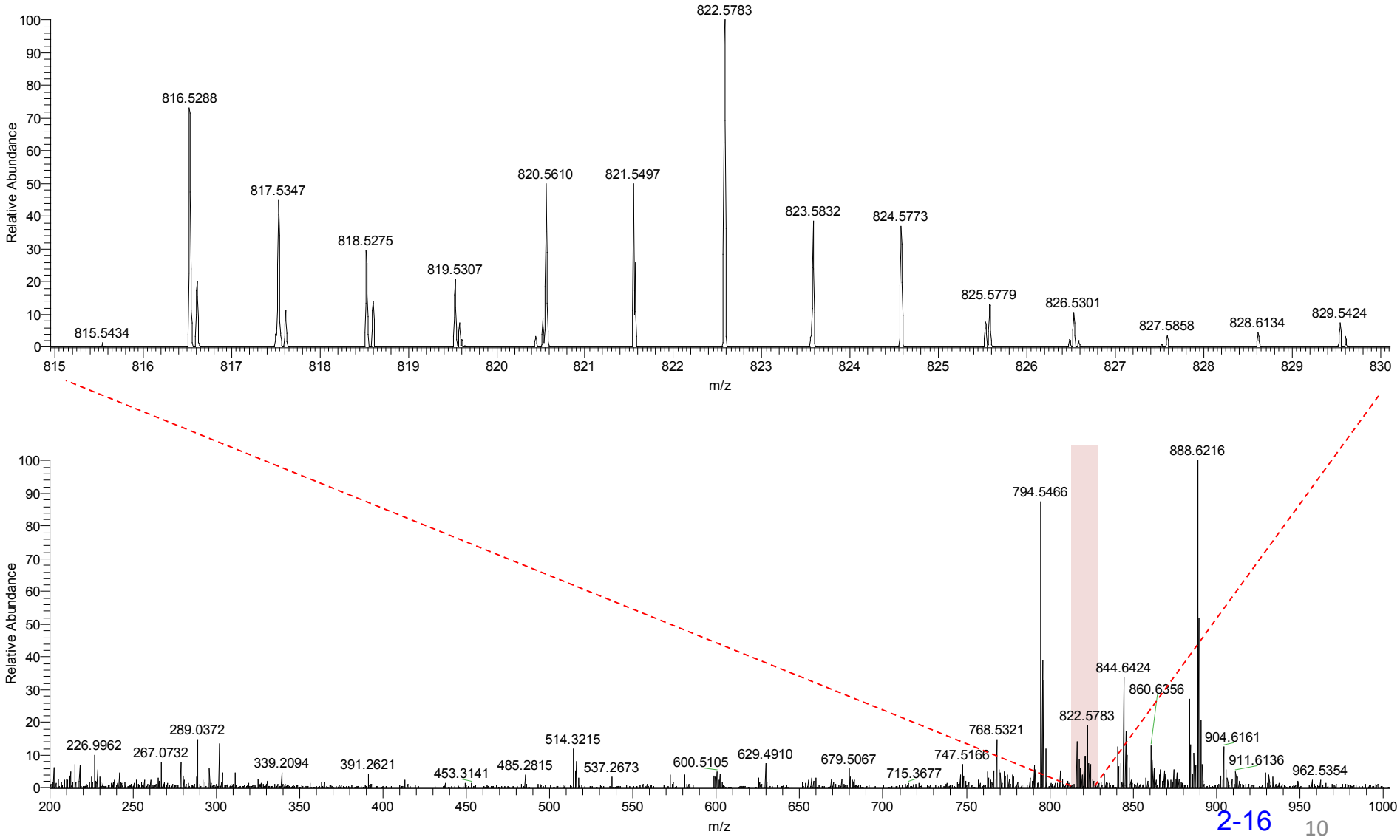


Molecular Data from Biological Tissues

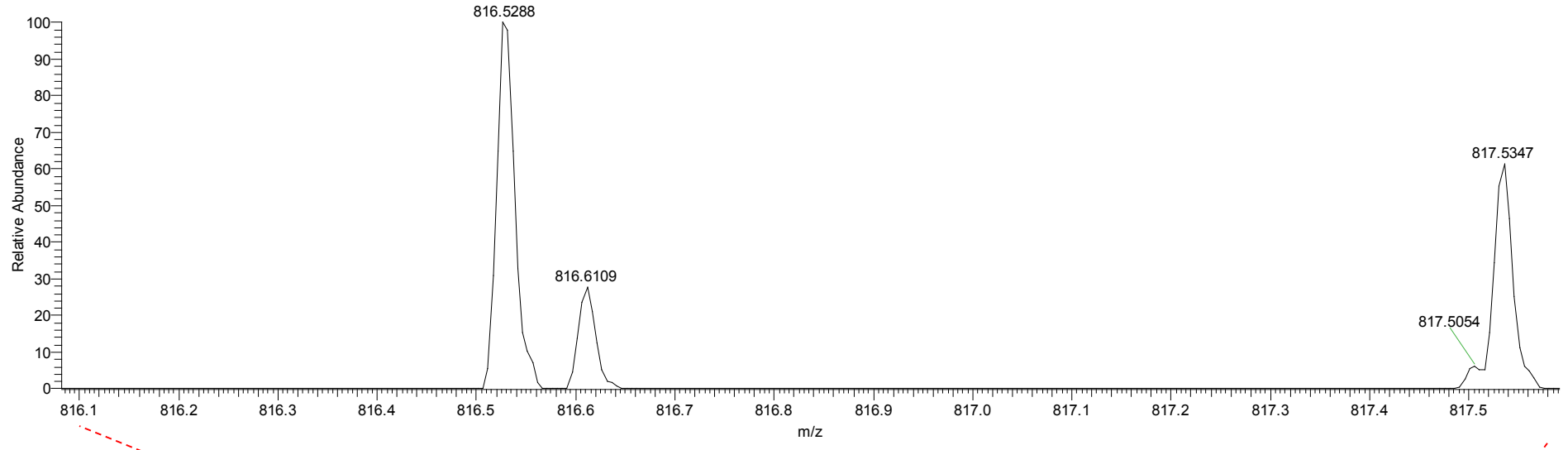


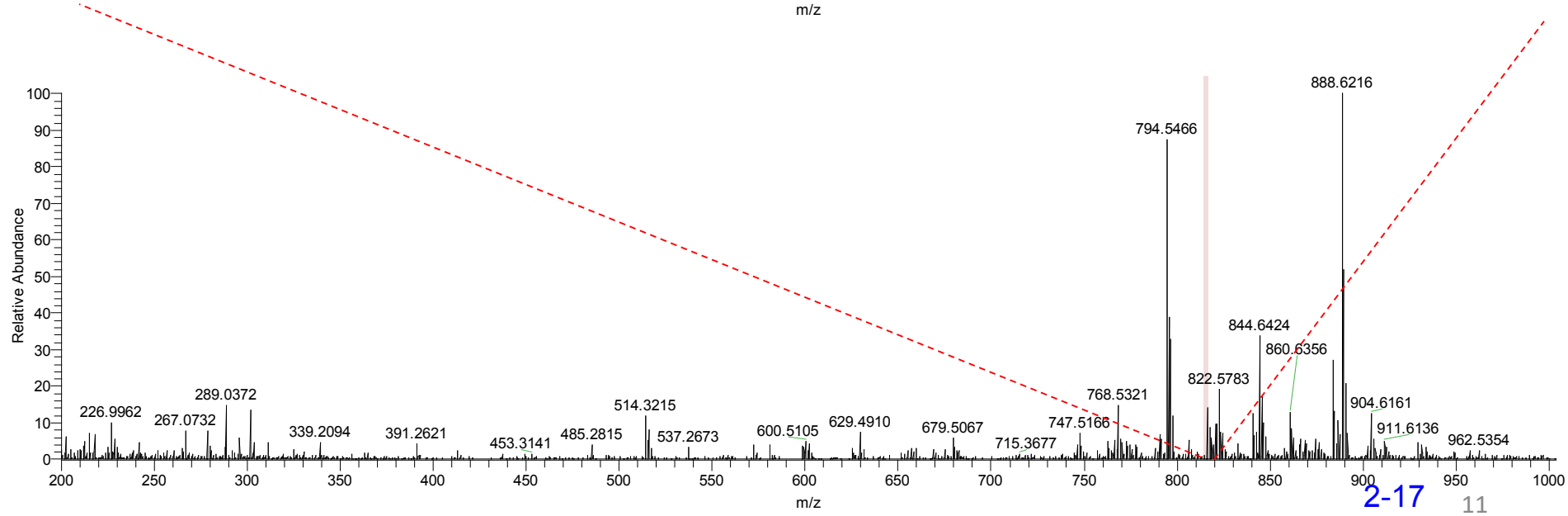
Molecular Data from Biological Tissues

- How much information do we get?



Molecular Data from Biological Tissues



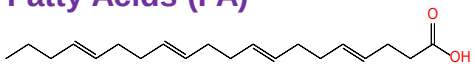


2-17

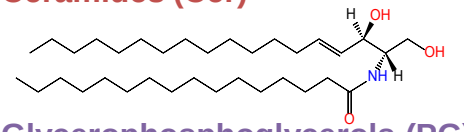
Molecular Data from Biological Tissues

Small Metabolites

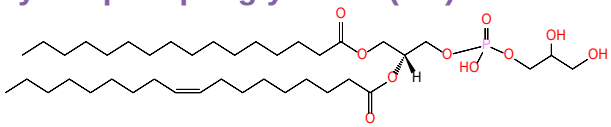
Fatty Acids (FA)



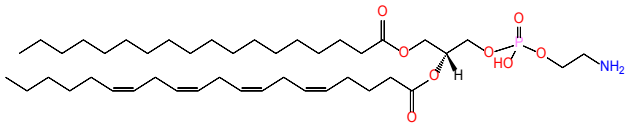
Ceramides (Cer)



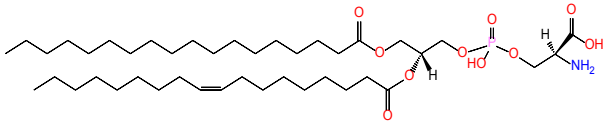
Glycerophosphoglycerols (PG)



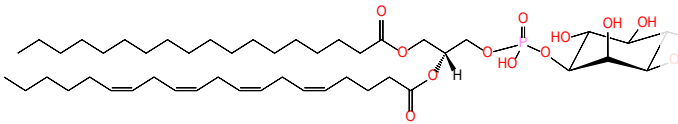
Glycerophosphoethanolamines (PE)



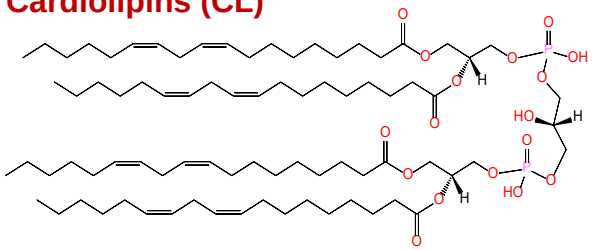
Glycerophosphoserines (PS)

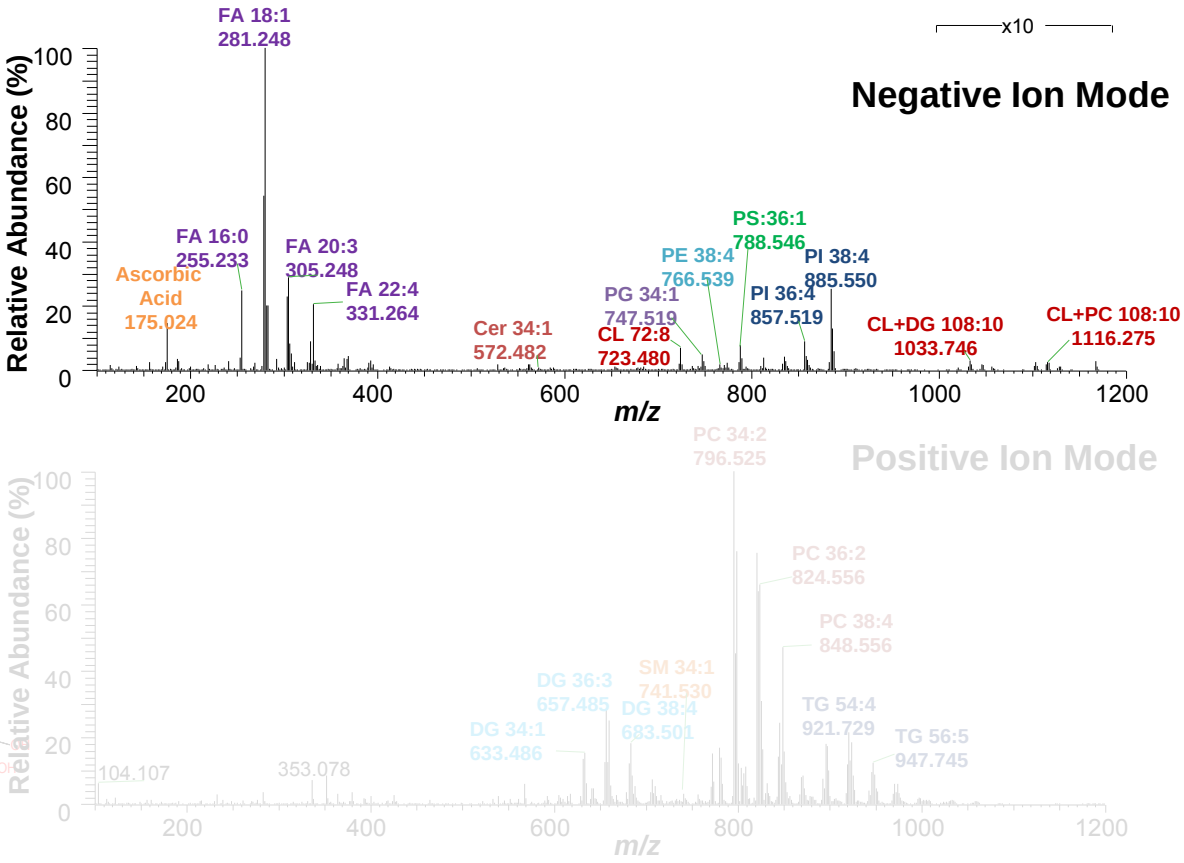


Glycerophosphoinositols (PI)



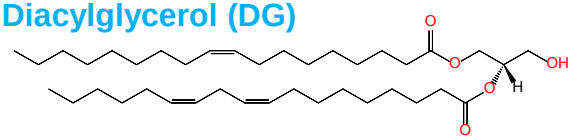
Cardiolipins (CL)



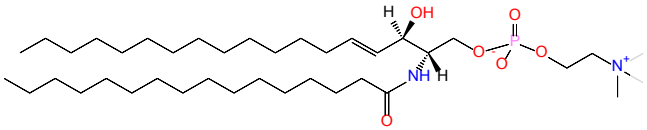


Molecular Data from Biological Tissues

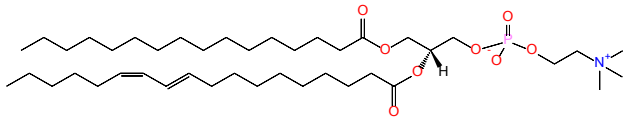
Diacylglycerol (DG)



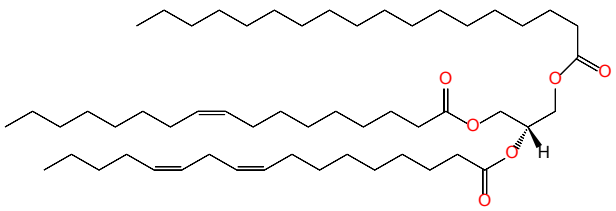
Sphingomyelin (SM)



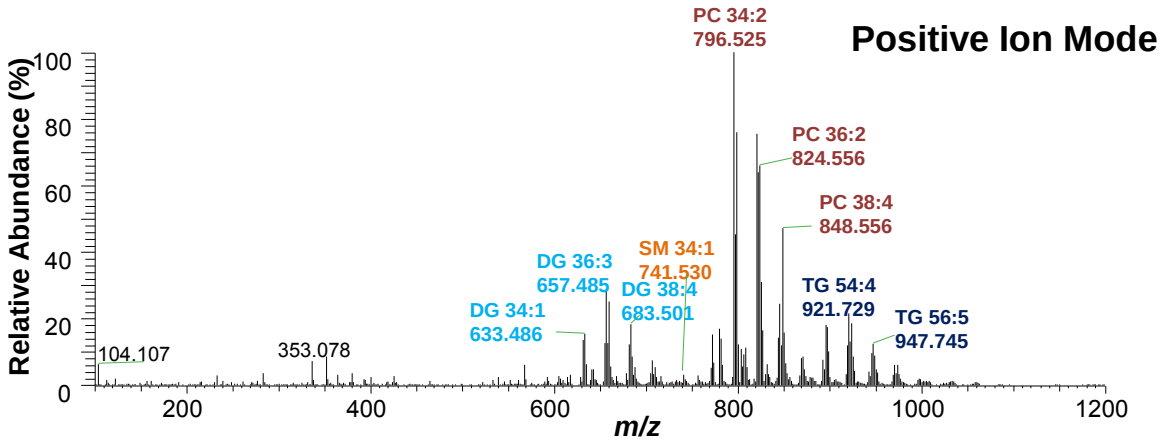
Glycerophosphocholine (PC)



Triacylglycerol (TG)



Negative Ion Mode



Pre-Operative Diagnosis

Biopsy analysis:

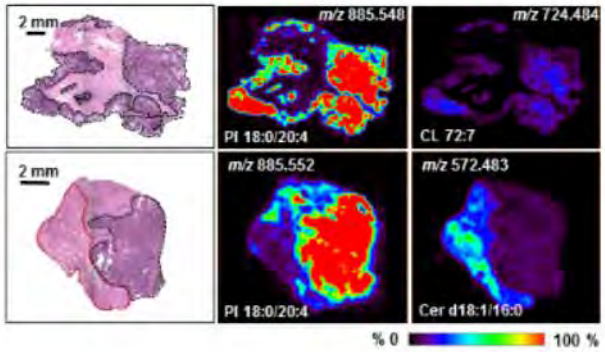
- Liquid biopsies
- FNA
- Core biopsies

Intra-Operative Diagnosis

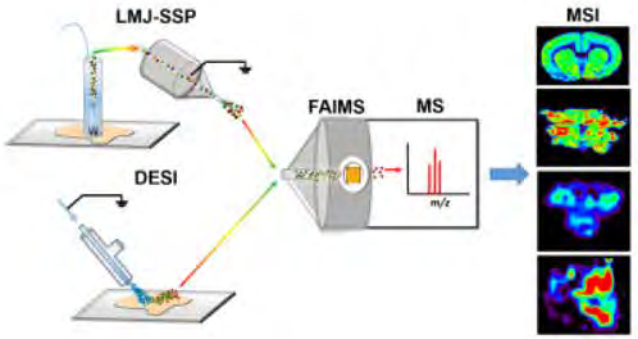
Surgical Margin Evaluation

Sentinel Lymph Node

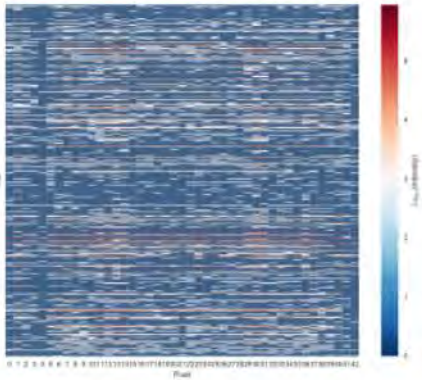
Clinical Mass Spectrometry



Molecular Imaging of Disease Markers



Methodology Development in MS Imaging



Statistics and Informatics

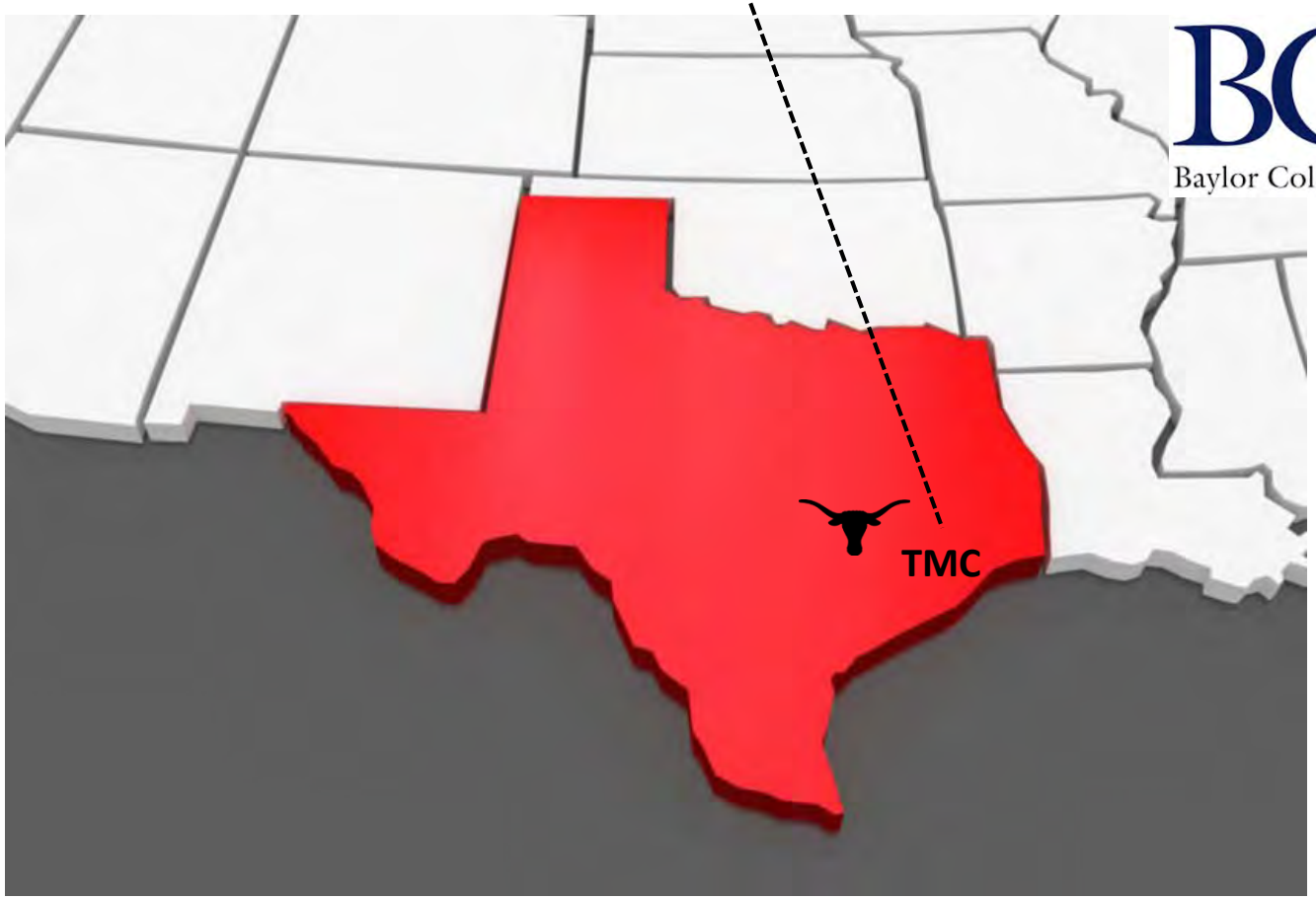
https://eberlin.cm.utexas.edu/

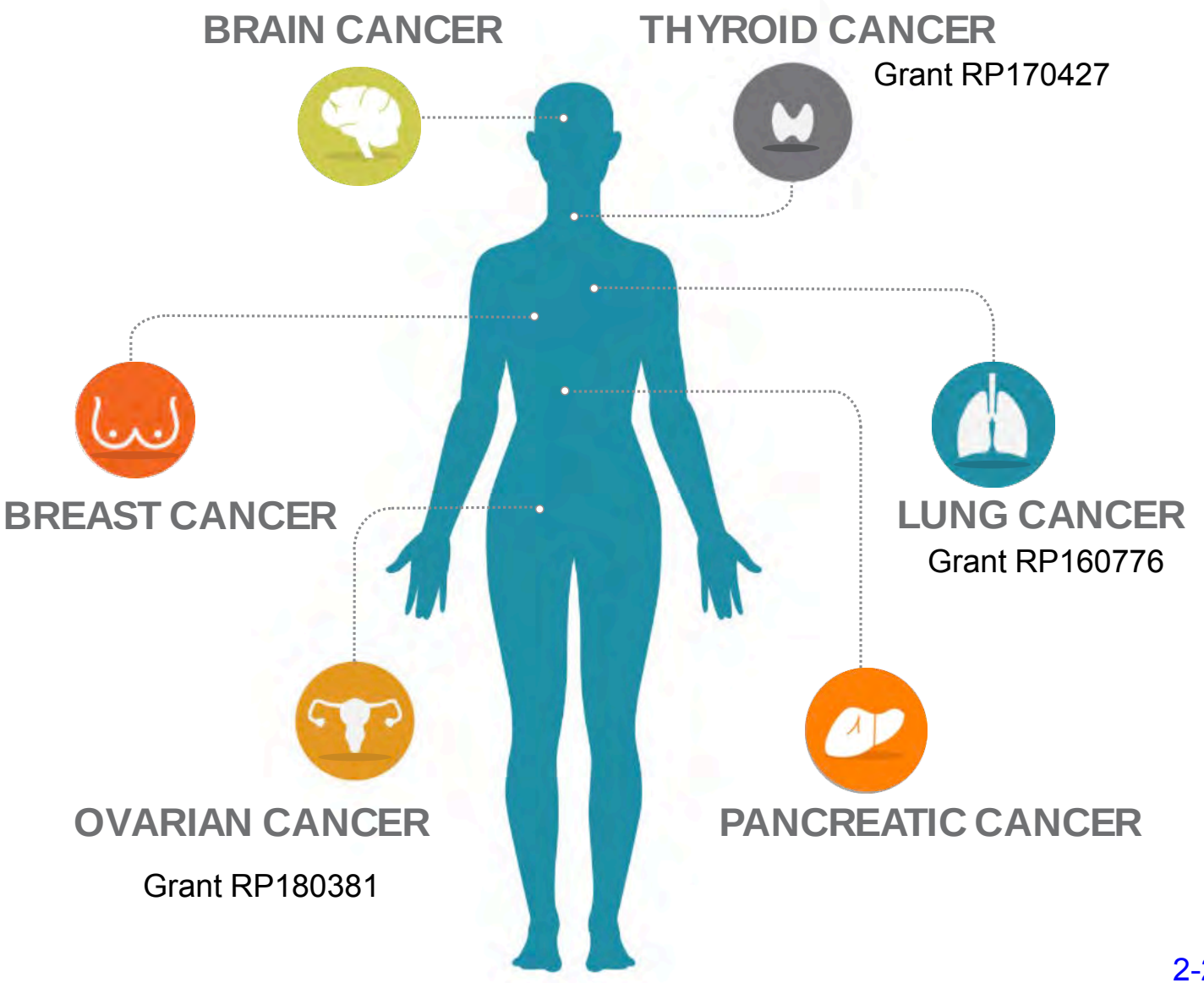
The University of Texas at Austin
Dell Medical School

Texas Medical Center
>5 million annual patient visits

THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

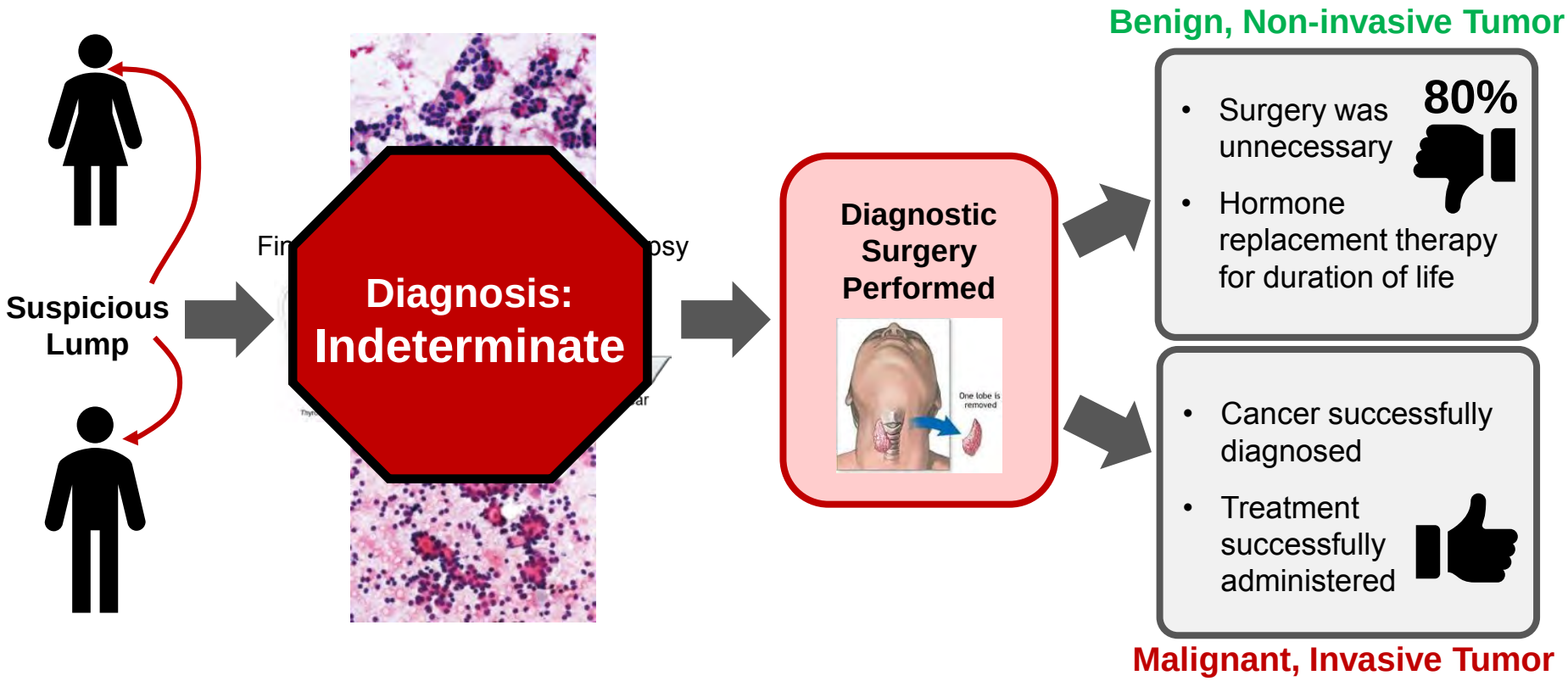
BCM
Baylor College of Medicine




BRAIN CANCER
THYROID CANCER
Grant RP170427
BREAST CANCER
LUNG CANCER
Grant RP160776
OVARIAN CANCER
Grant RP180381
PANCREATIC CANCER

Pre-Operative Diagnosis of Thyroid Cancer

- **Thyroid Cancer is the Most Rapidly Increasing Cancer in the U.S.**
- **20-30% of FNAs are called “indeterminate” or “suspicious”.**



Yoo, C. et al. *Korean J Pathol* **2013,** *47* (1), 61-6.

https://www.mayoclinic.org/tests-procedures/needle-biopsy

McHenry, C. R.; *Oncologist* **2011,** *16* (5), 585-93.

Pre-Operative Diagnosis of Thyroid Cancer

Dr. James Suliburk

Dr. Wendong Yu

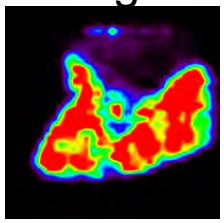
BCM
Baylor College of Medicine

DESI-MS analysis:
N=141
37 Normal
71 FTA
33 FTC
282 DESI-MS Images

Pathological Evaluation

—Tumor Region

Correlate to Ion Images



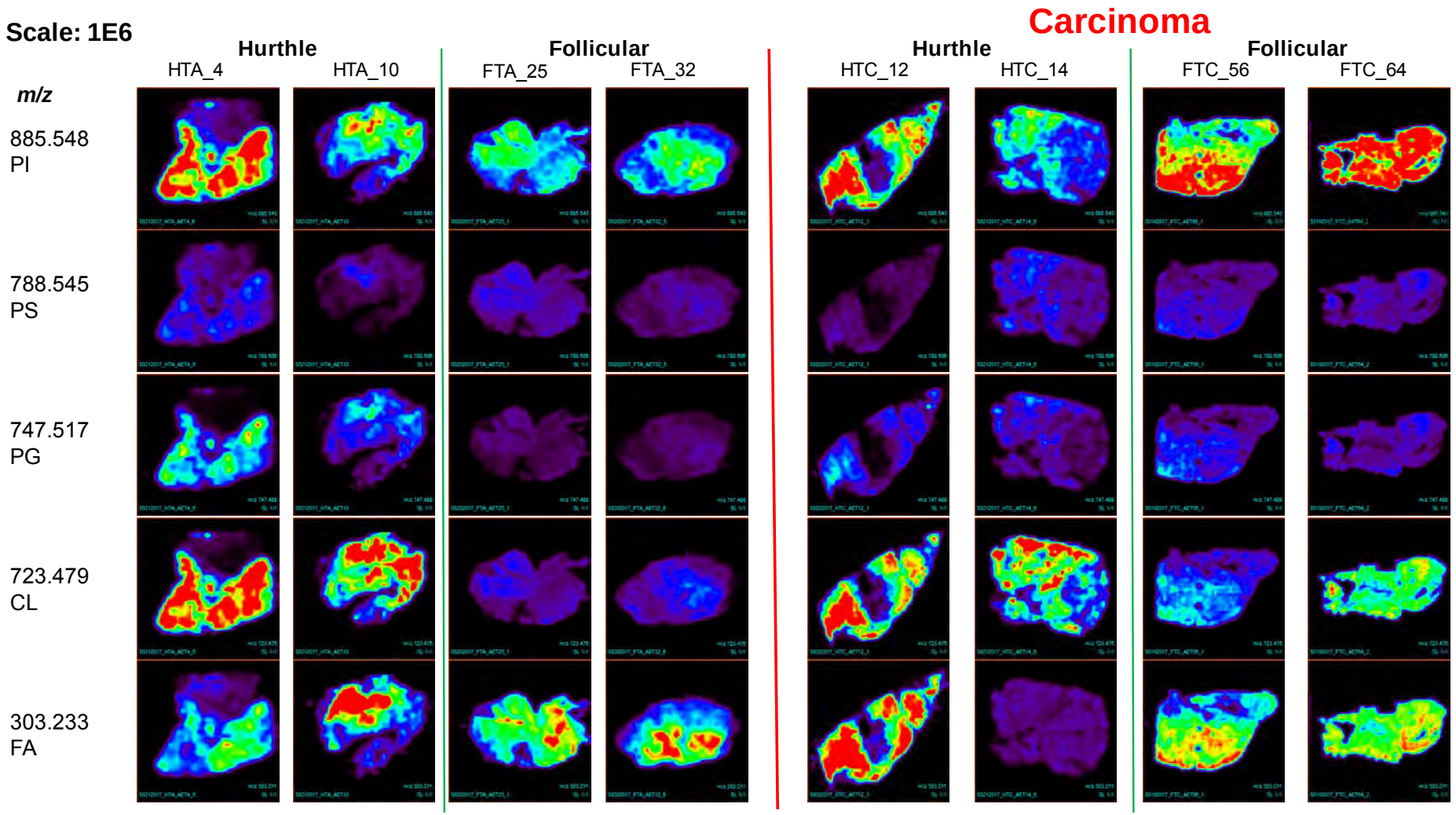
Positive Ion Mode:
92,731 mass spectra

Negative Ion Mode:
85,805 mass spectra

Grant RP170427
CPRIT

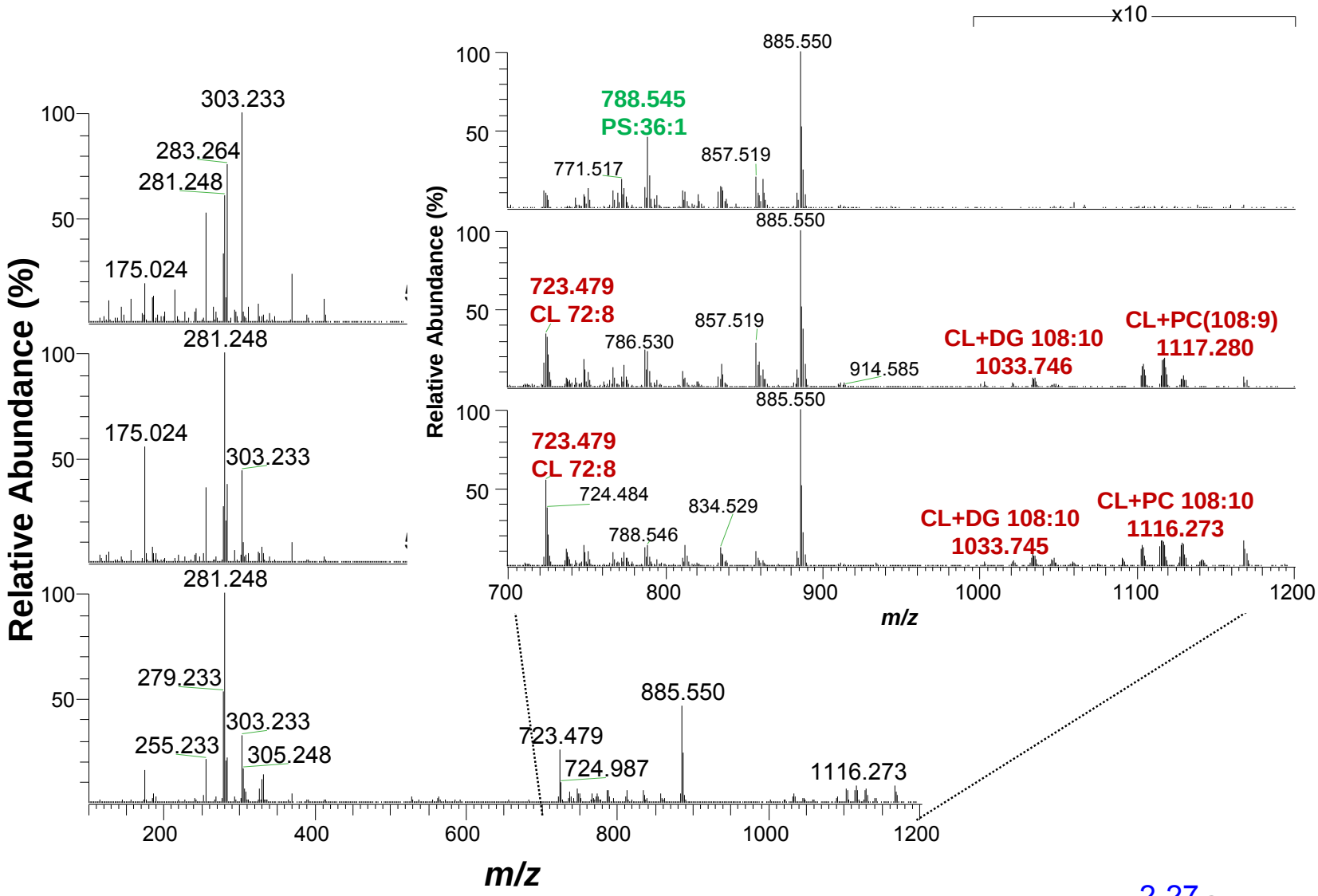
DESI-MS Imaging of Thyroid Tissues

Negative Ion Mode DESI-MS Results



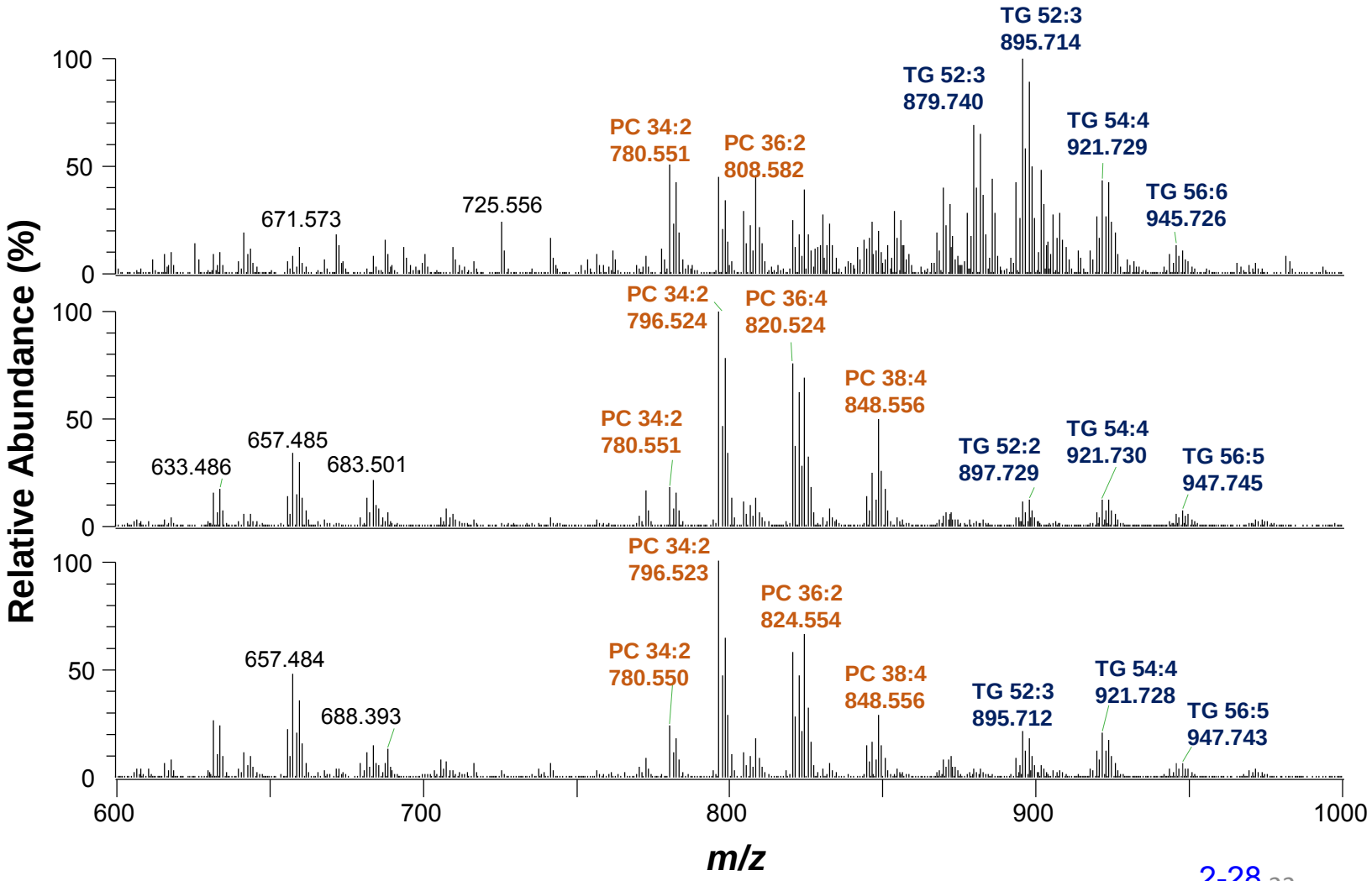
DESI-MS Imaging of Thyroid Tissues

Negative Ion Mode DESI-MS Results



DESI-MS Imaging of Thyroid Tissues

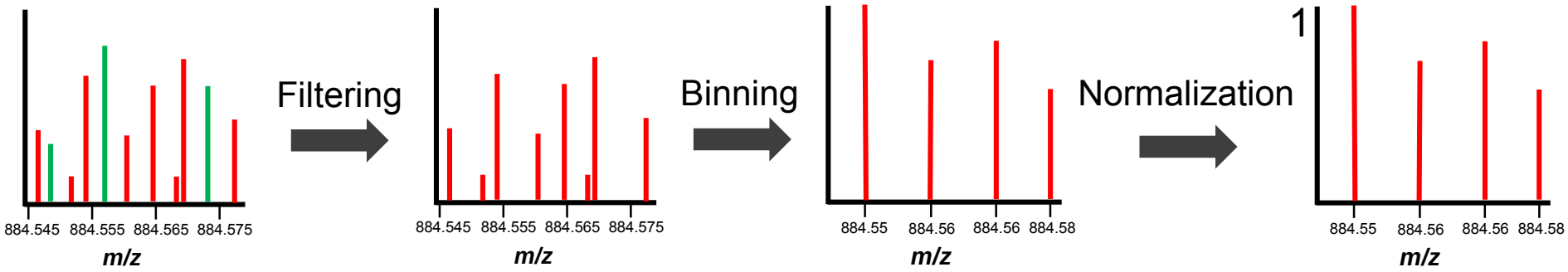
Positive Ion Mode DESI-MS Results



Statistical Analysis & Machine Learning

1) Histologically-Validated Tissue Database

2) Data pre-processing

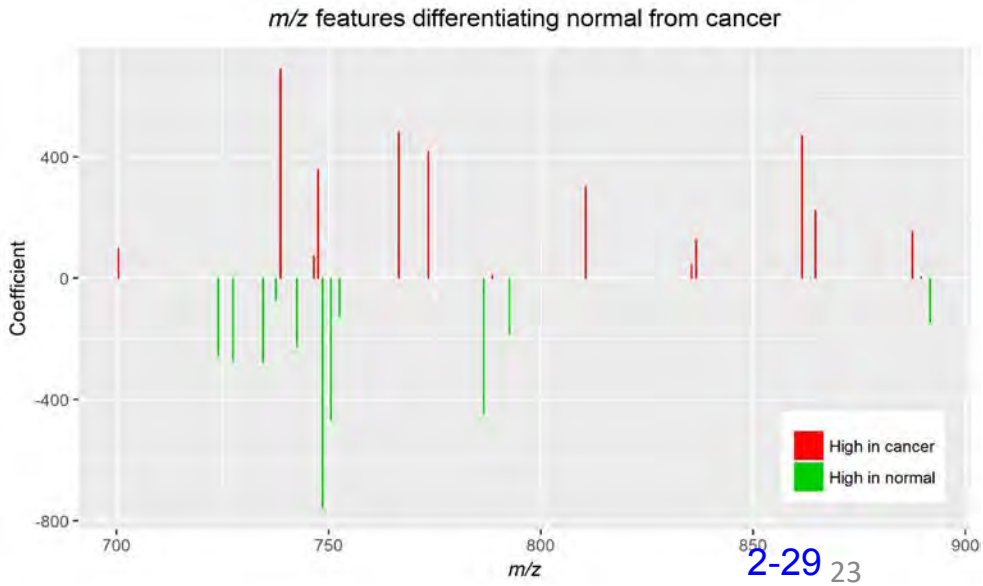


3) Build Statistical Models[1]

$$\min_{(\beta_0,\beta)\in\mathbb{R}^{p+1}} \left[\sum_{i=1}^{n} \left(y_i - \beta_0 - \sum_{j=1}^{p} \beta_j x_{ij} \right)^2 + \lambda \sum_{j=1}^{p} |\beta_j| \right]$$

Probabilities

$$P(Y|X) = \frac{e^{\beta_0+\beta_1 X_1+\cdots+\beta_p X_p}}{1+e^{\beta_0+\beta_1 X_1+\cdots+\beta_p X_p}}$$

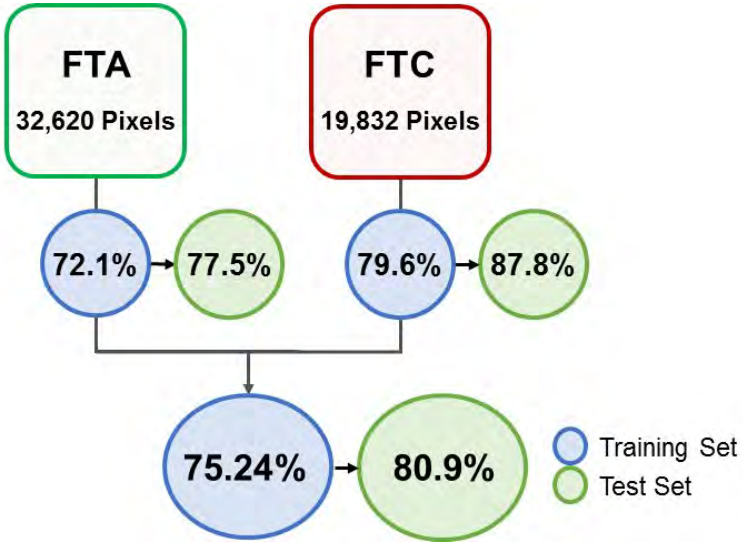


[1] R. Tibshirani, *Journal of the Royal Statistics Society*, 1996, 58, 267-288

Predictive Results

Negative Ion Mode

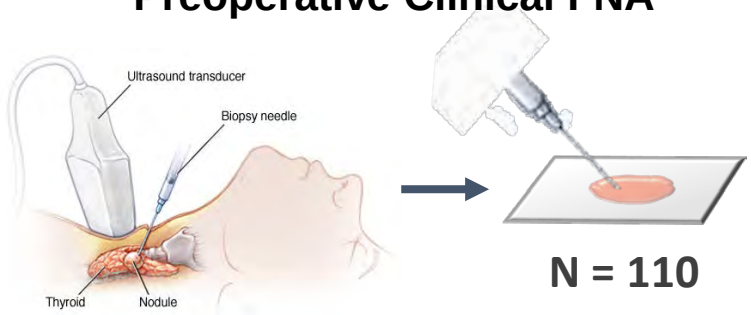
Training Set: 25,801 Pixels
Test Set: 26,651 Pixels



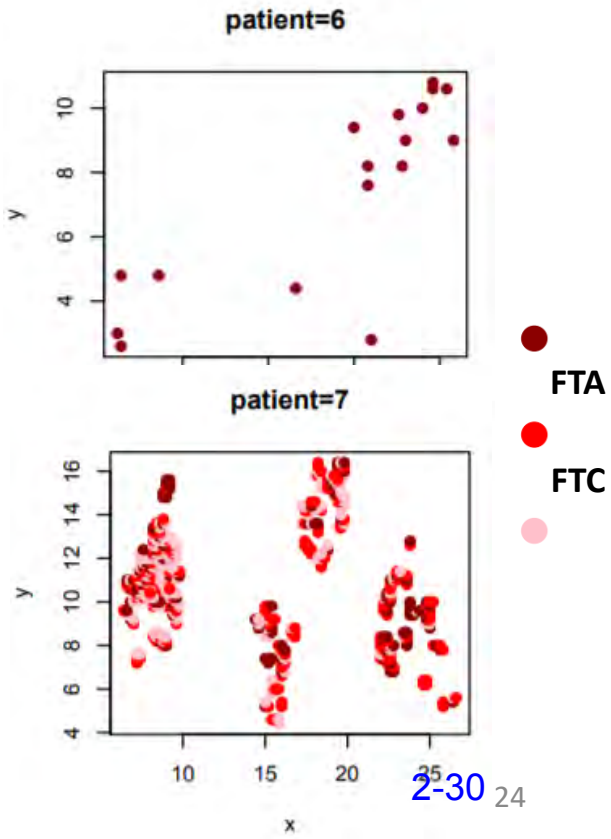
N = 265	Sensitivity	Specificity	PPV	NPV
Afirma GEC	92 %	52 %	38 %	94-95 %

Nishino, M. *Cancer Cytopathol* **2016,** *124* (1), 14-27.
Moore, M. D. et al. *Expert Rev Mol Diagn* **2017,** *17* (6), 567-576.

