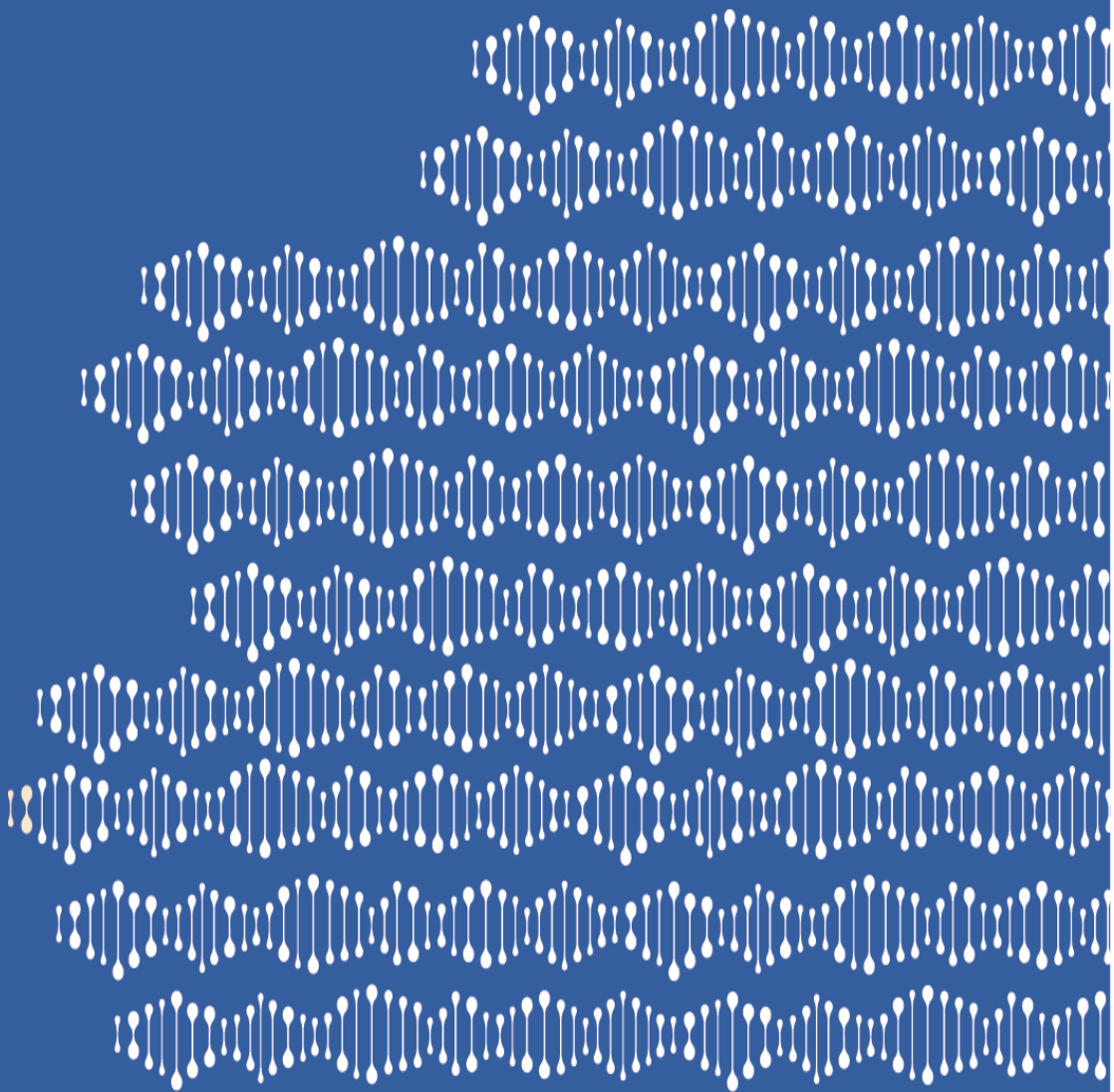
CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

# Oversight Committee Meeting

November 15, 2023



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**Summary Overview of the November 15, 2023, Oversight Committee Meeting**

This summary provides an overview of major agenda items and background on key issues for Committee consideration at the November 15, 2023, Oversight Committee meeting.