Preoperative Clinical FNA

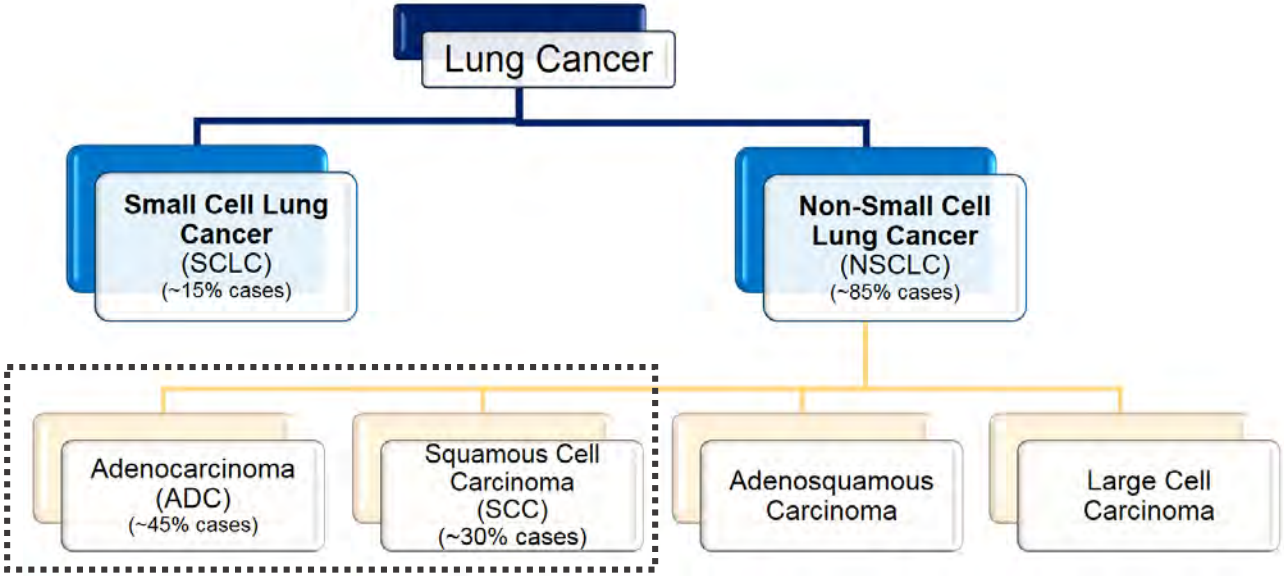


N = 110



Pre-Operative Diagnosis of Lung Cancer

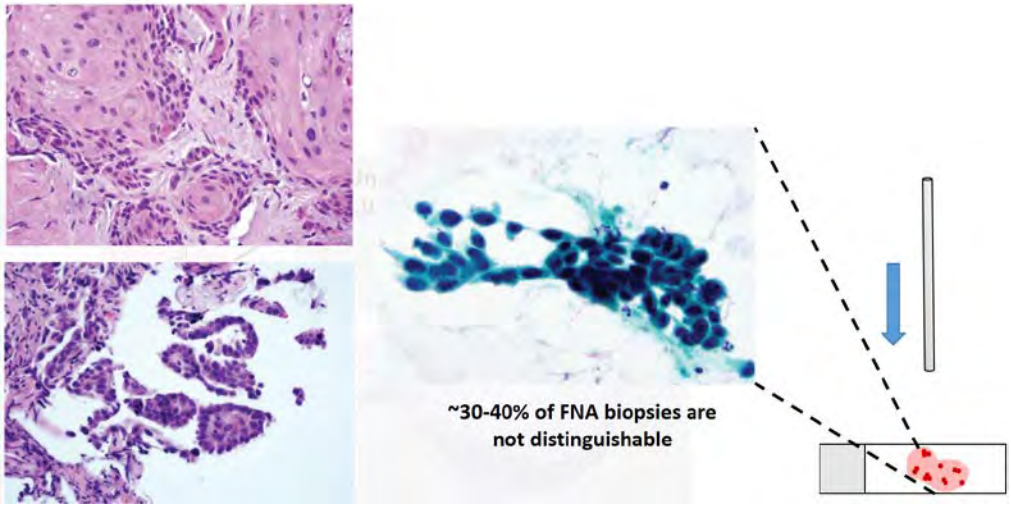
- **Lung Cancer Subtype Determines Targeted Chemotherapy Treatment Options**



- **Pre-Operative FNA diagnosis:**

Squamous Cell Carcinoma
keratinization and/or intracellular bridges

Adenocarcinoma
glandular differentiation or mucin production



30-40% of lung FNA biopsies are not distinguishable

Pre-Operative Diagnosis of Lung Cancer

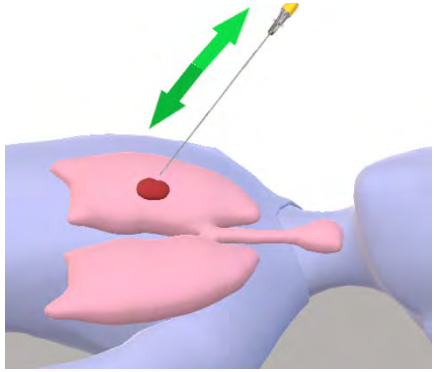
MD Anderson Cancer Center

Dr. Erik Cressman

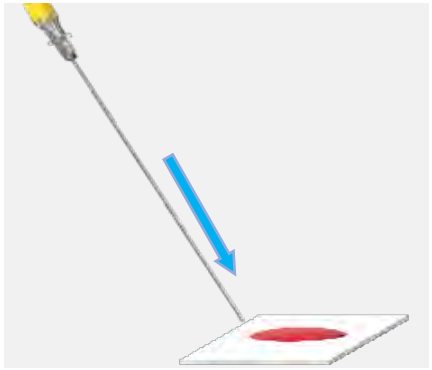
Dr. Ruth Katz

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

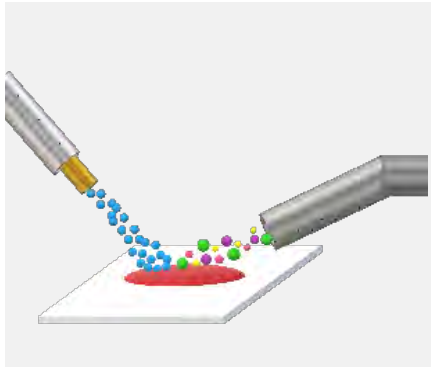
Grant RP160776



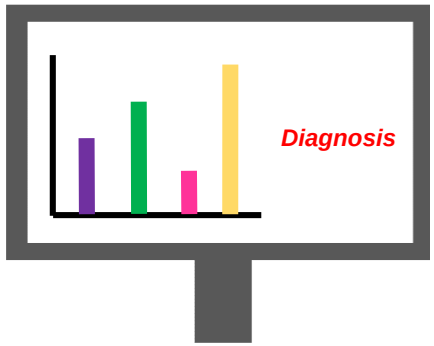
FNA biopsy of unidentified lung tumor



Sample deposition on glass slide



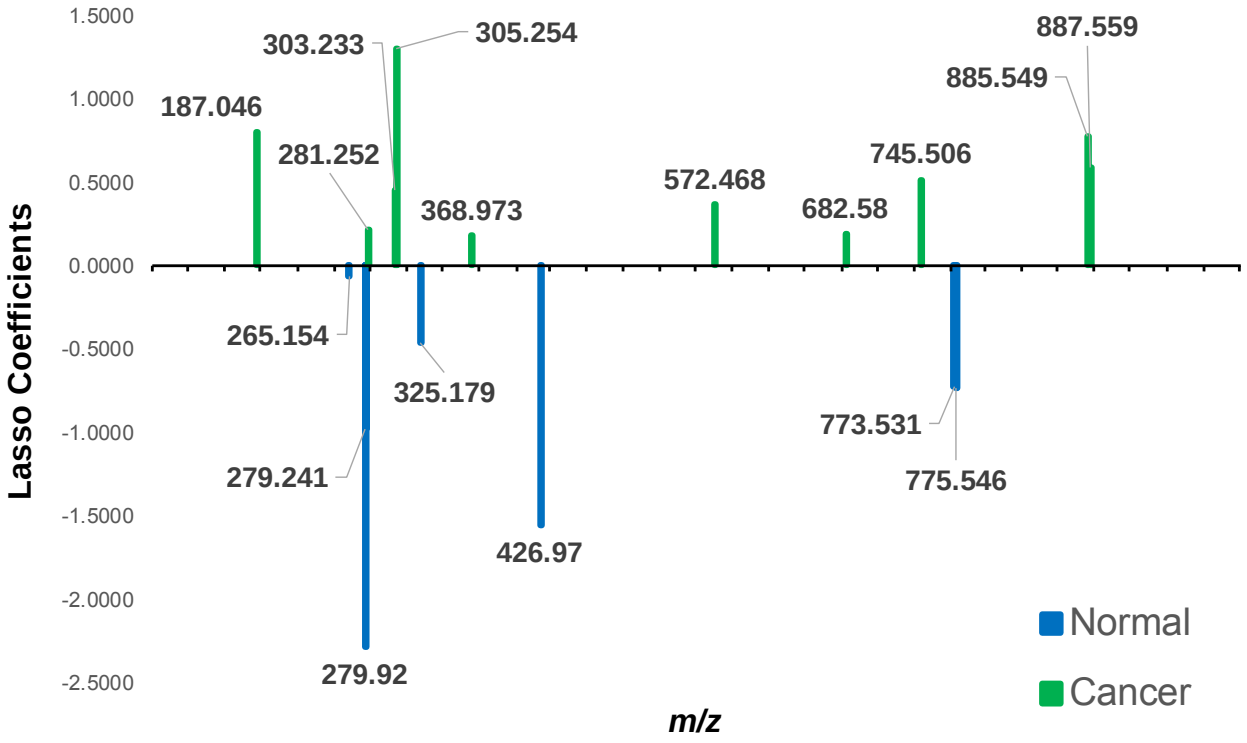
Ambient Ionization-MS analysis of sample



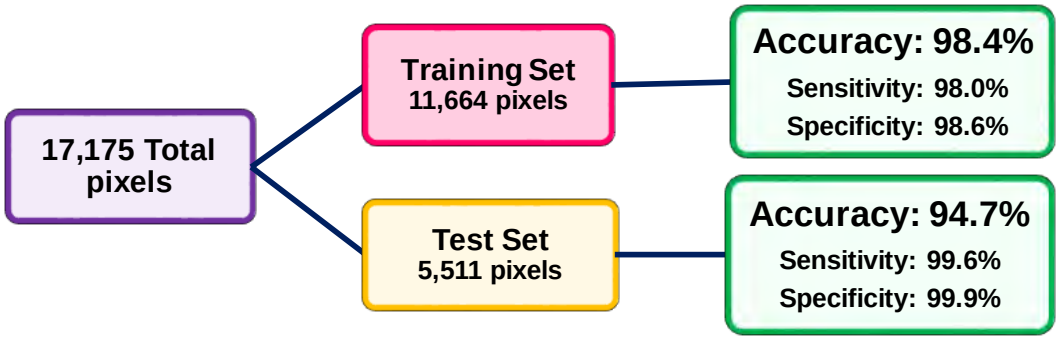
Readout and diagnosis

DESI-MS Imaging of Lung Tissues

- Normal Lung versus Lung Cancer

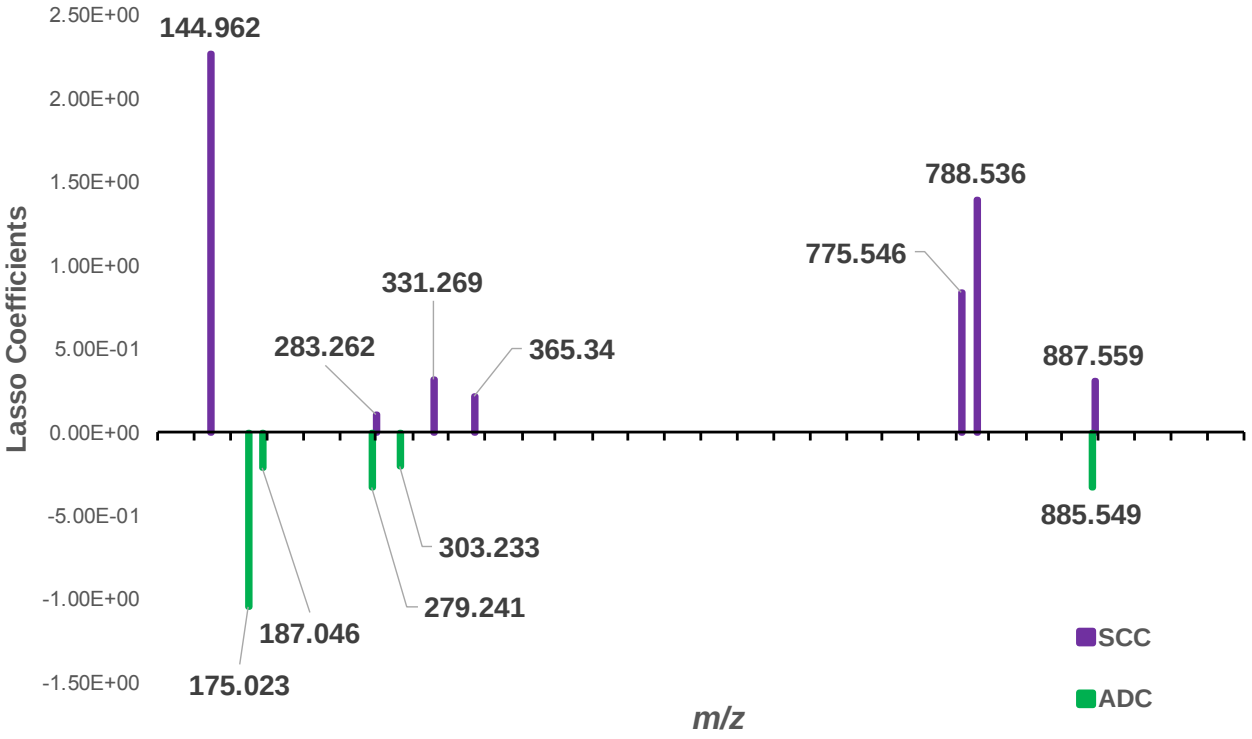


Normal	
279.241	FA(19:0)
773.531	PG(34:1)
775.546	PG(36:1)
Cancer	
281.252	FA(18:0)
303.233	FA(20:4)
572.468	Cer(34:1)
682.58	Cer(24:1)
745.506	PG(34:2)
885.549	PI(38:4)
887.559	PI(38:2)



DESI-MS Imaging of Lung Tissues

- **Lung Cancer Adenocarcinoma versus SCC**



ADC	
175.02	Ascorbic Acid
279.24	FA(18:2)
303.23	FA(20:4)
885.55	PI(38:4)
SCC	
283.26	FA(18:0)
331.27	FA(22:4)
365.34	FA(24:1)
775.55	PG(36:1)
788.54	PS(36:1)
887.56	PI(38:2)

ADC vs SCC

Overall Training Set Accuracy:

76.6%

Overall Test Set Accuracy:

82.4%

Test in 15 clinical FNA samples

Molecular Markers of Serous Ovarian Cancer

- Serous borderline ovarian tumors (15% of epithelial ovarian tumors) → a more favorable outcome.
- High grade serous ovarian cancers (70% of epithelial ovarian tumors) → very poor outcome.
- Elevated expression levels of the **fatty acid binding protein gene (FABP4)** in HGSC.

- *What are the molecular differences between a non-aggressive borderline tumor, and a high grade serous ovarian cancer?*
- *Can we use this technology to recognize cancer during debulking surgeries?*

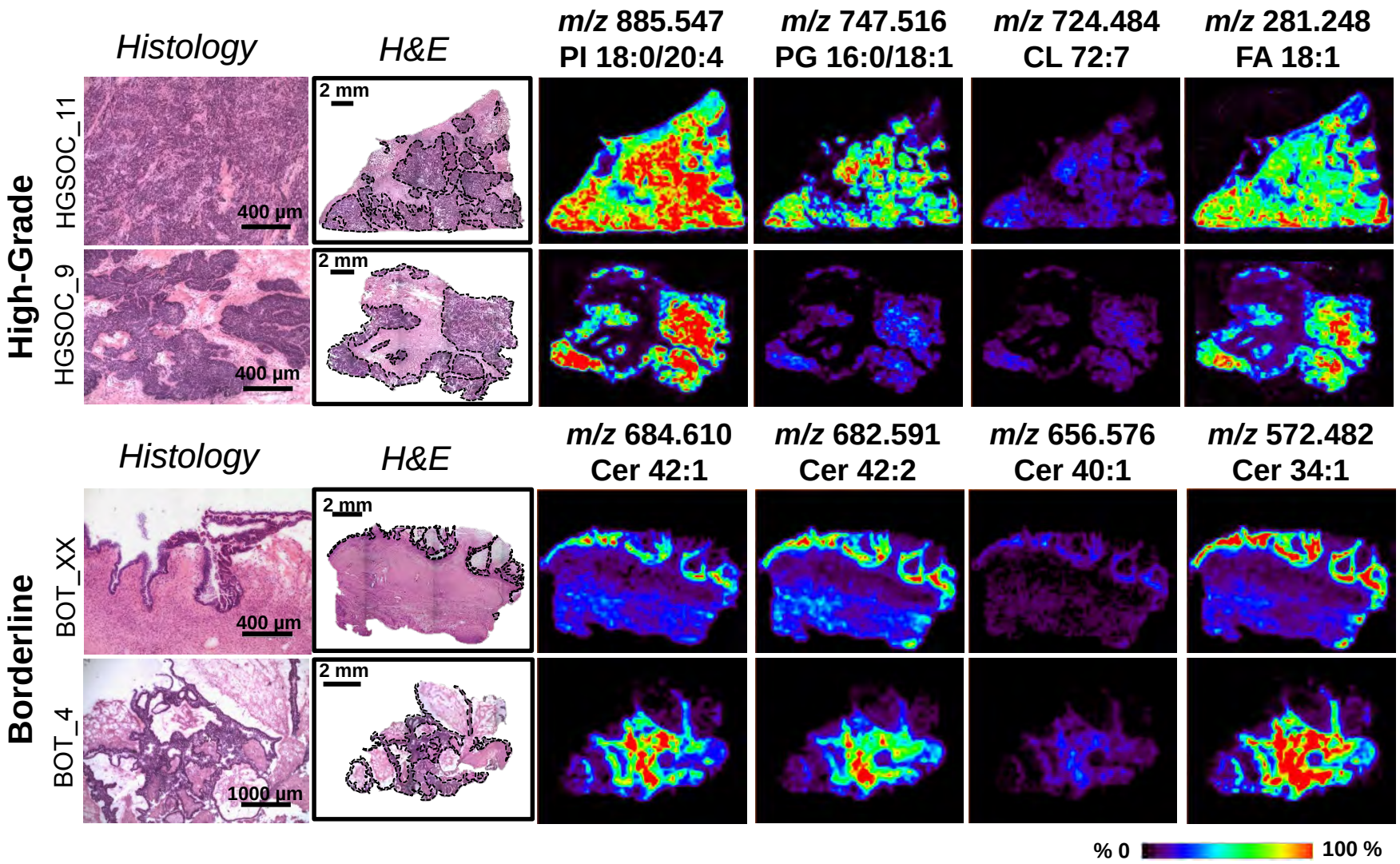
Dr. Anil Sood

Dr. Jinsong Liu

THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

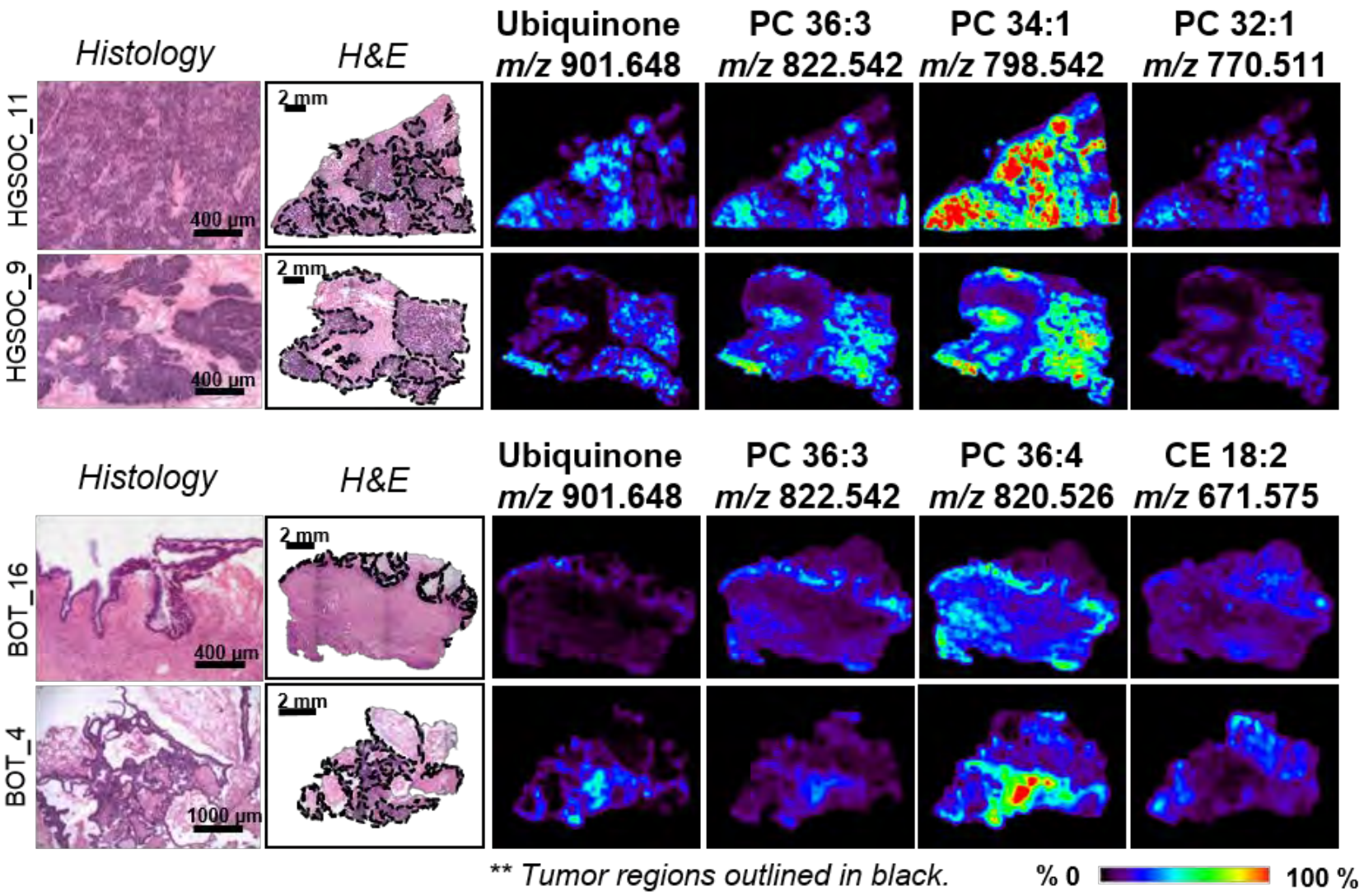
Molecular Markers of SOC Aggressiveness

Negative ion mode

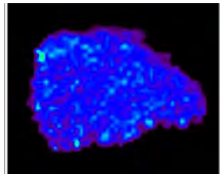


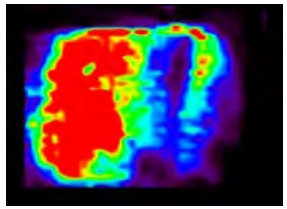
Molecular Markers of SOC Aggressiveness

Positive ion mode

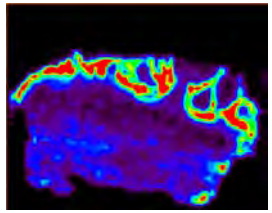


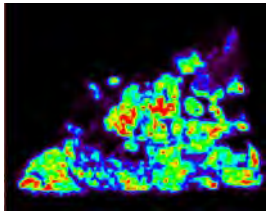
Molecular Predictors



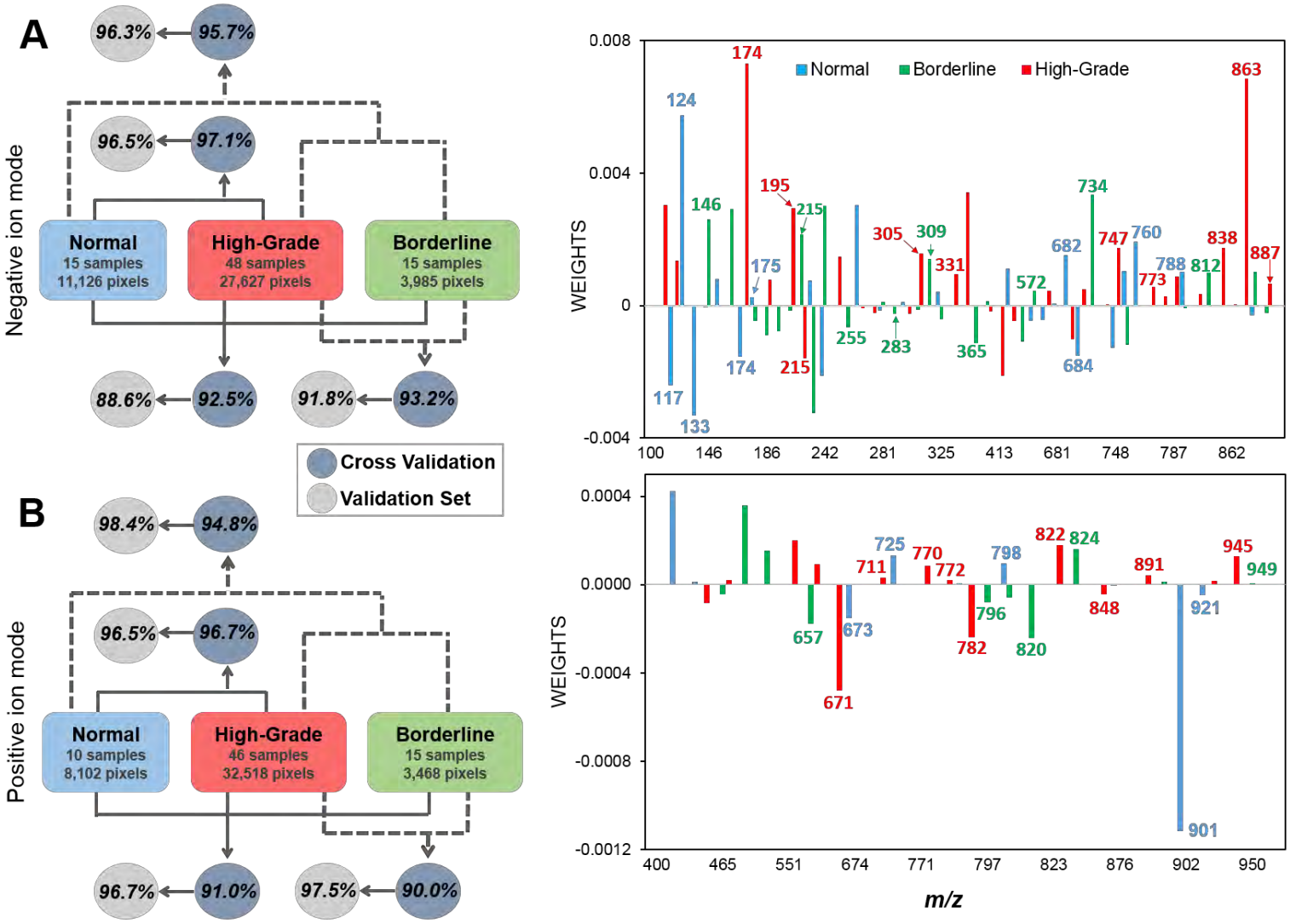


Attribution	Weights by Lasso			Detected *m/z*
	Normal	Borderline	High-Grade	
Succinate	- -		++	117.020
Malate	- -			133.014
Glutamic acid	-	++		146.046
Amino-oxo-hexanedioic acid	- -		++	174.041
Ascorbic acid	+	-		175.025
Gluconic acid		-	++	195.051
Glucose		++	- -	215.033
2,5-didehydro-gluconic acid	+	- -		226.996
FA (16:0)		-		255.233
FA (18:2)			-	279.233
FA (18:1)	-	+		281.248
FA (18:0)		-		283.264
FA (20:4)	+		-	303.233
FA (20:3)		-	++	305.248
FA (20:1)		++		309.280
FA (22:4)			+	331.264
MG (16:0)		- -		365.246
Methylacetophenone	++		-	421.226
Cer (34:2)		- -		570.466
Cer (34:1)	-	+		572.481
3OH-Cer (37:0)	-		+	626.536
Cer (42:3)	+			680.575
Cer (42:2)	++		-	682.590
Cer (42:1)	- -		+	684.607
GlcCer (d34:1)		++		734.535
PE (18:1/18:1)			+	742.538
PG (16:0/18:1)	- -		++	747.520
PE (O-16:0/22:6) or (P-18:0/20:5)	++	- -		748.528
PS (16:0/18:1)	++			760.515
PG (18:1/18:1)			+	773.533
PG (18:0/18:1)			+	775.548
PS (36:2)			+	786.528
PS (18:0/18:1)	++	-		788.547
PG (20:4/18:1)			+	795.515
PS (38:3)		+		812.544
PS (22:4/18:0)			++	838.560
PI (18:0/18:2)			+	861.552
PI (18:0/18:1)			++	863.567





Molecular Predictors & Classification

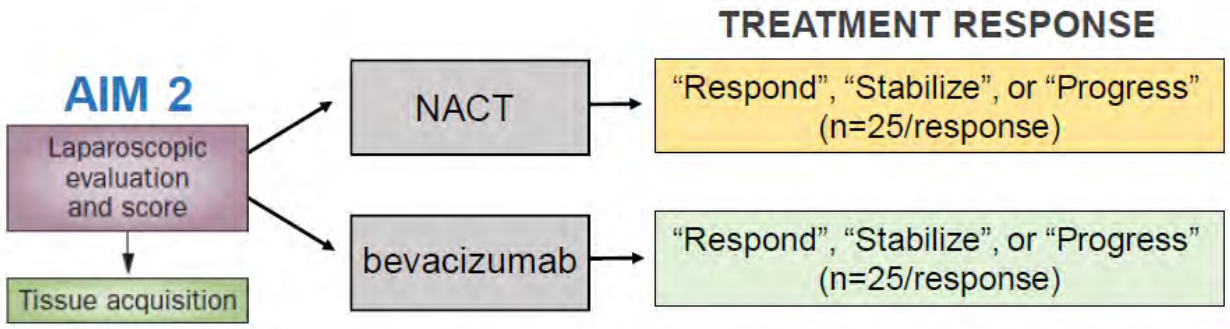


M. Sans, K. Gharpure, A.K. Sood, L. S. Eberlin, et al "Metabolic Markers and Statistical Prediction of Serous Ovarian Cancer Aggressiveness by Ambient Ionization Mass Spectrometry Imaging", *Cancer Research*, 2017, 77, 2903-2913.

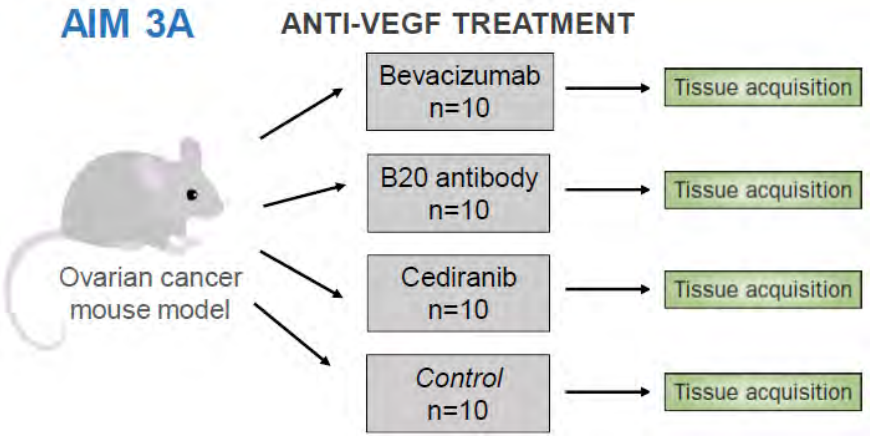
Gharpure, S. Pradeep, M. Sans, L.S. Eberlin, A.K. Sood, et al "FABP4 as a molecular determinant of residual disease in ovarian cancer", *Nature Communications*, 2018, 9:2923.

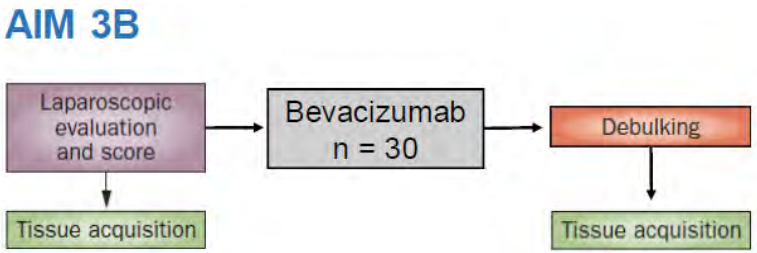
Molecular Markers of Treatment Response

- Define and validate predictive metabolic signatures of ovarian cancer treatment response.



- Investigate adaptive metabolic changes due to anti-VEGF therapies of the tumor tissue microenvironment in pre-clinical models as well as pre- and post-treatment patient tissues.

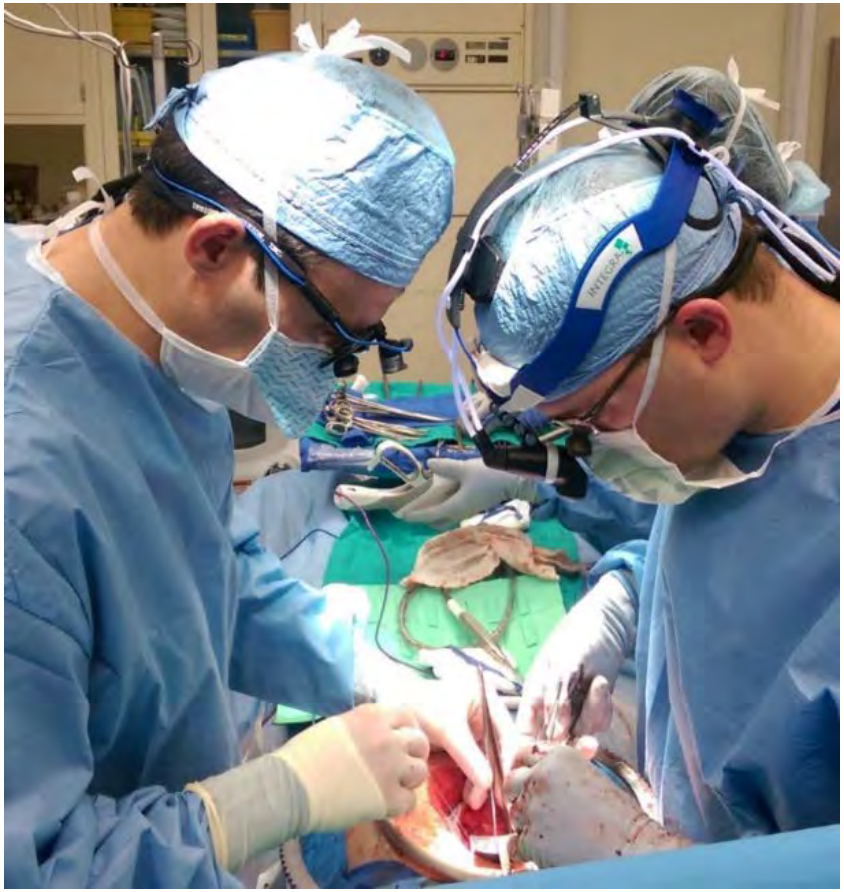




Grant RP180381
2-40

Intraoperative Diagnosis & Margin Evaluation

Cancer Surgery



- Complex procedures
- Maximize cancer resection
- Minimize resection of viable tissue

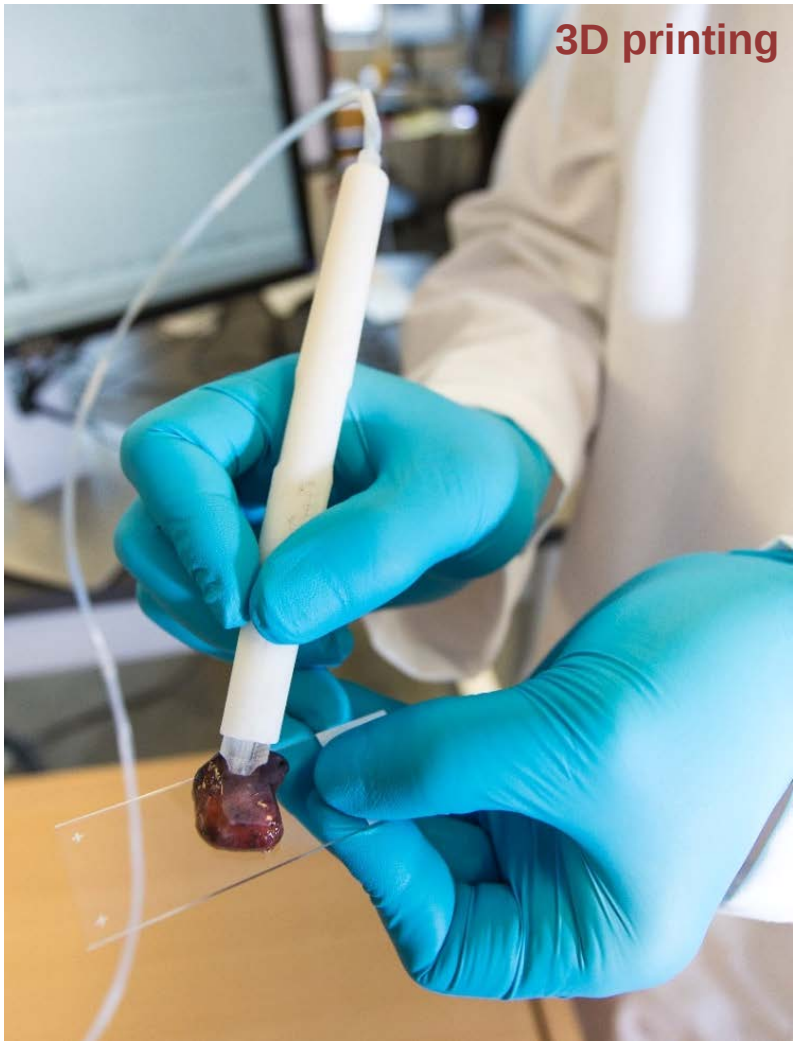
Ex-Vivo Frozen Section Analysis

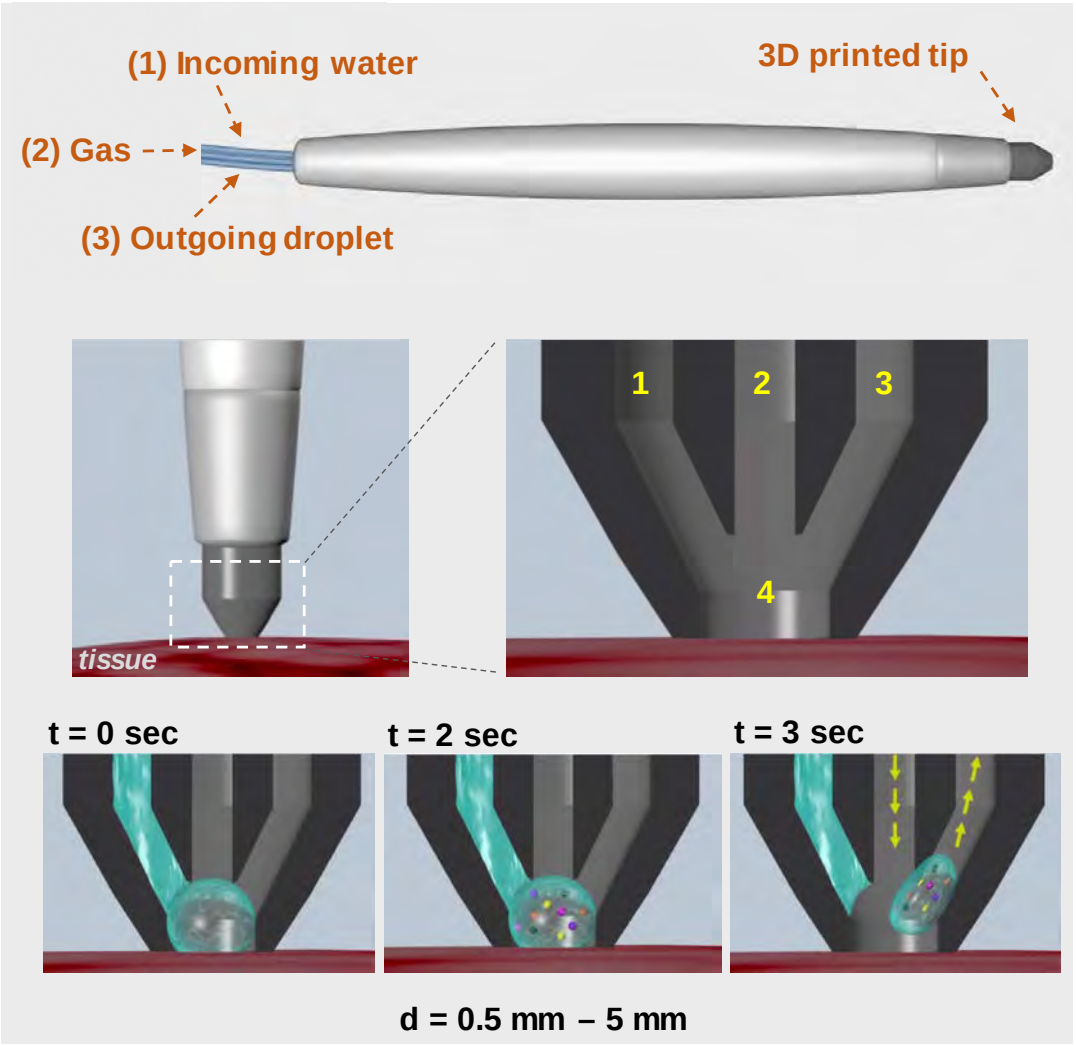
- Subjective
- Inaccurate (~25% for GI cancers)[1,2]
- Time consuming & costly

2-41

1. Al-Ghnaniem R, *et al. Anz Journal of Surgery*, **2008**, 78, 237-239.; 2. Shen JG, *et al. Hepato-Gastroenterology,* **2006**, 53, 976-978.

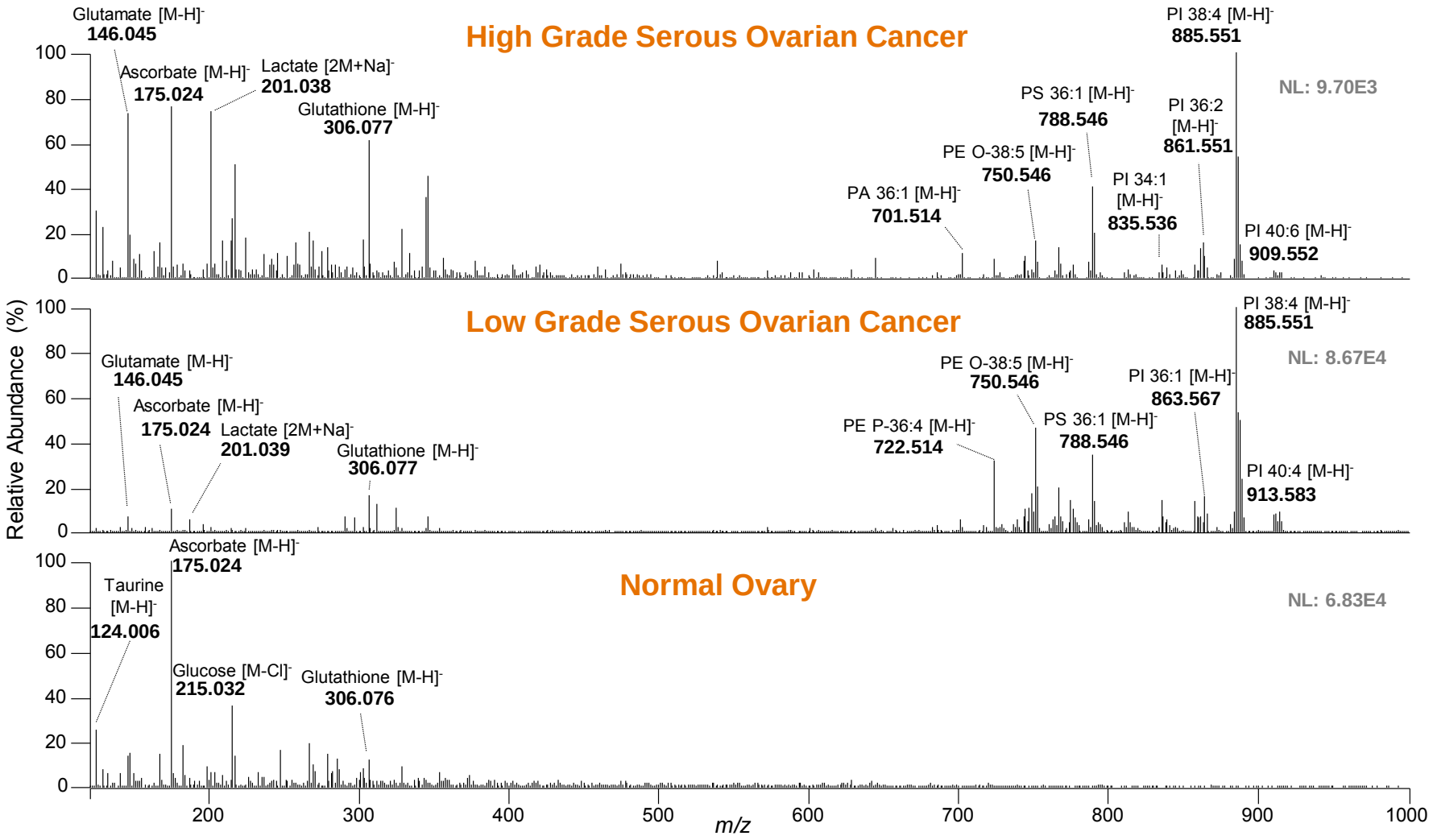
MasSpec Pen





Zhang J., Rector J., Lin J., Young J.H., Sans M., Katta N., Giese N., Yu W., Nagi C., Suliburk J., Liu J., Bensussan A., DeHoog R.J., Garza K.Y., Ludolph B., Sorace A.G., Syed A., Zahedivash A., Milner T., and Eberlin L.S. (2017). ***Science Translational Medicine***, 9, eaan3968

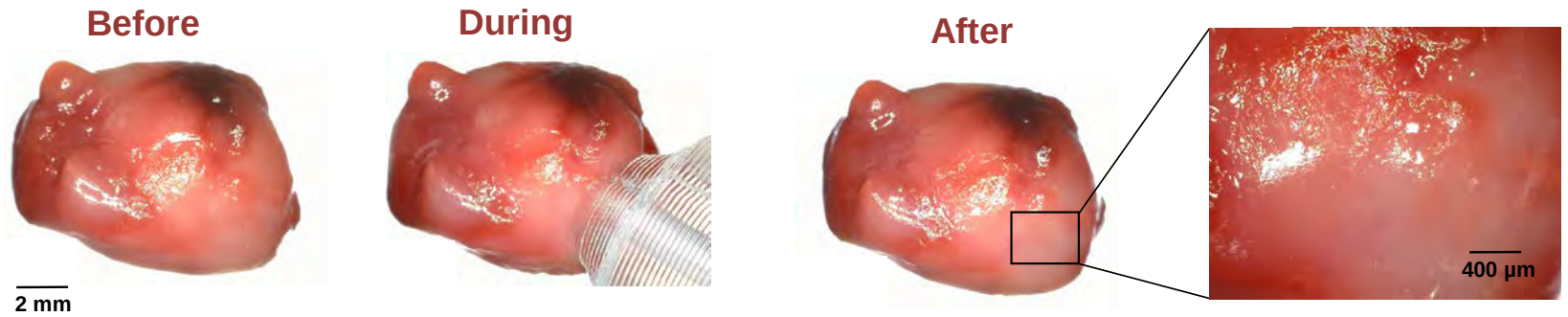
Molecular Information



PI: glycerophosphoinositols; PS: glycerophosphoserines; PE: glycerophosphoethanolamine; PA: glycerophosphoacid.
(X:Y) represents the total number of carbon atoms (X) and double bonds (Y) in the fatty acid chains.

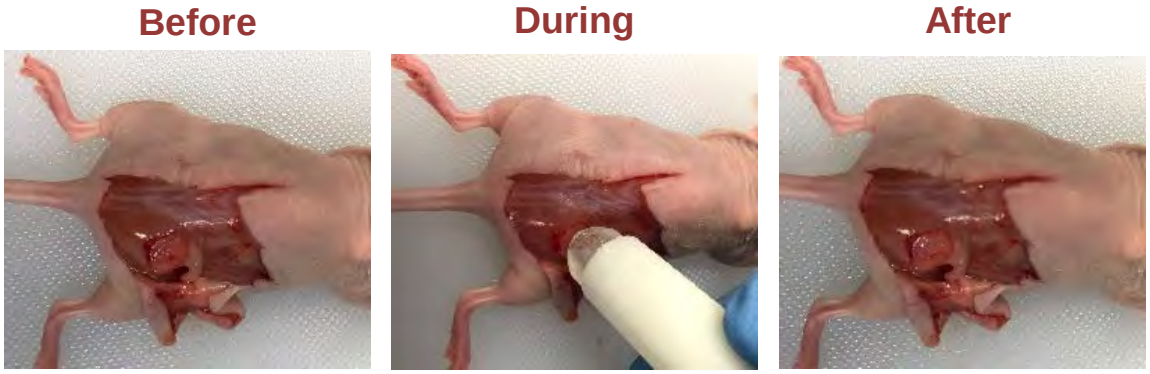
Non-destructive Analysis

- ***Ex vivo* Tissue Analysis:**



✓ *No histologic damage*

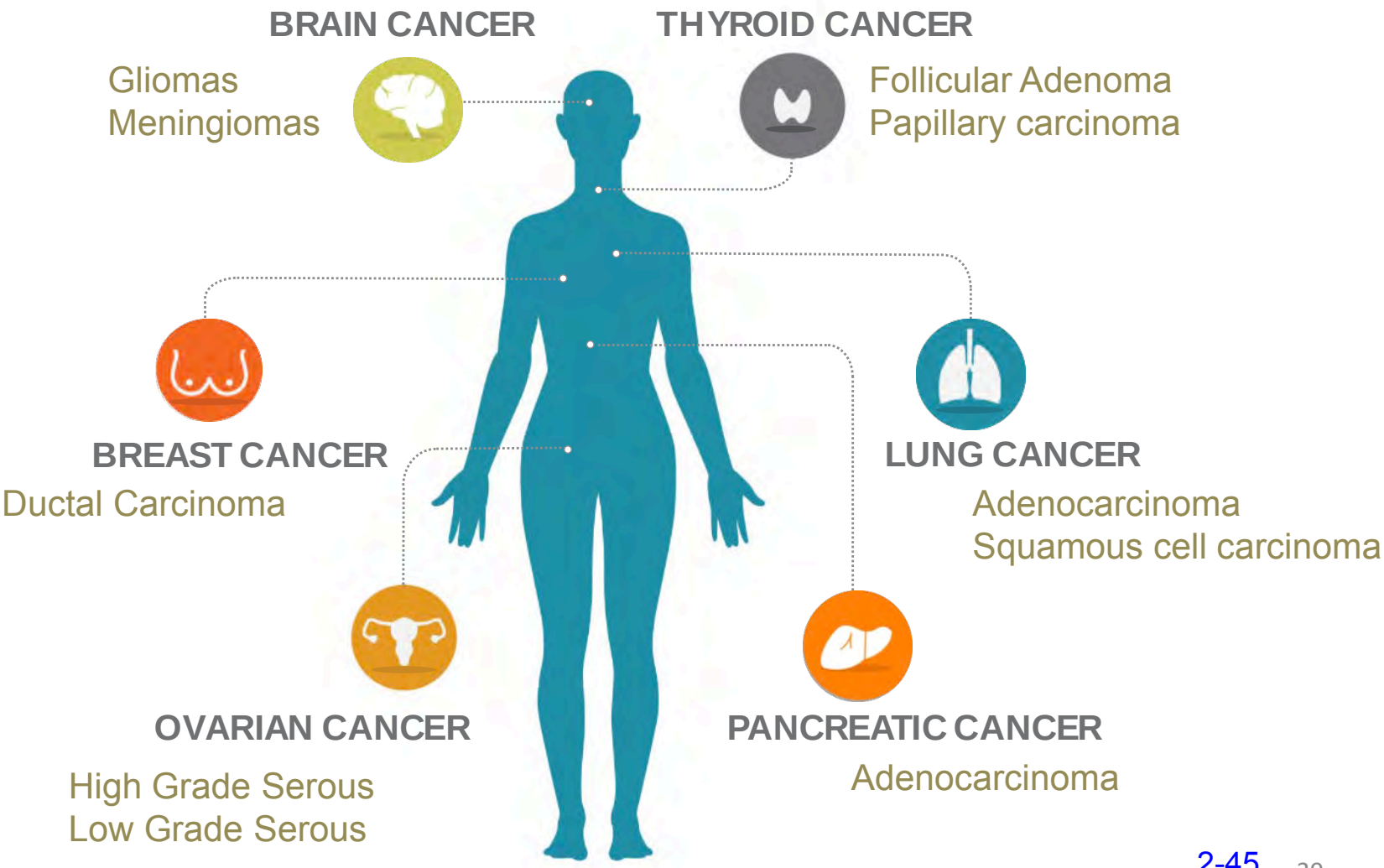
- ***In Vivo* Tissue Analysis:**



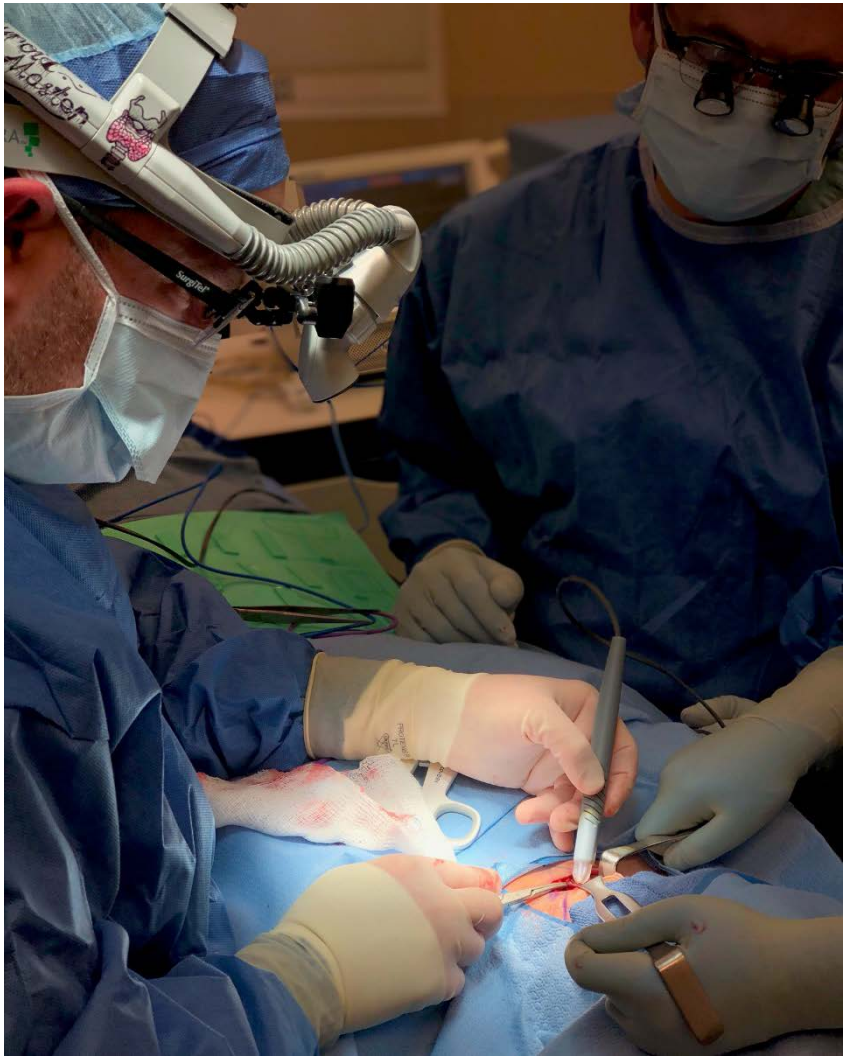
✓ *No harm*

Performance

✓ **n= 705 ex vivo human tissues, ~97% Accurate (n = 705)**



Pilot Clinical Study

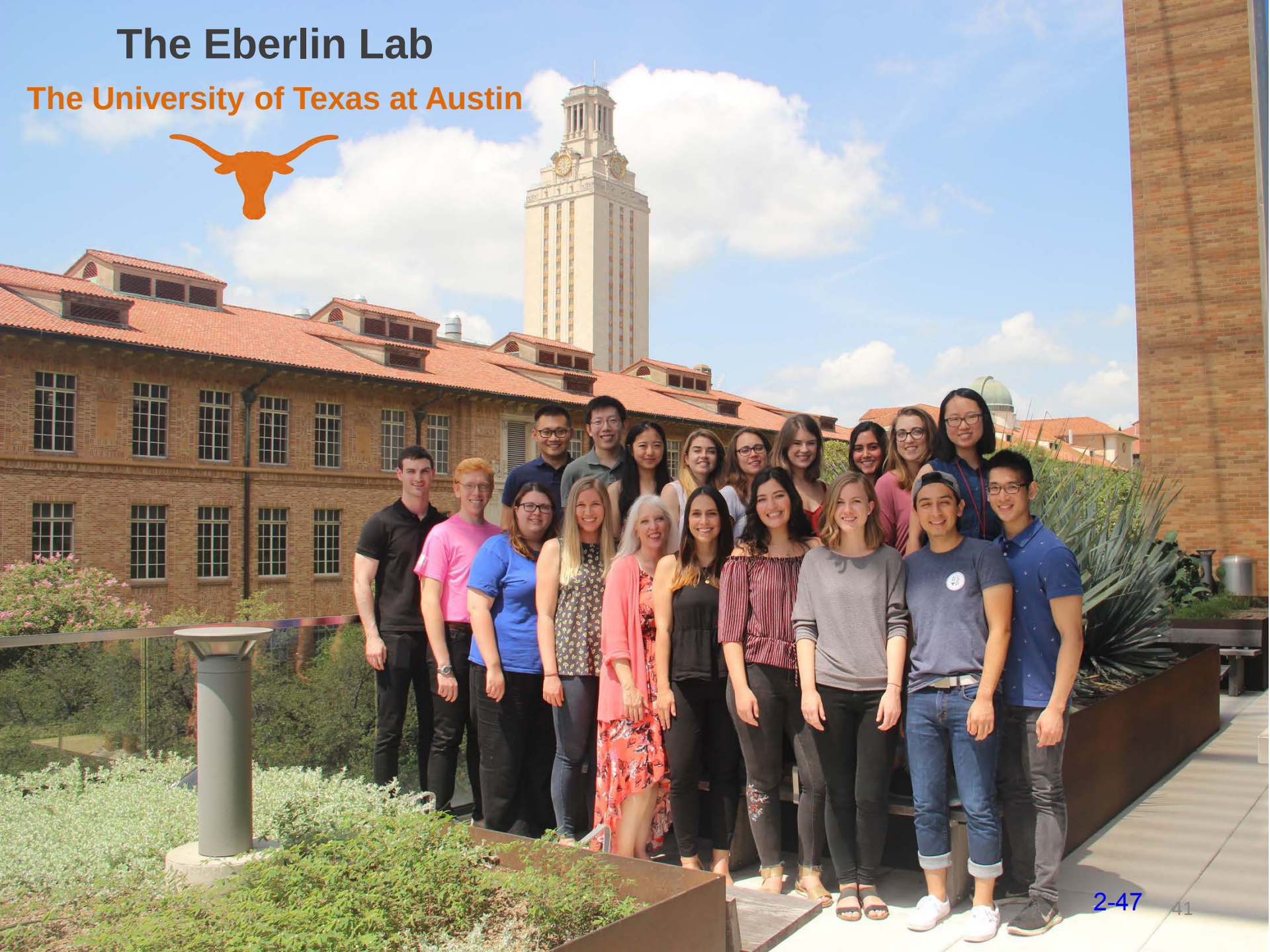


*IRB approved (two institutions)

2-46

The Eberlin Lab

The University of Texas at Austin



Clinical Collaborators

The University of Texas at Austin
Department of Chemistry
College of Natural Sciences

BCM
Baylor College of Medicine

THE UNIVERSITY OF TEXAS
MD Anderson
Cancer Center

CAISM


Dr. James Suliburk


Dr. Wendong Yu


Dr. Anil Sood

Dr. Jinsong Liu


Dr. Luiz Sarian


Dr. Nagi Chandandeep

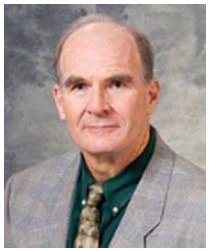

Dr. Stacey Carter

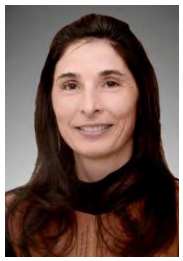

Dr. Erik Cressman


Dr. Ruth Katz


Dr. Sadhna Dhingra


Dr. George Van Buren


Dr. Michael Breen


Dr. Suzanne Ledet

The University of Texas at Austin
Dell Medical School

Funding

THE UNIVERSITY OF TEXAS AT AUSTIN

THE STATE OF TEXAS

CPRIT

Grant RP160776
Grant RP170427
Grant RP180381

THE Welch FOUNDATION
Advancing Chemistry. Improving Life.

Alfred P. Sloan FOUNDATION

GORDON AND BETTY MOORE FOUNDATION

AAAS
ADVANCING SCIENCE, SERVING SOCIETY

NATIONAL INSTITUTES OF HEALTH

NATIONAL CANCER INSTITUTE

MacArthur Foundation

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	AGENDA ITEM 7: CHIEF EXECUTIVE OFFICER REPORT
DATE:	NOVEMBER 14, 2018

As of this writing the Chief Executive Officer's Report for the November 28, 2018, Oversight Committee meeting will consist of the following items:

- Personnel update
- FY 2018 Grant Award Funds Available (attached)
- Pre-filed legislation affecting CPRIT: House Joint Resolution No. 12 (Zerwas), House Bill No. 39 (Zerwas), and Senate Bill 200 (Schwertner)

Other topics may be added as warranted.

In addition, for your reference copies of the September and October 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 **1,317** grants totaling **$2.153 billion**

- 209 prevention awards totaling $223.1 million
- 1,108 academic research and product development research awards totaling $1.930 billion

Of the $1.930 billion in academic research and product development research awards,

- 30.7% of the funding ($592.8 million) supports clinical research projects
- 25.5% of the funding ($491.7 million) supports translational research projects
- 26.2% of funding ($506.0 million) supports recruitment awards
- 14.5% of the funding ($279.1 million) supports discovery stage research projects
- 3.1% of funding ($59.9 million) supports training programs.

CPRIT has 9 open Requests for Applications (RFAs)

- 3 Research Recruitment
- 5 Academic Research
- 4 Prevention

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
Unapproved 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						
	$ -	$ -	$ -			
Announced Grant Award Subtotal	$ -	$ -	$ -	$ -		$ -
Grant Award Adjustments						
Revised Grant Award Subtotal	$ -	$ -	$ -			$ -
Available Funds as of September 1, 2018	$ 28,022,956	$ 174,287,869	$ 74,694,801			$ 277,005,626
Pending Grants-PIC Recommendations						
AR Recruitment Awards (4)	$ -	$ 16,000,000				
Pending Award Subtotal	$ -	$ 16,000,000	$ -			$ 16,000,000
Total Potential Grant Funding Committed	$ -	$ 16,000,000	$ -			$ 16,000,000
Available Funds as of November 28, 2018	$ 28,022,956	$ 158,287,869	$ 74,694,801			$ 261,005,626
1% Grant Funding Buffer	$ -	$ 1,958,626	$ 839,411			$ 2,798,037

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

By: Zerwas H.J.R. No. 12

A JOINT RESOLUTION

proposing a constitutional amendment authorizing the legislature to increase the maximum bond amount authorized for the Cancer Prevention and Research Institute of Texas.

BE IT RESOLVED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Section 67(c), Article III, Texas Constitution, is amended to read as follows:

(c) The legislature by general law may authorize the Texas Public Finance Authority to provide for, issue, and sell general obligation bonds of the State of Texas on behalf of the Cancer Prevention and Research Institute of Texas in an amount not to exceed $6 [~~$3~~] billion and to enter into related credit agreements. The Texas Public Finance Authority may not issue more than $300 million in bonds authorized by this subsection in a year. The bonds shall be executed in the form, on the terms, and in the denominations, bear interest, and be issued in installments as prescribed by the Texas Public Finance Authority.

SECTION 2. This proposed constitutional amendment shall be submitted to the voters at an election to be held November 5, 2019. The ballot shall be printed to permit voting for or against the proposition: "The constitutional amendment authorizing the legislature to increase by $3 billion the maximum bond amount authorized for the Cancer Prevention and Research Institute of Texas."

By: Zerwas H.B. No. 39

A BILL TO BE ENTITLED

AN ACT

relating to the repeal of certain time limitations on the award of grants by the Cancer Prevention and Research Institute of Texas Oversight Committee.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Section 102.254, Health and Safety Code, is repealed.

SECTION 2. This Act takes effect immediately if it receives a vote of two-thirds of all the members elected to each house, as provided by Section 39, Article III, Texas Constitution. If this Act does not receive the vote necessary for immediate effect, this Act takes effect September 1, 2019.

By: Schwertner S.B. No. 200

A BILL TO BE ENTITLED

AN ACT

relating to the financial self-sufficiency of the Cancer Prevention and Research Institute of Texas.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Subchapter A, Chapter 102, Health and Safety Code, is amended by adding Section 102.005 to read as follows:

Sec. 102.005. FINANCIAL SELF-SUFFICIENCY PLAN. (a) The institute shall develop a detailed plan for the institute to become financially self-sufficient and to continue operations without state funds other than patent royalties and license revenues realized as a result of projects undertaken with money awarded under Subchapter E.

(b) The plan described by Subsection (a) must:

(1) specify the steps the institute will take to accomplish the transition to financial self-sufficiency after issuance of the $3 billion in general obligation bonds authorized by Section 67, Article III, Texas Constitution;

(2) specify sources of funding other than state money that may be used to operate the institute after issuance of the $3 billion in general obligation bonds authorized by Section 67, Article III, Texas Constitution; and

(3) describe the institute's method for structuring each state-funded grant to ensure that a grant recipient completes any contractual obligation for which the grant was awarded after

all of the $3 billion in general obligation bonds authorized by Section 67, Article III, Texas Constitution, is awarded to reimburse grant recipients for allowable expenditures pursuant to the institute's grant contract terms.

(c) The institute shall submit the plan described by Subsection (a) to the legislature not later than December 1, 2020. The institute shall submit any modification to the plan before December 1 of each subsequent year.

(d) This section expires September 1, 2023.

SECTION 2. This Act takes effect immediately if it receives a vote of two-thirds of all the members elected to each house, as provided by Section 39, Article III, Texas Constitution. If this Act does not receive the vote necessary for immediate effect, this Act takes effect September 1, 2019.

CPRIT MANAGEMENT DASHBOARD
FISCAL YEAR 2018

	SEPT	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	CUMULATIVE (ANNUAL)	CUMULATIVE (TO DATE)
ACCOUNTABILITY														
Announced Grant Awards	0		4			57			9			64	134	
New Grant Contracts Signed	9	19	7	11	6	44	2	35	12	4	5	2	156	
New Grant Contracts In Negotiation			12			24			8			52	96	
Grant Reimbursements Processed (#)	191	172	138	120	126	216	174	163	193	208	138	204	2,043	
Grant Reimbursements Processed ($)	$ 14,402,580	$ 24,849,514	$ 12,652,218	$ 16,464,363	$ 12,888,800	$ 15,287,606	$ 30,698,463	$ 20,199,295	$ 13,292,876	$ 19,226,586	$ 22,476,261	$ 12,946,440	$ 215,385,002	
Revenue Sharing Payments Received	$ 1,500	$ 35,140	$ 7,557	$ -	$ 21,969	$ -	$ 6,298	$ 18,165	$ -	$ 64,631	$ -	$ 31,077	$ 186,337	$ 3,420,553
Total Value of Grants Contracted ($)	$ 11,469,175	$ 30,088,458	$9,750,000	$ 16,294,571	$ 10,138,500	$ 23,821,567	$ 6,200,000	$ 37,619,680	$ 20,798,445	$ 4,600,994	$ 7,794,086	$ 1,499,617	$ 180,075,093	
Grants Awarded (#)/ Applications Rec'd (#)	13%	13%	13%	13%	12%	13%	13%	13%	13%	12%	12%	13%		
Debt Issued ($)/Funding Awarded ($)	73%	73%	72%	72%	72%	70%	75%	75%	75%	75%	78%	70%		
Grantee Compliance Trainings/Monitoring Visits	0	1	0	0	1	1	4	6	5	10	9	7	44	
Awards with Delinquent Reimbursement Submission (FSR)			1			1			0			0		
Awards with Delinquent Matching Funds Verification			8			19			0			5		
Awards with Delinquent Progress Report Submission			7			3			1			0		
IA Agency Operational Recommendations Implemented	0	0	0	0	0	3	3	3	3	3	3	19	19	
IA Agency Operational Recommendations In Progress	22	22	22	22	22	19	19	19	19	19	19	3		
Open RFAs	6	7	7	12	12	9	4	4	9	16	10	10		
Prevention Applications Received	38	4	0	1	0	31	1	0	0	1	0	3	79	795
Product Development Applications Received	0	0	0	0	0	20	0	0	0	0	0	41	61	463
Academic Research Applications Received	2	2	5	1	208	8	9	12	6	406	3	3	665	6,678
Help Desk Calls/Emails	161	192	121	132	285	243	189	125	230	147	212	252	2,289	
MISSION														
ACADEMIC RESEARCH PROGRAM														
Number of Research Grants Announced (Annual)	0		3			49			8			51	111	
Recruited Scientists Announced														222
Recruited Scientists Accepted														165
Recruited Scientists Contracted														153
Published Articles on CPRIT-Funded Projects (#)													2,401	
Jobs Created & Maintained (#)													2,916	
Clinical Trials (#)														71
Number of Patents Resulting from Research													192	
Number of Patent Applications													245	

CPRIT MANAGEMENT DASHBOARD
FISCAL YEAR 2018

	SEPT	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	CUMULATIVE (ANNUAL)	CUMULATIVE (TO DATE)
Number of Investigational New Drugs													35	
PRODUCT DEVELOPMENT RESEARCH PROGRAM														
Number of Product Development Grant Announced (Annual)			0			0			0			3	3	
Life Science Companies Recruited (in TX)														9
Published Articles on CPRIT-Funded Projects													123	
Number of Jobs Created & Maintained													490	
Clinical Trials (#)														15
Number of Patents Resulting from Research													34	
Number of Patent Applications													70	
Number of Investigational New Drugs													13	
PREVENTION PROGRAM														
Number of Prevention Grants Announced (Annual)			1			8			1			10	20	
People Served by CPRIT-Funded Prevention and Control Activities			282,167			218,357			239,125			232,369	972,018	
People Served through CPRIT-Funded Education and Training			201,481			111,558			142,772			141,939	597,750	
People Served through CPRIT-Funded Clinical Services			80,686			106,799			96,353			90,430	374,268	
TRANSPARENCY														
Total Website Hits (Sessions)	5,959	5,881	5,928	5,613	7,209	6,655	5,736	5,671	8,299	5,705	5,020	9,039	76,715	
Total Unique Visitors to Website (Users)	4,359	4,234	4,305	4,417	4,773	4,657	4,281	4,114	5,771	4,218	3,722	5,935	54,786	

CPRIT MANAGEMENT DASHBOARD-DRAFT METRICS		
	Type of Measure	**Reporting Period**
ACCOUNTABILITY		
Announced Grant Awards	**Workload**	Periodic and Annual Cumulative
New Grant Contracts Signed	**Workload**	Periodic and Annual Cumulative
New Grant Contracts In Negotiation	**Workload**	Periodic and Annual Cumulative
Grant Reimbursements Processed (Number)	**Workload**	Periodic and Annual Cumulative
Grant Reimbursements Processed ($)	**Workload**	Periodic and Annual Cumulative
Revenue Sharing Payments Received	**Qualitative**	Periodic and Cumulative (YTD)
Total Value of Grants Contracted ($)	**Workload**	Periodic and Annual Cumulative
Percent Grants Awarded (#)/Applications Received (#)	**Efficiency**	Calculated monthly as grant cycles close and OC approves grant awards
Percent Debt Issued (#)/Funding Awarded (#)	**Efficiency**	Calculated monthly as debt issued and grants awarded
Grantee Compliance Trainings/Monitoring Visits	**Workload**	Periodic and Annual Cumulative
Awards with Delinquent Reimbursement Submission	**Workload**	Periodic
Awards with Delinquent Matching Funds Verification	**Workload**	Periodic
Awards with Delinquent Progress Report Submission	**Workload**	Periodic
IA Agency Operational Recommendations	**Workload**	Periodic and Annual Cumulative
IA Agency Operational Recommendations In Progress	**Workload**	Periodic
IA Grantee Recommendations Implemented	**Workload**	No longer applicable because Compliance Program in operation
IA Grantee Recommendations In Progress	**Workload**	No longer applicable because Compliance Program in operation
Open RFAs	**Workload**	Periodic
Prevention Applications Received	**Workload**	Periodic and Annual Cumulative
Product Development Applications Received	**Workload**	Periodic and Annual Cumulative
Research Applications Received	**Workload**	Periodic and Annual Cumulative
Help Desk Calls/Emails	**Workload**	Periodic and Annual Cumulative
MISSION		
ACADEMIC RESEARCH PROGRAM		
Number of Research Grants Awarded (Annual)	**Workload**	Periodic and Annual Cumulative
Recruited Scientists Announced	**Qualitative**	Cumulative YTD
Recruited Scientists Accepted	**Qualitative**	Cumulative YTD
Recruited Scientists Contracted	**Qualitative**	Cumulative YTD
Published Articles on CPRIT-Funded	**Qualitative**	Cumulative (Annual)
Jobs Created & Maintained	**Qualitative**	Cumulative (Annual)
Trainees in CPRIT-Funded Training Programs	**Qualitative**	Cumulative (Annual)
Open Clinical Trials	**Qualitative**	Cumulative YTD

Number of Patents Resulting from Research	**Qualitative**	Cumulative (Annual)
Number of Patent Applications	**Qualitative**	Cumulative (Annual)
Number of Investigational New Drugs	**Qualitative**	Cumulative (Annual)
PRODUCT DEVELOPMENT RESEARCH PROGRAM		
Number of Product Development Research Grants Awarded (Annual)	**Workload**	Periodic and Annual Cumulative
Life Science Companies Recruited (in TX)	**Qualitative**	Cumulative (Annual & YTD)
Published Articles on CPRIT-Funded	**Qualitative**	Cumulative (Annual)
Number of Jobs Created and Maintained	**Qualitative**	Cumulative YTD
Open Clinical Trials	**Qualitative**	Cumulative YTD
Number of Patents Resulting from Research	**Qualitative**	Cumulative (Annual)
Number of Patent Applications	**Qualitative**	Cumulative (Annual)
Number of Investigational New Drugs	**Qualitative**	Cumulative (Annual)
PREVENTION PROGRAM		
Number of Prevention Grants Awarded (Annual)	**Workload**	Periodic and Annual Cumulative
People Served by CPRIT-Funded Prevention and Control Activities	**Qualitative**	Periodic and Annual Cumulative
People Served through CPRIT-Funded Education and Training	**Qualitative**	Periodic and Annual Cumulative
People Served through CPRIT-Funded Clinical Services	**Qualitative**	Periodic and Annual Cumulative
TRANSPARENCY		
Total Website Hits	**Workload**	Periodic and Annual Cumulative
Total Unique Visitors to Website	**Workload**	Periodic and Annual Cumulative

* Periodic means either monthly or quarterly depending on the decision of the Oversight Committee. There

CPRIT MANAGEMENT DASHBOARD-DRAFT METRICS
ACCOUNTABILITY
Announced Grant Awards
New Grant Contracts Signed
New Grant Contracts In Negotiation
Grant Reimbursements Processed (#)
Grant Reimbursements Processed ($)
Revenue Sharing Payments Received
Total Grants Contracted ($)
Grants Awarded (#)/Applications Rec'd (#)
Debt Issued ($)/Funding Awarded ($)
Grantee Compliance Trainings/Monitoring Visits
Awards with Delinquent Reimbursement Submission
Awards with Delinquent Matching Funds Verification
Awards with Delinquent Progress Report Submission
IA Agency Operational Recommendations Implemented
IA Agency Operational Recommendations In Progress
IA Grantee Recommendations Implemented
IA Grantee Recommendations In Progress
Open RFAs
Prevention Applications Received
Product Development Applications Received
Research Applications Received
Help Desk Calls/Emails

MISSION
RESEARCH PROGRAM
Scientists Recruited (#)
Published Articles on CPRIT-Funded Projects (#)
Jobs Created & Maintained (#)
Trainees in CPRIT-Funded Training Programs (#)
Open Clinical Trials (#)
Number of Patents Resulting from Research
PRODUCT DEVELOPMENT PROGRAM
Life Science Companies Recruited (in TX)
Published Articles on CPRIT-Funded Projects
Number of Jobs Created & Maintained
PREVENTION PROGRAM
People Served by CPRIT-Funded Prevention and Control Activities
People Served through CPRIT-Funded Education and Training
People Served through CPRIT-Funded Clinical Services
TRANSPARENCY
Total Website Hits
Total Unique Visitors to Website

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	CPRIT ACTIVITIES UPDATE SEPTEMBER 2018
DATE:	OCTOBER 1, 2018

Topics in this memo cover the month of September 2018 and an include an Oversight Committee member appointment, recent milestones in our fight against cancer, a staffing summary, CPRIT outreach efforts, CPRIT's legislative appropriations request presentation, the 2018 Texas Cancer Plan release, and notable events across the state featuring CPRIT, and updates from Compliance, Programs, and Operations.

CPRIT Scholar James Allison, Ph.D. is Awarded Nobel Prize in Medicine

On October 1 the members of the Nobel Committee for Physiology or Medicine announced that CPRIT Established Investigator James Allison, Ph.D., The University of Texas M.D. Anderson Cancer Center (MD Anderson) and Tasuku Honjo, M.D., Ph.D., have won the 2018 Nobel Prize in Medicine for immune checkpoint theory. The committee said that this approach has "revolutionized cancer treatment and has fundamentally changed the way we view how cancer can be managed." According to the Nobel committee, Dr. Allison and Dr. Honjo's research harnessing the body's immune system to attack cancer cells is a "landmark in our fight against cancer."

Dr. Allison studies a protein that functions as a brake on the immune system. He discovered that once it is released, the body's immune cells can attack tumors. Most scientists at the time believed the protein amplified people's immune system. Dr. Allison's counter-intuitive discovery was translated into the drug Yervoy, the first drug of its kind to show survival benefits in melanoma patients. Yervoy is now a standard of care therapy for late-stage melanoma patients.

MD Anderson successfully recruited Dr. Allison to Texas in 2011 with a $10 million CPRIT Scholar award. He returned to Texas from Memorial Sloan-Kettering in New York and now leads MD Anderson's immunology department. There, he has established the cancer immunotherapy platform, a combination of talented research associates and CPRIT-funded laboratory infrastructure working together to better understand and advance cancer immunotherapy and translating basic research to the bedside.

Dr. Allison was elected as a member of the National Academy of Sciences in 1997. In 2015, he won the Lasker-DeBakey Clinical Medical Research Award, one of the world's most prestigious scientific awards. Dr. Allison was also honored with the first-ever 2013 American Association of Cancer Research-Cancer Research Institute Lloyd J. Old Award in Cancer Immunology, the 2013 Breakthrough Prize for Biosciences and the 2014 Tang Prize for Biopharmaceutical

Science. His other major honors include the Dana Foundation Award in Human Immunology Research, the Richard V. Smalley, M.D. Memorial Lectureship Award, a Lifetime Achievement Award from the American Association of Immunologists, the 2018 Albany Medical Center Prize in Medicine and Biomedical Research, and a Roche Award for Cancer Immunology and Immunotherapy.

Governor Appoints David Cummings, M.D., to the Oversight Committee

Governor Abbott on August 27 reappointed David A. Cummings, M.D., to the Oversight Committee. Dr. Cummings is a physician and Medical Director for Shannon Medical Center/Shannon Oncology Center in San Angelo. He practices Medical Oncology and Hematology. Two Oversight Committee positions remain vacant.

Recent Milestones in the Fight Against Cancer

CPRIT Grantees in the News

- The Albany Medical College awarded Dr. Allison the 2018 Albany Medical Center Prize in Medicine and Biomedical Research on September 26, along with Carl June, M.D., University of Pennsylvania, and Steven A. Rosenberg, M.D., Ph.D., National Cancer Institute. They were honored for their groundbreaking research in immunology, the translation of their ideas into clinically meaningful therapies for diseases, including metastatic melanoma, lung cancer and leukemia, and their leadership in moving the field of immunotherapy forward.

  The late Morris "Marty" Silverman, a New York City businessman and philanthropist, established the annual $500,000 Albany Medical Center Prize to honor scientists whose work has demonstrated significant outcomes that offer medical value of national or international importance. It has been referred to as "America's most prestigious prize in medicine." Since the Albany Medical College began awarding the prize in 2001, six Albany Prize recipients have gone on to win the Nobel Prize, including Dr. Allison, whose Nobel Prize in Physiology or Medicine was announced five days after he received the Albany Prize.

- Dorothy Gibbons, a recipient of multiple CPRIT awards to provide breast cancer screening using mobile mammography vans, spoke at the American Cancer Society Cancer Action Network (ACS CAN) forum on August 21 in Austin. KXAN aired an interview with Ms. Gibbons about the importance of CPRIT funding to the women in the 38-county region served by The Rose. The program has provided more than 5,000 mammograms to women who have never been screened and detected 300 breast cancers; these cancers would not have been found without CPRIT funding.

Notable CPRIT Supported Research and Prevention Accomplishments

- Fasiha Kanwal, M.D., Professor of Internal Medicine, Baylor College of Medicine and Amit Singal, M.D., Associate Professor of Internal Medicine, The University of Texas Southwestern Medical Center received two new five-year research awards of $3.7 million each in August as part of a National Cancer Institute (NCI) liver cancer early detection consortium developed to address the dramatic rise of liver cancer in the United States. Drs.

Kanwal and Singal are co-principal investigators on a CPRIT Multi-investigator Research Award, *Texas Hepatocellular Carcinoma Consortium*, awarded in 2015. At the center of the national consortium is their CPRIT-sponsored cohort of more than 3,000 patients at high-risk for developing liver cancer who are monitored as part of the study. These new awards establish Texas' leadership role in response to the emerging liver cancer health crisis.

- Hashem El-Serag, M.D., Baylor College of Medicine, reported in the August 22 issue of the journal *Gastroenterology* that the risk for developing liver cancer is significantly higher in patients with non-alcoholic fatty liver. The findings provide guidance for monitoring and modifying risks for those at increased likelihood for liver cancer. The findings arise at least partially from the *Texas Hepatocellular Carcinoma Consortium* CPRIT grant project.

- UT Southwestern investigators, supported by a CPRIT grant awarded in 2014 as well as a NIH grant, dosed patients undergoing surgery to remove a kidney cancer with intraoperative infusions of radio-labeled glucose to assess how the tumors use glucose. The study, published August 23 in the journal *Cell Metabolism,* found that kidney cancers process glucose differently than normal tissues. Rather than breaking glucose down completely to extract the maximum amount of energy, the tumor cells stopped the break down prematurely and used the remaining glucose to enhance tumor growth. The results underscore the unique metabolic shift that occurs in cancers and suggest a pathway to new treatments that could be cancer specific.

- Christopher Sullivan, Ph.D., associate professor of molecular biosciences at The University of Texas at Austin, uncovered a naturally occurring protein used by the bovine virus to cause leukemia. He made this finding while studying the bovine leukemia virus that killed Bevo XIV. Dr. Sullivan discovered that the protein had a different effect on the human virus hepatitis C – curbing, rather than promoting replication of the virus. The research, supported by a CPRIT individual investigator research grant awarded in 2014 and reported July 23 in the journal *Proceedings of the National Academy*, sheds light on how human defenses fight off hepatitis C virus infections and exemplifies the serendipity often encountered in science.

- George Georgiou, Ph.D., professor at UT Austin's School of Engineering, developed a novel approach to treating cancer using enzyme therapy. The enzyme, PEG-KYNase, does not directly kill cancer cells; instead it empowers the immune system to eradicate unwanted cells on its own. PEG-KYNase degrades kynurenine, a metabolite produced by numerous tumors that suppresses the immune system. The findings, supported by a CPRIT Early Translational Research Award and published July 16 in *Nature Biotechnology*, have led to a new company, Kyn Therapeutics, that is pursuing the clinical development of this approach. A CPRIT-funded company, Aeglea Biotherapeutics, was founded in 2013 to develop and bring to market the engineered human enzymes invented in Dr. Georgiou's lab.

- Immatics Biotechnologies announced on August 16 the enrollment of its first patients into a single-center phase I trial of IMA202 at The University of Texas MD Anderson Cancer Center. IMA202 is an investigational immunotherapy that uses Immatics' proprietary

ACTengine® approach to redirect and activate the T cells to treat solid tumors. This is the company's second T-cell receptor-transduced adoptive cell therapy program.

The study is comprised of patients with relapsed and/or refractory solid tumors, such as advanced non-small cell lung cancer and hepatocellular carcinoma, for which no standard of care therapy is available. Immatics received a $19.7 million CPRIT Product Development Research award in February 2015 and licensed their core technology from MD Anderson.

- Aravive Biologics, Inc announced on August 20 that the U.S. Food and Drug Administration granted Fast Track Designation for AVB-S6-500 as a potential treatment for platinum-resistant recurrent ovarian cancer. The Fast Track Designation helps important new drugs get to patients earlier by facilitating development and expediting regulatory review. Results of a Phase 1 study of AVB-S6-500 in healthy volunteers showed a favorable safety profile. The company plans to initiate a Phase Ib study combining AVB-S6-500 with standard-of care therapies in patients with platinum-resistant ovarian cancer by the end of the year.

  Aravive is developing novel therapies to inhibit GAS6 proliferation in tumor cells. GAS6 is an important tumor signaling agent in multiple cancers. Patients expressing GAS6 and its receptor AXL are likely to have a poor cancer prognosis. The company received a $20 million Product Development award from CPRIT in November 2015.

- On September 5 Asuragen Inc. announced the launch of the QuantideX® NGS DNA Hotspot 21 Kit, a targeted, next-generation sequencing panel for the detection of clinically relevant deviations across many tumor types. Asuragen is a molecular diagnostics company providing diagnostic systems composed of proprietary chemistry and software. Physicians use these tools to identify a patient's specific genetic sequence to classify cancer subtypes. The information helps the physician select an appropriate therapy regime. Asuragen received a $6.84 million CPRIT Product Development Research award in March 2012.

- On September 19 Molecular Templates, Inc. announced that the company recently closed a $662.5M deal with Takeda Pharmaceuticals. Takeda optioned Molecular Templates' CD38-targeted engineered toxin bodies for the treatment of patients with diseases such as multiple myeloma. Molecular Templates is developing engineered toxin bodies that use a genetically engineered form of the Shiga-like toxin to specifically target and destroy cancer cells. Takeda has agreed to pay Molecular Templates $30 million up front and potential milestone payments of as much as $632.5 million should Takeda choose to co-develop CD38-targeted engineered toxin bodies for the treatment of multiple myeloma and other cancers.

  Molecular Templates plans to raise an additional $30 million in a public offering to fund the company's ongoing Phase Ib and Phase II studies of its engineered toxin bodies for diffuse large B-cell lymphoma, as well as programs targeting HER2 and PD-L1 and its share of development expenses in the Takeda collaboration. The company initiated a Phase II combination study of its therapy in patients with advanced diffuse large B-cell lymphoma earlier this quarter.