**CEO Report**
Wayne Roberts will present the CEO's report and address issues including a personnel update, grant funds available for FY 2024 and other topics. He will also introduce a special guest for a brief presentation to the Oversight Committee.

**Grantee Presentations**
CPRIT grantees CPRIT Scholar Dr. Omid Veiseh (Rice University) and Atom Mines will make presentations to the Oversight Committee about their CPRIT-funded work.

**Chief Compliance Officer Report and Grant Award Certification**
Compliance Program Manager Stephen Nance will report on the status of required grantee reports, financial status report reviews, desk reviews and site visits, annual compliance attestation, audit tracking, and training. He will also answer any questions regarding Chief Compliance Officer Vince Burgess' certification of the proposed academic research and product development awards and review process.

**Chief Scientific Officer Report and Grant Award Recommendations**
Dr. Michelle Le Beau will provide an update on the Academic Research Program and present the Program Integration Committee's (PIC) two recruitment award recommendations, totaling $7.9 million.

*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 Officer Report**
Ramona Magid will update the Oversight Committee regarding the agency's prevention activities and present the proposed FY 2025 requests for applications.

**Chief Product Development Officer Report and Grant Award Recommendation**
Dr. Ken Smith will provide an update on the Product Development Program and present the PIC's six company award recommendations, totaling $55.2 million.

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

**FY 2025 Program Priorities**
Health and Safety Code Chapter 102 requires the Oversight Committee to establish program priorities on an annual basis. Mr. Roberts will present the proposed FY 2025 Program Priorities.

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

**Advisory Committee Appointments**
Mr. Roberts will present one new appointment to the Advisory Committee on Clinical Trials.

**Health & Safety Code § 102.1062 Waivers**
Mr. Roberts will present a FY 2024 conflict of interest waiver pursuant to Texas Health and Safety Code 102.1062 for Product Development Program Manager Dr. Michelle Leeuwon.

**Proposed Amendments to 25 TAC Chapters 701**
Ms. Eckel will present the final order approving a proposed amendment to the agency's Chapter 701 administrative rules, which the Oversight Committee provisionally approved at the August meeting. If approved, the amendment will become effective in December.

**Chief Operating Officer Report, 2023 Innovations VI Conference Wrap Up and Contract Approvals**
Ms. McConnell will discuss the operating budget, performance measures, and debt issuance history for the fourth quarter of FY 2023 and provide a comprehensive wrap up of the CPRIT Innovations VI Conference held in early October. Ms. McConnell will also present a recommendation to approve the FY 2024 contract for internal audit services.

**Communications Report**
Mr. Loeffler will update the Oversight Committee on CPRIT's communication efforts, including coverage of the agency and grantees in earned media, digital media, and social media.

**Internal Auditor Report**
Weaver and Tidwell, CPRIT's internal auditor, will present an internal audit update, the FY 2024 Internal Audit Plan, the FY 2023 Annual Internal Audit Report, and the following internal audit reports:

- Internal Audit Report over Purchasing Compliance
- Internal Audit Advisory Report over Post-Award Grant Compliance
- Internal Audit Follow-up Procedures Report over Vendor Contract Compliance
- Internal Audit Follow-up Procedures Report over Communications
- Internal Audit Advisory Follow-up Procedures Report over Disaster Recovery and Business Continuity Planning

- Internal Audit Report over Information Technology General Controls

Due to the sensitive IT security issues addressed in the Internal Audit Report over Information Technology General Controls, CPRIT will provide the report to Oversight Committee members separately. The IT General Controls audit report presentation and discussion will take place in closed session.

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# Oversight Committee Meeting Agenda

November 15, 2022
8:30 a.m.