Molecular Templates has received two Product Development awards from CPRIT; CPRIT announced the first $10.6 million award in November 2011 and the second $15.2 million award in November 2016.

- Cell Medica announced September 20 that it successfully dosed the first neuroblastoma patient with innovative chimeric antigen receptor (CAR) therapy utilizing natural killer T cells (NKT). The CAR-NKT therapy is targeting pediatric neuroblastoma. This is the first time an engineered NKT cell therapy has been used in humans. The company is collaborating with both Baylor College of Medicine and Texas Children's Hospital to carry out the Phase I study. According to Dr. Andras Heczey, the Principal Investigator on the trial and Assistant Professor, Pediatrics-Oncology Baylor College of Medicine, "Dosing the first patient with this novel CAR-NKT therapy is an important milestone for all pediatric patients with neuroblastoma. CAR-NKTs may offer an exciting new therapeutic option for these patients and potentially for others with solid and hematological cancers. I am extremely grateful to the patients and families participating in this ground-breaking study."

  Cell Medica received a $15.5 million Product Development award from CPRIT in March 2012.

- The NCI selected a CPRIT-funded project run by Navkiran Shokar, M.D., M.P.H., M.A., director for Cancer Prevention and Control at Texas Tech University Health Science Center El Paso, to include in NCI's database of Research-Tested Intervention Programs (RTIPs). RTIPs are evidence-based cancer control interventions and associated program materials designed to provide program planners and public health practitioners easy and immediate access to research-tested materials. Experts in the field of research integrity, intervention impact, and dissemination capability review and select projects to include in the RTIPs database. Dr. Shokar's CPRIT prevention project *Against Colorectal Cancer in Our Neighborhoods (ACCION)* is a bilingual, community-based intervention designed to increase colorectal cancer screening among uninsured Hispanic adults.

- Simon Craddock Lee, Ph.D., associate professor at UT Southwestern, spoke at the NCI's Rural Cancer Control meeting in April about the CPRIT-funded BSPAN breast cancer screening project. Because of the program's impressive results, the CDC has invited Dr. Lee to present on the policy implications of the BSPAN program evaluation in Atlanta this fall.

- Paula Cuccaro, Ph.D., assistant professor of Health Promotion and Behavioral Sciences at The University of Texas School of Public Health, will present the findings of her CPRIT-funded prevention project, *Using Social Marketing and Mobile School-Based Vaccination Clinics to Increase HPV Vaccination Uptake in High-Risk Geographic Areas*, at the 32nd International Papillomavirus Conference in October.

Personnel

CPRIT has filled all 35 of its authorized full-time equivalent (FTE) positions. A contract employee is working temporarily as Grant Compliance Specialist while CPRIT is interviewing to fill the position permanently.

CPRIT Outreach

- Kristen Doyle, Deputy Executive Officer and General Counsel, Heidi McConnell, Chief Operating Officer, and I briefed the Lieutenant Governor's staff on September 5. We discussed CPRIT's request made to the Legislative Budget Board to transfer funds now as well as CPRIT's fiscal requests for the 86th Texas Legislature.

- I presented "Delivering on the Promise: CPRIT Impact" at the Texas Society of Clinical Oncology's annual meeting in Houston on September 8.

- I briefed Representative Philip Cortez, Ph.D., on September 13 about CPRIT's plans for the 86th Texas Legislature.

- On September 17 Ms. Doyle, Ms. McConnell and I updated Representative Sarah Davis' staff on CPRIT activities and plans for the 86th Texas Legislature.

- On September 19 Ms. McConnell and I briefed staff of Speaker Straus and the House Committee on Appropriations on CPRIT's request to the Legislative Budget Board to transfer funds as well as CPRIT's fiscal requests for the 86th Texas Legislature.

- More than 135 individuals attended the webinar hosted by Chief Scientific Officer Jim Willson and Chief Product Development Office Michael Lang on September 19. Dr. Willson and Mr. Lang briefed academics and the Texas entrepreneurial community on CPRIT's new Early Translational Research Award and Seed Award requests for applications.

- Dr. Willson participated in a panel entitled, "CPRIT: Expediting Innovation" at the Biden Cancer Summit held September 21 at the UT- Austin Dell Medical School.

- On September 24 I discussed CPRIT's plans for the 86th Texas Legislature with the executive staff of the Texas Association of Business.

- On September 27-29 Oversight Committee Member Dee Margo and I attended the 2018 Tribfest, an annual public affairs conference presented by the *Texas Tribune*. Officials from all levels of government, the media, and state agencies presented on and discussed current issues and those expected to be addressed during the 86th Texas Legislature. Mr. Margo, in his capacity as Mayor of El Paso, participated on a panel on "The Way Forward is Urban." I had brief but substantive discussions with Representatives John Zerwas, Four Price, Garnet Coleman, and Comptroller Glen Hegar, as well as a number of Capitol observers.

- Ms. Doyle presented an update on CPRIT's activities, the Texas Cancer Plan, and CPRIT's legislative agenda to the Committee on Cancer at the Texas Medical Association's annual fall conference on September 28.

American Cancer Society Cancer Action Network Events Featuring CPRIT

The American Cancer Society's Cancer Action Network (ASC CAN) held three events in August highlighting CPRIT activities. This is the third year that ASC CAN has featured CPRIT in its annual policy forum series, which are well attended by legislators and the advocate community around Texas. This year's events featured CPRIT's prevention program and early detection work. Dr. Garcia, Chief Prevention and Communications Officer, spoke at each of the events, as did area legislators, program directors for CPRIT-funded prevention projects, and Texans that have benefitted from our prevention services. Several CPRIT staff attended these events as well as Oversight Committee members Will Montgomery and Mahendra Patel. At the San Antonio event On August 29, Dr. James Willson, Chief Science Officer, announced the Collaborative Action Program to reduce liver cancer mortality in Texas.

ACS CAN will also host a "Texas Research Breakfast" on October 25 in Houston. NBC correspondent Janet Shamlian will emcee the event. The guests of honor will be Texas A&M Chancellor John Sharp and U.S. Energy Secretary Rick Perry (invited). ACS CAN will recognize Chancellor Sharp and Secretary Perry for their roles in establishing CPRIT.

ACS CAN invites Oversight Committee members to attend the remaining events. Please let me know as soon as possible if you would like to attend.

Texas Healthcare & Bioscience Institute Business Roundtables Featuring CPRIT

Texas Healthcare & Bioscience Institute (THBI), the state's largest association of life science industry businesses, is hosting a series of roundtables that will discuss their priorities for the 86th Texas Legislature. Prominent in these discussions will be CPRIT. THBI is finalizing details, but the schedule and location of the roundtable events will be:

- October 16 in the Metroplex
- October 25 in Austin
- October 30 in San Antonio

I will attend the October 16 and 30 events, but the Austin roundtable conflicts with the ACS CAN Texas Research Breakfast in Houston. I will keep you informed of final scheduling details.

BioHouston and THBI Host CPRIT Product Development Company Day

BioHouston and THBI are sponsoring an October 31 event in Houston featuring presentations from companies that have received CPRIT awards. The event will be open to local media, legislators, and legislative staff. I will keep you informed BioHouston and THBI finalize event details.

CPRIT Presents 2020-2021 Legislative Appropriations Request to Legislative Budget Board

Ms. McConnell and I presented the agency's 2020-2021 Legislative Appropriations Request to a September 4 joint hearing of the Governor's Office and Legislative Budget Board (LBB) staff. The statute requires a hearing on an agency's budget as part of the state's budget process. In addition to the Governor's staff and the LBB, there was also staff representing the Lieutenant Governor, Senate Finance Committee, House Appropriations Committee, and Rep. Drew Darby.

CPRIT Releases the 2018 Texas Cancer Plan

CPRIT launched the new *2018 Texas Cancer Plan* with a press release on September 25 and outreach to the media. The *Plan*, available through its website since August 31, serves as a guide outlining actionable, achievable goals, objectives, and strategies to reduce the burden of cancer for communities and individuals across Texas. The *Plan* identifies five high priority areas, each poised to have a significant impact on cancer, and it also reflects changes, progress and advances in cancer prevention and control since the last revision in 2012. CPRIT plans to print a limited number of copies in September.

Compliance Program Update

Submission Status of Required Grant Recipient Reports

CPRIT's grant management system (CGMS) produces a summary of delinquent reports each week; this is the primary source used by CPRIT's compliance staff to follow up with grantees. CPRIT typically has 560+ grants that are either active or wrapping up grant activities and receives an average of 560 grantee reports each month.

As of September 26, 2018, three entities have not filed three required reports by the due date; two (67%) were for Academic Research grants and one (33%) was for a Product Development Research grant. 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 162 second-level reviews of grantee Financial Status Reports (FSRs) for the month of September. Seven FSRs (4%) 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 audit findings are compiled in an independent audit report and submitted to CPRIT within 30 days of receipt, but no later than 9 months after the grantee's fiscal year.

Compliance Specialists are working with one grantee to remediate audit findings. CPRIT gives grantees 30 days from the receipt of the audit to submit supporting documentation to demonstrate remediation efforts. Currently, there are no grantees with a delinquent audit. Grantees are unable to receive reimbursements or advances if they are delinquent in filing the required audit and corrective action plan unless the grantee requested additional time by the due date of the required audit and CPRIT's CEO approved the request.

CPRIT recently revised the Annual Single Audit Determination (SAD) form process. Grantees will now complete one form for their institution annually and submit the completed form to CPRIT via email. Prior to this change, the grantee completed a SAD form for each active grant held by the grantee and submitted each through CPRIT's grants management system. The due date for all future SAD forms will be 60 days after the organization's fiscal year end date. As of September 26, 2018, 49 grantees have submitted their updated SAD forms to CPRIT. remaining One grantee has not submitted their SAD form; compliance staff will follow up with the grantee.

Desk Reviews

Compliance Specialists performed 13 desk-based financial monitoring/reviews in September to verify that grantees expend funds in compliance with specific grant requirements and guidelines. Desk reviews may target an organization's internal controls, current and past fiscal audits, and timeliness of required grantee report submission. Compliance Specialists are working with 11 grantees to remediate desk review findings from the prior fiscal year.

Training and Support

CPRIT staff will conduct a grantee training webinar on October 10, 2018. The training will cover grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. This is the third and final training offered this calendar year in support of the annual compliance training obligation that requires the Authorized Signing Official (ASO) and at least one other employee from each grantee organization to attend compliance training by CPRIT by November 1 of each year.

CPRIT has scheduled three new ASO trainings for September 26, September 28, and October 3. These trainings will cover 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 1 (19.1) RFAs Update

Applicants submitted more than 400 proposals for FY 2019 Cycle 1 (19.1) grant awards. CPRIT will conduct peer review October 18 – October 25 in Dallas. Dr. Willson plans to present the Scientific Review Council's award recommendations to the Program Integration Committee (PIC) and the Oversight Committee in February 2019.

Table 1: FY 2019.1 (19.1) Application Data by Mechanism

Mechanism	Received	Funds Requested	In Full Review	Funds Requested
Individual Investigator Research Award (IIRA)	268	$233,976,917	144	$126,157,080
IIRA for Cancer in Children and Adolescents	37	$44,382,130	24	$29,026,405
IIRA for Clinical Translation	33	$52,321,758	23	$37,874,514
IIRA for Computational Biology	27	$20,580,933	12	$9,544,680
IIRA for Prevention and Early Detection	36	$34,294,805	26	$26,970,288
TOTAL	**401**	**$385,556,543**	**229**	**$229,572,967**

Recruitment Summary Data

CPRIT received six recruitment applications during recruitment cycles 19.1 and 19.2. Dr. Willson will present the Scientific Review Council's award recommendations to the PIC and the Oversight Committee in November.

Table 2: FY 2019.1 Recruitment RFA data by Mechanism for Cycles 19.1 and 19.2

Mechanism	Received	Funds Requested	Rec'd by SRC	Funds Requested
Recruitment Established Investigators	1	$6,000,000	1	$6,000,000
Recruitment Rising Stars	1	$4,000,000	0	
Recruitment of First-Time Tenure Track Faculty Members	4	$8,000,000	1	$2,000,000
TOTAL	**6**	**$18,000,000**	**2**	**$8,000,000**

FY 2019 Cycle 2 Academic Research RFAs

The Oversight Committee approved the FY 2019 schedule for the second cycle of RFAs in February 2018.

- *Recruitment of Established Investigators (FY19)*
  Outstanding senior research faculty with distinguished professional careers and established cancer research programs to academic institutions in Texas.
  Award: Up to $6 million over a period of five years.

- *Recruitment of Rising Stars (FY19)*
  Outstanding early-stage investigators who have demonstrated the promise for continued and enhanced contributions to the field of cancer research.
  Award: Up to $4 million over a period of five years.

- *Recruitment of First-Time Tenure Track Faculty Members (FY19)*
  Promising emerging investigators, pursuing their first faculty appointment who have the ability to make outstanding contributions to the field of cancer research.
  Award: Up to $2 million over a period of five years.

- *Core Facilities Support Awards (CFSA) (RFA R-19.2 CFSA)*
  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 $3 million (total costs) for the first 2 years and up to $1 million (total costs) for each subsequent year; maximum duration: 5 years.

- *High Impact/High Risk Research Awards (HIHR) (RFA R-19.2 HIHR)*
  Short-term funding to explore the feasibility of high-risk projects that, if successful, would contribute major new insights into the etiology, diagnosis, treatment, or prevention of cancers.
  Award: Up to $200,000 (total costs); Maximum duration: 2 years.

- *Early Translational Research Awards (ETRA) (RFA-R-19.2 ETRA)*
  Projects that "bridge the gap" between promising new discoveries achieved in the research laboratory and commercial development for a therapeutic, device, or diagnostic assay through activities including preclinical proof-of-principle data that demonstrate applicability to the planned clinical scenario and preclinical toxicology and formulation to de-risk the development of lead compounds or devices. Any not-for-profit institution that conducts research is eligible to apply for funding. CPRIT requires a presentation of a time line with stage gates for development. A public or private company is not eligible.
  Award: $1 to 2 million in total costs over a period of 1-2 years.

- *Collaborative Action Program to Reduce Liver Cancer Mortality in Texas: Collaborative Action Center Award (RFA-R-19.2 CAP: CAC)*
  Single Collaborative Action Center (Center) whose function is to: (1) promote interactions and collaborations across the CAP Research Awards funded under the companion RFA, R-19.2 CAP:RA; (2) provide opportunities for academic content experts, health care providers and community stakeholders to exchange ideas and to explore new opportunities to impact

the rise of hepatocellular cancer (HCC) in Texas, and (3) educate health care providers and the public on best practices to alter the trajectory of HCC in Texas.
Award: CPRIT plans to make one award to a single applicant in response to this RFA. Up to $3 million in total costs over 5 years.

- *Collaborative Action Program to Reduce Liver Cancer Mortality in Texas: Investigator Initiated Research Awards (RFA-R-19.2 CAP: RA)*
  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 in total costs per year for 5 years.

Advisory Committees

The Clinical Trials Advisory Committee met on September 18, 2018. Dr. Willson will provide an update for Oversight Committee members at the November meeting.

The University of Houston System appointed Dr. Claudia Neuhauser to the University Advisory Committee.

Product Development Research Program Update

Product Development Research FY 2018 Cycle 2

The Oversight Committee approved three product development applications at its August meeting. The Oversight Committee's approval of one of the projects included contingencies that the company must address before CPRIT can execute the award contract. The company, Korysso Therapeutics, has been updating Product Development staff with its progress toward addressing the contract contingencies. The company notified CPRIT that Magnolia Neurosciences Corporation has acquired Korysso as a fully-owned, Texas-based subsidiary, and are renaming it Magnolia Tejas. Once the company fulfills all contract contingencies and executes the contract, CPRIT will change the name of the company to Magnolia Tejas in CPRIT's award database to reflect the acquisition.

The Product Development Review Council (PDRC) requested more information from two companies before completing their review. The PDRC will finalize the review these applications Mr. Lang will bring any award recommendations to the Oversight Committee for consideration.

Product Development Research Applications FY 2019 Cycle 1

The Oversight Committee approved the schedule and RFA topics for the Product Development FY 2019 Award Cycle 1 at the February 21 meeting. CPRIT released three RFAs in mid-May and accepted applications through August 8. Applicants submitted 38 proposals.

Table 3: FY 2019.1 (19.1) Application Data by Mechanism

Mechanism	Received	Funds Requested	In Person Presentation	Funds Requested
Texas Company	5	$42,389,966	2	$16,680,008
Relocation Company	8	$113,790,609	4	$63,474,499
Seed Company	25	$64,956,585	11	$29,569,259
TOTAL	**38**	**$221,137,160**	**17**	**$109,723,766**

The significant response to the new Seed Application indicates this new award mechanism addresses a critical funding gap in the development cycle. CPRIT held the initial screening conference of all applications September 24 – 25 to determine the applicants to invite for in-person presentations and peer review. CPRIT has scheduled this review for October 23-26 in Dallas. Mr. Lang will present the PDRC's award recommendations to the PIC and the Oversight Committee in February 2019.

Prevention Program Update

FY 2019 Cycle 1 (19.2) Prevention Applications

CPRIT released four RFAs in June 2018 for the first review cycle of FY 2019. CPRIT received 22 applications requesting $36,106,520 (see table below) by the September 5 deadline. CPRIT has scheduled peer review for December 10 - 13. Dr. Garcia will present the PIC recommendations to the Oversight Committee in February 2019.

Table 4: FY 2019.1 (19.1) Application Data by Mechanism

Mechanism	Received	Funds Requested
Evidence-based Cancer Prevention Services	10	$13,804,996
Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations	7	$15,830,685
Tobacco Control and Lung Cancer Screening	5	$6,470,839
Dissemination of CPRIT-Funded Cancer Control Interventions	0	$0
TOTAL	**22**	**$36,106,520**

FY 2019 Cycle 2 Prevention RFAs

CPRIT will release FY2019 Cycle 2 RFAs on November 19 with applications due by February 20, 2019. Peer review will take place May 20 – 23, 2019. Dr. Garcia plans to present the Prevention Review Council's recommendations to the PIC and the Oversight Committee in August 2019.

FY 2019 Cycle 2 Prevention RFAs

- *Evidence-Based Cancer Prevention Services*
  Evidence-Based Cancer Prevention Services - This award mechanism seeks to fund projects that will deliver evidence-based cancer prevention and control clinical services. 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; Maximum duration of 36 months.

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

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

- *Dissemination of CPRIT-Funded Cancer Control Interventions*
  This award mechanism 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; Maximum duration of 24 months.

Communications Update

Special Events

- Communications is assisting THBI with planning the roundtables discussed earlier in this newsletter.

- Communications is assisting with media outreach for the ACS CAN forum in College Station on October 8th.

Cancer Awareness Months

- CPRIT is producing a liver cancer video featuring both academic research and prevention grantees for release in October for Liver Cancer Awareness Month. We will also pitch stories to the media on CPRIT grantees in El Paso and San Antonio.

Other activities

- The communications team continues to design and develop content for CPRIT's soon-to-be-launched website including a digital newsroom; a multi-channel platform for posting, curating, and distributing CPRIT and related content.

Social media

Facebook (last 28 days):

- Reach: 1,951
- Engagement: 414
- Most popular post: "Today, with the approval of 64 new cancer research, product development, and prevention grants totaling more than $177 million, the Cancer Prevention & Research Institute of Texas (CPRIT) has awarded $2.15 billion of the $3 billion approved by Texas voters in 2007 to fight cancer."

Twitter:

- 15,800 impressions
- Top tweet: "How does Texas measure up in the fight against cancer? Find out in the annual @ACSCAN report on state efforts effecting cancer patients and survivors: https://cprit.us/2OWiC2C."

Operations, Audit and Finance Update

Several CPRIT staff and the McConnell & Jones audit team had an entrance meeting on September 26, 2018, to initiate the audit of FY 2018 financials.

Upcoming Subcommittee Meetings
Listed below are the regularly scheduled subcommittees in advance of the November 28, 2018, Oversight Committee meeting.

Board Governance	November 1 at 10:00 a.m.
Audit	November 5 at 10:00 a.m.
Prevention	November 6 at 10:00 a.m.
Academic Research	November 7 at 10:00 a.m.
Product Development	November 8 at 10:00 a.m.
Nominations	November 9 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 **1,317** grants totaling **$2.153 billion**

- 209 prevention awards totaling $223.1 million
- 1,108 academic research and product development research awards totaling $1.930 billion

Of the $1.930 billion in academic research and product development research awards,

- 30.7% of the funding ($592.8 million) supports clinical research projects
- 25.5% of the funding ($491.7 million) supports translational research projects
- 26.2% of funding ($506.0 million) supports recruitment awards
- 14.5% of the funding ($279.1 million) supports discovery stage research projects
- 3.1% of funding ($59.9 million) supports training programs.

CPRIT has 9 open Requests for Applications (RFAs)
- 3 Research Recruitment
- 5 Academic Research
- 1 Prevention

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	CPRIT ACTIVITIES UPDATE OCTOBER 2018
DATE:	NOVEMBER 1, 2018

Topics in this memo cover the month of October 2018 and include recent milestones in our fight against cancer, a staffing summary, CPRIT outreach efforts, and updates from Compliance, Programs, and Operations.

Upcoming Oversight Committee Meeting

The Oversight Committee will meet November 28, 2018, at 10:00 a.m. in Room E1.012 of the Texas Capitol Extension. CPRIT will post the final agenda for the Oversight Committee meeting by November 20; I have attached a tentative agenda. We have seven members of the Oversight Committee and do not expect new appointments before the November meeting. One member has already notified me that he will be unable to attend the November meeting. A quorum of five members is necessary to conduct official business. **Please notify me as soon as possible if you are unable to attend the November meeting or have travel arrangements that will cause you to arrive late or leave the meeting early.**

You will receive an email from CPRIT by November 5 with a link and password to access the Program Integration Committee's four award recommendations via the grant award portal. The portal has supporting documentation regarding each project proposed for an award, including the application, CEO affidavit, summary statement, and grant pedigree. A summary of the award slate will also be available through the portal. Please allow some time to complete the individual conflict of interest checks and review the supporting material.

Oversight Committee members will receive an electronic copy of the agenda packet by November 15. Hard copies of the agenda packet will be available at the meeting.

Recent Milestones in the Fight Against Cancer

CPRIT Grantees in the News

- On October 4, The John D. and Catherine T. MacArthur Foundation announced that CPRIT grantee Livia Schiavinato Eberlin, Ph.D., was one of 25 people to win its prestigious fellowship this year. Dr. Eberlin, an assistant professor of chemistry at The University of Texas at Austin, received the $625,000, no-strings-attached fellowship, unofficially known as

the "genius grant," in recognition of her invention of the MassSpec Pen, a handheld device that identifies cancerous tissue within 10 seconds during surgical procedures. Dr. Eberlin has received CPRIT awards totaling $2.4 million to support her research testing the MassSpec Pen's feasibility and impact in the clinical setting, including a High Impact/High Risk Award, a Bridging the Gap Early Translational Research Award, and an Individual Investigator Research Award for Clinical Translation.

- CPRIT grantee Zhijian "James" Chen, Ph.D., is the winner of the 2019 Breakthrough Prize in Life Sciences for his discovery of the cGAS enzyme that launches the body's immune defense against infections and cancers. The Breakthrough Prize, announced October 17, recognizes achievements in the Life Sciences, Fundamental Physics, and Mathematics, the disciplines that ask the biggest questions and find the deepest explanations. CPRIT has awarded Dr. Chen $6.9 million to investigate how cGAS links to the development of cancer and to exploit its role in immune defense against malignant cells. This work is expected to lead to new immunotherapy drugs for cancer based on cGAMP and its derivatives used as adjuvants for vaccines and cancer immunotherapies.

- The National Academic of Medicine (NAM) announced the election of Dr. Sean Morrison, CPRIT Established Investigator, as a NAM member. This is one of the highest honors in the fields of health and medicine. Dr. Morrison, a Professor of Pediatrics at the University of Texas at Southwestern Medical Center and director of the Children's Medical Center Research Institute, is known for his significant discoveries in stem cell biology and cancer. UT Southwestern recruited Dr. Morrison to Texas with a $10 million CPRIT recruitment award in 2011. In addition to his election to NAM, Dr. Morrison is a Howard Hughes Medical Institute investigator. He currently holds three active CPRIT awards including a Multi-Investigator Research Award to identify new therapeutic strategies that inhibit melanoma progression.

- Texans Caring for Texans recognized Dr. Izi Obokhare, Brenda Hernandez, and Michelle Marsh of Texas Tech University, at its 2018 award ceremony on August 9 for the team's *Get FIT to Stay Fit* project which helps bridge disparities in the community and provide colorectal cancer screening in rural areas.

- The Nursing Research & Evidence Based Practice Council presented Dr. Barbara Turner, the James D. and Ona I. Dye Professor of Medicine at The University of Texas Health Science Center at San Antonio (UT Health San Antonio), an award for her abstract, *Surveillance Compliance among Underserved & Insured Hereditary Cancer Mutation Carriers*. The abstract is based on her CPRIT project supporting genetic services patient navigator. Dr. Turner also met with Texas Senators Ted Cruz and John Cornyn on Capitol Hill to discuss care for cancer patients as one of the Texas delegates for the Oncology Nursing Society.

- Aravive Biologics, Inc. announced the completion of a merger with Versartis, Inc. on October 15. The newly merged, publicly traded company will be known as Aravive Inc. It is a clinical stage biotechnology company focusing on developing innovative therapies that target important survival pathways for cancer. The company is developing a first-in-class,

GAS6 binding protein designed to prevent AXL signaling, a pathway known to play a role in tumor metastasis and treatment resistance. Aravive completed the first Phase I clinical trial of its lead candidate, AVB-S6-500, and will initiate the Phase Ib portion of its Phase Ib/2 trial in patients with platinum resistant ovarian cancer before the end of the year. Based on compelling results from the company's non-clinical studies, Aravive also plans to evaluate AVB-S6-500 in additional tumor types and, longer term, its potential for treating fibrosis. Aravive (formerly Ruga Corporation) received a $20 million CPRIT Product Development Award in November 2015, which funded the preclinical and Phase 1 clinical trial work.

Notable CPRIT Supported Research and Prevention Accomplishments

- Tvardi Therapeutics Inc., a clinical-stage, Houston-based biopharmaceutical company recently announced the completion of a $9 million Series A financing round. The company helps develop inhibitors to STAT3, an oncogene implicated in cancers, and is based upon discoveries by CPRIT grantee David Tweardy, M.D., Professor of Internal Medicine at The University of Texas MD Anderson Cancer Center. A CPRIT individual investigator grant to Dr. Tweardy supported the early discovery of a new cancer drug that selectively targets STAT3. A subsequent "Bridging the Gap: Early Translational Research Award" award from CPRIT supported the manufacturing and preclinical testing required for first-in-man human studies of this new cancer drug. CPRIT now supports a clinical trial of this new drug in patients with hepatocellular carcinoma. In all CPRIT has awarded $5.8 million for the development of the new STAT3 inhibitor from concept to first-in-man testing.

- A major outcome from a CPRIT Prevention Program grant project examining clinical practices used to increase HPV vaccination rates directed by Dr. Maria Jibaja-Weiss, Baylor College of Medicine, resulted in a Harris Health System-wide quality improvement effort. Led by nursing staff, the effort facilitated practice changes in all nineteen pediatric clinics.

- Medicenna Therapeutics presented insights from its Phase IIb clinical trial of its lead immunotherapeutic agent targeting brain tumors at the European Society for Medical Oncology Congress on October 22 in Munich, Germany. In the study, investigators are administering Medicenna's lead therapy, MDNA55-05, directly into brain tumors. Medicenna's Phase IIb clinical trial is currently enrolling adult patients with recurrent glioblastoma (rGBM) at leading brain cancer centers, including those in Texas and across Europe.

  On October 31, the company announced promising interim efficacy and safety results from patients treated at low doses in the on-going Phase IIb clinical trial for rGMB. Results showed promising median overall survival of 9.8 months following a single treatment for the 27 enrolled patients, with an overall survival rate of 89% at 6 months, 58% at 9 months and 47% at 12 months. According to the company, this materially exceeds survival rates reported for approved drugs for rGBM; survival rates for MDNA55 at 6, 9 or 12 months are 44% to 81% better than that of Avastin and 35% to 57% better than Lomustine. Medicenna received a $14 million Product Development Award in February 2015, to support the clinical trials.

Personnel

CPRIT has 35 authorized full-time equivalent (FTE) positions of which 34 are filled. A contract employee is working temporarily as Grant Compliance Specialist. Chief Product Development Officer Michael Lang resigned to take a position at Arizona State University. CPRIT Deputy Executive Officer and General Counsel Kristen Doyle assumed the Chief Product Development Officer responsibilities until CPRIT brings a permanent replacement on board.

CPRIT Outreach

- Chief Scientific Officer James Willson, M.D, and Senior Program Manager Patty Moore, Ph.D., toured the Austin Community College BioScience Incubator on October 3.

- I briefed the Governor's Office staff on CPRIT activities and plans for the 86th Texas Legislature on October 3.

- Senior Program Manager for Product Development Rosemary French attended the Health Tech Track at Austin Startup Week 2018 at the Capital Factory on October 3 – 4.

- Ms. French attended the Small Molecule Drug Development Course on October 8 in San Antonio at the Southwest Research Institute.

- On October 16 Presiding Officer Will Montgomery and I attended a Texas Healthcare and Bioscience Institute (THBI) business roundtable in Dallas to discuss plans for the 86th Texas Legislature with board members of THBI. THBI is the state's largest association of life science industry businesses.

- Ms. Doyle, Chief Operating Officer Heidi McConnell, and I attended the Biennial Legislative Communications Conference on October 17 in Austin. The conference, hosted by The University of Texas LBJ School of Public Affairs and Strategic Partnerships Inc., included speakers addressing topics relevant to the upcoming legislative session.

- Ms. French attended the *Texas Medical Device: CEO Fireside Chat* on October 18 at the Norris Conference Center in Austin.

- On October 22 Ms. Doyle, Ms. McConnell, and I discussed plans for the 86th Texas Legislature with staff of the Senate Committee on Finance.

- On October 25, Mr. Montgomery, Ms. McConnell, and I attended the American Cancer Society Cancer Action Network "Texas Research Breakfast" in Houston. This event informed American Cancer Society donors and area legislators about CPRIT activities and the imminent exhaustion of CPRIT general obligation bond authority. About 160 attendees heard presentations from Representative John Zerwas, CPRIT grantees, and cancer survivors who have benefitted from the activities of CPRIT grantees.

- I attended a THBI business roundtable on October 30 in San Antonio to discuss plans for the 86th Texas Legislature with board members of THBI and other area life sciences executives.

- On October 31 I attended a THBI business roundtable in Houston to discuss plans for the 86th Texas Legislature with board members of THBI and other area life sciences executives.

- Dr. Willson and Dr. Moore will provide an overview of the new Early Translational Research Award RFA to researchers at the Dell Medical School on November 6.

- On November 8 Oversight Committee member Dee Margo, Senior Communications Specialist Chris Cutrone, and I will attend two events in El Paso - a regional legislative briefing hosted by THBI and the BIO El Paso-Juarez launch and press conference.

- Ms. Doyle and I will provide a legislative preview to the Greater Houston Partnership Health Care Committee on November 8.

- On November 13 Ms. Doyle, Dr. Moore, and I will meet with an expert advisory group from Innovate UK visiting Austin to discuss advancing digital health innovations for cancer diagnosis and treatment.

- On November 13 Ms. French will be a panelist for a global entrepreneurship training session "How Startup Investment Works" hosted by the US Department of State in Washington DC.

2020 Program Priorities

The three program subcommittees held special meetings in October to discuss program priorities for FY 2020. As part of the program priorities discussion, each of the programs also address potential future opportunities for the CPRIT academic research, product development research, and prevention programs in the event CPRIT is reauthorized. The Oversight Committee will vote to adopt the 2020 program priorities at its November meeting.

Compliance Program Update

Submission Status of Required Grant Recipient Reports

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

As of October 23, 2018, two entities had not filed four reports by the due date; all four reports were for Academic Research grants. 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 115 second-level reviews of grantee Financial Status Reports (FSRs) for the month of October. One FSR (1%) 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 audit findings are compiled in an independent audit report and submitted to CPRIT within 30 days of receipt, but no later than 270 days after the grantee's fiscal year end.

Compliance Specialists are working with one grantee to remediate audit findings. CPRIT gives grantees 30 days from the receipt of the audit to submit supporting documentation to demonstrate remediation efforts. Currently, there 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.

CPRIT revised the Annual Single Audit Determination (SAD) form process earlier this year. Grantees will now complete one form for their institution annually and submit the completed form to CPRIT via email. Prior to this change, grantees completed a SAD form for each active grant held by the grantee and submitted each through CPRIT's grants management system. The due date for all future SAD forms will be 60 days after the organization's fiscal year end date. As of October 23, 2018, seven grantees have not submitted their SAD form; compliance staff will follow up with the grantees.

Desk Reviews

Compliance Specialists performed 27 desk-based financial monitoring reviews in October to verify that grantees expend funds in compliance with specific grant requirements and guidelines. Desk reviews may target an organization's internal controls, current and past fiscal audits, and timeliness of required grantee report submission. Compliance Specialists are working with five grantees to remediate desk review findings.

On-Site Reviews

Compliance Specialists conducted three on-site reviews in October. 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. Compliance Specialists are working with seven grantees to remediate on-site review findings.

Training and Support

CPRIT staff conducted a new Authorized Signing Official (ASO) training on October 3, 2018. The training covered grant reporting requirements, administrative rule changes, the grant closeout process, a hands-on navigation of CPRIT's grants management system, and an overview of the compliance program including fraud, waste, and abuse reporting. Pursuant to Texas Administrative Code §703.22, CPRIT requires new ASOs to complete a compliance training within 60 days of the change.

CPRIT staff also conducted a grantee training webinar on October 10, 2018, with approximately 150 grantee staff in attendance. The training covered grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. This was the third and final training offered this year in support of the annual compliance training obligation that requires the ASO and at least one other employee from each grantee organization to attend an annual compliance training by November 1 of each year. One grantee has not met the training requirement for this year. CPRIT does not disburse grant funds if the Grant Recipient fails to complete the annual compliance training program by November 1. Compliance Specialists will work with the grantee to complete the training requirements by the required deadline.

Academic Research Program Update

FY 2019 Cycle 1 (19.1) RFAs Update

Applicants submitted 401 proposals for FY 2019 Cycle 1 (19.1) grant awards. Peer review panels met October 18 through October 25, 2018, in Dallas to conduct peer review. Dr. Willson will present the Scientific Review Council's (SRC) award recommendations to the Program Integration Committee (PIC) and the Oversight Committee in February 2019.

19.1 RFA Data by Mechanism

Mechanism	Number Received	Funds Requested	Full Review	Funds Requested
Individual Investigator Research Award (IIRA)	268	$233,976,917	144	$126,157,080
IIRA for Cancer in Children and Adolescents	37	$44,382,130	24	$29,026,405
IIRA for Clinical Translation	33	$52,321,758	23	$37,874,514
IIRA for Computational Biology	27	$20,580,933	12	$9,544,680
IIRA for Prevention and Early Detection	36	$34,294,805	26	$26,970,288
TOTAL	**401**	**$385,556,543**	**229**	**$229,572,967**

Recruitment Summary Data

CPRIT received 13 recruitment applications for Recruitment Cycles 19.1, 19.2, and 19.3. Dr. Willson will present the SRC's award recommendations for Cycles 19.1 and 19.2 to the PIC and the Oversight Committee at the November meeting.

FY 2019 Recruitment RFA data by Mechanism for Cycles 19.1, 19.2, and 19.3**.**

Mechanism	Number Received	Funds Requested	Rec'd by SRC	Funds Requested
Recruitment Established Investigators	6	$33,999,094	2	$12,000,000
Recruitment Rising Stars	2	$7,035,730	0	0
Recruitment of First-Time Tenure Track Faculty Members	5	$10,000,000	2	$4,000,000
TOTAL	**13**	**$51,034,824**	**4**	**$16,000,000**

RFAs for the FY2019 - 19.2 Review Cycle

CPRIT released the following RFAs in August. Applications are due by January 30, 2019. Peer review of the applications will begin in February, with the Oversight Committee considering award recommendations in August 2019:

- *Core Facilities Support Awards (CFSA) (RFA R-19.2 CFSA)*
  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 $3 million (total costs) for the first 2 years and up to $1 million (total costs) for each subsequent year; maximum duration: 5 years.

- *High Impact/High Risk Research Awards (HIHR) (RFA R-19.2 HIHR)*
  Short-term funding to explore the feasibility of high-risk projects that, if successful, would contribute major new insights into the etiology, diagnosis, treatment, or prevention of cancers.
  Award: Up to $200,000 (total costs); maximum duration: 2 years.

- *Early Translational Research Awards (ETRA) (RFA-R-19.2 ETRA)*
  Projects that "bridge the gap" between promising new discoveries achieved in the research laboratory and commercial development for a therapeutic, device, or diagnostic assay through activities including preclinical proof-of-principle data that demonstrate applicability to the planned clinical scenario and preclinical toxicology and formulation to de-risk the development of lead compounds or devices. Any not-for-profit institution that conducts

research is eligible to apply for funding. CPRIT requires presentation of a time line with stage gates for development is required. A public or private company is not eligible.
Award: $1 to 2 million in total costs over a period of 1-2 years.

- *Collaborative Action Program to reduce liver cancer mortality in Texas: Collaborative Action Center Award (RFA-R-19.2 CAP: CAC)*
  Single Collaborative Action Center (Center) whose function is to: (1) promote interactions and collaborations across the CAP Research Awards funded under the companion RFA, R-19.2 CAP:RA; (2) provide opportunities for academic content experts, health care providers and community stakeholders to exchange ideas and to explore new opportunities to impact the rise of hepatocellular cancer (HCC) in Texas and (3) educate health care providers and the public on best practices to alter the trajectory of HCC in Texas.
  Award: CPRIT plans to make one award to a single applicant in response to this RFA. Up to $3 million in total costs over a period of 5 years.

- *Collaborative Action Program to reduce liver cancer mortality in Texas: Investigator Initiated Research Awards (RFA-R-19.2 CAP: RA)*
  Investigator-initiated research projects designed to understand the reasons for the increased incidence of 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 in total costs per year for 5 years.

Advisory Committees

University Advisory Committee

The University Advisory Committee met by phone on October 10, 2018.

The Texas A&M University System notified CPRIT that it has appointed Dr. Peter Davies, Director of Texas A&M Institute of Biosciences and Technology and Professor, Center for Translational Cancer Research, to the University Advisory Committee.

Advisory Committee on Childhood Cancers

I appointed two new members to the Advisory Committee on Childhood Cancers. The Oversight Committee will consider my appointments at the November meeting.

- Dr. Richard Gorlick, Mosbacher Pediatrics Chair at The University of Texas MD Anderson Cancer Center.

- Dr. Will Parsons, Director, Pediatric Center for Precision Oncology, Texas Children's Cancer and Hematology Centers and Associate Professor, Pediatrics-Oncology at Baylor College of Medicine.

Product Development Research Program Update

Product Development Research FY 2018 Cycle 2 (18.2)

The Oversight Committee approved three applications from the second cycle of FY 2018 for funding in August. The Product Development Review Council (PDRC) requested more information on two other applications in the 18.2 review cycle to complete their evaluation. The PDRC met on October 17 to review additional information provided by one of the companies and decided not to recommend the application for funding. The other company will submit their information in December for PDRC review. If the PDRC recommends the application for funding, CPRIT will present it to the PIC and the Oversight Committee in February.

Product Development Research Applications FY 2019 Cycle 1 (19.1)

The Oversight Committee approved three requests for applications for Product Development Award FY 2019 Cycle 1 in February. In addition to the Texas Company and Company Relocation Product Development Awards, CPRIT released a new request for applications for Seed Awards to support new company formation and preclinical work at early stage companies.

CPRIT received 38 applications by the August 8 deadline. After the initial peer review in late September, the Product Development review panels selected 17 companies to present their applications and answer questions in Dallas October 23-26. Following the in-person presentations, the peer review panels recommended nine applications to move forward to due diligence review. The PDRC will meet in January to review the due diligence reports and make final recommendations regarding 19.1 Product Development awards. The PIC and the Oversight Committee will consider the recommendations at the February 2019 meeting.

Review Cycle 19.1 Data by Mechanism

Mechanism	Apps	Funds Requested	In Person	Funds Requested	Due Diligence	Funds Requested
Texas Company	5	$42,389,966	2	$16,680,008	2	$16,680,008
Relocation Company	8	$113,790,609	4	$63,474,499	3	$49,363,074
Seed Company	25	$64,956,585	11	$29,569,259	4	$11,912,313
TOTAL	**38**	**$221,137,160**	**17**	**$109,723,766**	**9**	**$77,955,395**

Prevention Program Update

FY 2019 Cycle 1 (19.1) Prevention Applications

CPRIT released four RFAs in June 2018 for the first review cycle of FY 2019. Twenty applications requesting $33,712,818 will undergo peer review, scheduled for December 11-

12. Dr. Garcia will present the Prevention Review Council's 19.1 recommendations to the PIC and the Oversight Committee in February 2019.

19.1 Review Cycle Data by Mechanism

Mechanism	Applications	Funds Requested
Evidence-based Cancer Prevention Services	9	$12,304,996
Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations	7	$15,830,685
Tobacco Control and Lung Cancer Screening	4	$5,577,137
Dissemination of CPRIT-Funded Cancer Control Interventions	0	$0
TOTAL	**20**	**$33,712,818**

FY 2019 Cycle 2 (19.2) Prevention RFAs

CPRIT will release FY 2019 Cycle 2 RFAs on November 19 with applications due by February 20, 2019. Peer review will occur May 20 – 23, 2019. Dr. Garcia plans to present the PRC's recommendations to the PIC and the Oversight Committee in August 2019. The Cycle 2 RFAs are:

- *Evidence-Based Cancer Prevention Services*
  Seeks to fund 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; Maximum duration of 36 months.

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

- *Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations*
  Seeks to support the coordination and expansion of evidence-based services to prevent cancer in underserved populations 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; Maximum duration of 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; Maximum duration of 24 months.

CPRIT mailed a copy of the *2018 Texas Cancer Plan* to each Oversight Committee member in early October.

Communications Update

- CPRIT issued press releases this month in response to three prestigious awards and appointments announced for CPRIT grantees including Dr. Jim Allison's Nobel prize, Dr. Livia Eberlin's MacArthur Fellowship Grant, and Dr. Sean Morrison's appointment to the National Academy of Medicine.

Cancer Awareness Months

- In recognition of Liver Cancer Awareness month in October, CPRIT produced and released a video via social media about liver cancer, featuring interviews with CPRIT grantees at UT Health San Antonio who have CPRIT Prevention Program and Academic Research awards.

- Mr. Cutrone worked with KVIA-TV in El Paso to promote the new Hepatitis C Virus screening grant for liver cancer prevention awarded to Centro San Vicente in El Paso. The story ran on KVIA-TV on October 26.

Other activities

- The communications team continues to design and develop content for CPRIT's new website including a digital newsroom; a multi-channel platform for posting, curating, and distributing CPRIT and related content. The new website is expected to launch November 30.

Social media

Facebook (last 28 days):

- Reach: 2,172
- Engagement: 626

- Most popular post: *JUST ANNOUNCED: CPRIT Scholar James Allison, eminent scholar and pioneer of cancer immunotherapy at MD Anderson Cancer Center, was awarded a share of the 2018 Nobel Prize in physiology or medicine. The award recognizes his breakthrough work in studying a protein known as CTLA-4, proving that it behaves like a brake on immune responses.*

Twitter:

- 19,300 impressions
- Top tweet: *ICYMI: @WIRED ran an article on Nobel Prize winner and CPRIT Scholar James Allison, pioneer of cancer immunotherapy at @MDAndersonNews.*

Operations, Audit and Finance Update

The internal audit team from Weaver initiated field work on the State Reporting audit and follow-up procedures on the SAO audit over CPRIT performance measures on October 22.

The McConnell & Jones audit team were at CPRIT's office during the week of October 29, sampling documents and testing processes and procedures for CPRIT's annual financial audit.

Upcoming Subcommittee Meetings

Listed below are the regularly scheduled subcommittees in advance of the November 28, 2018, Oversight Committee meeting.

Board Governance	November 1 at 10:00 a.m.
Audit	November 5 at 10:00 a.m.
Prevention	November 6 at 10:00 a.m.
Academic Research	November 7 at 10:00 a.m.
Product Development	November 8 at 10:00 a.m.
Nominations	November 9 at 10:30 a.m.

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

*****

CPRIT has awarded **1,317** grants totaling **$2.153 billion**

- 209 prevention awards totaling $223.1 million
- 1,108 academic research and product development research awards totaling $1.930 billion

Of the $1.930 billion in academic research and product development research awards,

- 30.7% of the funding ($592.8 million) supports clinical research projects
- 25.5% of the funding ($491.7 million) supports translational research projects
- 26.2% of funding ($506.0 million) supports recruitment awards
- 14.5% of the funding ($279.1 million) supports discovery stage research projects
- 3.1% of funding ($59.9 million) supports training programs.

CPRIT has 9 open Requests for Applications (RFAs)

- 3 Research Recruitment
- 5 Academic Research
- 1 Prevention

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	VINCE BURGESS, CHIEF COMPLIANCE OFFICER
SUBJECT:	COMPLIANCE PROGRAM UPDATE
DATE:	NOVEMBER 7, 2018

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

As of October 23, 2018, two entities had not filed four reports by the due date; all four were for Academic Research grants. 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

Compliance specialists performed 115 second-level reviews of grantee Financial Status Reports (FSRs) for the month of October. One FSR (1%) required resubmission due to insufficient or inaccurate documentation submitted by the grantee. Grantees report expenditures that CPRIT will reimburse with grant award funds on the quarterly FSR form. 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 compiles the audit findings in an independent audit report and submits to CPRIT within 30 days of receipt, but no later than 270 days after the grantee's fiscal year end.

Compliance specialists are working with one grantee to remediate audit findings. CPRIT gives grantees 30 days from the receipt of the audit to submit supporting documentation to demonstrate remediation efforts. Currently, there 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.

CPRIT revised the Annual Single Audit Determination (SAD) form process earlier this year. Grantees will now complete one form for their institution annually and submit the completed form to CPRIT via email. Prior to this change, grantees completed a SAD form for each active grant held by the grantee and submitted each through CPRIT's grants management system. The due date for all future SAD forms will be 60 days after the organization's fiscal year end date. As of October 23, 2018, seven grantees had not submitted their SAD form; compliance staff will follow up with the grantees.