The Barbara Jordan Building
1601 Congress Avenue, Austin, TX 78701
Room 2.035A

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. If the Oversight Committee meets in closed session, it will do so in the Barbara Jordan Building, Room 2.027.

Also as authorized by Texas Government Code § 551.127, one or more Oversight Committee members may participate remotely in the meeting by videoconference. The Oversight Committee member presiding over the meeting will be physically present at the above-listed location, which will be open to the public.

Anyone wishing to offer public comments must notify the Chief Executive Officer in writing prior to the start of the meeting. The Committee may limit the time a member of the public may speak.

1. Call to Order
2. Roll Call/Excused Absences
3. Adoption of Minutes for the August 16, 2023, meeting — Tab 1
4. Public Comment
5. Chief Executive Officer Report — Tab 2
6. Grantee Presentations — Tab 3
7. Chief Compliance Officer Report and Compliance Certification of Grant Award Process — Tab 4
8. Chief Scientific Officer Report — Tab 5
   - Grant Award Recommendations
9. Chief Prevention Officer Report — Tab 6
   - FY 2025 Requests for Applications
10. Chief Product Development Officer Report — Tab 7
    - Grant Award Recommendations
11. Program Priorities for FY 2025 — Tab 8
12. Scientific Research and Prevention Program Committee Appointments — Tab 9
13. Advisory Committee Appointments — Tab 10
14. Health & Safety Code Section 102.1062 Waiver — Tab 11
15. Amendment to 25 T.A.C. Chapter 701 — Tab 12
    - Final Order Approving Amendment to Chapter 701

16. Chief Operating Officer Report — Tab 13
17. Contract Approvals — Tab 14
    - Internal Audit Services Contract
18. Communications Program Update — Tab 15
19. Internal Auditor Report — Tab 16
    - Internal Audit Report over Purchasing Compliance
    - Internal Audit Advisory Report over Post-Award Grant Compliance
    - Internal Audit Follow-up Procedures Report over Vendor Contract Compliance
    - Internal Audit Follow-up Procedures Report over Communications
    - Internal Audit Advisory Follow-up Procedures Report over Disaster Recovery and Business Continuity Planning
    - Internal Audit Report over Information Technology General Controls
    - FY 2024 Internal Audit Plan
    - FY 2023 Annual Internal Audit Report
20. Subcommittee Business
21. Compliance Investigation Pursuant to Health & Safety Code § 102.2631
22. Consultation with General Counsel
23. Future Meeting Dates and Agenda Items
24. Adjourn

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**Oversight Committee Meeting Minutes**
**August 16, 2023**

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

**Call to Order – Agenda Item 1**

Presiding Officer Dr. Mahendra Patel announced a quorum present and called the meeting to order at 8:32 a.m.

**Roll Call/Excused Absences – Agenda Item 2**

Committee Members Present
Mahendra Patel, M.D., P.A.
David Cummings, M.D.
Donald (Dee) Margo
Ambrosio Hernandez, M.D.
Will Montgomery (joined via videoconference)
Cindy Barberio Payne
Bill Rice, M.D. (joined via videoconference)
Craig Rosenfeld, M.D.

Presiding Officer Dr. Patel noted that Dr. Rice and Mr. Montgomery joined the meeting via videoconference. He explained that this is an option permitted by the Open Meetings Act and they will count towards a quorum so long as the audience can see and hear them.

**Adoption of Minutes from the May 19, 2023, Meeting – Agenda Item 3, Tab 1**

> **MOTION:**
> On a motion by Mr. Margo and seconded by Dr. Rosenfeld, the Oversight Committee voted unanimously to approve the minutes of the May 19, 2023, Oversight Committee meeting as presented.

**Public Comment – Agenda Item 4**

Presiding Officer Dr. Patel noted for the record that no member of the public asked to provide comments.



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**Chief Executive Officer Report – Agenda Item 5, Tab 2**

Presiding Officer Dr. Patel recognized Chief Executive Officer Wayne Roberts to present his report. Mr. Roberts informed the Oversight Committee that if they approved the recommended awards, the agency would have approximately $7 million remaining in the FY2023 budget. He introduced new personnel and informed members that Ms. Tracey Davies' accepted a job opportunity at a company in California and would be resigning from CPRIT.

There were no questions for Mr. Roberts.

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

Presiding Officer Dr. Patel recognized Chief Compliance Officer Vince Burgess and Program Manager Stephen Nance to present the Compliance Report and Compliance Certification of Grant Award Process.

Mr. Nance presented the Compliance Report for the past quarter's activities. There were no questions for Mr. Nance.

Following Mr. Nance's report, Mr. Burgess presented the Compliance Certification for the proposed academic research and prevention grant awards, confirming that the proposed awards and review process complied with all applicable state and agency requirements.

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

Presiding Officer Dr. Patel recognized Dr. Le Beau to provide the academic research program update and introduce the Program Integration Committee's grant award recommendations.

Dr. Le Beau directed Oversight Committee members to Table 1 on page 4 of the "Proposed Grant Awards" Book, which displayed the Program Integration Committee's (PIC) proposed award recommendations for academic research grant cycle 23.2 and for recruitment grant cycles 23.5 and 23.6. Dr. Le Beau provided an overview of the recommended awards.

The recommendations comprised six slates of 20 recommended awards totaling $36,044,691 as displayed below.

| Rank | ID | RFA | Final Score | Application Title | Candidate/PI | Organization | Budget |
|---|---|---|---|---|---|---|---|
| 1 | RR230040 | RFTFM | **1.0** | First-Time, Tenure- Track: Dr. Graham Erwin | Graham Erwin | Baylor College of Medicine | $2,000,000 |
| 2 | RR230042 | RFTFM | **1.0** | First-Time Tenure-Track: Dr. Michael Robertson | Michael Robertson | Baylor College of Medicine | $2,000,000 |