Desk Reviews

Compliance specialists performed 27 desk-based financial monitoring reviews in October to verify that grantees expend funds in compliance with specific grant requirements and guidelines. Desk reviews may target an organization's internal controls, current and past fiscal audits, and timeliness of required grantee report submission. Compliance specialists are working with five grantees to remediate desk review findings.

On-Site Reviews

Compliance specialists conducted three on-site reviews in October. 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. Compliance specialists are working with seven grantees to remediate on-site review findings.

Training and Support

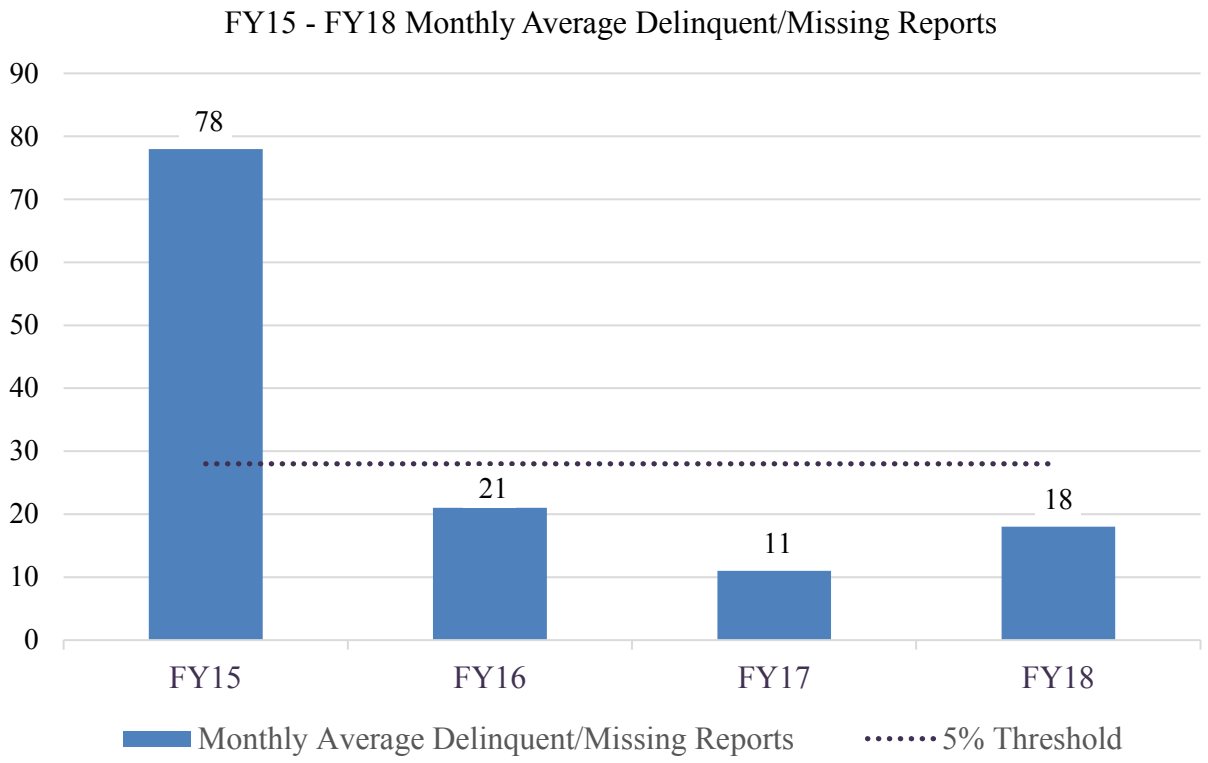
CPRIT staff conducted a new Authorized Signing Official (ASO) training on October 3, 2018. The training covered grant reporting requirements, administrative rule changes, the grant closeout process, a hands-on navigation of CPRIT's grants management system, and an overview of the compliance program including fraud, waste, and abuse reporting. Pursuant to Texas Administrative Code §703.22, CPRIT requires new ASOs to complete a compliance training within 60 days of the change.

CPRIT staff also conducted a grantee training webinar on October 10, 2018 with approximately 150 grantee staff in attendance. The training covered grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. This was the third training offered this year in support of the annual compliance training obligation that requires the ASO and at least one other employee from each grantee organization to attend an annual compliance training by November 1 of each year. The ASO for one grantee failed to attend one of the three trainings offered during the year. CPRIT staff scheduled a one-on-one training for the grantee's ASO on October 31 to meet the November 1 deadline.

FY18 Compliance Program Activities Summary

During FY18, the Compliance Program continued to refine and strengthen existing compliance functions that support the integrity and transparency of CPRIT's agency processes. Compliance Program highlights include:

- Grant Recipient Report Monitoring – The number of delinquent reports in FY18 showed a slight increase from FY17, with an average of 18 reports per month. Analysis shows this increase is attributable to the change in Matching Compliance Certification (MCC) form reporting requirements in CGMS, as mentioned in previous meetings. The chart shows the average number of delinquent reports for the past four fiscal years.



- Compliance Monitoring Reviews (Desk and On-site) – The Compliance team performed 258 compliance reviews (226 desk reviews, 32 on-site reviews) during FY18.

- Training and Education – In FY18, CPRIT staff conducted 10 grantee trainings including annual compliance trainings, new grantee trainings, and trainings for new ASOs. Over 540 grantee staff attended these training opportunities provided to our active grantees.

- Second-level Reviews of Financial Status Reports (FSRs) – The Compliance team performed a second-level review of approximately 2,200 FSRs.

- Single Audit Reviews – The Compliance team reviewed over 40 audits and agreed upon procedures (AUP) reports and actively worked with five grantees to remediate audit findings.

- Annual Compliance Attestation – The Compliance team further refined the annual compliance attestation process, reviewed 56 attestations submitted by grantees, and collaboratively worked with four grantees to remediate deficiencies.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	JAMES WILLSON, MD., CHIEF SCIENTIFIC OFFICER
SUBJECT:	ACADEMIC RESEARCH PROGRAM UPDATE
DATE:	NOVEMBER 28, 2018

Action Items

FY 2020 Academic Research Program Priorities (proposed)

The Oversight Committee Academic Research Subcommittee met November 7 and recommends that the Oversight Committee approve the staff's recommendations for FY 2020 Academic Research Program priorities.

Proposed FY 2020 Program Priorities

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

The Academic Research Subcommittee also recommends that the Oversight Committee approve the proposed requests for applications (RFAs) and timeline for the first review cycle of FY 2020.

FY 2020.1 RFAs (proposed)

- *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.

Informational Items

FY 2019 Cycle 1 (19.1) RFAs Update

Table 1 displays an overview of FY 2019 Cycle 1 (19.1) data by mechanism. CPRIT held peer review for the 19.1 cycle October 18, 2018 through October 25, 2018 in Dallas. Dr. Willson will present the Scientific Review Committee's award recommendations to the Program Integration Committee and the Oversight Committee in February 2019.

Table 1: FY 2019.1 (19.1) RFA Data by Mechanism

Mechanism	Number Received	Funds Requested
Individual Investigator Research Award (IIRA)	268	$233,976,917
IIRA for Cancer in Children and Adolescents	37	$44,382,130
IIRA for Clinical Translation	33	$52,321,758
IIRA for Computational Biology	27	$20,580,933
IIRA for Prevention and Early Detection	36	$34,294,805
Total	**401**	**$385,556,543**

Recruitment Summary Data

Table 2 displays an overview of FY 2019 recruitment data for the first quarter (Cycles 19.1, 19.2 and 19.3. Dr. Willson will present this slate to the Oversight Committee on November 28, 2018.

Table 2: FY 2019 Recruitment RFA data by Mechanism for Cycles 19.1, 19.2 and 19.3

Mechanism	Number Received	Funds Requested	Number Recommended by SRC	Number Recommended by PIC
Recruitment Established Investigators	6	$33,999,094	2	2
Recruitment Rising Stars	2	$7,035,730	0	0
Recruitment of First-Time Tenure Track Faculty Members	5	$10,000,000	2	2
TOTAL	**13**	**$51,034,824**	**4**	**4**

FY 2019 Cycle 2 Academic Research RFAs

The Oversight Committee approved the FY 2019.2 RFAs and release schedule on February 21, 2018. CPRIT released the RFAs (described below) on August 17, 2018 and will receive applications October 17, 2018, through January 30, 2019. CPRIT will convene the peer review panels in May. Dr. Willson will present the Scientific Review Council's recommendations to the Program Integration Committee and Oversight Committee in August 2019.

- *Core Facility Support Awards (CFSA) (RFA R-19.2 CFSA)*

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

- *High Impact/High Risk Research Awards (HIHR) (RFA R-19.2 HIHR)*
  Provides short-term funding to explore the feasibility of high-risk projects that, if successful, would contribute major new insights into the etiology, diagnosis, treatment, or prevention of cancers.
  Award: Up to $200,000 (total costs); Maximum duration: 2 years.

- *Early Translational Research Awards (ETRA) (RFA-R-19.2 ETRA)*
  Supports projects that "bridge the gap" between promising new discoveries achieved in the research laboratory and commercial development for a therapeutic, device, or diagnostic assay through activities including preclinical proof-of-principle data that demonstrate applicability to the planned clinical scenario and preclinical toxicology and formulation to de-risk the development of lead compounds or devices. Any not-for-profit institution that conducts research is eligible to apply for funding under this award mechanism. Presentation of a time line with stage gates for development is required. A public or private company is not eligible.
  Award: up to $ 2 million in total costs over a period of 1-2 years.

- *Collaborative Action Program to reduce liver cancer mortality in Texas: Collaborative Action Center Award (RFA-R-19.2 CAP: CAC)*
  Supports a Collaborative Action Center whose function will be to: (1) promote interactions and collaborations across the CAP Research Awards funded under the companion RFA, R-19.2 CAP:RA; (2) provide opportunities for academic content experts, health care providers and community stakeholders to exchange ideas and to explore new opportunities to impact the rise of hepatocellular cancer (HCC) in Texas and (3) educate health care providers and the public on best practices to alter the trajectory of HCC in Texas.
  Award: CPRIT plans to make one award. Up to $3,000,000 in total costs over a period of 5 years.

- *Collaborative Action Program to reduce liver cancer mortality in Texas: Investigator Initiated Research Awards (RFA-R-19.2 CAP: RA)*
  Supports investigator-initiated research projects designed to understand the reasons for the increased incidence of 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 each in total costs per year for 5 years.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

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

SUBJECT: PREVENTION PROGRAM UPDATE

DATE: NOVEMBER 19, 2018

FY 2019 Cycle 1 (19.1) Prevention Applications

CPRIT released four RFAs in June 2018 for the first grant cycle of FY 2019. Twenty-two applications were received by the September 5 deadline. After administrative review, 20 applications requesting $33,712,818 (see table below) will undergo peer review, scheduled for December 11-12. Dr. Garcia will present the Program Integration C recommendations to the Oversight Committee in February 2019.

Mechanism	Number Received	Total $ Requested
Evidence-based Cancer Prevention Services	9	$12,304,996
Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations	7	$15,830,685
Tobacco Control and Lung Cancer Screening	4	$5,577,137
Dissemination of CPRIT-Funded Cancer Control Interventions	0	$0
TOTAL	**20**	**$33,712,818**

FY 2019 Cycle 2 (19.2) Prevention RFAs

CPRIT released FY2019 Cycle 2 RFAs (described below) on November 19. Applications are due on February 20, 2019. CPRIT has scheduled peer review May 20 – 23. Dr. Garcia will present the Prevention Review Council's recommendations to the PIC and the Oversight Committee in August 2019.

Evidence-Based Cancer Prevention Services

Evidence-Based Cancer Prevention Services - This award mechanism seeks to fund projects that will deliver evidence-based cancer prevention and control clinical services. Priority will be given to projects that propose to address CPRIT areas of emphasis and serve areas of the state not well addressed by current CPRIT funded projects.
Award: Maximum of $1M; Maximum duration of 36 months.

Tobacco Control and Lung Cancer Screening

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

Expansion of Cancer Prevention Services to Rural and Medically Underserved Populations

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

FY 2020 Program Priorities

The Oversight Committee Prevention Subcommittee met November 6 and recommends to the Oversight Committee approval of the staff recommended FY 2020 Prevention Program priorities which would remain unchanged from those adopted for FY 2019.

Proposed FY 2020 Program Priorities

- Prioritize populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence
- Prioritize geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence

- Prioritize underserved populations

Other activities

- A copy of the 2018 Texas Cancer Plan was mailed to each OC member in early October.

- Ramona Magid, Sr. Program Manager for Prevention, and I attended the Healthier Texas Summit October 25 and 26 in Austin where several CPRIT grantees presented.

- Ramona Magid presented an overview of the 2018 Texas Cancer Plan at the quarterly Cancer Alliance of Texas meeting on November 8, 2018.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: REBECCA GARCIA, PH.D. CHIEF PREVENTION AND COMMUNICATIONS OFFICER

SUBJECT: COMMUNICATIONS UPDATE

DATE: NOVEMBER 28, 2018

Earned Media August 7-November 8, 2018

Coverage:

- 3 articles featured CPRIT
- 70 additional articles mentioned CPRIT (stories primarily focused on work of grantees)

Coverage Highlights: (see clipped articles following report)

- August 17, 2018, *D Healthcare, Conversation with: Ray Perryman, CEO of The Perryman Group, on the Economic Cost of Cancer*
- August 21, 2018, *KXAN (NBC Austin), Breast Cancer Nonprofit Dependent on State Funds Worried About Cuts*
- August 27, 2018, *Xconomy, New Houston Biotech Magnolia Tejas Plans Trials with $20M CPRIT Grant*
- August 29, 2018, *El Paso Herald-Post, TTUHSC El Paso Cancer Intervention Program Recognized by National Cancer Institute*
- August 29, 2018, *KSAT (ABC San Antonio), New Initiative Aimed at Prevention, Early Detection of Liver Cancer*
- September 17, 2018, *Dallas Morning News, UTSW Attracts $37 Million For Cancer Research, Including Database of Rare Childhood Cases*
- October 29, 2018, *The Katy News, Dr. Allison's Step Towards a Cure*

Cancer Awareness Months

- In recognition of Liver Cancer Awareness month in October, CPRIT produced and released a video via social media about liver cancer, featuring interviews with CPRIT grantees at UT Health San Antonio who have CPRIT Prevention Program and Academic Research awards.

- Mr. Cutrone worked with KVIA-TV in El Paso to promote the new Hepatitis C Virus screening grant for liver cancer prevention awarded to Centro San Vicente in El Paso. The story ran on KVIA-TV on October 26, and featured an interview with Mayor Margo.

Other activities

- CPRIT issued press releases this month in response to three prestigious awards and appointments announced for CPRIT grantees including Dr. Jim Allison's Nobel prize, Dr. Livia Eberlin's MacArthur Fellowship Grant, and Dr. Sean Morrison's appointment to the National Academy of Medicine.

- Mr. Cutrone accompanied Mr. Roberts to El Paso on November 8 for a THBI roundtable discussion hosted by the Medical Center of the Americas. Mr. Cutrone prepared briefing documents, talking points and remarks for Mayor Margo, who participated in the press conference immediately following the roundtable announcing the launch of the new BIO El Paso/Juarez partnership.

- Mr. Miller-Payne is continuing to lead the communications team efforts to design and develop content for CPRIT's new website including a digital newsroom; a multi-channel platform for posting, curating, and distributing CPRIT and related content. A notable project is working with our partner institutions on the new, revamped CPRIT Scholars section. A soft launch of the new website is planned for November 30 and a public announcement in early December.

Social Media

Facebook (last 28 days):

- Reach: 844 (decreased dramatically after Dr. Allison's announcement)
- Engagement: 239
- Most popular post: ICYMI: CPRIT-funded research at UNT Health Science Center discovered a new targeted treatment for combating melanoma, a skin cancer that kills about 9,000 people in the United States each year.

Twitter (last 28 days):

- 16,000 impressions (decreased since Dr. Allison's announcement)
- Top tweet: ICYMI: @WIRED ran a great article on Nobel Prize winner and CPRIT Scholar James Allison, pioneer of cancer immunotherapy at @MDAndersonNews.

Twitter (October):

- 25,000 impressions
- Top tweet: ICYMI: @WIRED ran a great article on Nobel Prize winner and CPRIT Scholar James Allison, pioneer of cancer immunotherapy at @MDAndersonNews.

D CEO HEALTHCARE
The Business of Healthcare in North Texas

Conversation With: Ray Perryman, CEO of The Perryman Group, On The Economic Cost of Cancer

08/17/2018 | *by Shawn Shinneman* | Share Post

In the world of executive level pitches, just about anything that makes an impact is going to have a dollar amount attached to it. Perhaps that's why there's a market for the work of Dr. Ray Perryman, a financial analyst whose practice spends part of its time quantifying the dollars lost to cancer each year.

Later this month, I'll be saying a few quick, intro-y words at an event taking on "The Business, Breakthroughs and Future of Cancer Care," put on by Cancer Support Community North Texas and featuring three experts chatting on the policy and investment sides of the disease.

One of these three is Perryman, CEO of economic research and analysis firm The Perryman Group. Before the event, I took the opportunity to get him on the phone to hear more about his work.

How does cancer impact the economy in North Texas?

Ray Perryman, of The Perryman Group, says cancer costs DFW $24.2 billion a year.

There are three fundamental ways that cancer impact the economy. In terms of pure dollars and cents we can measure, we have three broad categories. One of them is, obviously, healthcare cost. A lot of resources get converted into cancer care and cancer treatment. The second thing is morbidity. When people have cancer, they miss work or they're less productive at work or their work life is cut short. The economy loses not only their productivity but all the multiplier effects of everything their work would generate. And then, of course, you have the mortality issue. The number of people who die from cancer in Texas is about 40,000 a year. When that happens, in many cases you're losing years of work life and years of work productivity from those individuals, as well as the adjustment time and that sort of thing that happens with their loved ones.

Have you quantified the impact?

For the Dallas-Fort Worth area specifically, the amount of gross area product that is lost each year because of cancer is about $24.2 billion. There's also about 243,000 years of work—that is, job years—lost each year as well. That's roughly 5 percent or so of the Dallas economy in terms of output and about 6.5 percent in terms of employment. In other words, if cancer could suddenly go away, the Dallas economy would suddenly be that much bigger. It's very significant, from a purely economic perspective.

What's the impact on businesses?

A lot of the losses are absorbed by businesses, in several forms: out-of-pocket healthcare costs, higher insurance premiums. Many of them self-insure, and of course they pay taxes to support the part of healthcare that's funded by Medicare and Medicaid. And then, there are employees who have out-of-pocket costs. The company doesn't pay that directly, but nonetheless when you're negotiating pay with people, all that comes into play.

What's your objective in doing this research?

I started doing research on cancer and cancer impact about 12 or 15 years ago when MD Anderson Cancer Center asked me to take a look at it and try to quantify it for Texans. Later, when the Cancer Prevention and Research Institute of Texas was being talked about, I put together some numbers to first just talk about the importance of cancer research. Since the entity has been in existence, we do an evaluation of the cost of cancer to Texas and the impact CPRIT is having on the state.

If you want to go beyond that … I lost my father to cancer and I lost my mother-in-law to cancer, and I think most people have some type of personal connection like that that makes it a very important issue for them and their families.

Anything else you'd like to mention?

We've done a number of different things on major diseases, we've done hunger, we've done child maltreatment. The economics—we talk about that as a way to get our arms around it, perhaps it helps some people justify the spending and that sort of thing. But really, the real cost of cancer, to me, is the impact it has on families and the impact it has on individuals. That's the part that our numbers don't really capture.

https://healthcare.dmagazine.com/2018/08/17/conversation-with-ray-perryman-ceo-of-the-perryman-group-on-the-economic-cost-of-cancer/

Breast cancer nonprofit dependent on state funds worried about cuts

By: Steffi Lee

Posted: Aug 21, 2018 05:17 PM CDT
Updated: Aug 22, 2018 09:44 AM CDT

AUSTIN (KXAN) -- Dorothy Gibbons' says without grant funding from the Cancer Prevention Research Institute of Texas, uninsured and underinsured women in the 38-county region her non-profit serves wouldn't have access to much-needed screenings.

"We're screening women in so many different counties that never had mammography services before,"

Gibbons said. "We're finding cancers that would not have been found without CPRIT funding. It allows us to keep going back. Cancer and prevention screenings – it's not a one-time thing. You have to keep going back. You have to keep showing up so that the folks trust you and know that you're going to be back again and you're going to take them all the way through."

Gibbons' non-profit, The Rose, has been a CPRIT grantee since 2010. Since then, it's caught breast cancer in more than 300 women and provided more than 5,000 first-time mammograms. A 3-D mammogram can cost around $225 and a biopsy could cost almost $2,000, according to Gibbons.

> "We're finding cancers that would not have been found without CPRIT funding...

Women are recommended to get screenings once they're 40 years old, but those who are uninsured or underinsured sometimes have to make a sacrifice.

"It's really hard for anyone to justify a preventative screening when you don't have the money for rent, groceries and you're worried about your kid going to school," Gibbons said.

The American Cancer Society Action Network of Texas hosted a forum Tuesday in Austin highlighting the ongoing prevention projects, like The Hope's screenings, taking place statewide.

"The grantees have done a lot of work to improve their healthcare systems, the delivery of their preventative services," Dr. Rebecca Garcia, chief prevention and communications officer of CPRIT, said. "They've trained a lot of people in terms of community health workers and other professionals."

But CPRIT is scheduled to lose funding beginning in 2020, unless the Texas Legislature acts next year and some lawmakers have pushed for the agency to be self-sufficient once state funding runs out.

"It is still going to be a challenge because it's a lot of money and there's no real clarity whether this program was intended to continue indefinitely or not," ACS CAN Texas Senior Government Relations Director Cam Scott said.

Gibbons also presented a letter that a Hurricane Harvey survivor shared after getting help from The Rose.

"She had lost her home to Harvey," Gibbons said. "She'd lost her car. The year before she'd lost her daughter to another cancer."

Stories like this are what Gibbons hopes sticks with lawmakers and healthcare advocates as they continue conversations about CPRIT's funding and future.

https://www.kxan.com/news/breast-cancer-nonprofit-dependent-on-state-funds-worried-about-cuts/1386298161

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New Houston Biotech Magnolia Tejas Plans Trials with $20M CPRIT Grant

Angela Shah
August 27th, 2018

Xconomy Texas — *Houston*—Magnolia Tejas, a **new biotech company** formed to develop drugs to treat neurological side effects from chemotherapy, has received a grant of nearly **$20 million** from the Cancer Prevention and Research Institute of Texas.

Magnolia Tejas is a wholly owned subsidiary of Magnolia Neurosciences, which launched earlier this month with $31 million from investors to develop potential drugs for nervous system disorders based on discoveries at the University of Texas MD Anderson Cancer Center. Magnolia Neurosciences is based in New York and is co-founded by Seattle-based life sciences investment firm Accelerator Life Science Partners and the University of Texas MD Anderson Cancer Center in Houston.

Magnolia Tejas—"Tejas" came from a Native American word that became "Texas"—is the new name adopted by existing biotech Korysso Therapeutics, and is based in Houston. David Schubert, Accelerator's chief operating officer, is moving to Houston from Seattle to become the company's president, at least temporarily. "We're going to be transitioning that to a senior management team," he says. "I expect my role to be complete by the end of the year."

Once Magnolia Tejas receives the CPRIT award (which Schubert says he estimates to be around mid-October,) the company will apply the cash to clinical studies testing its lead molecule to treat conditions such as chemotherapy-induced peripheral neuropathy (CIPN) and chemotherapy-induced cognitive dysfunction (CICD or chemo brain) based on technology developed at MD Anderson's therapeutics discovery division and its neurodegeneration consortium. The company says it expects to start a Phase 1 clinical trial in the second half of 2019. The cash is expected to be enough to bring the drug through Phase 2a testing.

"The neuropathy and neurocognitive challenges caused by chemotherapy not only decrease a patient's quality of life, but also can prevent them from completing the optimal chemotherapy regimen, ultimately affecting survival," Philip Jones, vice president of therapeutics discovery at MD Anderson and a scientific advisor to Magnolia Neurosciences, said in a press release.

The company says there are about two million people in the United States with CIPN, in which drug-damaged peripheral nerves result in patients experiencing pain, numbness, and tingling in the hands and feet. CICD affects more than 200,000 people and is characterized by cognitive and memory problems that can last for years, Magnolia Tejas stated in the press release.

For Schubert, Magnolia Tejas is a return to the Houston life sciences community. **From 2012 to 2014**, he was executive director of the Houston Area Translational Research Consortium, or HATRC. The organization, known as HATRC (pronounced "hat-trick), served as a "pre-commercialization center" that connected researchers from Rice University and Texas Medical Center institution entrepreneurs with funding and management expertise.

Schubert says the launch of Magnolia Tejas illustrates the potential of Houston's biotech ecosystem. "This is just one of the deals that's possible," he says. "There is great tech here."

https://www.xconomy.com/texas/2018/08/27/new-houston-biotech-magnolia-tejas-plans-trials-with-20m-cprit-grant/

EL PASO HERALD-POST

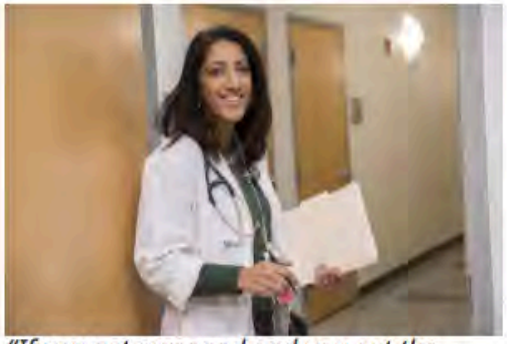
TTUHSC EL PASO CANCER INTERVENTION PROGRAM RECOGNIZED BY NATIONAL CANCER INSTITUTE

A Texas Tech University Health Sciences Center El Paso initiative that is increasing the number of screenings for colorectal cancer across West Texas has caught the eye of the National Cancer Institute.

The federal agency has added TTUHSC El Paso's ACCION (Against Colorectal Cancer in Our Neighborhoods) program to its database of Research-Tested Intervention Programs, making ACCION instructional and educational materials available to public health practitioners across the world.

Colorectal cancer is one of the leading causes of death from cancer in the U.S. for both men and women. But in many cases the disease can be cured, or even prevented, with early detection through colorectal cancer screenings.

Unfortunately, many at-risk people don't have easy access to colorectal cancer screenings. Poverty, lack of health insurance, lack of transportation, and low levels of health education are some of the barriers that prevent adults from receiving screenings. The beginning recommended age for colorectal cancer screenings is 50.



"If you get screened and you get the appropriate follow-up, you really do prevent cancer," Shokar said. "You find it early and the outcome is a lot better." | Photo Courtesy TTUHSC El Paso

UTEP Launches Comprehensive Events Calendar

August 30, 2018

Launched in 2011 by , director for Cancer Prevention and Control at TTUHSC El Paso, ACCION brings colorectal cancer screenings and preventative information to the community, in settings such as churches, health fairs, food pantries, low-income housing complexes, community centers and clinics serving the uninsured.

Its aim has been to increase screening rates across West Texas, currently around 50 percent, compared to a national average of about 70 percent. The program has been funded by grants from the Cancer Prevention Research Institute of Texas (CPRIT).

"If you get screened and you get the appropriate follow-up, you really do prevent cancer," Shokar said. "You find it early and the outcome is a lot better."

The program uses *promotoras*—bilingual community health care workers—to connect with at-risk individuals. ACCION currently works with over 160 community organizations to help make screening more accessible.

"People have big transportation barriers," Dr. Shokar said. "They don't have access to cars, or the person with the transport is working and they only have one car. It's very important that this program go to the community where people live, work and play, and that's what we try to do."

The success of the program has led to additional CPRIT funding. In August 2017, CPRIT awarded Dr. Shokar a three-year, $3.7 million grant to implement ACCION in major hospital and clinic systems throughout El Paso County. The grant will also be used to expand the program into West Texas; ACCION's service area will now cover a 25-county area by partnering with service providers in those areas.

And now, thanks to the National Cancer Institute, the methods and materials behind the ACCION's success can reach across the globe.

Learn more about ACCION and download program materials from the NCI's RTIPs website.

https://elpasoheraldpost.com/ttuhsc-el-paso-cancer-intervention-program-recognized-by-national-cancer-institute/

New initiative aimed at prevention, early detection of liver cancer

Texas has highest liver cancer incidence rate in US

Posted: 4:45 PM, August 29, 2018
Updated: 4:45 PM, August 29, 2018

SAN ANTONIO - A new initiative to raise awareness about liver cancer has been created to stop the growing number of people being diagnosed with the disease in its late stages.

While the problem is one that affects the nation, Texas is especially impacted by the disease with the highest liver cancer incidence rate in the U.S.

The Cancer Prevention and Research Institute of Texas will invest up to $18 million to fund the state's first collaborative action program for liver cancer.

The money will fund prevention and early-detection policies.

"We're talking about the Cancer Prevention and Research Institute of Texas and the prevention and early-detection service that this institute provides across the state. A lot of Texans don't realize the value the CPRIT brings," said Cam Scott, Texas government relations spokesman for the American Cancer Society. "But there are thousands of lives that have been saved because of the prevention and early-detection screenings that are available through CPRIT."

The organization is currently in operation, but is facing a critical need for funding.

The program was established via bonds. The legislature will need to decide next session whether it wants to continue funding the group's work.

That session begins in January.

https://www.ksat.com/news/new-initiative-aimed-at-prevention-early-detection-of-liver-cancer

RIVARD REPORT

HEALTH & WELLNESS

UT Health SA Receives $2.7M to Expand Cancer Research and Prevention Programs

ROSEANNA GARZA | AUGUST 29, 2018

The Cancer Prevention and Research Institute of Texas (CPRIT) awarded UT Health San Antonio more than $2.7 million to fund projects aimed at smoking cessation, increasing HPV vaccination rates, and developing new drugs to treat leukemia.

A $1.3 million grant announced Aug. 24 will expand Quitxt, a bilingual messaging service that provides motivational texts and links to online support to smokers looking to quit at no cost. The program, which started in 2015, reportedly helped 20 percent of participants quit smoking, said Dr. Amelie Ramirez, study leader and director of Salud America!, the Latino-focused health education advocacy program at UT Health San Antonio.

"Smoking still continues to be our No. 1 health problem. It shortens an individual's life, and it is also very costly if these individuals are diagnosed with lung cancer," Ramirez said. "We realize that people have a difficult time quitting, and we want to be there to offer them help."

The Quitxt messaging service adapted parts of federal smoking cessation programs and built a messaging system with content to fit the culture and language of Latino adults age 18 and older who use tobacco products. The funding will help expand the program from South Texas to include rural counties and urban areas of South, West, and Central Texas.

"We are hoping this [expansion] will help us continue to refine our message so that it will be more effective," Ramirez said, adding that the program will also expand to include more information about nicotine replacement therapy and other local and national support systems.

People who receive primary care through the UT Health Physicians medical practice or oncology care through the UT Health San Antonio MD Anderson Cancer Center, are directed toward the program if they indicate that they use tobacco products. Otherwise, people interested in the program can text "iquit," or "*Iodejo*," to 57682 to receive the interactive support in either English or Spanish.

Related: Following $25M Gift, UT Health SA Cancer Center Renamed After Mays Family

The CPRIT grant also provides $1 million for a brand-new project that will expand human papillomavirus (HPV) vaccination coverage to 113 counties throughout South Texas. Led by Dr. Allison Grimes, pediatric oncologist with UT Health San Antonio, the program will focus on completing vaccination cycles for people under the age of 26 and educating childhood cancer survivors about the risk of developing a second cancer.

"Bexar County has the lowest HPV vaccination uptick count in the entire state, which is particularly concerning because we have a large young population, with 40 percent of the population in the area under age 25," Grimes said. "We knew at this point we needed to do something more."

The program will also educate survivors of childhood cancer who are at greater risk for developing a second cancer, which Grimes said was lacking in the Childhood Cancer Survivorship Program. Less than 5 percent of childhood cancer survivors in the area have completed the HPV vaccine series, she said, noting that females who have had cancer of the cervix, vulva, or vagina are at a 40 percent greater risk for developing cancer again, while men who have had genital cancers have a 150 percent greater risk.

HPV contributes to 33,700 new cancers in the U.S. every year, yet only 43 percent of young females and 32 percent of young males are completing the vaccine series, according to the Centers for Disease Control and Prevention.

"We hope that by targeting the most vulnerable populations at greatest risk we will have the most significant impact," Grimes said.

The remaining $400,000 of the CPRIT grant funding will go toward two research studies examining BCR-ABL protein, which can increase genomic mutations and the risk of cancers including leukemia.

One study will use a new class of drugs developed in the laboratory of Dr. Edward Hasty, professor of molecular medicine at UT Health San Antonio. A separate project, led by Hai Rao, associate professor of molecular medicine, seeks to develop small molecules that would rapidly destroy BCR-ABL proteins.

https://therivardreport.com/ut-health-sa-receives-2-7m-to-expand-cancer-research-and-prevention-programs/

$20 million in grants for Texas Tech Health Science Center

By Marcos Ortiz **CONNECT**

LUBBOCK, Texas - Day after day, research advancements are occurring inside the labs of the Texas Tech's Health Science Center and those efforts have been bolstered by $20.5 million in grants. Dr. Tedd Mitchell, Texas Tech System Interim Chancellor and HSC president said getting federal funding for research is extremely difficult.

"Having your researchers stay excited enough about the work they are doing,' said Mitchell. "And be able to translate that work into papers and proposals that people in Washington look at and grade very high and score very high for us as a university it is incredible."

The National Institutes of Health (NIH), including the National Cancer Institute (NCI), the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and the National Institute of Neurological Disorders and Stroke (NINDS), the Department of Defense (DOD), along with others from the National Science Foundation (NSF), and the Cancer Prevention Research Institute of Texas (CPRIT), awarded the grants. The research areas targeted vary and are significant.

"From pancreatic cancer to ovarian cancer, to prostate cancer to breast cancer to childhood brain cancer on one end," said Mitchell. "And over here you have neurodegenerative changes with Alzheimer and Parkinson's and then you have all the stuff related to microbiology with infectious diseases as well."

Dr. Steven Berk, Dean of the school of medicine adds that these research grants will also help expand the school's research programs, fund additional equipment, and renovate laboratories.

http://www.fox34.com/story/39089548/20-million-in-grants-for-texas-tech-health-science-center

LUBBOCK AVALANCHE-JOURNAL
lubbockonline.com
MEDIA

Texas Tech HSC researchers secure more than $20 million in grants

By Jayme Lozano / A-J Media
Posted Sep 13, 2018 at 6:02 PM
Updated Sep 13, 2018 at 6:02 PM

The Texas Tech University Health Sciences Center School of Medicine announced Thursday it had secured $20.5 million in new research grant funding this year.

Tedd Mitchell, TTUHSC president and interim chancellor for Texas Tech University System, said the grants go toward several different areas of research, such as chronic pain, neurodegenerative diseases, adult and pediatric cancers and microbiology. During an event at TTUHSC honoring the faculty who received the funds, Mitchell said the university is proud of the researchers and their work.

"It's these small, constant steps forward that eventually lead to big leaps forward with things," said Mitchell. "All this work is going on in these labs day in and day out, but it moves the ball down the court for this university, region, and patients of the future that will be benefiting from the work that's done."

The more than 20 grants were awarded by a number of institutions and foundations including the National Institutes of Health, the National Cancer Institute, the Department of Defense, the National Institute of Neurological Disorders and Stroke, the National Institute of Diabetes and Digestive and Kidney Diseases, the National Science Foundation, and the Cancer Prevention Research Institute of Texas.

Among the recipients are Dr. Sanjay Awasthi who will receive $1.14 million over three years from the DOD for studying how to prevent breast cancer; Dr. Susan Bergeson will get $60,000 over one year from the NIH/NIAAA for studies into alcohol use disorder treatment; Dr. Ion Bobulescu will receive $1.04 million for studying obesity-related kidney disease; and Dr. Josee Guindon will receive $691,332 over five years to study the mechanisms of cannabinoid tolerance.

"This really means a lot," said Guindon. "I'll be able to pursue the subject further and to improve the clinical outcome and understand better how to allocate pain and to have more clinical relevance and better improve patient care in chronic pain states."

Mitchell said the studies being done can also be paired with work from other researchers around the country that will hopefully lead to results for patients in the future.

"You've got this silent army around the country that is moving forward together," said Mitchell. "We're just proud to be a part of it. The things that they're doing for their fellow man are nothing short of miraculous."

http://www.lubbockonline.com/news/20180913/texas-tech-hsc-researchers-secure-more-than-20-million-in-grants

DALLASNEWS
Powered by The Dallas Morning News

UTSW attracts $37 million for cancer research, including a database of rare childhood cases

Paul O'Donnell, Business Editor

Texas is awarding more than $37 million in grants to UT Southwestern Medical Center to further boost cancer research and prevention in North Texas.

The grants, doled out by the state's Cancer Prevention and Research Institute of Texas, include $12 million to support the work of four cancer investigators and $5.3 million to create a platform for collecting pediatric cancer data from multiple institutions.

UT Southwestern Dr. Yang Xie and Dr. Stephen Skapek will develop the pediatric cancer database. It's expected to become a resource for Texas childhood cancer programs, drawing data from clinical trials, electronic health records, molecular and imaging studies, and tissue banks.

"Inconsistent terminology and other issues often hamper researchers' efforts to combine data," Xie said. "Our goal is to break down these academic silos and create a broad database that will benefit all."

UT Southwestern also will receive $6 million to negotiate recruitment offers to three first-time, tenure-track faculty members. Two are from out-of-state universities -- Princeton and University of California, San Diego.

Prevention programs for liver and breast cancer will benefit from the grants as well.

UT Southwestern's grants were among 64 recently awarded by the state agency. CPRIT has now handed out $2.1 billion of the $3 billion in cancer-fighting funds approved by Texas voters in 2007.

Here's how the most recent awards break down:

- **$6 million** to Dr. Yang-Xin Fu to study how radiation turns on the immune system to fight cancer. Treatments that combine radiation with immunotherapy, which also uses the immune system to fight cancer, are considered especially promising.
- **$6 million** to researchers at UTSW's Children's Medical Center Research Institute. Drs. Sean Morrison, Ralph DeBerardinis and Prashant Mishra will study how to slow or prevent melanoma from spreading. The team hopes to develop therapies that would block the spread.
- **$3.7 million** to Dr. Michael Story for a preclinical radiation therapy facility. More than 50 percent of cancer patients are treated with radiation therapy.
- **$2.6 million** to Dr. Mamta Jain for hepatitis screening. Liver cancer is the fastest-growing cancer in Texas and most cases are caused by hepatitis C, which is curable. This grant extends a screening and treatment program among high-risk groups in Dallas County, South Texas and El Paso.
- **$2 million** to recruit Glen Liszczak from Princeton University.
- **$2 million** to recruit Peter Ly from University of California, San Diego School of Medicine.
- **$2 million** to retain Kenneth Chen at UT Southwestern.

- **$1.35 million** to Dr. Simon Lee for breast cancer screening of rural and underinsured women across 35 North Texas counties through the Moncrief Cancer Institute in Fort Worth. The money will pay for at least 1,500 screening mammograms, 750 diagnostic mammograms and 138 biopsies.

- **$200,000** to Dr. Neal Alto to explore drug resistance in lung cancer. Identifying biomarkers that predict drug resistance in patients is a key challenge in cancer treatment.

- **$200,000** to Dr. Nan Yan to study adverse effects of cancer immunotherapy. This study will use autoimmune-prone mice to develop ways to predict adverse reactions to immunotherapy.
- **$200,000** to Dr. Jian Xu to develop experimental and computational tools for studying acute myeloid leukemia. The study will search for human genome variations, such as insertions or deletions in DNA. The results could translate findings from cancer genetic studies into therapies for blood cancers.

- **$200,000** to Dr. Zbyszek Otwinowski to study repair of broken DNA. Deletions of short fragments of cancer patients' DNA may serve as a biomarker in cancer diagnosis and treatment.

UT Southwestern provides care in about 80 specialties to more than 100,000 hospitalized patients, 600,000 emergency room cases and 2.2 million outpatient visits a year. It has 2,700 faculty members.

https://www.dallasnews.com/business/health-care/2018/09/17/utsw-brings-home-37-millionfor-cancer-research-including-database-rare-childhood-cases

TEXAS PUBLIC RADIO
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Childhood Cancer Survivors At Greater Risk Of Developing HPV-Related Cancer

By BONNIE PETRIE • SEP 17, 2018

CREDIT PAWAN SINGH / HTTP://BIT.LY/2OSXXXT

Childhood cancer survivors are at a much greater risk of developing HPV-related cancer than the general population, yet far less likely to get vaccinated.

Listen
2:01

Dr. Allison Grimes, the director of the Adolescent and Young Adult Cancer Program at UT Health San Antonio, said both women and men who've survived childhood cancer are much more likely to get HPV-related cancer later in life.

"In fact, females have a 40-fold increased risk of an HPV malignancy, and male survivors of childhood cancer have a 150-fold increased risk of developing HPV-related cancers," Grimes said.

Grimes said just over 13 percent of the people treated for childhood cancer at UT Health San Antonio started the HPV vaccine series, and only 6 percent completed it. She thinks these kids, who often have more than one doctor, are simply falling through the cracks.

"Pediatricians might think it's the job of the oncologists since it's a cancer prevention vaccine, and oncologists don't routinely provide vaccines in their cancer clinics, and so they generally assume this is going to happen in the primary pediatric or family medicine type clinic," Grimes said.

Grimes wants to fix that, and in August she received a $1 million grant from the Cancer Prevention and Research Institute of Texas to teach health care providers about the increased HPV related cancer risk survivors of childhood cancer face, and to offer to kids eligible for the HPV vaccine the shots at five pediatric oncology clinics across Texas.

She also hopes to educate the patients.

"If survivors of childhood cancers knew how vulnerable they were to second cancers from HPV and also knew it was highly recommended from their oncologist to receive the vaccine," she said, "then I think that patients and their families would be really encouraged to do so and to follow through with completing the vaccine series."

Grimes hopes to increase the rate of HPV-vaccinated childhood cancer survivors at those five clinics by at least 50 percent. The clinics included in the grant funding are at UT Health San Antonio, Methodist Children's Hospital in San Antonio, Dell Children's Hospital in Austin, Driscoll Children's Hospital in Corpus Christi, and Texas Tech University Health Sciences Center in El Paso.

DALLASNEWS
Powered by The Dallas Morning News

Texas' latest Nobel winner says there's a simple thing we need to do to keep winning the prize

Dallas Morning News Editorial

Texas native Jim Allison was awarded the 2018 Nobel Prize in Physiology or Medicine this week for developing an "entirely new principle for cancer therapy" that unleashes a patient's immune system to attack tumors.

Allison, a professor at the University of Texas M.D. Anderson Cancer Center in Houston and a mean blues harmonica player, developed the groundbreaking cancer treatment known as "immune checkpoint therapy" along with fellow Nobelist Tasuku Honjo of Kyoto University.

The Nobel has been awarded for cancer research in the past, but this is the first time an actual treatment for cancer has been rewarded. "By stimulating the ability of our immune system to attack tumor cells, this year's Nobel Prize laureates have established an entirely new principle for cancer therapy," said the Nobel committee.

"I'm honored and humbled to receive this prestigious recognition," Allison said in a statement after Monday's announcement. "A driving motivation for scientists is simply to push the frontiers of knowledge. I didn't set out to study cancer, but to understand the biology of T cells, these incredible cells that travel our bodies and work to protect us."

It was this basic science that led to Allison's breakthrough — the development of an antibody to block the "checkpoint" protein on T cells, freeing those cells to attack cancer. This led directly to the first immune checkpoint inhibitor drug, Ipilimumab, approved by the Food and Drug Administration in 2011 for the treatment of late-stage melanoma. This and other immunotherapy drugs have since been used to treat patients suffering from lymphoma, lung, renal and other forms of cancer.

We reached out to the 70-year-old Nobel laureate this week to congratulate him, but also to discuss how basic science — and the federal and state funding behind so much of it — was crucial to his nearly 40 years of research, and scientific and medical progress in general.

"Basic science provides the fundamental foundation for major advances in medical treatment," Allison said. "My early research in T-cell biology was funded by the National Cancer Institute. Basic research isn't often understood. It's complex and requires a thick skin to endure failure after failure in search of success. Getting to answers requires money and patience, but the payoff has the opportunity to save many, many lives."

The National Institutes of Health, Allison said, "remains the largest funding mechanism of medical research in the world." But he also praised his home state, saying, "Texas recognized the opportunity to accelerate discovery and basic science by investing $3 billion over 10 years through the Cancer Prevention and Research Institute of Texas."

Jim Allison of the University of Texas M.D. Anderson Cancer Center developed the groundbreaking cancer treatment known as "immune checkpoint therapy" along with fellow Nobel Prize winner Tasuku Honjo of Kyoto University. (/)

Biotech and pharmaceutical companies, explained Allison, fund the late-stage research that brings well-developed therapies to clinical trial — and philanthropy also is quite helpful. "But without that early funding of basic science from the government, many of the therapies that currently treat millions of cancer patients worldwide simply wouldn't exist," he said.

Allison says investment by the federal government has been a "roller-coaster ride over the past 20 years." It's been no different under the Trump administration, with the president first threatening to slash National Institutes of Health funding by more than 20 percent, only to have Congress approve a two-year budget agreement that actually boosts spending by about $3 billion — a nearly 9 percent increase.

We agree with Allison that investing in basic science is one of the best uses of federal and state taxpayer money. When politicians talk of cutting funding to the National Institutes of Health and other funders of basic research, they are not "draining the swamp" but strangling the goose that lays the golden egg.

COMMENTARY

Clinical trials exclude too many patients

When it comes to cancer treatment, and perhaps one day a cure, Allison speaks enthusiastically but bluntly: "We've had some wonderful results in the clinic with immune checkpoint blockade helping 20-30 percent of patients with some types of cancer. But that clinical success has outrun our scientific knowledge of how these drugs can be combined with other therapies to improve treatment for more patients and reduce unwanted side effects. We need sustained basic science research to more efficiently guide our progress."

The need for greater basic understanding has not passed, Allison says. "I hope everyone — including our government — can see what's possible when time and money are invested in understanding the basics of how our bodies function. There is so much more to learn, and steady funding of basic science can help us get there faster."

THE Katy News

Dr. Allison's Step Towards a Cure

Oct 29, 2018 0 Comments

by U.S. Sen. John Cornyn, R-Texas

Earlier this month, the esteemed 2018 Nobel Prize winners were announced from Stockholm, Sweden. In accordance with Swedish scientist Alfred Nobel's will, the Nobel Prize celebrates those who "have conferred the greatest benefit to humankind" within five fields: Physics, Chemistry, Physiology or Medicine, Literature, and Peace. Just a handful of exceptional men and women have been honored each year since 1901.