| Rank | ID | RFA | Final Score | Application Title | Candidate/PI | Organization | Budget |
|---|---|---|---|---|---|---|---|
| 3 | RR230054 | RFTFM | **1.1** | Nomination of Xiaofeng Qi, Ph.D. for a CPRIT recruitment of a First-Time Tenure- Track Faculty Member Award | Xiaofeng Qi | The University of Texas Southwestern Medical Center | $2,000,000 |
| 4 | RP230446 | TRECPDTA | **1.1** | UTEP Postdoctoral Career Transition Program in Cancer Research | Lu, Weiqin | The University of Texas at El Paso | $850,000 |
| 5 | RR230072 | RFTFM | **1.3** | Recruitment of First- Time, Tenure-Track Faculty Members - Simon Eschweiler | Simon Eschweiler | The University of Texas M. D. Anderson Cancer Center | $2,000,000 |
| 6 | RP230447 | TRECMIA | **1.4** | Fluorescence-Activated Cell Sorting: FACSAria Fusion | Kang, Min | Texas Tech University Health Sciences Center | $901,225 |
| 7 | RR230078 | REI | **1.5** | Recruitment of Established Investigator, Simon Gayther | Simon Gayther | The University of Texas Health Science Center at San Antonio | $6,000,000 |
| 8 | RR230050 | RFTFM | **1.9** | Recruitment of First- Time, Tenure-Track Faculty Member - Dr. Zunlong Ke | Zunlong Ke | The University of Texas at Austin | $2,000,000 |
| 9 | RR230052 | RFTFM | **2.0** | First-Time, Tenure- Track: Dr. Varun Venkataramani | Varun Venkataramani | Baylor College of Medicine | $2,000,000 |
| 10 | RR230053 | RFTFM | **2.0** | Recruitment of First- Time, Tenure-Track Faculty Member - Dr. Chen Cao | Chen Cao | The University of Texas at Dallas | $1,800,000 |
| 11 | RR230066 | RFTFM | **2.0** | Recruitment of First- Time, Tenure-Track Faculty Member - Dr. Qian Yin | Qian Yin | The University of Texas at Austin | $2,000,000 |
| 12 | RP230449 | TRECMIA | **2.0** | The acquisition of an instrument suite to set up a high-throughput screening core at Texas A&M University | Liu, Wenshe | Texas A&M University | $995,767 |
| 13 | RP230445 | TRECMIA | **2.2** | Core Imaging Instrumentation for Cancer Studies in Rodent Models: Acquisition of an IVIS Spectrum/Quantum GX2 optical/microCT Small Animal Imaging System | Becker, Christopher | Baylor University | $997,701 |
| 14 | RR230081 | RFTFM | **2.6** | Nomination of Annika Wylie for CPRIT Recruitment of First- TimeTenure-Track Faculty Member | Annika Wylie | Southern Methodist University | $2,000,000 |
| 15 | RP230443 | TRECPSA | **2.9** | “Click” Assembled Colloidal Molecules with Tunable Plasmon Bands as Novel Agents for Photothermal Tumor Therapy | Liang, Hongjun | Texas Tech University Health Sciences Center | $200,000 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 16 | RP230454 | TRECPSA | **2.9** | Role of transcription factor UBTF in pancreatic cancer | Hafeez, Bilal | The University of Texas Rio Grande Valley | $200,000 |
| 17 | RP230431 | TRECPSA | **3.2** | Unraveling the Therapeutic Potential of Osr1 Overexpression in Hepatocellular Carcinoma Management | Xie, Linglin | Texas A&M University | $200,000 |
| 18 | RP230444 | TRECPSA | **3.6** | A Role for PSMD2, PSMD7, and PSMD9 in Drug Resistance of Acute Myeloid Leukemia (AML) | Eiring, Anna | Texas Tech University Health Sciences Center at El Paso | $200,000 |
| 19 | RP230451 | TRECPSA | **3.7** | The Role of Renal Lipotoxicity in Carcinogenesis | Bobulescu, Ion | Texas Tech University Health Sciences Center | $200,000 |
| 20 | RP230426 | Texas CONNECT for Cancer Prevention Study Awards | **2.8** | Baylor Scott and White Health Texas Connect for Cancer Prevention Cohort | Katherine Sanchez | Baylor Research Institute | $7,499,998 |

RFTFM- Recruitment of First-Time Tenure Track Faculty
REI- Recruitment of Established Investigators
TREC: MIA - TREC: Major Instrument Award
TREC: PDTA- TREC: Institutional Postdoctoral Training Award
TREC: PSA - TREC: Pilot Study Award

In response to a question by an Oversight Committee member inquiring about more information on the CONNECT study, Dr. Le Beau answered she would be available to discuss further after the meeting.

Proposed Academic Research RFAs for Fiscal Year 2024 Cycle 2 (FY24.2)

Dr. Le Beau provided an overview of the Proposed 24.2 RFAs for Academic Research: Core Facility Support Awards, High-Impact/High-Risk Research Awards, Multi-Investigator Research Awards, and Clinical Investigator Award.

Compliance Certification

Presiding Officer Dr. Patel reminded members that Mr. Burgess previously certified compliance of the academic research awards process.

Conflict of Interest Notification

Presiding Officer Dr. Patel noted for the record that no Oversight Committee member reported a conflict of interest with any award academic research recommendation presented.

Academic Research Awards Approval

**MOTION:**
On a motion made by Mr. Montgomery and seconded by Mr. Margo, the Oversight Committee members voted unanimously to approve the PIC's recommendations for the Texas CONNECT for Cancer Prevention Study Award, TREC: Institutional Postdoctoral Training Award, TREC: Major Instrumentation Award, TREC: Pilot Study Award, Recruitment of First-Time, Tenure-Track Faculty Members; and Recruitment of Established Investigators.

**MOTION:**
On a motion made by Mr. Margo and seconded by Dr. Hernandez, the Oversight Committee members voted unanimously 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.

Academic Research Proposed FY2024 Cycle 2 RFAs Approval

**MOTION:**
On a motion made by Mr. Margo and seconded by Dr. Cummings, the Oversight Committee members voted unanimously to approve the Academic Research FY2024 Cycle 2 proposed RFAs.

**Chief Prevention Officer Report and Grant Recommendations – Agenda Item 8, Tab 5**

Presiding Officer Dr. Patel recognized Prevention Program Manager Carlton Allen to provide the prevention program update and introduce the Program Integration Committee's grant award recommendations.

Mr. Allen directed Oversight Committee members to the proposed award recommendations for prevention grant cycle 23.2 in the "Proposed Grant Awards" Book at page 38. He provided an overview of the recommended awards.

The recommendations comprised four slates of nine recommended awards totaling $13,343,163 as displayed below.

| App. ID | Mech | Application Title | PD | Organization | Score | Rank Order | Budget |
|---|---|---|---|---|---|---|---|
| PP230078 | DI | Implementation and Dissemination of an Evidence-Based Intervention to Increase Tobacco Treatment Capacity in Opioid Treatment Programs | Reitzel, Lorraine R | The University of Texas M. D. Anderson Cancer Center | 2.0 | 1 | $449,776 |
| PP230060 | CCC | Coordinating Center for Colorectal Cancer | Shokar, Navkiran K | The University of Texas at Austin | 2.3 | 2 | $3,000,000 |

| App. ID | Mech | Application Title | PD | Organization | Score | Rank Order | Budget |
|---|---|---|---|---|---|---|---|
| | | Screening Across Texas (CONNECT) | | | | | |
| PP230074 | PPC | Active Living After Cancer: Combining a Physical Activity Program with Survivor Navigation | Basen-Engquist, Karen M | The University of Texas M. D. Anderson Cancer Center | 2.5 | 3 | $1,999,989 |
| PP230061 | PPC | Expansion of HPV Vaccination Among Survivors of Childhood Cancer | Grimes, Allison | The University of Texas Health Science Center at San Antonio | 3.2 | 4 | $999,999 |
| PP230059 | CSD | De Casa en Casa 4: Cervical Cancer Screening in Underserved Rural and Border Communities Throughout West and South Texas | Molokwu, Jennifer C | Texas Tech University Health Sciences Center at El Paso | 3.3 | 5 | $2,499,437 |
| PP230003 | DI | Taking Texas Tobacco Free: Dissemination to and Implementation within CentersServing Texans who Identify as LGBTQ+ | Reitzel, Lorraine R | University of Houston | 3.3 | 6 | $448,835 |
| PP230056 | PPC | Continuation and Expansion of a Highly Successful Postpartum HPV Vaccination Program | Berenson, Abbey B | The University of Texas Medical Branch at Galveston | 3.6 | 7 | $2,499,207 |
| PP230030 | CSD | ACTION for Big Country | Byrd, Theresa L | Texas Tech University Health Sciences Center | 3.7 | 8 | $997,266 |
| PP230069 | DI | Dissemination of the Active Living After Cancer Program | Basen-Engquist, Karen M | The University of Texas M. D. Anderson Cancer Center | 3.8 | 9 | $448,654 |

CCC: Texas Colorectal Cancer Screening Coordinating Center
CSD: Cancer Screening and Early Detection
DI: Dissemination of CPRIT-Funded Cancer Control Interventions
PPC: Primary Prevention of Cancer

In response to a question by an Oversight Committee member inquiring if grantees screen individuals for multiple cancers, Mr. Allen explained that prevention grantees will often screen individuals for multiple cancer sites if individuals meet the recommended guidelines and if grantees have those services.