This year, among the brilliant men and women honored from around the globe is Houston's own Dr. Jim Allison.

Dr. Allison was shocked when he heard the news. The boy who grew up in Alice, Texas – and who lost his mother and uncle to cancer at a young age – had been working to find alternative treatments to radiation and chemotherapy, but he never dreamed he'd one day make a groundbreaking discovery towards cancer's cure that would merit a Nobel Prize.

Through their research of T cells, Dr. Allison and Japanese immunologist Tasuku Honjo found a way to unleash a patient's own immune system to fight against cancer cells.

Now known as the Godfather of Cancer Immunotherapy, Dr. Allison has helped create drugs to treat common forms of cancer like melanoma, lung cancer, and Hodgkin's lymphoma.

But don't let Dr. Allison's resounding success let you think it's been easy. "Science is a long and frustrating road," he announced at a press conference. "There's no instant gratification... You've got to be comfortable with a lot of failures to get there."

Dr. Allison also acknowledges how critical teamwork is when it comes to medical research. Without ~~federal~~ funding through the National Institutes of Health (NIH), the Cancer Prevention and Research Institute of Texas (CPRIT) and private funding, he says many of the therapies that currently treat millions of cancer patients worldwide simply wouldn't exist.

Thanks to the perseverance and dedication of Dr. Allison and his team, scientists are one step closer to curing cancer. Andthanks to them, it's not a question of if we will cure cancer, but when.

I'm proud this discovery came from Texas. But Dr. Allison is not the only Nobel Laureate from the Lone Star State. There are at least 10 Nobel Laureates living in Texas today, and even more Texans who have been honored with Nobel Prizes since they were created more than a century ago.

In 1946, former University of Texas professor Hermann J. Muller won a Nobel Prize for his research showing X-rays can cause genetic mutations, proving the danger of radiation for the first time.

Jack Kilby, inventor of the handheld calculator and thermal printer, won the Nobel Prize in Physics in 2000 for building the first integrated circuit while working for Texas Instruments in 1958. He then went on to teach electrical engineering at Texas A&M University.

Just last year, University of Texas alum Michael W. Young won a Nobel Prize for his discovery of the gene that controls our biological clock, including processes like sleep and metabolism throughout the day.

Each of these incredible discoveries, and many more being made each day at labs across our state, have pushed the needle forward on our understanding of the world we live in. But there's always more we can learn. Thomas Edison once said, "When you have exhausted all possibilities, remember this: you haven't."

There's so much more we can discover, and with science advancing at practically lighting speed thanks to minds like Dr. Allison's, I know we'll have more answers soon.

I encourage all young boys and girls – from Alice, Texas, and all across our state – to look up at Dr. Allison and all of Texas' Nobel Prize winners and know that whatever you set your mind to, the sky is the limit.

Senator John Cornyn, a Republican from Texas, is a member of the Senate Finance, Intelligence, and Judiciary Committees.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO:	CPRIT OVERSIGHT COMMITTEE
FROM:	KRISTEN DOYLE, INTERIM CHIEF PRODUCT DEVELOPMENT OFFICER
SUBJECT:	CPRIT PRODUCT DEVELOPMENT UPDATE
DATE:	NOVEMBER 28, 2018

Product Development Research Award Update

Product Development Research FY 2018 Cycle 2

The Oversight Committee approved awards for three companies from the second cycle of FY 2018 (18.2) for funding in August. Magnolia Neurosciences acquired one of the newly-awarded CPRIT companies, Korysso Therapeutics, earlier this summer and renamed it Magnolia Tejas. The Oversight Committee's approval of the Korysso award is contingent upon the company satisfying several conditions identified by the Product Development Review Council (PDRC) during the due diligence review. Korysso/Magnolia Tejas has been diligently working with CPRIT to address the remaining contingencies. CPRIT and the company will execute the award contract once the company has satisfied all the contingencies.

CPRIT's PDRC requested more information to complete their review for two other applications in the 18.2 review cycle. The PDRC met on October 17 to review additional information provided by one applicant and declined to recommend the application for funding. The one company remaining from the 18.2 review cycle plans to submit requested information to CPRIT in December for PDRC review. If the PDRC recommends the application for funding, CPRIT will present that recommendation to the Program Integration Committee (PIC) and the Oversight Committee in February.

Product Development Research Applications FY 2019 Cycle 1

The Oversight Committee approved three requests for applications (RFAs) for Product Development Award FY 2019 Cycle 1 (19.1) in February. In addition to the Texas Company and Company Relocation Product Development Awards, CPRIT released a new Seed Award RFA to support new company formation and preclinical work at early stage companies.

CPRIT received 38 applications by the August 8 deadline. After the initial peer review in late September, the Product Development review panels selected 17 companies to present their applications and answer questions in Dallas on October 23-26. The peer review panels recommended nine applications to move forward to due diligence review following the in-person presentations. The PDRC will meet in January to review the due diligence reports and make final recommendations regarding Product Development awards. The PIC and the Oversight Committee will consider the recommendations at the February 2019 meeting.

The following table reflects the information by grant mechanism for Review Cycle 19.1

Review Cycle 19.1 Data by Mechanism

Mechanism	Apps	Funds Requested	In Person	Funds Requested	Due Diligence	Funds Requested
Texas Company	5	$42,389,966	2	$16,680,008	2	$16,680,008
Relocation Company	8	$113,790,609	4	$63,474,499	3	$49,363,074
Seed Company	25	$64,956,585	11	$29,569,259	4	$11,912,313
TOTAL	**38**	**$221,137,160**	**17**	**$109,723,766**	**9**	**$77,955,395**

Product Development Research Applications FY 2019 Cycle 2

CPRIT plans to release three RFAs in late November, with applications due to CPRIT by January 30. Following peer review and due diligence, the Chief Product Development Officer will present the PDRC's recommendations to the PIC and Oversight Committee at the August 2019 Oversight Committee meeting. We anticipate that CPRIT will continue to receive a high number of Seed Award applications, including several resubmitted applications from review cycle 19.1.

The three RFAs CPRIT will release this month are:

- *Texas Company Product Development Research Award*
  This 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 be headquartered in Texas.

Award: Maximum amount $20M; Maximum duration of 36 months

- *Relocation Company Research Award*
  This 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 $20M; Maximum duration of 36 months

- *Seed Award for Product Development Research*
  The award supports projects that are earlier in their development timeline than CPRIT's two other Product Development Awards, the Texas Company Award (TXCO) and the Company Relocation Award (RELCO). 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 be headquartered in Texas or be willing to relocate to Texas upon receipt of award.

  Award: Maximum amount of $3M; Maximum duration of 36 months.

FY 2020 Program Priorities

The Product Development Subcommittee discussed the FY 2020 priorities at its meeting on November 9. The subcommittee recommends that the Oversight Committee approved the proposed FY 2020 product development program priorities. The FY 2020 product development program priorities are the same as the priorities adopted for FY 2019.

Outreach Efforts

- Senior Program Manager for Product Development Rosemary French attended the Health Tech Track at Austin Startup Week 2018 at the Capital Factory on October 3 – 4.

- On October 8 Ms. French attended the Small Molecule Drug Development Course in San Antonio at the Southwest Research Institute.

- Ms. French attended the *Texas Medical Device: CEO Fireside Chat* on October 18 at the Norris Conference Center in Austin.

- Ms. French attended the Texas Health Catalyst Demo Day 2018 on November 6 held on UT Austin campus.

- On November 13 CPRIT CEO Wayne Roberts, Senior Program Manager for Academic Research Dr. Patty Moore, and I will meet with an expert advisory group from Innovate UK visiting Austin to discuss advancing digital health innovations for cancer diagnosis and treatment.

- Ms. French will serve as a panelist for a global entrepreneurship training session "How Startup Investment Works" hosted by the US Department of State in Washington D.C. on November 13.

- Ms. Doyle attended a meeting on November 14 in San Antonio hosted by Xconomy to discuss opportunities to grow the city's life science community.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	CAMERON ECKEL, STAFF ATTORNEY
SUBJECT:	APPOINTMENTS TO THE SCIENTIFIC RESEARCH AND PREVENTION PROGRAMS COMMITTEE
DATE:	NOVEMBER 13, 2018

Summary and Recommendation

The Chief Executive Officer has appointed 21 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 discussed the appointments at its meeting on November 9 and recommends that the Oversight Committee vote to approve the appointments.

Discussion

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

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

The Nominations Subcommittee considered the 21 pending peer reviewer appointments and recommends Oversight Committee approval.

Recommendations for Product Development Peer Review Panels

- Sunil J. Advani, M.D.
- Kelly Leigh Bolton
- William Douglas Figg, Sr
- Gary B. Gordon, M.D., Ph.D.
- Carrie Hetrick
- Jill M. Kolesar, PharmD
- Matthew V. Lorenzi, PhD
- David Loyd Mccormick PhD
- Fred Ramsdell, PhD
- Marc S. Rudoltz, M.D.
- Shah, Chirag, Sudhir
- Sharma, Sunil
- Matthew A. Spear, M.D.
- Harold Trent Spencer, Ph.D.
- Diane M. Sudduth
- Kristine M. Swiderek
- Cameron John Turtle, PhD
- Pin Wang
- Steven D. Weinstein
- Pan Zheng, MD, PhD

Recommendation for Advocate Reviewer

- Eva May

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	CAMERON ECKEL, STAFF ATTORNEY
SUBJECT:	APPOINTMENTS TO THE ADVISORY COMMITTEE ON CHILDHOOD CANCERS
DATE:	NOVEMBER 13, 2018

Summary and Recommendation

At its November 9 meeting, the Nominations subcommittee discussed Presiding Officer Will Montgomery's three proposed appointments to the Advisory Committee on Childhood Cancers (ACCC) and recommends that the Oversight Committee vote to approve the appointments.

Discussion

Texas Health and Safety Code Section 102.155 directs the Oversight Committee to create an advisory committee specifically related to childhood cancers. The ACCC reviews current information regarding innovative research on the prevention, control, and cure of childhood cancers and advises the Oversight Committee on issues surrounding childhood cancer. 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 ACCC must be approved by the Oversight Committee.

The Nominations Subcommittee considered the three pending ACCC appointments and recommends Oversight Committee approval.

Recommendations for Advisory Committee on Childhood Cancers

- Dr. Richard Gorlick
- Dr. Donald Parsons
- Mrs. Carol Basso

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: Richard Gorlick

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

POSITION TITLE: Division Head and Department Chair, Pediatrics and Robert A Mosbacher Chair of Pediatrics, Professor of Pediatrics, University of Texas MD Anderson Cancer Center

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
Brooklyn College, Brooklyn, NY	B.S.	06/1987	Chemistry
SUNY Health Science Center, Brooklyn, NY	M.D.	06/1990	Medicine
Babies Hospital, Columbia Presbyterian		06/1993	Pediatric Residency
Memorial Sloan-Kettering Cancer Center		06/1996	Hem/Onc Fellowship

A. Personal Statement

I am the Division Head and Department Chairman of Pediatrics at the University of Texas MD Anderson Cancer Center. I previously led the Division of Pediatric Hematology, Oncology, Marrow and Blood Cell and was Vice Chairman of the Department of Pediatrics at the Children's Hospital at Montefiore and the Albert Einstein College of Medicine for 12 years prior to relocation to MD Anderson in late 2016. I lead a molecular pharmacology research laboratory focused on studying mechanisms of drug resistance and pathogenesis in osteosarcoma. We served as a Bone Tumor Resource Laboratory for the Children's Oncology Group, from the inception of bone tumor tissue banking by the legacy pediatric cooperative groups in 1998. My laboratory has been a member of the NCI funded Pediatric Preclinical Testing Program (PPTP) also since its inception with my laboratory performing the testing in osteosarcoma models. I am a practicing pediatric oncologist who is active in clinical trials. I serve as the Chair of the Bone Tumor Disease Committee for the Children's Oncology Group and I am a member of the Clinical Research Committee of the Sarcoma Alliance for Research through Collaboration (SARC). I formerly served as chair the Internal Advisory Board of the Specialized Program of Research Excellence (SPORE) that supports SARC as well as serve as a member of their Career Development Award Program review committee. I am a Past President of the Connective Tissue Oncology Society. I have been involved in numerous therapeutic clinical trials, as well as tumor banking and investigations of biomarkers in pediatric oncology patients with a particular focus on sarcomas. My long-standing focus has been basic, translational and clinical research in osteosarcoma which qualifies me to support the current application.

1. Chi SN, Conklin L, Meyers PA, Huvos AG, Healey JH, Gorlick R. The pattern of relapse in osteosarcoma: The Memorial Sloan-Kettering experience. Ped Blood Cancer 2004;42:46-51.
2. Nathan SS, Gorlick R, Bukata S, Chou A, Morris CD, Boland PJ, Huvos AG, Meyers PA, Healey JH. Treatment algorithm for locally recurrent osteosarcoma based on local disease free interval and the presence of lung metastasis. Cancer 2006;107:1607-1616.

B. Positions and Honors

Positions

1994-1998 Research Fellow, Dr. Joseph Bertino's Laboratory, Memorial Sloan-Kettering Cancer Center
1996-1998 Clinical Instructor, Pediatrics, Memorial Sloan-Kettering Cancer Center

1998-2004 Assistant Attending, Pediatrics, Memorial Sloan-Kettering Cancer Center
1998-2004 Director, Pediatric Sarcoma Research Laboratory, Memorial Sloan-Kettering Cancer
2004-2016 Division Chief, Pediatric Hematology/Oncology/SCT, The Children's Hospital at Montefiore
2004-2010 Associate Professor of Molecular Pharmacology and Pediatrics, AECOM
2004-2016 Director, Sarcoma Research Laboratory, Albert Einstein College of Medicine (AECOM)
2005-2016 Vice Chairman, Department of Pediatrics, The Children's Hospital at Montefiore
2010-2016 Professor of Pediatrics and Molecular Pharmacology, AECOM
2016-present Division Head and Department Chair, Pediatrics, Mosbacher Chair and Professor of Pediatrics, University of Texas MD Anderson Cancer Center

Honors

1996-1997 ASCO Young Investigator Award
1998-2000 American Society of Hematology Junior Faculty Scholar Award
1998-2001 American Society of Clinical Oncology Career Development Award
2015 Sarcoma Foundation of America, Nobility in Science Award
2016 The Soul R. Korey Award for Translational Research, AECOM

Other Roles

1998-present Director, Bone Tumor Resource Laboratory, Children's Oncology Group (COG)
2004-present Member, Bone Tumor Disease Committee, COG
2001-2011 Subcommittee Chair, Biology, Bone Tumor Disease Committee, COG
2005-2011 Vice Chair, Bone Tumor Disease Committee, COG
2006-present Chair, A COG Protocol for Collecting and Banking Osteosarcoma Specimens, AOST06B1
2006-present Member, Consumer Advocate in Research and Related Activities, National Cancer Institute
2007-present Ad hoc reviewer for the BMCT, SBIB, NCI Subcommittee H, NCI P01 cell-mediated oncology studies special emphasis panel and SBDD (OBM-2) NIH Study Sections
2011-present Member, SARC, Clinical Research Committee
2011-present Chair, Bone Tumor Disease Committee, COG
2013-2014 Vice President, The Connective Tissue Oncology Society
2014-2015 President, The Connective Tissue Oncology Society

C. Contribution to Science

1. My early publications performed in the context of a research fellowship in the laboratory of Joseph R. Bertino, MD, focused on the mechanisms of antifolate resistance in the acute leukemias. My work in the Bertino Laboratory demonstrated that impaired transport is the basis of acquired resistance in acute lymphocytic leukemia and further investigated impaired polyglutamylation as the basis of intrinsic resistance in acute myeloid leukemia. Subsequently, my independent laboratory effort began with defining the mechanisms of antifolate resistance in osteosarcoma, a disease which became the focus of my laboratory efforts, throughout my career. My laboratory defined impaired transport as the basis of intrinsic methotrexate resistance in osteosarcoma. This is the reason high dose methotrexate is needed for the treatment of that disease, as these doses permit methotrexate to enter these cells via alternative transport pathways. In contrast to the acute leukemias, the impairment in antifolate transport is due to mutations which impair the function of the reduced folate carrier as opposed to changes in expression.
    a. Gorlick R, Goker E, Trippett T, Waltham M, Banerjee D, Bertino JR. Intrinsic and acquired resistance to methotrexate in acute leukemia. N Engl J Med 1996; 335:1041-1048.
    b. Gorlick R, Goker E, Trippett T, Steinherz P, Elisseyeff Y, Mazumdar M, Flintoff WF, Bertino JR. Defective transport is a common mechanism of acquired methotrexate resistance in acute leukemia and is associated with decreased reduced folate carrier expression. Blood 1997; 89:1013-1018.
    c. Guo W, Healey JH, Meyers PA, Ladanyi M, Huvos AG, Bertino JR, Gorlick R. Mechanisms of methotrexate resistance in osteosarcoma. Clin Cancer Res 1999; 5:621-627.
    d. Yang R, Mazza B, Sowers R, Healey JH, Huvos A, Grier H, Bernstein M, Beardsley GP, Krailo M, Devidas M, Bertino JR, Meyers PA, Gorlick R. Sequence alterations in the reduced folate carrier are observed frequently in osteosarcoma tumor samples. Clin Cancer Res 2003; 9:837-844.
2. Performing studies of antifolate resistance in osteosarcoma led to a recognition that the limited availability of tumor samples precluded translational research in this field. After initially developing a biology study at Memorial Sloan-Kettering Cancer Center, I recognized that even a large single institution could not create an adequate tissue bank for this rare entity and therefore approached the Pediatric Oncology Group and the Children's Cancer Group about establishing a biology study focused on osteosarcoma. The clinical protocol

was created under the mentorship of Paul Meyers, MD, and Peter Beardsley, MD, PhD with my laboratory becoming the founding Bone Tumor Resource Laboratory for these groups in 1998. This banking effort has been highly successful becoming by far the largest tissue bank from patients with osteosarcoma in the world. In part as recognition of this accomplishment I chaired bone tumor biology efforts in the pediatric cooperative groups through their inception in 2001 through 2011 when I became Chair of the entire Bone Tumor Disease Committee of the Children's Oncology Group. The existence of these tissue banks both facilitated our own work as well as permitted the work of numerous other investigators.

a. Gorlick R, Huvos AG, Heller G, Aledo A, Beardsley GP, Healey JH, Meyers PA. Expression of HER2/ErbB-2 correlates with survival in osteosarcoma. J Clin Oncol 1999; 17:2781-2788.
b. Laverdiere C, Hoang BH, Yang R, Sowers R, Qin J, Meyers PA, Huvos AG, Healey JH, Gorlick R mRNA expression levels of CXCR4 correlate with metastatic behavior and outcome in patients with osteosarcoma. Clin Cancer Res 2005; 11:2561-2567.
c. Kubo T, Piperdi S, Rosenblum J, Antonescu CR, Chen W, Kim HS, Huvos AG, Sowers R, Meyers PA, Healey JH, Gorlick R. Platelet-derived growth factor receptor as a prognostic marker and a therapeutic target for imatinib mesylate therapy in osteosarcoma. Cancer. 2008;112:2119-2129. Epub Mar 2008.
d. Glover J, Krailo M, Tello T, Marina N, Janeway K, Barkauskas D, Fan TM, Gorlick R, Khanna C; COG Osteosarcoma Biology Group. A summary of the osteosarcoma banking efforts: A report from the Children's Oncology Group and the QuadW Foundation. Pediatr Blood Cancer. 2015; 62:450-5. Epub Dec 2014.

3. Tumor specimens from patients with osteosarcoma were used to derive cell lines as well as patient derived xenograft (PDX) models. When the Pediatric Preclinical Testing Program was established, the existence of these PDX models led to osteosarcomas inclusion in the program. Our laboratory has been a member of the Pediatric Preclinical Testing Program since its inception, specifically performing the work on the osteosarcoma PDX models. This screening program, testing drugs in a blinded fashion through osteosarcoma PDX models, has had a major influence on the development of therapeutic trials including several phase 2 trials being performed by the Children's Oncology Group.
    a. Houghton PJ, Morton CL, Tucker C, Payne D, Favours E, Cole C, Gorlick R, Kolb EA, Zhang W, Lock R, Carol H, Tajbakhsh M, Reynolds CP, Maris JM, Courtright J, Keir ST, Friedman HS, Stopford C, Zeidner J, Wu J, Liu T, Billups CA, Khan J, Ansher S, Zhang J, Smith MA. The pediatric preclinical testing program: Description of models and early testing results. Pediatr Blood Cancer. 2007;49:928-40. Epub Oct 2006.
    b. Whiteford CC, Bilke S, Greer BT, Chen Q, Braunschweig TA, Cenacchi N, Wei JS, Smith MA, Houghton P, Morton C, Reynolds CP, Lock R, Gorlick R, Khanna C, Thiele CJ, Takikita M, Catchpoole D, Hewitt SM, Khan J. Credentialing preclinical pediatric xenograft models using gene expression and tissue microarray analysis. Cancer Res 2007;67:32-40.
    c. Neale G, Su X, Morton CL, Phelps D, Gorlick R, Lock RB, Reynolds CP, Maris JM, Friedman HS, Dome J, Khoury J, Triche TJ, Seeger RC, Gilbertson R, Khan J, Smith MA, Houghton PJ. Molecular characterization of the pediatric preclinical testing panel. Clin Cancer Res. 2008;14: 4572-4583.
4. Given the increasing reliance on preclinical data for driving therapeutic trials development for patients with osteosarcoma I have been involved in numerous clinical trials for these patients. Although a significant proportion of patients with osteosarcoma are cured with the appropriate application of local control with reconstructive surgical ablation and appropriate systemic chemotherapy, additional progress in improving survival outcomes has been elusive. The prognosis for patients with osteosarcoma who present with radiographically metastatic disease or those with recurrent disease unfortunately remains poor. It is believed that additional biological insights along with appropriately designed clinical trials may correct this stalled progress.
    a. Whelan JS, Bielack SS, Marina N, Smeland S, Jovic G, Hook JM, Krailo M, Anninga J, Butterfass-Bahloul T, Böhling T, Calaminus G, Capra M, Deffenbaugh C, Dhooge C, Eriksson M, Flanagan AM, Gelderblom H, Goorin A, Gorlick R, Gosheger G, Grimer RJ, Hall KS, Helmke K, Hogendoorn PC, Jundt G, Kager L, Kuehne T, Lau CC, Letson GD, Meyer J, Meyers PA, Morris C, Mottl H, Nadel H, Nagarajan R, Randall RL, Schomberg P, Schwarz R, Teot LA, Sydes MR, Bernstein M; EURAMOS collaborators. EURAMOS-1, an international randomised study for osteosarcoma: results from pre-randomisation treatment. Ann Oncol. 2014; 26:407-14. Epub Nov 2014.

b. Roth M, Linkowski M, Tarim J, Piperdi S, Sowers R, Geller D, Gill J, Gorlick R. Ganglioside GD2 as a therapeutic target for antibody-mediated therapy in patients with osteosarcoma. Cancer. 2014; 120:548-554. Epub Oct 2013.
c. Roth M, Barris DM, Piperdi S, Kuo V, Everts S, Geller D, Houghton P, Kolb EA, Hawthorne T, Gill J, Gorlick R. Targeting glycoprotein NMB with antibody-drug conjugate, glembatumumab vedotin, for the treatment of osteosarcoma. Pediatr Blood Cancer. 2016; 63:32-8.Epub Aug 2015.

Complete List of Published Work in MyBibliography:
At present I am a co-author on 257 PubMed cited manuscripts which can be obtained from the following link.
http://www.ncbi.nlm.nih.gov/pubmed/?term=gorlick+r

D. Research Support

Ongoing Research Support

ACTIVE

CPRIT (RP180819) (PI) 10/1/18-9/30/23
Pediatric Solid Tumors Comprehensive Data Resources Core
Cancer Prevention Research Institute of Texas
This grant supports pediatric solid tumor acquisition, epigenomic profiling, enhanced immune profiling and deposition of the resulting data in the public domain.

NCI (1U01CA199221-01) (PI) 7/10/15-6/30/20
Osteosarcoma: Patient Derived Xenograft Preclinical Testing
National Cancer Institute
Bone Tumor Resource Laboratory and Bone Tumor Committee Chair
This grant supports testing of new chemotherapy agents in pediatric osteosarcoma PDX models. Our laboratory tests osteosarcoma PDX models in the context of the Pediatric Preclinical Testing Consortium.

NIH (U10 CA180886) (subcontract PI) 3/1/14-2/28/19
Children's Oncology Group Chairs Grant – renewed annually
NCI/Children's Oncology Group (COG)
Bone Tumor Committee Chair
This provides support for the time spent as the COG bone tumor disease committee chair.

Foundation Fellowship (Gorlick) 7/1/06-6/30/19
Swim Across America/Foster Foundation
Developing Targeted Therapy for Osteosarcoma
This grant supports an orthopedic oncology research fellowship in my laboratory.

COMPLETED

4172175 (Gorlick) 1/1/15-12/5/16
New York Community Trust
Circulating tumor DNA in patients with osteosarcoma
This grant supports a pilot study examining whether circulating tumor DNA can be detected in patients with osteosarcoma.

8 UL1 TR000086-05 (Shamoon) 5/19/08-12/5/16
National Center for Advancing Translational Sciences
The overall grant supports the Institute of Clinical and Translational Research (ICTR) at the Albert Einstein College of Medicine. Support is received for activities as Chair of the Scientific and Advisory Review Committee of the ICTR

BIOGRAPHICAL SKETCH

NAME: Parsons, Donald (Will)

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

POSITION TITLE: Associate Professor

EDUCATION/TRAINING:

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Princeton University	A.B.	1992	Chemistry
Ohio State University College of Medicine	M.D, Ph.D.	2001	Medicine, Pathology
Johns Hopkins University	Residency	2004	Pediatrics
Johns Hopkins University/National Cancer Institute	Fellowship	2007	Hematology/Oncology
Johns Hopkins University/National Cancer Institute	Fellowship	2008	Neuro-Oncology
Johns Hopkins University	Postdoctoral	2008	Cancer Genetics

A. Personal Statement

Dr. Parsons is a board-certified pediatric oncologist and the Co-Director of the Neuro-Oncology Program and the Cancer Genetics & Genomics Program at Texas Children's Cancer Center (TCCC), Baylor College of Medicine (BCM). He is also the Director of the Center for Precision Oncology at TCCC, with joint appointments in the BCM Department of Molecular and Human Genetics and at the BCM Human Genome Sequencing Center. His work has been instrumental in the characterization of the genetic landscapes of a variety of pediatric and adult cancers, including the first identification of IDH1 and IDH2 as critical genes in gliomas. His current research primarily focuses on the clinical application of genomic technologies in pediatric cancer care. Dr. Parsons was the dual PI of the BASIC3 study (2011-2017), an NHGRI and NCI-funded U01 Clinical Sequencing Exploratory Research (CSER) program project involving clinical exome sequencing of tumor and blood specimens from children with newly-diagnosed solid tumors and will next be leading the upcoming KidsCanSeq project as part of the NHGRI CSER2 consortium. He is the Children's Oncology Group (COG) study chair for the NCI-COG Pediatric MATCH study, a precision oncology clinical trial for children with relapsed and refractory solid tumors, lymphomas, and histiocytoses that opened in July 2017. Dr. Parsons has contributed to numerous CPRIT-funded projects studying pediatric CNS and non-CNS solid tumors.

B. Positions and Honors

Positions and Employment

1995-2001 Fellow, Ohio State University Medical Scientist Training Program
2001-2004 Resident, Department of Pediatrics, Johns Hopkins Children's Center
2004-2007 Clinical Fellow and Chief Fellow, Pediatric Hematology/Oncology
Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins
Pediatric Oncology Branch, National Cancer Institute
2007-2008 Instructor and Neuro-Oncology Fellow, Division of Pediatric Oncology
Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins
2008-2015 Assistant Professor, Departments of Pediatrics, Molecular and Human Genetics, and Human Genome Sequencing Center, Baylor College of Medicine
2011- Director, Pediatric Center for Precision Oncology, TCCC
2012- Co-Director, Neuro-Oncology Program, TCCC
2013- Co-Director, Cancer Genetics & Genomics Program, TCCC

2015- Associate Professor, Departments of Pediatrics, Molecular and Human Genetics, Pathology and Immunology, and Human Genome Sequencing Center, Baylor College of Medicine

Other Experience and Professional Memberships

2009- Co-Chair, Translational Biology Committee, Pediatric Brain Tumor Consortium
2010- CNS Disease Committee, Children's Oncology Group
2011-2014 Program Committee, American Society of Pediatric Hematology-Oncology
2012- Steering Committee, NHGRI Clinical Sequencing Exploratory Research Program
2013- Scientific Advisory Board, Alex's Lemonade Stand Foundation
2014-2017 Chair, Tumor Sequencing Working Group, NHGRI CSER Program
2014- Scientific Advisory Board, MD Anderson Moon Shots Program
2015- Research Advisory Network Member, Pediatric Brain Tumor Foundation
2015- Genomics Core Lead, Pediatric Brain Tumor Consortium
2015- Scientific Advisory Board, INFORM Clinical Trials Consortium
2016-2017 Pediatric Cancer Working Group Member, National Cancer Moonshot Initiative Blue Ribbon Panel
2016- COG Study Chair, NCI-COG Pediatric MATCH trial

Honors

1994 Donald A. Senhauser Post-Sophomore Fellowship in Pathology
1994 Samuel J. Roessler Scholarship Fund Research Fellowship
1995 Roy A. Koenigsknecht Graduate Alumni Fellowship
1995 Alpha Omega Alpha Medical Honor Society
1997 Presidential Fellowship
2000 Ohio State University Department of Pathology Outstanding Graduate Student Award
2000 J. Hutchison Williams Award for Outstanding Third Year Medical Student
2001 Ohio State University Department of Pediatrics Award
2001 Ohio State University Medical Scientist Award
2004 Society for Pediatric Research House Officer Research Award
2004 Johns Hopkins Children's Center Department of Pediatrics Schwentker Award
2007 American Society of Clinical Oncology Young Investigator Award
2007 American Brain Tumor Association Basic Research Fellowship
2007 Alex's Lemonade Stand Foundation Young Investigator Award
2009 Peter A. Steck Memorial Award for Brain Tumor Research
2010 Sidney Kimmel Foundation Translational Scholar Award
2010 Alex's Lemonade Stand Foundation "A" Award
2010 Doris Duke Charitable Foundation Clinical Scientist Development Award
2011 Houston Business Journal Health Care Hero, Biomedical
2011 Sontag Foundation Distinguished Scientist Award
2015 Pediatric Brain Tumor Foundation Hero Award
2016 BCM Department of Pediatrics Research Mentorship Award

C. Contribution to Science

1. Advances in sequencing technologies in the early 2000s facilitated the use of high-throughput genomic methods to characterize the spectrum of genetic alterations occurring in human tumors. These studies were among the first to utilize these methods to analyze entire gene families (e.g. the protein kinases) of biological and clinical interest. The results demonstrated the scattering of mutations within multiple members of critical biological pathways (as opposed to targeting a single gene) and the heterogeneity of mutations present in tumors, emphasizing the need for more broad unbiased genomic approaches. This was my first involvement in cancer genetics/genomics research; in my role leading these projects I conducted the relevant experiments (primarily PCR and Sanger sequencing), analyzed sequencing data, and contributed to the interpretation of the data and writing of the resulting manuscripts.
    a. Bardelli A, Parsons DW*, Silliman N et al. Mutational analysis of the tyrosine kinome in colorectal cancers. *Science* 2003; 300:949. PubMed PMID: 12738854. *Co-first author.
    b. Parsons DW, Wang TL, Samuels Y et al. Colorectal cancer: mutations in a signaling pathway. *Nature* 2005; 436:792. PubMed PMID: 16094359.

2. Further developments in sequencing methods facilitated the analysis of tumor and germline exomes. These studies were among the first to utilize whole exome sequencing (WES) approaches to analyze human cancers. In addition to demonstrating the feasibility of conducting and interpreting high-throughput sequence analysis of ~20,000 genes and providing entirely novel views of the genetic landscape of human tumors, the results led to the identification of a number of novel biologically and clinically relevant cancer genes in multiple tumor types. The projects also contributed to the development of bioinformatic and statistical methods for the differentiation of "driver" from "passenger" mutations. In my role as a primary team member, I participated in all aspects of the projects, with a focus on sequencing data analysis and interpretation, and provided clinical oncologic expertise.
    a. Sjöblom T, Jones S, Wood LD, Parsons DW* et al. The consensus coding sequences of human breast and colorectal cancers. *Science* 2006; 314:268-74. PubMed PMID: 16959974. *Co-first author.
    b. Wood LD, Parsons DW*, Jones S, et al. The genomic landscapes of human breast and colorectal cancers. *Science* 2007; 318:1108-1113. PubMed PMID: 17932254. *Co-first author.
    c. Jones S, Zhang X, Parsons DW* et al. Core signaling pathways in human pancreatic cancers revealed by global genomic analyses. *Science* 2008; 321:1801-6. PubMed PMID: 18772397. *Co-first author.
3. The application of WES methods has provided particular insight into the genetics and biology of CNS tumors. These studies of glioblastoma multiforme (GBM) and medulloblastoma (MB), the most common malignant brain tumors in adults and children, respectively, were the first such analyses of these tumor types. The GBM studies first identified the isocitrate dehydrogenase genes *IDH1* and *IDH2* as critical frequently-mutated genes in both GBM and lower grade astrocytomas and oligodendrogliomas, opening a novel area of brain tumor research and identifying mutations with direct clinical relevance for brain tumor diagnosis and prognostication. In addition to revealing a significantly lower mutation rate as compared to adult cancers (which has been found to be true across pediatric solid tumor types), the WES analysis of MB revealed recurrent mutations in the mixed lineage leukemia genes *MLL2* and *MLL3*, genes affecting chromatin remodeling and gene regulation (another defining feature of pediatric cancers). I led the team conducting these studies.
    a. Parsons DW, Jones S, Zhang X et al. An integrated genomic analysis of human glioblastoma multiforme. *Science* 2008; 321:1807-12. PubMed PMID: 18772396.
    b. Yan H, Parsons DW* et al. *IDH1* and *IDH2* mutations in gliomas. *New Eng J Med* 2009; 360: 765-73. PubMed PMID: 19996293. *Co-first author.
    c. Parsons DW, Li M, Zhang X et al. The genetic landscape of the childhood cancer medulloblastoma. *Science* 2011; 331(6016):435-9. PubMed PMID: 21163964.
4. We have also utilized WES and other genomic and transcriptomic methods to identify recurrent alterations of biological and clinical significance in non-CNS pediatric malignancies. In the first study, we characterized the genomic landscape of Langerhans cell histiocytosis (LCH), providing valuable insight into the biology of the disease and identifying potential therapeutic interventions for these patients. I led this project in collaboration with Dr. Carl Allen (TCH histiocytosis program director). In the second study we identified an unusual genetic alteration (an internal tandem duplication) in *BCOR* in >85% of cases of clear cell sarcoma of the kidney (CCSK). This unexpected finding has defined a new focus for CCSK research and led to the development of the first molecular diagnostic test for this disease. I led this project in collaboration with Dr. Angshumoy Roy (TCH/BCM molecular pathologist). In the final study we performed a comprehensive genomic characterization of hepatoblastoma, identifying molecular targets for therapy (i.e. *NFE2L2* hotspot mutations) and proposing a novel molecular risk-stratification system.
    a. Chakraborty R, Burke TM, Hampton OA, et al. Alternative genetic mechanisms of *BRAF* activation in Langerhans cell histiocytosis. *Blood* 2016;128(21):2533-2537. PubMed PMID: 27729324.
    b. Roy A, Kumar V, Zorman B, et al. Recurrent internal tandem duplications of *BCOR* in clear cell sarcoma of the kidney. *Nat Comm* 2015;6:8891. PubMed PMID: 26573325.
    c. Sumazin P, Chen Y, Treviño LR, et al. Genomic analysis of hepatoblastoma identifies distinct molecular and prognostic subgroups. *Hepatology* 2017; 65(1):104-121. PubMed PMID: 27775819.

5. Although genome-scale sequencing methods have provided significant insight into the pathogenesis of cancer, experience with the clinical use of these tests in the care of childhood cancer patients, remains limited. Consequently, the implementation of genomic tests into the pediatric oncology clinic and design of prospective clinical trials has become a focal point of my research program. We opened the BASIC3 clinical tumor and germline WES study (an NHGRI/NCI-funded Clinical Sequencing Exploratory Research program project) for newly-diagnosed CNS and non-CNS solid tumor patients in August 2012 and successfully completed study enrollment of more than 280 patients and 420 parents in 2016. The first of these studies described the infrastructure and procedures developed to consent the families of pediatric cancer patients treated at a racially and ethnically diverse institution to clinical sequencing studies. The second reported the diagnostic yield of this testing for the initial 150 patients enrolled: the resulting view of the diversity of somatic and germline mutations and the identification of pathogenic germline cancer susceptibility variants in ~10% of patents provided critical data to guide the development of prospective precision oncology trials, including the NCI-COG Pediatric MATCH study (planned to open mid-2017). I serve as the study PI (with Sharon E. Plon, M.D., Ph.D.) and the senior author on these studies.
    a. Scollon S, Bergstrom K, Kerstein RA, et al. Obtaining informed consent for clinical tumor and germline exome sequencing of newly diagnosed childhood cancer patients. *Genome Med* 2014 Sep17;6(9):69. PubMed PMID: 25317207.
    b. Parsons DW, Roy A, Yang Y, et al. Diagnostic yield of clinical tumor and germline whole exome sequencing for children with solid tumors. *JAMA Oncol*, 2016 Jan 28. PubMed PMID: 26822237.

Complete List of Published Work in MyBibliography:
https://www.ncbi.nlm.nih.gov/sites/myncbi/1Z3fGP023gDA-/bibliography/46793332/public/?sort=date&direction=ascending

D. Additional Information: Research Support and/or Scholastic Performance

Ongoing Research Support

2 U01 HG006485-05 Parsons, McGuire, Plon (contact) 08/07/17-05/31/21
NHGRI/NCI
Evaluating utility and improving implementation of genomic sequencing for pediatric cancer patients in the diverse population and healthcare settings of Texas: The KidsCanSeq Study
Project Goal: To investigate the clinical application and comparative utility of multiple germline and tumor genomic tests for the care of diverse childhood cancer patients through a consortium of Texas institutions.

RP120685-P1 Parsons (PI) 08/31/12-02/28/19 (NCE)
CPRIT Multi-Investigator (MIRA) Award
Identification of Actionable Mutations in STS and ESFT Tumors
Project 1 of 'Molecularly Targeted Therapy for Soft Tissue Sarcoma in Texas' (RP120882), Skapek (PI)
Project Goal: To identify molecularly targetable genetic alterations in pediatric sarcomas through genomic analysis of both retrospectively and prospectively collected tumor samples through a Texas consortium.

U10CA180886
National Institutes of Health Parsons (subcontract) 03/01/17-02/28/19
Children's Hospital of Philadelphia subcontract
MATCH Scientific Leadership: NIH National Clinical Trials Network (NCTN) Grant
Project Goal: To participate in the COG scientific leadership and oversight for the COG-NCI Pediatric MATCH study, a precision oncology trial for children with relapsed and refractory cancers.

SU2C-AACR Maris (PI) 11/1/17 – 10/31/21
Stand up To Cancer / AACR / St. Baldrick's Foundation / CHOP
(Sub PI: Dr. Ahmed)
Dream Team Translational Cancer Research Grant
Immunogenomics to Create New Therapies for High-Risk Pediatric Cancers
Project Goal: To create new immunotherapies for high-risk pediatric solid tumors based on integrated genomic analyses of patient tumors.
Role: Co-Investigator

5 UM1 CA081457-18 Onar, Thomas, Dunkel 04/01/04-03/31/19
NCI/St. Jude's Children's Research Hospital (sub PI: Baxter)
Pediatric Brain Tumor Consortium
Project Goal: To continue the clinical research activities of the Pediatric Brain Tumor Consortium (PBTC) in order to identify new treatment approaches for children with brain tumors.
Role: Co-investigator

R01 CA185402 Li (PI) 05/15/14-04/30/18
(PQD-5) Patient Derived Orthotopic Xenograft Models for Drug Response Prediction
Project Goal: To utilize genomically-characterized orthotopic xenograft models of pediatric brain tumors to selected tumor-directed targeted therapies.
Role: Co-Investigator

RP150032 Li (PI) 03/01/15-02/28/19
CPRIT Individual Investigator Award
Developing New Combinatory Therapies for Pediatric High Grade Glioma
Project Goal: To develop novel treatment strategies for pediatric high grade glioma (pHGG) using combinatorial high-throughput drug screening.
Role: Co-Investigator

RP150334 Deneen (PI) 03/01/15-02/28/19
CPRIT Individual Investigator Award
Personalized Functionalization of Pediatric High Grade Glioma
Project Goal: To identify functional pHGG driver genes using a novel screening platform that enables rapid modeling of barcoded mutant genes based on the genomes of individual pHGG patient tumors.
Role: Co-Investigator

SBF 6253201 Rodriguez-Galindo (PI) 07/01/14-06/30/17
St. Baldrick's Foundation/ Dana Farber Cancer Institute (Sub PI: Allen)
Consortium Research Grant Award
Consortium for Clinical and Translational Research in Langerhans Cell Histiocytosis (LCH)
Project Goal: To design clinical & translational studies for the study of LCH and related histiocytic disorders.
Role: Co-Investigator

RP170169 Parsons (PI) 12/01/16-11/30/20
Cancer Prevention & Research Institute of Texas (CPRIT)
High Throughput Combinatory Drug Screening For Pediatric Medulloblastomas with a Dysregulated Ezh2 Pathway
Project Goal: To investigate the role of epigenetic dsysregulation in driving MB tumorigenesis, and the efficacy of inhibitors of the histone methyltransferase EZH2 in treating MB.
Role: transferred role from Co-Investigator to PI in anticipation of Dr. Li's departure from TCH/BCM

SBF Innovation Award Parsons (PI) 07/01/18-06/30/21
St. Baldrick's Foundation
Precision Medicine in the Pediatric Oncology Clinic
Project Goal: To develop, utilize, and evaluate precision oncology approaches for childhood cancer patients.

Carol R. Basso

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Dallas, Texas 75254

214-986-0009

carol@1million4anna.org

1Million4Anna.org

Experience

October 2011–Present
Co-Founder & Executive Director • 1 Million 4 Anna Foundation • Addison, TX

- Established and built the Foundation, honoring my daughter, Anna, and help others impacted by Ewing sarcoma. With the aid of family, friends, and many supporters, over $3.6 million has been raised supporting a three-part mission: promising research, college scholarships for survivors, and family assistance.

November 2009–June 2011
Cancer Mom • Basso Family • Dallas, TX

- Focused on caring for our youngest daughter, Anna, as she battled metastatic Ewing sarcoma. Navigated our family through an unknown world of childhood cancer diagnosis, treatment, recurrence, and Anna's end of life.

January 2000–2012
Homemaker & Mom • Basso Family • Dallas, TX

- Managed family and helped form roots in Dallas, Texas after moving from Atlanta, GA. Involved in parent activities at various schools – Fairhill School, Prince of Peace Catholic School, and John Paul II High School including: auctions, team mom, classroom mom, Prayer Partner, and tutoring.

September 1993–April 1999
Account Manager • Systemware Professional Services • Atlanta, GA

- Independently built and developed the Atlanta market for Dallas-based company providing contract programming services. Established 8 customers resulting in $2 million in annual sales.

October 1990–September 1993
Account Manager • AGS Information Services, Inc. • Raleigh, NC

June 1984–October 1990
Territory Manager • Armstrong World Industries • Memphis, TN & Raleigh, NC

Education

Milikin University, Decatur, Illinois, 1984

- Bachelor of Science in Marketing

Personal

Happily married to David J. Basso, Jr. for 30 years (July 1988) and proud mom of Patrice Basso, age 29

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	FY 2020 PROGRAM PRIORITIES
DATE:	NOVEMBER 20, 2018

Summary and Recommendation

Texas Health and Safety Code § 102.107 requires the Oversight Committee to set priorities for each grant program annually. Each program subcommittee discussed the fiscal year 2020 program priorities at least once; all the program subcommittees voted at their meetings earlier this month to recommend that the Oversight Committee approve the proposed fiscal year 2020 program priorities. Except for an addition to the priorities for the academic research program, the fiscal year 2020 program priorities are the same as the priorities adopted by the Oversight Committee in January for fiscal year 2019.

Discussion

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

The Oversight Committee reviews its priorities annually and adjusts as circumstances change and to incorporate the latest information concerning cancer-related advances in prevention, academic research, and product development research. After consideration and discussion at the Oversight Committee's special meeting in January 2018, the Oversight Committee elected to move up the timeline for approving the annual program priorities to provide CPRIT staff more lead time for preparing and releasing RFAs. The timeline change instituted by the Oversight Committee allows the priorities to guide, rather than follow, the fiscal year 2020 RFA process.

The Oversight Committee briefly addressed the process for considering the fiscal year 2020 program priorities at its August 2018 meeting. Since that meeting, each of the program subcommittees has met at least once to discuss the program priorities proposed for fiscal year 2020. The Prevention and Product Development Research Subcommittees both recommend proposed fiscal year 2020 priorities for their respective programs that are unchanged from the

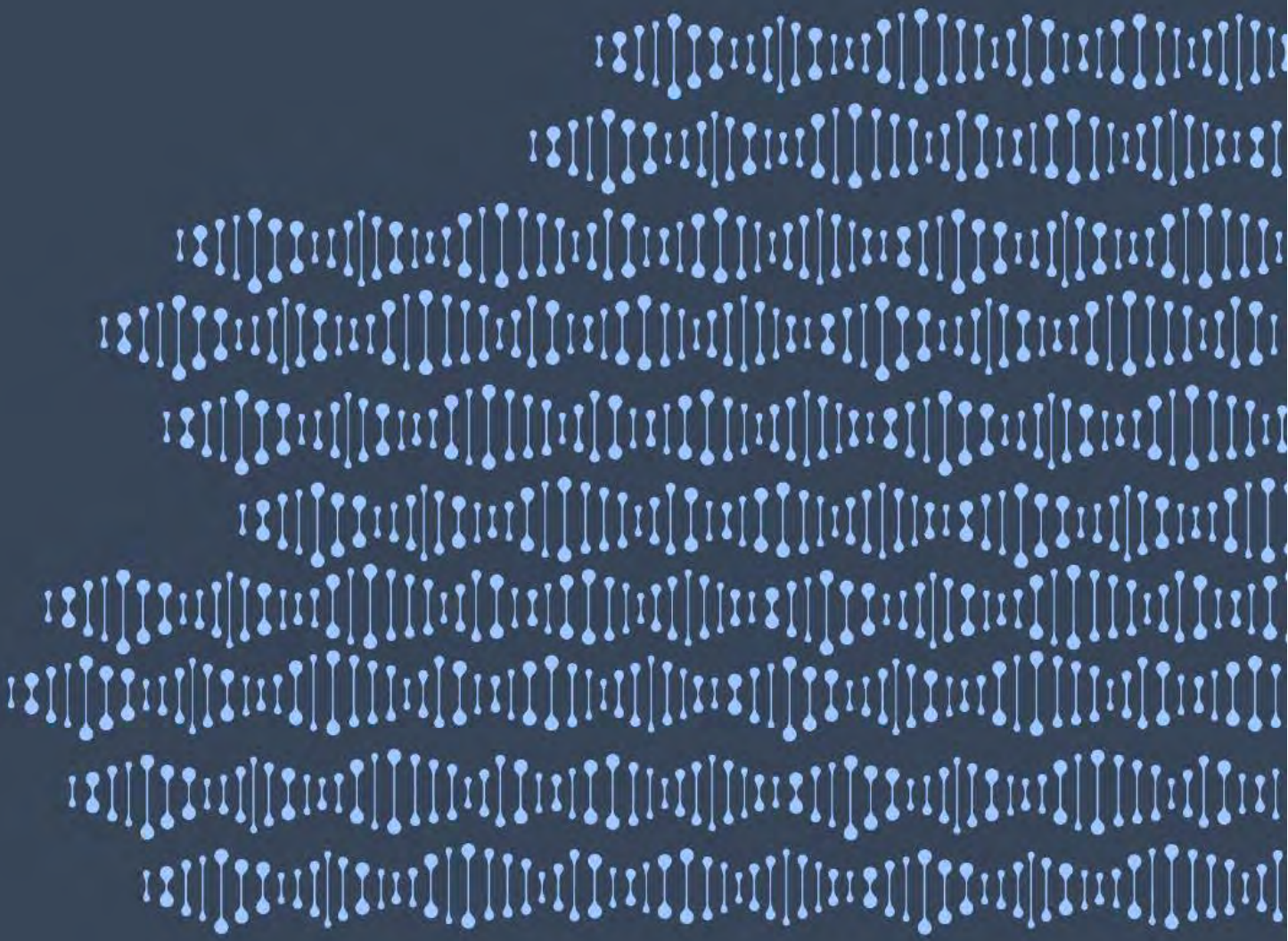
priorities adopted for fiscal year 2019. The Academic Research Subcommittee recommends that the Oversight Committee approve fiscal year 2020 academic research program priorities that are the same as those adopted for fiscal year 2019 with this addition of a new program priority– expanding access to innovative clinical trials. CPRIT program staff support the subcommittees' recommendation to approve the fiscal year 2020 priorities.

In addition to the priorities specific to each grant program, the proposed fiscal year 2020 program priorities also reflect priorities across CPRIT's three programs. These overarching priorities, which remain the same as those adopted for fiscal year 2019, inform the Program Integration Committee (PIC) on balancing the portfolio across the academic research, prevention, and product development research programs.

CPRIT staff will use the newly adopted program priorities to develop RFAs for the fiscal year 2020 CPRIT grant review cycles.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Program Priorities 2020



CONTENTS:

ABOUT CPRIT PROGRAM PRIORITIES PROJECT

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

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

CPRIT Purpose

Texas Health & Safety Code, Chapter 102

Sec. 102.002. PURPOSES. The Cancer Prevention and Research Institute of Texas is established to:

(1) create and expedite innovation in the area of cancer research and in enhancing the potential for a medical or scientific breakthrough in the prevention of cancer and cures for cancer;

(2) attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in this state; and

(3) develop and implement the Texas Cancer Plan.

Program Priorities Legislative Mandate

Texas Health & Safety Code, Chapter 102

Sec. 102.107. POWERS AND DUTIES. The oversight committee shall:

(1) hire a chief executive officer;

(2) annually set priorities as prescribed by the legislature for each grant program that receives money under this chapter; and

(3) consider the priorities set under Subdivision (2) in awarding grants under this chapter.

PROCESS TO DEVELOP PROGRAM PRIORITIES

The Oversight Committee initially approved the program priorities in November 2014 after a six-month process that included public input. The fiscal year 2015 program priorities were subsequently incorporated into the RFAs released by each program. The Oversight Committee continues to annually approve priorities for each program every year, most recently adopting the program priorities for fiscal year 2019 at a special meeting in January 2018.

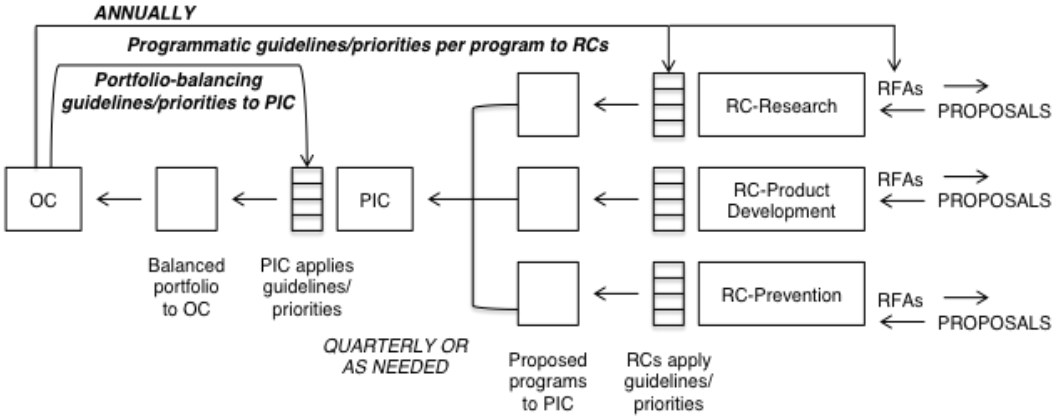
After consideration and discussion at the January 2018 special meeting, the Oversight Committee elected to move up the timeline for approving the annual program priorities to provide CPRIT staff more lead time for preparing and releasing RFAs. The timeline change instituted by the Oversight Committee allows the priorities to guide, rather than follow, the fiscal year 2020 RFA process.

SCOPE OF PROGRAM PRIORITIES PROJECT

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

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

Priorities and CPRIT's Grant Making Process



CPRIT'S LONG TERM VISION

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

Innovative projects funded by CPRIT will result in:

- A decrease in the burden of cancer in Texas through preventive measures, new diagnostics and treatments, and effective translation of discoveries into products;
- A recognition of and focus on disparities in cancer incidence, mortality, and access to care;
- Significant advancements in the scientific understanding of cancer; and
- An enhanced and expanded life sciences infrastructure in the state because of recruiting researchers, training health care/science professionals, attracting companies and supporting investigator startups.

PRIORITIES WITHIN EACH OF CPRIT'S PROGRAMS

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

Established key principles essential to executing CPRIT's purpose guide each of CPRIT's three programs. The main principle underlying all three programs is that each will continue to ensure

only applications with scientific merit moves forward in CPRIT's peer review grant process. In addition, each program has established unique program principles. The program priorities supplement these principles to guide the selection of meritorious applications to address CPRIT's strategic priorities as set annually by the Oversight Committee.

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

Academic Research Program

Background

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

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

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

cancer research. Also critical are the training programs that aim to produce the next generation of cancer researchers and increase the diversity of the cancer research workforce.

Established Principles

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

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

Prevention Program

Background:

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

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

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

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

- Potential for impact;
- Geographic distribution;
- Cancer type; and
- Type of program or service

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

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

Established Principles:

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

Prevention Program Priorities
• Populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence • Geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence • Underserved populations

Product Development Research Program

Background

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

Developing novel cancer treatments, diagnostics, and devices results from a series of research and development activities. As a product moves through the development process, the risk of failure decreases as the product successful navigates each step. Clinical research confirms the safety and efficacy of the new therapy on the target patient population.

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

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

Established Principles

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

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

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

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

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

PRIORITIES ACROSS CPRIT'S THREE PROGRAMS

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

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

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

Prevention and Early Detection Initiatives

Rationale

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

Emphasis

Ideally, academic research will create the evidence base for novel approaches to prevention and early detection. Product development research will provide new methods, diagnostics, imaging, or devices, for early cancer detection. The prevention program will implement interventions to put these innovative approaches into practice once a solid evidence base of effectiveness exists. Strategies include each program issuing either a targeted RFA or listing prevention or early detection as an area of emphasis (among others) within current RFAs. In addition, the programs can explore RFAs that could span programs, e.g. RFAs that would support a research component to a prevention project.

Early Translational Research

Rationale

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

Emphasis

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

Enhance Texas' Research Capacity and Life Science Infrastructure

Rationale

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

Emphasis

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

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

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

Summary: Priorities across CPRIT's Three Programs

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

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

November 2018 Oversight Committee
Internal Audit Status Report
As of October 29, 2018

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.

NEW INTERNAL AUDITS		
Internal Audit	**Description**	**Timing**
State Reporting	Internal Audit will include an evaluation of risks and internal controls in place related to CPRIT's State Reporting practices. Activities to be considered in the evaluation will include Annual Reports, Research/Analytical Supporting, Texas Cancer Plan, Public Information Act Requests, and Ad Hoc Reporting. Fieldwork for the audit began October 22, 2018.	In Progress
Budget and Planning	Internal Audit will include an evaluation of risks and internal controls in place related to CPRIT's Budgeting and Planning practices. Activities to be considered in the evaluation will include Strategic Plan, Budgeting and Planning Process, Legislative Appropriations Request, Review and Amendment, Capital Expenditures Budget, and Budget Monitoring.	December 3 – 21, 2018

FOLLOW-UP PROCEDURES		
Follow-Up	**Description**	**Timing**
SAO Performance Measures Follow-Up • 3 Findings	Internal Audit will perform follow-up procedures on the 3 open findings from the 2017 Audit to ensure corrective action has been taken. Fieldwork began on October 22, 2018.	In Process
Information Security Follow-Up	Internal Audit will perform follow-up procedures on the open findings from the 2016 Internal Audit to ensure corrective action has been taken.	February 4 – 8, 2019

Communications Follow-Up • 1 High Finding • 4 Moderate Findings	Internal Audit will perform follow-up procedures on the 5 open findings from the 2018 Internal Audit to ensure corrective action has been taken.	February 4 – 8, 2019
Post-Award Grant Monitoring Follow-up • 1 Moderate Finding	Internal Audit will perform follow-up procedures on the 1 open finding from the 2018 Internal Audit to ensure corrective action has been taken.	February 11-15, 2019
Procurement and P-Cards Follow-up • 1 Moderate Finding	Internal Audit will perform follow-up procedures on the 1 open finding from the 2017 Internal Audit to ensure corrective action has been taken.	February 11-15, 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.

We have submitted the 2018 Annual Internal Audit Report, and the periodic internal audit reports to the State Auditor's Office, Legislative Budget Board, Governor's Office, and Sunset Commission, as required by the Texas Internal Auditing Act.

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

Cancer Prevention and Research Institute of Texas
Internal Audit of State Reporting
Internal Audit Risk Coverage
October 2018

Scope: The audit will focus on CPRIT's State Reporting processes. We evaluated the following sub-processes:
- Due Date Monitoring and Tracking
- Research and Analytical Support
- Preparation
- Review and Approval
- Submission and Retention

Monitored Risks

State Reporting		
Process Area	**Risks Monitored**	
Due Date Monitoring and Tracking	**1**	Report deadlines are tracked and communicated to required CPRIT personnel
	2	Adequate planning is performed to complete reports by the required deadline
	3	Deadlines are monitored and reported to CPRIT management
Research and Analytical Support	**4**	Data sources are validated and approved
	5	Data compiled, analyzed and reported is accurate and complete
	6	Analysis of information reported is reviewed and approved prior to finalizing reports
Preparation	**7**	Report preparation is performed by appropriate personnel
	8	Reports are prepared according to authoritative criteria and requirements
	9	Development of reports begins according to CPRIT's timelines
	10	Personnel receive appropriate training to prepare reports
Review and Approval	**11**	Reports are reviewed by appropriate personnel for completeness and accuracy
	12	Reports are approved by management prior to release
Submission and Retention	**13**	Reports are delivered to the required recipients by the established deadlines
	14	Reports are published to all required locations
	15	Copies of reports are retained and accessible by appropriate CPRIT personnel

Cancer Prevention and Research Institute of Texas
Schedule of Audits, Status, and Findings Summary
As of October 29, 2018

					Open Findings				Closed Findings				Total Findings			
Audit	**Fiscal Year**	**Status/Timing**	**Report Date**	**Report Rating**	**High**	**Mod**	**Low**	**Total**	**High**	**Mod**	**Low**	**Total**	**High**	**Mod**	**Low**	**Total**
Fiscal Year 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 Grant Contracting Internal Audit	2018	Complete	February 1, 2018	Strong	-	1	-	1	-	-	-	-	-	1	-	1
Communication Internal Audit	2018	Complete	April 30, 2018	Satisfactory	1	4	-	5	-	-	-	-	1	4	-	5
State Reporting Internal Audit	2018	FY 2019	TBD	TBD	-	-	-	-	-	-	-	-	-	-	-	-
Information Technology Services Internal Audit	2018	FY 2019	TBD	TBD	-	-	-	-	-	-	-	-	-	-	-	-
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	In Process	TBD	TBD	-	-	-	-	-	-	-	-	-	-	-	-
Budget and Planning	2019	December 2018	TBD	TBD	-	-	-	-	-	-	-	-	-	-	-	-
2017 SAO Performance Measures Follow-up	2019	In Process	TBD	TBD	-	-	-	3	-	-	-	-	-	-	-	3
2016 Information Security Follow-Up	2019	February 2019	TBD													
2018 Communication Follow-Up	2019	February 2019	TBD	TBD	1	4	-	5	-	-	-	-	1	4	-	5
2018 Post Award Grant Monitoring Follow-Up	2019	February 2019	TBD	TBD	-	1	-	1	-	-	-	-	-	1	-	1
2018 Grant Contracting Follow-Up			TBD	TBD												
2017 Procurement and P-Card Follow-Up	2019	February 2019	TBD	TBD	-	7	2	9	-	6	2	8	-	1	-	1
Fiscal Year 2019 Subtotal					**1**	**12**	**2**	**18**	**-**	**6**	**2**	**8**	**1**	**6**	**-**	**10**

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	In Process	TBD	TBD	-	-	-	-	-	-	-	-	-	-	-	-	
Budget and Planning	2019	December 2018	TBD	TBD	-	-	-	-	-	-	-	-	-	-	-	-	
Post Award Grant Monitoring Internal Audit Grant Contracting Internal Audit	2018	February 2019	TBD	TBD	-	1	-	1	-	-	-	-	-	1	-	1	
Communication Internal Audit	2018	February 2019	TBD	TBD	1	4	-	5	-	-	-	-	1	4	-	5	
SAO Performance Measures	2017	In Process	TBD	TBD	-	-	-	3		-	-	-	-	-	-	3	
Procurement and P-Cards	2017	February 2019	TBD	TBD	-	7	2	9	-	6	2	8	-	1	-	1	
Information Security Internal Audit	2016	February2019	TBD														
Total Findings For Internal Audit Follow-Up					**1**	**12**	**2**	**18**	**-**	**6**	**2**	**8**	**1**	**6**	**-**	**10**	

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:	**NOVEMBER 13, 2018**

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 August 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 proposed rule amendments to §§ 703.11, 703.13, 703.14, 703.21, and 703.24 at the August meeting. Each of the proposed changes addresses one issue – allowing grantees to submit required filings otherwise due on a Saturday, Sunday, or federal holiday on the next business day. Currently, CPRIT's administrative rules require grantees to file reports on the due date, even if the due date falls on a weekend day or a federal holiday. The proposed change aligns CPRIT's reporting deadlines with other federal and state agencies, such as the NIH and the Texas Attorney General, which allow the deadline for required filings to move to the first business day following a due date that falls on a weekend or holiday. CPRIT can accommodate this change without incurring additional cost. CPRIT published the proposed rules in the *Texas Register* and made the rules available on the agency's website. CPRIT received no comments regarding the proposed changes.

The Board Governance Subcommittee met on November 1st 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.

TITLE 25. HEALTH SERVICES

PART 11. CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CHAPTER 703. Grants for Cancer Prevention and Research

The Cancer Prevention and Research Institute of Texas ("CPRIT" or "the Institute") adopts the amendments to §§703.11, 703.13, 703.14, 703.21, and 703.24 without changes to the proposed amendments as published in the September 28, 2018, issue of the Texas Register (43 TexReg 6432), therefore, the rules will not be republished. The amendments allow a grantee an extra business day to submit required reports that may be due on a weekend or federal holiday.

Reasoned Justification

The proposed amendment to §§703.11, 703.13, 703.14, 703.21, and 703.24 allow required grant filings to be submitted the next business day following a due date that falls on a weekend or federal holiday as designated by the U.S. Office of Personnel Management. For example, if the due date of a Financial Status Report (FSR) falls on a Saturday, the grant recipient may submit the FSR on the first business day following the due date without the Institute considering the report delinquent. Moving the due date to a business day is consistent with the practice of most state and federal agencies. Implementing this change assists CPRIT's grant recipients and may reduce the occurrence of delinquent reports.

Summary of Public Comments and Staff Recommendation

CPRIT received no public comments regarding the proposed amendment to § 703.11.

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

Certification

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

To be filed with the Office of Secretary of State on November 28, 2018.

§703.11.Requirement to Demonstrate Available Funds for Cancer Research Grants.

(a) Prior to the disbursement of Grant Award funds, the Grant Recipient of a Cancer Research Grant Award shall demonstrate that the Grant Recipient has an amount of Encumbered Funds equal to at least one-half of the Grant Award available and not yet expended that are dedicated to the research that is the subject of the Grant Award.

(1) The Grant Recipient's written certification of Matching Funds, as described in this section, shall be included in the Grant Contract.

(2) A Grant Recipient of a multiyear Grant Award may certify Matching Funds on a year-by-year basis for the amount of Award Funds to be distributed for the Project Year based upon the Approved Budget.

(3) A Grant Recipient receiving multiple Grant Awards may provide certification at the institutional level.

(4) Nothing herein restricts the Institute from requiring the Grant Recipient to demonstrate an amount of Encumbered Funds greater than one-half of the Grant Award available and not yet expended that are dedicated to the research that is the subject of the Grant Award. To the extent that a greater Matching Funds amount will be required, the Institute shall include the requirement in the Request for Applications and in the Grant Contract.

(b) For purposes of the certification required by subsection (a) of this section, a Grant Recipient that is a public or private institution of higher education, as defined by §61.003, Texas Education Code, may credit toward the Grant Recipient's Matching Funds obligation the dollar amount equivalent to the difference between the indirect cost rate authorized by the federal government for research grants awarded to the Grant Recipient and the five percent (5%) Indirect Cost limit imposed by §102.203(c), Texas Health and Safety Code, subject to the following requirements:

(1) The Grant Recipient shall file certification with the Institute documenting the federal indirect cost rate authorized for research grants awarded to the Grant Recipient;

(2) To the extent that the Grant Recipient's Matching Funds credit does not equal or exceed one-half of the Grant Award funds to be distributed for the Project Year, then the Grant Recipient's Matching Funds certification shall demonstrate that a combination of the dollar amount equivalent credit and the funds to be dedicated to the Grant Award project as described in subsection (c) of this section is available and sufficient to meet or exceed the Matching Fund requirement;

(3) Calculation of the portion of federal indirect cost rate credit associated with subcontracted work performed for the Grant Recipient shall be in accordance with the Grant Recipient's established internal policy; and

(4) If the Grant Recipient's federal indirect cost rate changes six months or less following the anniversary of the Effective Date of the Grant Contract, then the Grant Recipient may use the new federal indirect cost rate for the purpose of calculating the Grant Recipient's Matching Funds credit for the entirety of the Project Year.

(c) For purposes of the certification required by subsection (a) of this section, Encumbered Funds must be spent directly on the Grant Project or spent on closely related work that supports, extends, or facilitates the Grant Project and may include:

(1) Federal funds, including, but not limited to, American Recovery and Reinvestment Act of 2009 funds, and the fair market value of drug development support provided to the recipient by the National Cancer Institute or other similar programs;

(2) State of Texas funds;

(3) funds of other states;

(4) Non-governmental funds, including private funds, foundation grants, gifts and donations;

(5) Unrecovered Indirect Costs not to exceed ten percent (10%) of the Grant Award amount, subject to the following conditions:

(A) These costs are not otherwise charged against the Grant Award as the five percent (5%) indirect funds amount allowed under §703.12(c) of this chapter (relating to Limitation on Use of Funds);

(B) The Grant Recipient must have a documented federal indirect cost rate or an indirect cost rate certified by an independent accounting firm; and

(C) The Grant Recipient is not a public or private institution of higher education as defined by §61.003 of the Texas Education Code.

(6) Funds contributed by a subcontractor or subawardee and spent on the Grant Project, so long as the subcontractor's or subawardee's portion of otherwise allowable Matching Funds for a Project Year may not exceed the percentage of the total Grant Funds paid to the subcontractor or subawardee for the same Project Year.

(d) For purposes of the certification required by subsection (a) of this section, the following items do not qualify as Encumbered Funds:

(1) In-kind costs;

(2) Volunteer services furnished to the Grant Recipient;

(3) Noncash contributions;

(4) Income earned by the Grant Recipient that is not available at the time of Grant Award;

(5) Pre-existing real estate of the Grant Recipient including building, facilities and land;

(6) Deferred giving such as a charitable remainder annuity trust, a charitable remainder unitrust, or a pooled income fund; or

(7) Other items as may be determined by the Oversight Committee.

(e) To the extent that a Grant Recipient of a multiyear Grant Award elects to certify Matching Funds on a Project Year basis, the failure to provide certification of Encumbered Funds at the appropriate time for each Project Year may serve as grounds for suspending reimbursement or advancement of Grant Funds for project costs or terminating the Grant Contract.

(f) In no event shall Grant Award funds for a Project Year be advanced or reimbursed, as may be appropriate for the Grant Award and specified in the Grant Contract, until the certification required by subsection (a) of this section is filed and approved by the Institute.

(g) No later than thirty (30) days following the due date of the FSR reflecting expenses incurred during the last quarter of the Grant Recipient's Project Year, the Grant Recipient shall file a form with the Institute reporting the amount of Matching Funds spent for the preceding Project Year.

(h) If the Grant Recipient failed to expend Matching Funds equal to one-half of the actual amount of Grant Award funds distributed to the Grant Recipient for the same Project Year the Institute shall:

(1) Carry forward and add to the Matching Fund requirement for the next Project Year the dollar amount equal to the deficiency between the actual amount of Grant Award funds distributed and the actual Matching Funds expended, so long as the deficiency is equal to or less than twenty percent (20%) of the total Matching Funds required for the same period and the Grant Recipient has not previously had a Matching Funds deficiency for the project;

(2) Suspend distributing Grant Award funds for the project to the Grant Recipient if the deficiency between the actual amount of Grant Funds distributed and the Matching Funds expended is greater than twenty percent (20%) but less than fifty percent (50%) of the total Matching Funds required for the period;

(A) The Grant Recipient will have no less than eight months from the anniversary of the Grant Contract's effective date to demonstrate that it has expended Encumbered Funds sufficient to fulfill the Matching Funds deficiency for the project.

(B) If the Grant Recipient fails to fulfill the Matching Funds deficiency within the specified period, then the Grant Contract shall be considered in default and the Institute may proceed with terminating the Grant Award pursuant to the process established in the Grant Contract.

(3) Declare the Grant Contract in default if the deficiency between the actual amount of Grant Award funds distributed and the Matching Funds expended is greater than fifty percent (50%) of the total Matching Funds required for the period. The Institute may proceed with terminating the Grant Award pursuant to the process established in the Grant Contract; or

(4) Take appropriate action, including withholding reimbursement, requiring repayment of the deficiency, or terminating the Grant Contract if a deficiency exists between the actual amount of Grant Award funds distributed and the Matching Funds expended and it is the last year of the Grant Contract.

(i) Nothing herein shall preclude the Institute from taking action other than described in subsection (h) of this section based upon the specific reasons for the deficiency. To the extent that other action not described herein is taken by the Institute, such action shall be documented in writing and included in Grant Contract records. The options described in subsection (h)(1) and (2) of this section may be used by the Grant Recipient only one time for the particular project. A second deficiency of any amount shall be considered an event of default and the Institute may proceed with terminating the Grant Award pursuant to the process established in the Grant Contract.

(j) The Grant Recipient shall maintain adequate documentation supporting the source and use of the Matching Funds reported in the certification required by subsection (a) of this section. The Institute shall conduct an annual review of the documentation supporting the source and use of Matching Funds reported in the required certification for a risk-identified sample of Grant Recipients. Based upon the results of the sample, the Institute may elect to expand the review of supporting documentation to other Grant Recipients. Nothing herein restricts the authority of the Institute to review supporting documentation for one or more Grant Recipients or to conduct a review of Matching Funds documentation more frequently.

(k) 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.

§703.13.Audits and Investigations.

(a) Upon request and with reasonable notice, an entity receiving Grant Award funds directly under the Grant Contract or indirectly through a subcontract under the Grant Contract shall allow, or shall cause the entity that is maintaining such items to allow the Institute, or auditors or investigators working on behalf of the Institute, including the State Auditor and/or the Comptroller of Public Accounts for the State of Texas, to review, inspect, audit, copy or abstract its records pertaining to the specific Grant Contract during the term of the Grant Contract and for the three year period following the date the last disbursement of funds is made by the Institute or all reports required pursuant to the Grant Contract are submitted and approved, whichever date is later.

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

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

(b) Notwithstanding the foregoing, the Grant Recipient shall submit a single audit determination form no later than 60 days following the close of the Grant Recipient's fiscal year. The Grant Recipient shall report whether the Grant Recipient has expended $750,000 or more in state awards during the Grant Recipient's fiscal year. If the Grant Recipient has expended $750,000 or

more in state awards in its fiscal year, the Grant Recipient shall obtain either an annual single independent audit, a program specific independent audit, or an agreed upon procedures engagement as defined by the American Institute of Certified Public Accountants and pursuant to guidance provided in subsection (e) of this section.

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

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

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

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

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

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

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

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

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

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

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

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

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

(A) Processes and controls;

(B) The Grant Contract;

(C) Indirect Costs;

(D) Matching Funds, if appropriate;

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

(F) Equipment;

(G) Revenue Sharing and Program Income;

(H) Reporting; and

(I) Grant Award closeout.

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

(f) 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.

§703.14.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.

(A) The Grant Recipient's first no cost extension that is less than or equal to six months will be approved so long as the Grant Recipient is in good fiscal and programmatic standing

(B) 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.

§703.21.Monitoring Grant Award Performance and Expenditures.

(a) The Institute, under the direction of the Chief Compliance Officer, shall monitor Grant Awards to ensure that Grant Recipients comply with applicable financial, administrative, and programmatic terms and conditions and exercise proper stewardship over Grant Award funds. Such terms and conditions include requirements set forth in statute, administrative rules, and the Grant Contract.

(b) Methods used by the Institute to monitor a Grant Recipient's performance and expenditures may include:

(1) Financial Status Reports Review--The Institute shall review Grant Award expenditures reported by Grant Recipients on the quarterly Financial Status Reports and supporting documents to determine whether expenses charged to the Grant Award are:

(A) Allowable, allocable, reasonable, necessary, and consistently applied regardless of the source of funds; and

(B) Adequately supported with documentation such as cost reports, receipts, third party invoices for expenses, or payroll information.

(2) Timely submission of Grant Award Reports--The Institute shall monitor the submission of all required reports and implement a process to ensure that Grant Award funds are not disbursed to a Grant Recipient with one or more delinquent reports.

(3) Grant Progress Reports--The Institute shall review Grant Progress Reports to determine whether sufficient progress is made consistent with the scope of work and timeline set forth in the Grant Contract.

(A) The Grant Progress Reports shall be submitted at least annually, but may be required more frequently pursuant to Grant Contract terms or upon request and reasonable notice of the Institute.

(B) Unless specifically stated otherwise herein, the annual Grant Progress Report shall be submitted within sixty (60) days after the anniversary of the effective date of the Grant Contract. The annual Grant Progress Report shall include at least the following information:

(i) An affirmative verification by the Grant Recipient of compliance with the terms and conditions of the Grant Contract;

(ii) A description of the Grant Recipient's progress made toward completing the scope of work specified by the Grant Contract, including information, data, and program metrics regarding the achievement of project goals and timelines;

(iii) The number of new jobs created and the number of jobs maintained for the preceding twelve month period as a result of Grant Award funds awarded to the Grant Recipient for the project;

(iv) An inventory of the equipment purchased for the project in the preceding twelve month period using Grant Award funds;

(v) A verification of the Grant Recipient's efforts to purchase from suppliers in this state more than 50 percent goods and services purchased for the project with grant funds;

(vi) A Historically Underutilized Businesses report;

(vii) Scholarly articles, presentations, and educational materials produced for the public addressing the project funded by the Institute;

(viii) The number of patents applied for or issued addressing discoveries resulting from the research project funded by the Institute;

(ix) A statement of the identities of the funding sources, including amounts and dates for all funding sources supporting the project;

(x) A verification of the amounts of Matching Funds dedicated to the research that is the subject of the Grant Award for the period covered by the annual report, which shall be submitted pursuant to the timeline in §703.11 of this title (relating to Requirement to Demonstrate Available Funds for Cancer Research Grants). In order to receive disbursement of grant funds, the most recently due verification of the amount of Matching Funds must be approved by CPRIT;

(xi) All financial information necessary to support the calculation of the Institute's share of revenues, if any, received by the Grant Recipient resulting from the project; and

(xii) A single audit determination form, which shall be submitted pursuant to the timeline in §703.13.

(C) Notwithstanding subparagraph (B) of this paragraph, in the event that the Grant Recipient and Institute execute the Grant Contract after the effective date of the Grant Contract, the Chief Program Officer may approve additional time for the Grant Recipient to prepare and submit the outstanding reports. The approval shall be in writing and maintained in the Institute's electronic Grants Management System. The Chief Program Officer's approval may cover more than one report and more than one fiscal quarter.

(D) In addition to annual Grant Progress Reports, a final Grant Progress Report shall be filed no more than ninety (90) days after the termination date of the Grant Contract. The final Grant Progress Report shall include a comprehensive description of the Grant Recipient's progress made toward completing the scope of work specified by the Grant Contract, as well as other information specified by the Institute.

(E) The Grant Progress Report will be evaluated pursuant to criteria established by the Institute. The evaluation shall be conducted under the direction of the Chief Prevention Officer, the Chief Product Development Officer, or the Chief Scientific Officer, as may be appropriate. Required financial reports associated with the Grant Progress Report will be reviewed by the Institute's financial staff. In order to receive disbursement of grant funds, the final progress report must be approved by CPRIT.

(F) If the Grant Progress Report evaluation indicates that the Grant Recipient has not demonstrated progress in accordance with the Grant Contract, then the Chief Program Officer shall notify the Chief Executive Officer and the General Counsel for further action.

(i) The Chief Program Officer shall submit written recommendations to the Chief Executive Officer and General Counsel for actions to be taken, if any, to address the issue.

(ii) The recommended action may include termination of the Grant Award pursuant to the process described in §703.14 of this chapter (relating to Termination, Extension, and Close Out of Grant Contracts).

(G) If the Grant Recipient fails to submit required financial reports associated with the Grant Progress Report, then the Institute financial staff shall notify the Chief Executive Officer and the General Counsel for further action.

(H) In order to receive disbursement of grant funds, the most recently due progress report must be approved by CPRIT.

(I) If a Grant Recipient fails to submit the Grant Progress Report within 60 days of the anniversary of the effective date of the Grant Contract, then the Institute shall not disburse any Grant Award funds as reimbursement or advancement of Grant Award funds until such time that the delinquent Grant Progress Report is approved.

(J) In addition to annual Grant Progress Reports, Product Development Grant Recipients shall submit a Grant Progress Report at the completion of specific tranches of funding specified in the Award Contract. For the purpose of this subsection, a Grant Progress Report submitted at the completion of a tranche of funding shall be known as "Tranche Grant Progress Report."

(i) The Institute may specify other required reports, if any, that are required to be submitted at the time of the Tranche Grant Progress Report.

(ii) Grant Funds for the next tranche of funding specified in the Grant Contract shall not be disbursed until the Tranche Grant Progress Report has been reviewed and approved pursuant to the process described in this section.

(4) Desk Reviews--The Institute may conduct a desk review for a Grant Award to review and compare individual source documentation and materials to summary data provided during the Financial Status Report review for compliance with financial requirements set forth in the statute, administrative rules, and the Grant Contract.

(5) Site Visits and Inspection Reviews--The Institute may conduct a scheduled site visit to a Grant Recipient's place of business to review Grant Contract compliance and Grant Award performance issues. Such site visits may be comprehensive or limited in scope.

(6) Audit Reports--The Institute shall review audit reports submitted pursuant to §703.13 of this chapter (relating to Audits and Investigations).

(A) If the audit report findings indicate action to be taken related to the Grant Award funds expended by the Grant Recipient or for the Grant Recipient's fiscal processes that may impact Grant Award expenditures, the Institute and the Grant Recipient shall develop a written plan and timeline to address identified deficiencies, including any necessary Grant Contract amendments.

(B) The written plan shall be retained by the Institute as part of the Grant Contract record.

(c) All required Grant Recipient reports and submissions described in this section shall be made via an electronic grant portal designated by the Institute, unless specifically directed to the contrary in writing by the Institute.

(d) The Institute shall document the actions taken to monitor Grant Award performance and expenditures, including the review, approvals, and necessary remedial steps, if any.

(1) To the extent that the methods described in subsection (b) of this section are applied to a sample of the Grant Recipients or Grant Awards, then the Institute shall document the Grant Contracts reviewed and the selection criteria for the sample reviewed.

(2) Records will be maintained in the electronic Grant Management System as described in §703.4 of this chapter (relating to Grants Management System).

(e) The Chief Compliance Officer shall be engaged in the Institute's Grant Award monitoring activities and shall notify the General Counsel and Oversight Committee if a Grant Recipient fails to meaningfully comply with the Grant Contract reporting requirements and deadlines, including Matching Funds requirements.

(f) The Chief Executive Officer shall report to the Oversight Committee at least annually on the progress and continued merit of each Grant Program funded by the Institute. The written report shall also be included in the Annual Public Report. The report should be presented to the Oversight Committee at the first meeting following the publication of the Annual Public Report.

(g) The Institute may rely upon third parties to conduct Grant Award monitoring services independently or in conjunction with Institute staff.

(h) If a deadline set by this rule falls on a Saturday, Sunday, or federal holiday as designated by the U.S. Office of Personnel Management, the required filing may be submitted on the next business day. The Institute will not consider a required filing delinquent if the Grant Recipient complies with this subsection.

§703.24.Financial Status Reports.

(a) Grant Recipients shall report expenditures to be reimbursed with Grant Award funds on the quarterly Financial Status Report form.

(1) Expenditures shall be reported by budget category consistent with the Grant Recipient's Approved Budget.

(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.

(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.

(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.

(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:	**KRISTEN PAULING DOYLE, GENERAL COUNSEL** **CAMERON L. ECKEL, STAFF ATTORNEY**
Subject:	**CHAPTER 703 PROPOSED RULE CHANGES**
Date:	**NOVEMBER 13, 2018**

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 November 1st to discuss the proposed rule changes Chapter 703 with legal staff. The proposed amendments relate to processes, annual training and audit deadlines, and reporting periods for Institute grant recipients.

- The proposed amendment to §703.3(k) provides the process for a product development research grant applicant to receive a refund of the application fee if CPRIT removes the applicant's proposal from the review process prior to an evaluation by peer reviewers. CPRIT charges an application review fee to offset the increased review costs associated with the product development grant review. Occasionally, CPRIT withdraws a product development grant application from consideration before the initiating the peer review process, either at the request of the applicant or because the application is administratively noncompliant. Returning the application fee is equitable when the application does not begin the extensive peer review process. The new provision, §703.3(k)(4), establishes a process for the applicant to request the fee refund.

- The changes to § 703.13(b)(2) and (b)(2)(B) clarify that grantees must submit the required audit no later than nine months following the close of the grantee's fiscal year. Currently, § 703.13(b) sets the deadline at 270 days because CPRIT's grant management system tracks deadlines in terms of days, not months. However, grantees are more familiar with tracking deadlines by month. As a result, a grantee may inadvertently file the audit report one or two days past the 270-day deadline, even though the report is filed within the nine-month period.

- The proposed amendment, § 703.21(b)(3)(k), sets September 1 as the initial reporting period for prevention grants approved for an award during the last quarter of the state fiscal year. CPRIT requires prevention grant recipients to submit quarterly reports. The grant contract effective date for all grants approved for awards during the last quarter of the fiscal year is August 31. Because the contract effective date drives the reporting period, these prevention grants have a one-day reporting period (August 31). Not only is little meaningful information gained from a one-day report, but some grantees inadvertently overlook the one-day report and become noncompliant. Clarifying that these grantees should report on the full quarter beginning September 1 addresses these issues.

- The proposed amendment to § 703.22(c) changes the deadline for grant recipients to complete annual compliance training from November 1 to December 31. The change correlates the annual requirement to the calendar year.

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 on CPRIT's website and announce the opportunity for public comment via the CPRIT electronic list serve. CPRIT legal staff will summarize all public comments for the Oversight Committee's consideration when approving the final rule changes in February.

TITLE 25. HEALTH SERVICES

PART 11. CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CHAPTER 703. Grants for Cancer Prevention and Research

The Cancer Prevention and Research Institute of Texas (CPRIT or the Institute) proposes amendments to 25 Tex. Admin. Code §§703.3, 703.13, 703.21, and 703.22. The proposed amendments clarify the processes, annual training and audit deadlines, and reporting periods for Institute grant recipients.

Background and Justification

The proposed amendment to §703.3 provides the process for a product development research grant applicant to receive a refund of the application fee if the CPRIT or the grant applicant withdraws the proposal from the review process prior to an evaluation by peer reviewers. The changes to § 703.13 clarify the deadline for grantees to submit the required audit report, revising the deadline from 270 days to nine months after the close of the grantee's fiscal year. The proposed amendment to § 703.21 sets the initial reporting period for prevention grants approved for an award during the last quarter of the state fiscal year. The proposed change allows prevention grantees to report on a full initial quarter. The proposed amendment to § 703.22 changes the deadline for grant recipients to complete annual compliance training from November 1 to December 31. The change correlates the annual requirement to the calendar year.

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, deadlines, and reporting periods for grant recipients.

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 sufficient 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 February 4, 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.

<rules>

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. Notice of modifications will be announced and 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 Grants 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;

(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;

(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.

703.13 Audits and Investigations

(a) Upon request and with reasonable notice, an entity receiving Grant Award funds directly under the Grant Contract or indirectly through a subcontract under the Grant Contract shall allow, or shall cause the entity that is maintaining such items to allow the Institute, or auditors or investigators working on behalf of the Institute, including the State Auditor and/or the Comptroller of Public Accounts for the State of Texas, to review, inspect, audit, copy or abstract its records pertaining to the specific Grant Contract during the term of the Grant Contract and for the three year period following the date the last disbursement of funds is made by the Institute or all reports required pursuant to the Grant Contract are submitted and approved, whichever date is later.

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

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

(b) Notwithstanding the foregoing, the Grant Recipient shall submit a single audit determination form no later than 60 days following the close of the Grant Recipient's fiscal year. The Grant Recipient shall report whether the Grant Recipient has expended $750,000 or more in state awards during the Grant Recipient's fiscal year. If the Grant Recipient has expended $750,000 or more in state awards in its fiscal year, the Grant Recipient shall obtain either an annual single independent audit, a program specific independent audit, or an agreed upon procedures engagement as defined by the American Institute of Certified Public Accountants and pursuant to guidance provided in subsection (e).

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

(2) The audit must be submitted to the Institute within 30 days of receipt by the Grant Recipient but no later than nine (9) months [~~270 days~~] following the close of the Grant Recipient's fiscal year and shall include a corrective action plan that addresses any weaknesses, deficiencies, wrongdoings, or other concerns raised by the audit report and a summary of the action taken by the Grant Recipient to address the concerns, if any, raised by the audit report.

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

(B) The Grant Recipient's request for additional time must be submitted on or before the due date of the required audit and corrective action plan. For purposes of this rule, the "due date of the required audit" is no later than nine (9) months [~~the 270th day~~] following the close of the Grant Recipient's fiscal year.

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

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

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

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

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

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

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

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

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

(A) Processes and controls;

(B) The Grant Contract;

(C) Indirect Costs;

(D) Matching Funds, if appropriate;

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

(F) Equipment;

(G) Revenue Sharing and Program Income;

(H) Reporting; and

(I) Grant Award closeout.

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

703.21 Monitoring Grant Award Performance and Expenditures

(a) The Institute, under the direction of the Chief Compliance Officer, shall monitor Grant Awards to ensure that Grant Recipients comply with applicable financial, administrative, and programmatic terms and conditions and exercise proper stewardship over Grant Award funds. Such terms and conditions include requirements set forth in statute, administrative rules, and the Grant Contract.

(b) Methods used by the Institute to monitor a Grant Recipient's performance and expenditures may include:

(1) Financial Status Reports Review - The Institute shall review Grant Award expenditures reported by Grant Recipients on the quarterly Financial Status Reports and supporting documents to determine whether expenses charged to the Grant Award are:

(A) Allowable, allocable, reasonable, necessary, and consistently applied regardless of the source of funds; and

(B) Adequately supported with documentation such as cost reports, receipts, third party invoices for expenses, or payroll information.

(2) Timely submission of Grant Award Reports - The Institute shall monitor the submission of all required reports and implement a process to ensure that Grant Award funds are not disbursed to a Grant Recipient with one or more delinquent reports.

(3) Grant Progress Reports - The Institute shall review Grant Progress Reports to determine whether sufficient progress is made consistent with the scope of work and timeline set forth in the Grant Contract.

(A) The Grant Progress Reports shall be submitted at least annually, but may be required more frequently pursuant to Grant Contract terms or upon request and reasonable notice of the Institute.

(B) Unless specifically stated otherwise herein, the annual Grant Progress Report shall be submitted within sixty (60) days after the anniversary of the effective date of the Grant Contract. The annual Grant Progress Report shall include at least the following information:

(i) An affirmative verification by the Grant Recipient of compliance with the terms and conditions of the Grant Contract;

(ii) A description of the Grant Recipient's progress made toward completing the scope of work specified by the Grant Contract, including information, data, and program metrics regarding the achievement of project goals and timelines;

(iii) The number of new jobs created and the number of jobs maintained for the preceding twelve month period as a result of Grant Award funds awarded to the Grant Recipient for the project;

(iv) An inventory of the equipment purchased for the project in the preceding twelve month period using Grant Award funds;

(v) A verification of the Grant Recipient's efforts to purchase from suppliers in this state more than 50 percent goods and services purchased for the project with grant funds;

(vi) A Historically Underutilized Businesses report;

(vii) Scholarly articles, presentations, and educational materials produced for the public addressing the project funded by the Institute;

(viii) The number of patents applied for or issued addressing discoveries resulting from the research project funded by the Institute;

(ix) A statement of the identities of the funding sources, including amounts and dates for all funding sources supporting the project;

(x) A verification of the amounts of Matching Funds dedicated to the research that is the subject of the Grant Award for the period covered by the annual report, which shall be submitted pursuant to the timeline in §703.11. In order to receive disbursement of grant funds, the most recently due verification of the amount of Matching Funds must be approved by CPRIT;

(xi) All financial information necessary to support the calculation of the Institute's share of revenues, if any, received by the Grant Recipient resulting from the project; and

(xii) A single audit determination form, which shall be submitted pursuant to the timeline in §703.13.

(C) Notwithstanding subparagraph (B) of this paragraph, in the event that the Grant Recipient and Institute execute the Grant Contract after the effective date of the Grant Contract, the Chief Program Officer may approve additional time for the Grant Recipient to prepare and submit the outstanding reports. The approval shall be in writing and maintained in the Institute's electronic Grants Management System. The Chief Program Officer's approval may cover more than one report and more than one fiscal quarter.

(D) In addition to annual Grant Progress Reports, a final Grant Progress Report shall be filed no more than ninety (90) days after the termination date of the Grant Contract. The final Grant Progress Report shall include a comprehensive description of the Grant Recipient's progress made toward completing the scope of work specified by the Grant Contract, as well as other information specified by the Institute.

(E) The Grant Progress Report will be evaluated pursuant to criteria established by the Institute. The evaluation shall be conducted under the direction of the Chief Prevention Officer, the Chief Product Development Officer, or the Chief Scientific Officer, as may be appropriate. Required financial reports associated with the Grant Progress Report will be reviewed by the Institute's financial staff. In order to receive disbursement of grant funds, the final progress report must be approved by CPRIT.

(F) If the Grant Progress Report evaluation indicates that the Grant Recipient has not demonstrated progress in accordance with the Grant Contract, then the Chief Program Officer shall notify the Chief Executive Officer and the General Counsel for further action.

(i) The Chief Program Officer shall submit written recommendations to the Chief Executive Officer and General Counsel for actions to be taken, if any, to address the issue.

(ii) The recommended action may include termination of the Grant Award pursuant to the process described in §703.14 of this chapter (relating to Termination, Extension, and Close Out of Grant Contracts).

(G) If the Grant Recipient fails to submit required financial reports associated with the Grant Progress Report, then the Institute financial staff shall notify the Chief Executive Officer and the General Counsel for further action.

(H) In order to receive disbursement of grant funds, the most recently due progress report must be approved by CPRIT.

(I) If a Grant Recipient fails to submit the Grant Progress Report within 60 days of the anniversary of the effective date of the Grant Contract, then the Institute shall not disburse any Grant Award funds as reimbursement or advancement of Grant Award funds until such time that the delinquent Grant Progress Report is approved.

(J) In addition to annual Grant Progress Reports, Product Development Grant Recipients shall submit a Grant Progress Report at the completion of specific tranches of funding specified in the Award Contract. For the purpose of this subsection, a Grant Progress Report submitted at the completion of a tranche of funding shall be known as "Tranche Grant Progress Report."

(i) The Institute may specify other required reports, if any, that are required to be submitted at the time of the Tranche Grant Progress Report.

(ii) Grant Funds for the next tranche of funding specified in the Grant Contract shall not be disbursed until the Tranche Grant Progress Report has been reviewed and approved pursuant to the process described in this section.

(K) A Grant Award in the prevention program with a Grant Contract effective date within the last quarter of a state fiscal year (June 1-August 31) will have an initial reporting period beginning September 1 of the following state fiscal year.

(4) Desk Reviews - The Institute may conduct a desk review for a Grant Award to review and compare individual source documentation and materials to summary data provided during the Financial Status Report review for compliance with financial requirements set forth in the statute, administrative rules, and the Grant Contract.

(5) Site Visits and Inspection Reviews - The Institute may conduct a scheduled site visit to a Grant Recipient's place of business to review Grant Contract compliance and Grant Award performance issues. Such site visits may be comprehensive or limited in scope.

(6) Audit Reports - The Institute shall review audit reports submitted pursuant to §703.13 of this chapter (relating to Audits and Investigations).

(A) If the audit report findings indicate action to be taken related to the Grant Award funds expended by the Grant Recipient or for the Grant Recipient's fiscal processes that may impact Grant Award expenditures, the Institute and the Grant Recipient shall develop a written plan and timeline to address identified deficiencies, including any necessary Grant Contract amendments.

(B) The written plan shall be retained by the Institute as part of the Grant Contract record.

(c) All required Grant Recipient reports and submissions described in this section shall be made via an electronic grant portal designated by the Institute, unless specifically directed to the contrary in writing by the Institute.

(d) The Institute shall document the actions taken to monitor Grant Award performance and expenditures, including the review, approvals, and necessary remedial steps, if any.

(1) To the extent that the methods described in subsection (b) of this section are applied to a sample of the Grant Recipients or Grant Awards, then the Institute shall document the Grant Contracts reviewed and the selection criteria for the sample reviewed.

(2) Records will be maintained in the electronic Grant Management System as described in §703.4 of this chapter (relating to Grants Management System).

(e) The Chief Compliance Officer shall be engaged in the Institute's Grant Award monitoring activities and shall notify the General Counsel and Oversight Committee if a Grant Recipient fails to meaningfully comply with the Grant Contract reporting requirements and deadlines, including Matching Funds requirements.

(f) The Chief Executive Officer shall report to the Oversight Committee at least annually on the progress and continued merit of each Grant Program funded by the Institute. The written report shall also be included in the Annual Public Report. The report should be presented to the Oversight Committee at the first meeting following the publication of the Annual Public Report.

(g) The Institute may rely upon third parties to conduct Grant Award monitoring services independently or in conjunction with Institute staff

703.22 Required Training for Grant Recipients

(a) The Institute, under the direction of the Chief Compliance Officer, shall create a compliance training program for Grant Recipients addressing applicable financial, administrative, and programmatic requirements related to proper stewardship over Grant Award funds, including grant reporting.

(b) Initial Grant Recipient training program - A Grant Recipient that is approved for a Grant Award for the first time on or after September 1, 2015, shall complete an initial compliance training program. For purposes of this subsection, a Grant Recipient that has received at least one Grant Award prior to September 1, 2015, is not required to complete the initial compliance training program.

(1) The Chief Compliance Officer shall design the initial compliance training program.

(2) The Grant Recipient must complete the initial compliance training program prior to receiving disbursement of Grant Award funds, unless the Chief Compliance Officer finds good cause to disburse grant funds in advance of completing the initial compliance training program.

(3) Nothing herein prohibits the Chief Compliance Officer from requiring a Grant Recipient to complete the initial compliance training program.

(c) Annual Grant Recipient training program - All Grant Recipients shall complete an annual compliance training program by November 1, 2016, and then by December 31 [~~November 1~~] of each year thereafter that the Grant Recipient has at least one active Grant Award.

(1) The Chief Compliance Officer shall design the annual compliance training program.

(2) The Institute shall withhold disbursement of Grant Award funds if the Grant Recipient fails to complete the annual compliance training program by November 1, unless the Chief Compliance Officer finds good cause to disburse grant funds in advance of completing the annual compliance training program.

(d) Grant Recipient personnel required to attend training - The Grant Recipient's Authorized Signing Official and at least one other individual employed by the Grant Recipient must attend the trainings required by this rule.

(1) Upon a finding of good cause, the Chief Compliance Officer may allow the Grant Recipient to substitute another employee to attend a required training in place of the Authorized Signing Official.

(2) In the event that the Authorized Signing Official designated by the Grant Recipient changes on or after November 1, 2016, and the new Authorized Signing Official has not completed the annual compliance training program, the new Authorized Signing Official shall complete the annual compliance training program within 60 days of change. Failure to do so may result in the withholding of Grant Award funds until the training is completed.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	KRISTEN DOYLE, DEPUTY EXECUTIVE OFFICER AND GENERAL COUNSEL
SUBJECT:	PROPOSED AMENDMENT TO OVERSIGHT COMMITTEE BYLAWS
DATE:	NOVEMBER 20, 2018

The Board Governance Subcommittee recommends that the Oversight Committee approve an amendment to Section 3.15 of the Oversight Committee Bylaws. The proposed change revises the requirement regarding Oversight Committee compliance training to occur periodically, rather than "not less than once a year." Adopting the changing will make the Bylaws consistent with CPRIT's administrative rule 701.7(d), which directs that "Oversight Committee Members and Institute Employees shall participate in periodic Compliance Program training."

THE CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

OVERSIGHT COMMITTEE BYLAWS

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
OVERSIGHT COMMITTEE BYLAWS

ARTICLE 1
ESTABLISHMENT AND PURPOSES

Section 1.1 Establishment. The Cancer Prevention and Research Institute of Texas (the "Institute") was established by the Texas Legislature in 2007, as authorized by Article 3, Section 67 of the Constitution of the State of Texas. The statutory provisions establishing the Institute are set forth in Chapter 102 of the Health and Safety Code of the State of Texas (the "Health and Safety Code"). Administrative rules governing the Institute are set forth in Title 25, Chapters 701–704, of the Texas Administrative Code.

Section 1.2 Purposes. The Institute is established to:

(a) create and expedite innovation in the area of cancer research and in enhancing the potential for a medical or scientific breakthrough in the prevention of cancer and cures for cancer;

(b) attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in this state; and

(c) develop and implement the Texas Cancer Plan.

ARTICLE 2
AUTHORITY, AMENDMENT, AND INTERPRETATION

Section 2.1 Rulemaking Authority. These Bylaws ("Bylaws") have been adopted by the Oversight Committee (as defined herein) pursuant to the authority granted to the Oversight Committee in Section 102.108 of the Health and Safety Code.

Section 2.2 Amendment. These Bylaws may be amended or modified only with the approval of a simple majority of the members of the Oversight Committee as set forth in Section 3.13; provided, that no amendment or modification to these Bylaws may be made if such amendment or modification would cause these Bylaws to conflict with applicable law. All approved amendments or modifications shall be noted in a "Statement of Revisions" at the end of these Bylaws.

Section 2.3 Interpretation. These Bylaws are adopted subject to any applicable law, including, but not limited to, Chapter 102 of the Health and Safety Code and Title 25, Chapters 701–704, of the Texas Administrative Code. Whenever these Bylaws may conflict with applicable law, the conflict will be resolved in favor of the applicable law. If at any time the Oversight Committee determines that these Bylaws conflict with applicable law, then the Oversight Committee shall promptly act to amend these Bylaws to cause them to conform to applicable law.

ARTICLE 3
THE OVERSIGHT COMMITTEE

Section 3.1 General Powers. The Oversight Committee of the Institute (the "Oversight Committee") is the governing body of the Institute. The Oversight Committee may adopt such policies and practices, consistent with applicable law, as it may deem proper for the conduct of its meetings and the management of the Institute.

Section 3.2 Number. The Oversight Committee is composed of the following nine (9) members:

(a) three members appointed by the Governor of the State of Texas;

(b) three members appointed by the Lieutenant Governor of the State of Texas; and

(c) three members appointed by the Speaker of the House of Representatives of the State of Texas

Section 3.3 Composition; Disqualification.

(a) The members of the Oversight Committee must represent the geographic and cultural diversity of the State of Texas. In making appointments to the Oversight Committee, the Governor, Lieutenant Governor, and Speaker of the House of Representatives of the State of Texas shall each appoint at least one person who is a physician or a scientist with extensive experience in the field of oncology or public health and should attempt to include cancer survivors and family members of cancer patients if possible.

(b) A person may not be a member of the Oversight Committee if the person or the person's spouse: (i) is employed by or participates in the management of a business entity or other organization receiving money from the Institute; (ii) owns or controls, directly or indirectly, an interest in a business entity or other organization receiving money from the Institute; or (iii) uses or receives a substantial amount of tangible goods, services, or money from the Institute, other than reimbursement authorized by law for Oversight Committee membership, attendance, or expenses.

Section 3.4 Term. Each member of the Oversight Committee will hold office for such member's term or until such member's earlier death, resignation, disqualification, or removal. Members of the Oversight Committee appointed by the Governor, Lieutenant Governor, and Speaker of the House of Representatives of the State of Texas serve at the pleasure of the appointing office for staggered six-year terms, with the terms of three members expiring on January 31 of each odd-numbered year. Not later than the 30th day after the date an Oversight Committee member's term expires, the appropriate appointing authority shall appoint a replacement.

Section 3.5 Vacancy. If a vacancy occurs on the Oversight Committee, then the appropriate appointing authority shall appoint a successor, in the same manner as the original appointment, to serve for the remainder of the unexpired term. The appropriate appointing authority shall appoint the successor not later than the 30th day after the date the vacancy occurs.

Section 3.6 Resignation. Any appointed or designated member of the Oversight Committee may resign at any time by notice given in writing to the appropriate appointing authority and to the Chair of the Oversight Committee or to the Vice Chair if the Chairman is resigning. The resigning member will continue to serve until such time that the appropriate appointing authority appoints a successor.

Section 3.7 Removal. It is a ground for removal from the Oversight Committee that a member: (a) is ineligible for membership of the Oversight Committee under Section 3.3(b) of these Bylaws; (b) cannot, because of illness or disability, discharge the member's duties for a substantial part of the member's term; or (c) is absent from more than half of the regularly scheduled Oversight Committee meetings that the member is eligible to attend during a calendar year without an excuse approved by a majority vote of the Oversight Committee. If the Chief Executive Officer has knowledge that a potential ground for removal exists, then the Chief Executive Officer shall notify the Chairperson of the potential ground. The Chairperson shall then notify the appointing authority and the Attorney General of the State of Texas that a potential ground for removal exists. If the potential ground for removal involves the Chairperson, then the Chief Executive Officer shall notify the next highest ranking officer of the Oversight Committee, who shall then notify the appointing authority and the Attorney General of the State of Texas that a potential ground for removal exists. Notwithstanding, the foregoing, the validity of an action of the Oversight Committee is not affected by the fact that it is taken when a ground for removal of a committee member exists.

Section 3.8 Strategic Partnerships. To the fullest extent permitted by applicable law, the Oversight Committee retains the authority and power to approve strategic partnerships, alliances, and coalitions of the Institute subject to vote of the simple majority of the members of the Oversight Committee as set forth in Section 3.13.

Section 3.9 Regular Meetings. The Oversight Committee shall hold a public meeting at least once in each quarter of the calendar year, with appropriate notice and with a formal public comment period.

Section 3.10 Special Meetings. Special meetings of the Oversight Committee may be held upon the call of the Chairperson of the Oversight Committee, or the Vice Chairperson of the Oversight Committee when performing the duties of the Chairperson, as he or she may deem necessary, with appropriate notice and with a formal public comment period. Emergency meetings and telephonic meetings may be held only as provided under applicable law.

Section 3.11 Notice of Open Meetings. All meetings of the Oversight Committee are subject to the terms of the Open Meetings Act, Chapter 551 of the Texas Government Code (the "Open Meetings Act"). The Open Meetings Act provides that the public must be given notice of the time, place, and subject matter of meetings of governmental bodies. In absence of an emergency, notice of a meeting must be posted at a place that is readily accessible to the public at all times at least seven (7) days preceding the scheduled time of the meeting. In case of an emergency of urgent public necessity, which shall be clearly identified in the notice, it shall be sufficient if the notice is posted two hours before the meeting is convened.

Section 3.12 Quorum. The presence of a simple majority of the members of the Oversight Committee present is necessary and sufficient to constitute a quorum for the transaction of business at any meeting of the Oversight Committee.

Section 3.13 Action By Simple Majority Vote. Except as otherwise provided by these Bylaws or applicable law, the vote of a simple majority of the members of the Oversight Committee present at a meeting at which a quorum is present will be the prevailing action of the Oversight Committee.

Section 3.14 Expenses. A member of the Oversight Committee is not entitled to compensation, but is entitled to reimbursement for actual and necessary expenses incurred in attending meetings of the Oversight Committee or performing other official duties authorized by the Chairperson.

Section 3.15 Training. The Institute's General Counsel and Chief Compliance Officer shall provide training to all new members of the Oversight Committee. In addition, ~~and shall provide ongoing or continuing training to~~ all members of the Oversight Committee ~~not less than once a year~~ shall participate in periodic training.

(a) The form and substance of such training will be in the discretion of the Institute's General Counsel and Chief Compliance Officer.

(b) A new member shall also complete a course of training regarding the function and operation of the Institute, including his or her responsibilities pursuant to CPRIT's Conflict of Interest, Non-Disclosure, and Ethics Compliance policies. The new member shall complete the CPRIT training component within 30 business days of the new member's appointment.

(c) A new member shall also complete a course of training regarding his or her responsibilities under the Open Meetings Act, the Open Records Act, and Government Contracting within 90 days of becoming a member of the Oversight Committee.

(d) A new member that has not completed the required training may participate in any meeting of the Oversight Committee or its subcommittees, subject to the following restrictions: (1) the new member shall not participate in the discussion or vote on any award recommendation until the new member has completed the CPRIT training component; and (2) the new member shall not participate in the discussion or vote to approve a contract until the new member has completed the Government Contract training.

ARTICLE 4
SUBCOMMITTEES OF THE OVERSIGHT COMMITTEE

Section 4.1 Generally. The Oversight Committee may designate one or more subcommittees of the Oversight Committee, each subcommittee to consist of three or more of the members of the Oversight Committee. The Oversight Committee shall appoint and approve members of the subcommittees specifically listed in Section 4.2, except for the members of the Executive Committee, which shall be comprised of the designated members as set forth below in Section 4.3. The Oversight Committee may designate one or more members of the Oversight Committee as alternate members of any subcommittee, who may replace any absent or disqualified

member at any meeting of the subcommittee. If a member of a subcommittee is absent from any meeting, or disqualified from voting thereat, then the remaining member or members present at the meeting and not disqualified from voting, whether or not such member or members constitute a quorum, may, by a unanimous vote, appoint another member of the Oversight Committee to act at the meeting in the place of any such absent or disqualified member. Unless the Oversight Committee provides otherwise, at all meetings of a subcommittee, a majority of the then authorized members of the subcommittee will constitute a quorum, and the vote of a majority of the members of the subcommittee present at any meeting at which there is a quorum will be the act of the subcommittee. Unless the Oversight Committee provides otherwise, each subcommittee designated by the Oversight Committee shall adopt a subcommittee charter and may make, alter, and repeal rules and procedures for the conduct of its business. The Subcommittee charter shall be approved by a vote of a simple majority as set forth in Section 3.13. In the absence of a subcommittee charter, each subcommittee shall conduct its business in the same manner as the Oversight Committee conducts its business. Each subcommittee will have a chairperson, who will be selected by the Oversight Committee at large.

Section 4.2 Certain Subcommittees. Without limiting in any way the previous Section, the following are subcommittees of the Oversight Committee (each of which has the powers and authority set forth in this Article in addition to any other powers and authority as may be delegated to it by the Oversight Committee):

(a) Executive Subcommittee;

(b) Audit Subcommittee;

(c) Board Governance and Ethics Subcommittee;

(d) Nominations Subcommittee;

(e) Product Development Subcommittee;

(f) Scientific Research Subcommittee;

(g) Prevention Subcommittee; and

(h) Diversity Subcommittee.

Section 4.3 Executive Subcommittee. There is a subcommittee of the Oversight Committee to be known as the Executive Subcommittee (the "Executive Subcommittee").

(a) The purpose of the Executive Subcommittee is to transact all normal business referred to it by the Oversight Committee and to conduct the Chief Executive Officer's annual performance review.

(b) The Executive Subcommittee will be composed of no more than four (4) members of the Oversight Committee. Members of the Executive Subcommittee will serve until their successors are duly appointed and qualified or their earlier resignation or removal from their positions by action of the Oversight Committee.

(c) The Executive Subcommittee shall meet as often as the Chair deems appropriate, but at least quarterly, to perform its duties and responsibilities under these Bylaws.

(d) Meetings of the Executive Subcommittee shall be conducted in accordance with the Texas Open Meetings Act.

Section 4.4 Audit Subcommittee. There is a subcommittee of the Oversight Committee to be known as the Audit Subcommittee (the "Audit Subcommittee").

(a) The purpose of the Audit Subcommittee is to review and make recommendations to the Oversight Committee with respect to the following:

(i) The annual operating budget and strategic plan;

(ii) Policies for monitoring grant performance;

(iii) Variances in the operating budget of the Institute of more than 5% or $25,000;

(iv) Non-grant contracts exceeding $100,000; and

(v) Any variance of more than 10% in any announced grant award.

(b) The members of the Audit Subcommittee will be appointed by the Oversight Committee. The Audit Subcommittee will be composed of not less than three members of the Oversight Committee. Members of the Audit Subcommittee will serve until their successors are duly appointed and qualified or their earlier resignation or removal. The Oversight Committee may replace any member of the Audit Subcommittee.

(c) The Audit Subcommittee shall meet as often as the Chairperson of the Audit Subcommittee deems appropriate, but at least quarterly, to perform its duties and responsibilities under these Bylaws.

Section 4.5 Board Governance and Ethics Subcommittee. There is a subcommittee of the Oversight Committee to be known as the Board Governance and Ethics Subcommittee (the "Board Governance and Ethics Subcommittee").

(a) The purpose of the Board Governance and Ethics Subcommittee is to review and recommend proposed changes for approval to the Oversight Committee with respect to the following:

(i) These Bylaws;

(ii) Any policies or administrative rules of the Institute;

(iii) Legislation regarding or affecting the Institute;

(iv) The delegation of authority to the Chief Executive Officer;

(v) The ethics policies of the Institute and their administration; and

(vi) An annual review of the internal policies and processes of the Oversight Committee.

(b) The members of the Board Governance and Ethics Subcommittee will be appointed by the Oversight Committee. The Board Governance and Ethics Subcommittee will be composed of not less than three members of the Oversight Committee. Members of the Board Governance and Ethics Subcommittee will serve until their successors are duly appointed and qualified or their earlier resignation or removal. The Oversight Committee may replace any member of the Board Governance and Ethics Subcommittee.

(c) The Board Governance and Ethics Subcommittee shall meet as often as the Chairperson of the Board Governance and Ethics Subcommittee deems appropriate, but at least quarterly, to perform its duties and responsibilities under these Bylaws.

Section 4.6 Nominations Subcommittee. There is a subcommittee of the Oversight Committee to be known as the Nominations Subcommittee (the "Nominations Subcommittee").

(a) The purpose of the Nominations Subcommittee is to identify members for the Institute's advisory committees and to accept nominations for and recommend candidates to serve as Oversight Committee officers.

(b) The members of the Nominations Subcommittee will be appointed by the Oversight Committee. The Nominations Subcommittee will be composed of not less than three members of the Oversight Committee. Members of the Nominations Subcommittee will serve until their successors are duly appointed and qualified or their earlier resignation or removal. The Oversight Committee may replace any member of the Nominations Subcommittee.

(c) The Nominations Subcommittee shall meet as often as the Chairperson of the Nominations Subcommittee deems appropriate, but at least quarterly, to perform its duties and responsibilities under these Bylaws.

Section 4.7 Product Development Subcommittee. There is a subcommittee of the Oversight Committee to be known as the Product Development Subcommittee (the "Product Development Subcommittee").

(a) The purpose of the Product Development Subcommittee is to develop policies for the Oversight Committee's adoption that will ensure that the Institute properly exercises its duty to award grants for research, including translational research, to develop therapies, protocols, medical pharmaceuticals, or procedures for the cure or substantial mitigation of all types of cancer. In addition, the Product Development Subcommittee will work with CPRIT staff to oversee the design and improvement of processes for the solicitation, review, award and performance monitoring of CPRIT product development research grants.

(b) The members of the Product Development Subcommittee will be appointed by the Oversight Committee. The Product Development Subcommittee will be composed of not less than three members of the Oversight Committee. Members of the Product Development Subcommittee will serve until their successors are duly appointed and qualified or their earlier resignation or removal. The Oversight Committee may replace any member of the Product Development Subcommittee.

(c) The Product Development Subcommittee shall meet as often as the Chairperson of the Product Development Subcommittee deems appropriate, but at least quarterly, to perform its duties and responsibilities under these Bylaws.

Section 4.8 Scientific Research Subcommittee. There is a subcommittee of the Oversight Committee to be known as the Scientific Research Subcommittee (the "Scientific Research Subcommittee").

(a) The purpose of the Scientific Research Subcommittee is to provide appropriate program oversight and feedback to the Oversight Committee related to program policies, including, but not limited to, policies for implementing, monitoring, and revising the Texas Cancer Plan. In addition, the Scientific Research Subcommittee will work with CPRIT staff to oversee the design and improvement of processes for the solicitation, review, award and performance monitoring of CPRIT scientific research grants. The purpose of the Scientific Research Subcommittee is to develop policies for the Oversight Committee's adoption that will ensure that the Institute properly exercises its duty to award grants for research into the causes of and cures for all types of cancer in humans and to create and expedite innovation in the area of cancer research and in enhancing the potential for a medical or scientific breakthrough in the prevention of cancer and cures for cancer. In addition, the Scientific Research Subcommittee will work with CPRIT staff to oversee the design and improvement of processes for the solicitation, review, award and performance monitoring of CPRIT research grants.

(b) The members of the Scientific Research Subcommittee will be appointed by the Oversight Committee. The Scientific Research Subcommittee will be composed of not less than three members of the Oversight Committee. Members of the Scientific Research Subcommittee will serve until their successors are duly appointed and qualified or their earlier resignation or removal. The Oversight Committee may replace any member of the Scientific Research Subcommittee.

(c) The Scientific Research Subcommittee shall meet as often as the Chairperson of the Scientific Research Subcommittee deems appropriate, but at least quarterly, to perform its duties and responsibilities under these Bylaws.

Section 4.9 Prevention Subcommittee. There is a subcommittee of the Oversight Committee to be known as the Prevention Subcommittee (the "Prevention Subcommittee").

(a) The purpose of the Prevention Subcommittee is to provide appropriate program oversight and feedback to the Oversight Committee related to program policies, including, but not limited to, policies for implementing, monitoring, and revising the Texas Cancer Plan. In addition, the Prevention Subcommittee will work with CPRIT staff to oversee the design and improvement of processes for the solicitation, review, award and performance monitoring of CPRIT prevention grants. The purpose of the Prevention Subcommittee is to develop policies for the Oversight Committee's adoption that will ensure that the Institute properly exercises its duty to award grants for cancer prevention and control programs to mitigate the incidence of all types of cancers in humans and to implement the Texas Cancer Plan. In addition, the Prevention Subcommittee will work with CPRIT staff to oversee the design and improvement of processes for the solicitation, review, award and performance monitoring of CPRIT prevention grants.

(b) The members of the Prevention Subcommittee will be appointed by the Oversight Committee. The Prevention Subcommittee will be composed of not less than three members of the Oversight Committee. Members of the Prevention Subcommittee will serve until their successors are duly appointed and qualified or their earlier resignation or removal. The Oversight Committee may replace any member of the Prevention Subcommittee.

(c) The Prevention Subcommittee shall meet as often as the Chairperson of the Prevention Subcommittee deems appropriate, but at least quarterly, to perform its duties and responsibilities under these Bylaws.

Section 4.10 Diversity Subcommittee. There is a subcommittee of the Oversight Committee to be known as the Diversity Subcommittee (the "Diversity Subcommittee").

(a) The purpose of the Diversity Subcommittee is to ensure that the Institute makes every effort to outreach to all communities about the cancer research and prevention funding opportunities in the State of Texas.

(b) The members of the Diversity Subcommittee will be appointed by the Oversight Committee. The Diversity Subcommittee will be composed of not less than three members of the Oversight Committee. Members of the Diversity Subcommittee will serve until their successors are duly appointed and qualified or their earlier resignation or removal. The Oversight Committee may replace any member of the Diversity Subcommittee.

(c) The Diversity Subcommittee shall meet as often as the Chairperson of the Diversity Subcommittee deems appropriate, but at least quarterly, to perform its duties and responsibilities under these Bylaws.

ARTICLE 5
CHAIRPERSON AND VICE CHAIRPERSON

Section 5.1 Election. The Oversight Committee shall elect from among its members a Chairperson and a Vice Chairperson in accordance with the selection provisions of these Bylaws. Nothing herein restricts the ability of the Oversight Committee to elect additional officers from among its members by a vote of a simple majority of the members of the Oversight Committee.

Section 5.2 Election, Term of Office and Removal. At the first regular Oversight Committee meeting following the adoption of these bylaws, the members of the Oversight Committee shall elect the Chairperson and Vice Chairperson by a vote of a simple majority as set forth in Section 3.13. Thereafter, the members of the Oversight Committee shall elect the Chairperson and Vice Chairperson by a vote of a simple majority of as set forth in Section 3.13 at the last regular Oversight Committee meeting of the state fiscal year in each odd-numbered year. The Nominations Subcommittee may recommend candidates for the Oversight Committee's consideration prior to the vote by the Oversight Committee. The Chairperson and the Vice Chairperson will hold office until death, resignation, or removal from office, or the election and qualification of a successor, whichever occurs first; provided, however, that neither the Chairperson nor the Vice Chairperson may hold office for two consecutive terms. If the person holding the office or Chairperson or Vice Chairperson holds office for one term, and a successor has not been elected by the Oversight Committee to take office at the expiration of the term, then the person holding the office of Chairperson or Vice Chairperson, as applicable, shall continue to

hold the office until such time that a quorum of the Oversight Committee can meet and elect a successor. The Chairperson or the Vice Chairperson may be removed at any time, with or without cause, by the vote of a simple majority of the members of the Oversight Committee as set forth in Section 3.13. If the office of the Chairperson or the Vice Chairperson becomes vacant for any reason, including by the expiration of the term, then the vacancy must be filled by the vote of a simple majority of the members of the Oversight Committee as set forth in Section 3.13.

Section 5.3 Chairperson. The Chairperson is the presiding officer of the Oversight Committee. The Chairperson shall preside at each meeting of the Oversight Committee. The Chairperson will also have such authority, duties, roles, and responsibilities as may be assigned by applicable law or recommended by the Board Governance and Ethics Subcommittee and approved by the Oversight Committee. The Chairperson may authorize official duties of members of the Oversight Committee, the University Advisory Committee, or any Ad Hoc Advisory Committee in accordance with applicable law. The Chairperson may not serve as the presiding officer for any other foundation or organization created to specifically benefit the Institute.

Section 5.4 Vice Chairperson. The Vice Chairperson shall, in the absence of the Chairperson, preside at each meeting of the Oversight Committee. The Vice Chairperson will also have such authority, duties, roles, and responsibilities as may be assigned by the Board Governance and Ethics Subcommittee or applicable law and approved by the Oversight Committee.

Section 5.5 Presiding Officers in the Absence of the Chairperson and Vice Chairperson. In the absence of the Chairperson and Vice Chairperson, the Chairperson of the Scientific Research Subcommittee shall preside at each meeting of the Oversight Committee. In the absence of Scientific Research Subcommittee Chairperson, then the Chairperson of the Product Development Subcommittee shall preside. In the absence of the Chairpersons of the Scientific Research and Product Development Subcommittees, then the Chairperson of the Prevention Subcommittee shall preside.

ARTICLE 6
THE CHIEF EXECUTIVE OFFICER

Section 6.1 General Powers. There will be one Chief Executive Officer of the Institute (the "Chief Executive Officer"). The Chief Executive Officer has such powers as are delegated to the Chief Executive Officer by the Oversight Committee and such powers as are vested in the Chief Executive Officer pursuant to applicable law.

Section 6.2 Selection by the Oversight Committee. The Oversight Committee shall hire the Chief Executive Officer.

Section 6.3 Performance of Duties. The Chief Executive Officer shall perform the duties of the Chief Executive Officer as provided by these Bylaws, applicable law, or the Oversight Committee. In performance of such duties, the Chief Executive Officer is authorized to execute contracts on behalf of CPRIT. Such authority is limited when CPRIT's enabling statute specifically authorizes the Oversight Committee to enter into a written contract. In that event, the Chief Executive Officer may execute contract(s) pursuant to a specific delegation by the Oversight Committee. Subject to prior authorization by the Chief Executive Officer, CPRIT's Chief Operating Officer may execute contracts on behalf of CPRIT. The Chief Executive Officer must

notify the Oversight Committee in writing prior to authorizing the Chief Operating Officer to execute contracts on behalf of CPRIT; such notification shall specify the time period the Chief Operating Officer is authorized to do so. The Oversight Committee Chairperson and Vice Chairperson may authorize the Chief Operating Officer to execute contracts on behalf of CPRIT and waive prior notification by the Chief Executive Officer upon a finding that an emergency exists preventing such prior notification. The emergency authorization shall be in writing.

Section 6.4 Grant Review. The Chief Executive Officer shall oversee the grant review process and may terminate grants that do not meet contractual obligations.

Section 6.5 Quarterly Report. Each quarter, the Chief Executive Officer shall report to the Oversight Committee on any new grant awards and the progress and continued merit of scientific research and prevention programs previously awarded funding. The report must include a summary of the allocation of funding among scientific research and prevention programs and details regarding the final results of completed projects under these programs.

Section 6.6 Duties Regarding Foundations or Organizations Created to Specifically Benefit CPRIT. The Chief Executive Officer shall annually report to the Oversight Committee on guidelines for the governance of any foundation or organization created specifically to benefit CPRIT and the relationship between the Institute and the foundation or organization. The Chief Executive Officer shall also annually solicit a report from the foundation or organization created specifically to benefit the Institute regarding the funds the foundation or organization holds, the pledges it has received, and the identities of contributors.

ARTICLE 7
OTHER OFFICERS OF THE INSTITUTE

Section 7.1 Creation and Selection of Other Officers of the Institute. The Oversight Committee may direct the Chief Executive Officer to create other officer positions of the Institute and to hire individuals to fill such positions.

Section 7.2 Certain Officers. Without limiting in any way the previous Section, the following officer positions of the Institute have been created (each of which has the duties and authority set forth in this Article in addition to any other duties and authority as may be delegated to such officer by the Oversight Committee):

(a) Chief Operating Officer, whose duties include oversight of the Institute's daily operations, including financial administration, grants management administration, communications, governmental relations, and information technology services;

(b) Chief Compliance Officer, whose duties include reporting to the Oversight Committee on the agency's compliance with applicable law, administrative rules, and policies, and building, developing, and maintaining a compliance program that fosters ethical business behavior and includes requirements for risk assessments, program governance, metrics, and reporting;

(c) Chief Scientific Officer, whose duties include oversight of the scientific research application submission process, coordinating the review of research proposals,

monitoring grant progress, and fostering collaboration among the cancer and disease scientific research community to maximize the Institute's impact

(d) Chief Product Development Officer, whose duties include oversight of the cancer research development application submission process, coordinating review of the cancer research product development proposals, monitoring grant progress and fostering collaboration among the bioscience community to maximize the Institute's impact;

(e) Chief Prevention Officer, whose duties include oversight of the prevention application submission process, coordinating the review of prevention proposals, monitoring grant progress, and fostering collaboration among the cancer and disease prevention community to maximize the Institute's impact; and

(f) General Counsel, whose duties include oversight of the legal issues that arise as part of the Institute's operations.

ARTICLE 8
COMMITTEES OF THE INSTITUTE

Section 8.1 Creation of Committees of the Institute. Pursuant to applicable law and in accordance with this Article, the Oversight Committee may create Committees of the Institute and appoint and approve members of such committees.

Section 8.2 Scientific Research and Prevention Program Committee. There will be one or more scientific research and prevention programs committees of the Institute (each, a "Scientific Research and Prevention Programs Committee"). Each Scientific Research and Prevention Programs Committee has such powers as are vested in it pursuant to applicable law. The Chief Executive Officer, with approval by simple majority of the members of the Oversight Committee as set forth in Section 3.13, shall appoint as members of one or more Scientific Research and Prevention Programs Committees experts in the field of cancer research, prevention, and patient advocacy to serve for terms as determined by the Chief Executive Officer. Individuals appointed to a Scientific Research and Prevention Programs Committee may be residents of another state. A member of a Scientific Research and Prevention Programs Committee may receive an honorarium according to a policy developed by the Chief Executive Officer in consultation with the Oversight Committee.

Section 8.3 University Advisory Committee. There will be one university advisory committee of the Institute (the "University Advisory Committee"). The University Advisory Committee has such powers as are vested in it pursuant to applicable law. The University Advisory Committee shall advise the Oversight Committee and each Scientific Research and Prevention Programs Committee regarding the role of institutions of higher education in cancer research. The University Advisory Committee is composed of the following members to serve for the term as determined by the appropriate appointing authority appointing such member:

(a) two members appointed by the chancellor of The University of Texas System to represent:

(i) The University of Texas Southwestern Medical Center at Dallas;

(ii) The University of Texas Medical Branch at Galveston;

(iii) The University of Texas Health Science Center at Houston;

(iv) The University of Texas Health Science Center at San Antonio;

(v) The University of Texas Health Center at Tyler; or

(vi) The University of Texas M. D. Anderson Cancer Center;

(b) one member appointed by the chancellor of The Texas A&M University System to represent:

(i) The Texas A&M University System Health Science Center; or

(ii) the teaching hospital for The Texas A&M Health Science Center College of Medicine;

(c) one member appointed by the chancellor of the Texas Tech University System to represent the Texas Tech University Health Sciences Center;

(d) one member appointed by the chancellor of the University of Houston System to represent the system;

(e) one member appointed by the chancellor of the Texas State University System to represent the system;

(f) one member appointed by the chancellor of the University of North Texas System to represent the system;

(g) one member appointed by the president of Baylor College of Medicine;

(h) one member appointed by the president of Rice University; and

(i) members appointed at the Chief Executive Officer's discretion by the chancellors of other institutions.

Section 8.4 Ad Hoc Advisory Committee on Childhood Cancers. The Oversight Committee shall create an ad hoc committee of experts to address childhood cancers. Members of the Ad Hoc Advisory Committee on Childhood Cancers shall be appointed by the Oversight Committee and serve for terms determined by the Oversight Committee. The Ad Hoc Advisory Committee on Childhood Cancers has the duties and authority set forth in the advisory committee's charter in addition to any other duties and authority as may be delegated by the Oversight Committee.

Section 8.5 Other Ad Hoc Advisory Committees of the Institute. The Oversight Committee, as necessary, may create additional ad hoc committees of experts to advise the Oversight Committee on issues relating to cancer. The number of members of each Ad Hoc Committee will be determined by the Oversight Committee. Ad Hoc Advisory Committee members are appointed by the Oversight Committee and serve for terms determined by the Oversight Committee.

Section 8.6 Certain Ad Hoc Advisory Committees of the Institute. Without limiting in any way the previous Section, the following are the Ad Hoc Advisory Committees of the Institute (each of which has the powers and authority set forth in this Article in addition to any other powers and authority as may be delegated to it by the Oversight Committee):

(a) Scientific and Prevention Advisory Council; and

(b) Product Development Advisory Committee;

Section 8.7 Annual Report to the Oversight Committee. Each Committee of the Institute shall report to the Oversight Committee at least annually regarding the work undertaken by such committee pursuant to a schedule and format dictated by the Oversight Committee.

ARTICLE 9
CODE OF CONDUCT AND ETHICS POLICY

Section 9.1 Adopted by Reference. The Oversight Committee herein by reference incorporates the *Code of Conduct and Ethics Policy* as approved by the Oversight Committee on February 25, 2013 and all approved amendments.

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STATEMENT OF REVISIONS

Approved November 1, 2013

Changes made to Sections 2.2, 3.2, 3.3(a) and (b), 3.4, 3.7, 3.15, 4.1, 4.2, 4.3(a) and(b), 4.4(a)(iii), 4.5(a)(iv), 4.6, 4.7, 4.8(a) and(b), 4.9(a) and(b), 5.1, 5.2, 5.3, 5.4, 5.5, 6.1, 6.2, 6.3, 6.4, 6.5, 6.6, 7.1, 7.2(b) and (d), 8.2, 8.3(i), 8.4, 9.1, Article 6 (title), and Article 9 (title) and text.

Reason for change(s): Revisions made to reflect statutory changes adopted in 2013 legislative session.

Approved May 21, 2014

Changes made to Sections 4.4(a)(ii), 8.6(b)

Reason for change(s): Revision made to reflect statutory changes adopted in 2013 legislative session and to change name of certain ad hoc advisory committees.

Approved May 20, 2015

Changes made to Section 4.6(a) and Section 5.2

Reason for change(s): Revision made to assign Nominations Subcommittee the responsibilities associated with officer elections.

Approved September 10, 2015

Nonsubstantive changes made to Article 9 to correct typographical errors.

Approved November 19, 2015

Change made to Section 6.3.

Reason for change: Clarifies the Chief Executive Officer's contract execution authority and process for delegating such authority to the Chief Operating Officer.

Approved August 16, 2017

Change made to Section 3.15 and Article 9, Section V.

Reason for change: Specifies new member training requirements, including deadlines for training and required forms, and clarifies participation in Oversight Committee meetings prior to completing required training.

Approved August 25, 2018

Change made to Article 9, Section V to delete (G).

Reason for change: Deleting the political contributions posting requirement makes the Code of Conduct consistent with the legislative change made to CPRIT statute in 2017.

Approved November 28, 2018

Change made to Section 3.15.

Reason for change: Aligns the timing of ongoing Oversight Committee training with CPRIT's administrative rule § 701.7, which requires periodic training.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

To:	**OVERSIGHT COMMITTEE MEMBERS**
From:	**HEIDI MCCONNELL, CHIEF OPERATING OFFICER**
Subject:	**CHIEF OPERATING OFFICER REPORT**
Date:	**NOVEMBER 8, 2018**

CPRIT Financial Overview for FY 2018, Quarter 4

FY 2018, Quarter 4 Operating Budget

CPRIT expended or obligated approximately $2.9 million in Indirect Administration during the year and approximately $14.5 million in Grant Review and Award Operations, or approximately 98% of the overall administrative budget for the fiscal year. In September, we notified the Legislative Budget Board and the Governor's Office that the agency is carrying forward $275,000 in unexpended balances into FY 2019 related to the GDIT contract with unfinished grants management system enhancement work continuing into the new fiscal year for completion.

During the fourth quarter, the agency received $95,708 in revenue sharing payments. Total revenue sharing payments received in FY 2018 were $186,337 deposited into the Cancer Prevention and Research Interest and Sinking Fund 5168.

FY 2018, Quarter 4 Performance Measure Report

CPRIT reported on its five key performance measures—two quarterly and three annual—to the Legislative Budget Board. CPRIT met or exceeded performance on four out of five measures. Performance was not met on the company relocations to Texas measure because no company grant recipients relocated to Texas during 2018.

Debt Issuance History

CPRIT had a final debt issuance of $55 million in July 2018, bring the total commercial paper notes issued in FY 2018 to $222.2 million.

Cancer Prevention and Research Institute of Texas
Quarterly Financial Report
As of August 31, 2018

Indirect Administration (B.1.1.)

		2018 Appropriated	2018 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	$ 1,254,933		$ 1,251,691	3,243	100%	$ 1,251,691	$ 3,243
1002	Other Personnel Costs	52,785	33,352		33,352	0	100%	33,352	0
2001	Professional Fees and Services	826,175	941,686		939,753	1,933	100%	939,753	1,933
2003	Consumable Supplies	27,584	27,584		18,518	9,066	67%	18,518	9,066
2004	Utilities	58,577	58,577		37,559	21,018	64%	37,559	21,018
2005	Travel	45,000	45,000		44,827	173	100%	44,827	173
2006	Rent-Building	-	33,076		32,542	534	0%	32,542	534
2007	Rent-Machine and Other	32,172	32,172		24,592	7,580	76%	24,592	7,580
2009	Other Operating Expenses	370,934	551,631		488,132	63,499	88%	488,132	63,499
	Subtotal - Indirect Administration (B.1.1.)	**$ 3,030,652**	**$ 2,978,011**	**1.00%**	**$ 2,870,965**	**$ 107,047**	**96%**	**$ 2,870,965**	**$ 107,047**

Grant Review and Award Operations (A.1.3.)

		2018 Appropriated	2018 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
1001	Salaries and Wages	$ 2,991,208	3,297,026		$ 3,297,026	$ 0	100%	$ 3,297,026	$ 0
1002	Other Personnel Costs	3,856	50,770		50,770	(0)	0%	50,770	(0)
2001	Professional Fees and Services	10,443,893	10,946,908		10,757,398	189,510	98%	10,757,398	189,510
2003	Consumable Supplies	-	-		-	-	0%	-	-
2004	Utilities	1,628	11,121		11,121	0	100%	11,121	0
2005	Travel	87,500	87,500		52,021	35,479	59%	52,021	35,479
2009	Other Operating Expenses	218,997	139,906		105,626	34,280	75%	105,626	34,280
	Conference		277,230		277,230	1	100%	277,230	1
	Subtotal - Grant Operations (A.1.3.)	**$ 13,747,082**	**$ 14,810,461**	**4.97%**	**$ 14,551,192**	**$ 259,269**	**98%**	**$ 14,551,192**	**$ 259,269**

Grants

		2018 Appropriated	2018 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		$ 13,400,377	$ 14,637,579	48%	$ 13,400,377	$ 14,637,579
4000	Grants - Research (A.1.1.)	255,239,310	$ 252,269,756		90,834,315	$ 161,435,441	36%	90,834,315	161,435,441
	Subtotal - Grants	**$ 283,277,266**	**$ 280,307,712**	**94.03%**	**$ 104,234,692**	**$ 176,073,020**	**37%**	**$ 104,234,692**	**$ 176,073,020**
	Grand Totals	**$ 300,055,000**	**$ 298,096,185**	**100.00%**	**$ 121,656,849**	**$ 176,439,336**	**41%**	**$ 121,656,849**	**$ 176,439,336**

Cancer Prevention and Research Institute of Texas

Cancer Prevention and Research Institute Fund Account - 5136

As of August 31, 2018

	08/01/2018-08/31/2018	AY 18 Year to Date as of 8/31/2018
Beginning Balance : 08/01/2018		**$ 600,506**
Increases:		
(1)	$ -	$ -
(2)	-	
Total Increases	**$ -**	**$ 600,506.00**
Reductions:		
Expenditures - Appropriated	$ -	$ -
	$ -	$ -
	$ -	$ -
Total Reductions	**$ -**	**$ -**
Ending Balance, 08/31/2018		**$ 600,506.00**

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

Cancer Prevention and Research Institute of Texas

License Plate Trust Fund Account - 0802

As of August 31, 2018

	08/01/2018-08/31/2018	AY 18 Year to Date as of 8/31/2018
Beginning Balance : 08/01/2018		**$ -**
Increases:		
(1) License Plate Revenue Received	$ 1,081.77	$ 10,743.16
Total Increases	**$ 1,081.77**	**$ 10,743.16**
Reductions:		
Expenditures - Appropriated	$ (2,810.00)	$ (2,810.00)
	-	-
Total Reductions	**$ (2,810.00)**	**$ (2,810.00)**
Ending Balance, 08/31/2018		**$ 7,933.16**

Note:

Cancer Prevention and Research Institute of Texas

Appropriated Receipts - 666

As of August 31, 2018

		08/01/2018-08/31/2018	AY 18 Year to Date as of 8/31/2018
Beginning Balance : 08/01/2018			**$ 58,079.19**
Increases:			
(1)	Product Development Application Fees Received	$ 21,500.00	$ 46,500.00
(2)	Appropriated Receipts applied to payments	$ -	$ -
(3)	Conference Registration Fees	$ -	$ 213,697.96
(4)	Conference Registration Fees-Credit Card	$ -	$ 5,452.71
Total Increases		**$ 21,500.00**	**$ 265,650.67**
Reductions:			
	Conference Expenditures - Appropriated		$ (229,469.00)
	Credit Card Fees Expended	$ -	$ (5,452.71)
	Legal Services Expenses (Application Fees)	$ -	$ -
Total Reductions		**$ -**	**$ (234,921.71)**
Ending Balance, 08/31/2018			**$ 88,808.15**

Begin balance is $58,079.19
($583.57 CC fees + $37,079.13 + 20,416.49 registration + $64.51 interest) for conference fees

Cancer Prevention and Research Institute of Texas

Interest & Sinking Fund Account - 5168

As of August 31, 2018

		08/01/2018-08/31/2018	AY 18 Year to Date as of 8/31/2018
Beginning Balance : 08/01/2018			**$ 38,695.04**
Increases:			
(1)	Revenue Sharing / Royalties	$ 31,418.97	$ 188,071.21
			\
Total Increases		**$ 31,418.97**	**$ 226,766.25**
Reductions:			
	Expenditures - Appropriated	$ -	$ -
		$ -	
		$ -	$ -
Total Reductions		**$ -**	**$ -**
Ending Balance, 08/31/2018			**$ 226,766.25**

Note: Beginning Balance $38,695.04

Cancer Prevention and Research Institute of Texas
FY 2018, Quarter 4 Performance Measure Report

Measure	Targeted Performance	QTR 1	QTR 2	QTR 3	QTR 4	Sum of QTRs	% of Mandate Attained
Number of People Served by Institute Funded Prevention and Control Activities	500,000	282,167	218,357	239,125	232,369	972,018	194.40%
Number of Entities Relocating to TX for Cancer Research Related Projects	2	0	0	0	0	0	0.00%
Annual Age-adjusted Cancer Mortality Rate	156.8	N/A	N/A	N/A	N/A	149.2	95.15%
Number of Published Articles on CPRIT-Funded Research Projects	900	N/A	N/A	N/A	N/A	2,524	280.44%
Number of New Jobs Created and Maintained	1,325	N/A	N/A	N/A	N/A	3,406	257.06%

Variance Explanations

Number of People Served by Institute Funded Prevention and Control Activities
CPRIT grantees have been able to collaborate with other organizations to serve more people than projected, making their grant funding go further.
Number of Entities Relocating to TX for Cancer Research Related Projects
This output is dependent on the number of companies outside Texas 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.
Number of Published Articles on CPRIT- Funded Research Projects
With more than 400 active academic and product development research grants in its portfolio, grantees were more successful than anticipated in being able to get articles about their funded research published.
Number of New Jobs Created and Maintained
CPRIT has more than 400 academic and product development research grantees at any time who have been able to create and maintain a larger than anticipated number of jobs.

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 Cost3.4622 %
				$ 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				
TOTAL ISSUED TO DATE				**$ 1,516,000,000**				