Compliance Certification

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

Conflict of Interest Notification

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

Approval Process – Prevention Awards

**MOTION:**
On a motion made by Mr. Margo and seconded by Dr. Rosenfeld, the Oversight Committee members voted unanimously to approve the PIC's nine recommendations for the following mechanisms: Cancer Screening and Early Detection, Colorectal Cancer Coordinating Center, Dissemination of CPRIT-Funded Cancer Control Interventions, and Primary Prevention of Cancer.

**MOTION:**
On a motion made by Mr. Margo and seconded by Dr. Rosenfeld, the Oversight Committee members voted unanimously 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 Dr. Patel invited Chief Product Development Officer Dr. Ken Smith, and Senior Program Manager Dr. Abria Magee to provide the product development program update.

As part of the program update, Dr. Magee introduced the newly developed CPRIT Resource Guide, which CPRIT will officially release at the October 2-3 CPRIT Innovations in Cancer Research conference.

An Oversight Committee member complimented the usefulness of the resource guide and recommended that CPRIT consider including economic development offices as well.
In response to another Oversight Committee member's question, Dr. Magee confirmed that the guide will be available online via QR code.

An Oversight Committee member asked Dr. Magee about the timeline between submitting a preliminary application and when they receive an invitation to submit a full application. She explained that it generally takes 3-4 weeks.

Dr. Smith responded to another Oversight Committee member's question about the decline in dealmaking in Silicon Valley, noting that this may be one reason that CPRIT is seeing an increased interest in the product development program.

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

Presiding Officer Dr. Patel recognized Mr. Roberts to present his 25 appointments to CPRIT's Scientific Research and Prevention Programs Committees.

> **MOTION:**
> On a motion by Mr. Margo and seconded by Dr. Rosenfeld, the Oversight Committee voted unanimously to approve the CEO's 25 appointments to CPRIT's Scientific Research and Prevention Program Committees.

**Advisory Committees – Item 12, Tab 9**

Presiding Officer Dr. Patel recognized Mr. Roberts to present the Presiding Officer's new appointments to the advisory committees. Mr. Roberts presented three appointments to the Clinical Trial Advisory Committee and Dr. Reiser's appointment to the Product Development Advisory Committee.

> **MOTION:**
> On a motion made by Dr. Rosenfeld and seconded by Dr. Cummings, the Oversight Committee voted unanimously to approve the four advisory committee appointments.

<u>Academic Research Advisory Committee Presentations</u>

Presiding Officer Dr. Patel called on Dr. Le Beau to provide the Clinical Trials Advisory Committee Annual Report.

Dr. Le Beau introduced Dr. William Kelly, who presented an overview of his current research.

Following his presentation, an Oversight Committee member inquired whether Dr. Kelly's trial focused on before-surgery or after surgery treatment. Dr. Kelly confirmed that this study does not involve surgery.

Another Oversight Committee member asked about dose reduction of the drug, given the side effects. Dr. Kelly explained the options available for investigators.

An Oversight Committee member praised Dr. Kelly for incorporating academic centers and community centers working together.

In response to an Oversight Committee member's question about quality of life, Dr. Kelly explained that quality of life is something they would like to study in future research. In a follow up question, Dr. Kelly and an Oversight Committee member discussed side effects and how the study is addressing those issues.

Dr. Kelly and an Oversight Committee member discussed the study observations regarding the blood-brain barrier in the context of plans to increase the systemic drug and transportation into

the target site.

At the conclusion of the Oversight Committee's discussion with Dr. Kelly, Dr. Le Beau introduced Dr. David Gerber, who presented updates on the Clinical Trial Network Award and Clinical Trial Participation Awards.

An Oversight Committee member asked about the paperwork challenges. Dr. Gerber explained the assistance provided for people not well versed in completing the paperwork and clarified that he was speaking about the documentation required to apply for the financial reimbursement program. His project partners with a California foundation to provide reimbursement for patients, the form is a single page and does require proof of income. The program navigator meets with the patient to tell them about the program and assists them with completion of the paperwork.

Responding to an Oversight Committee member's follow up question about the turnaround time from form submission to payment, Dr. Gerber explained that he did not have the information on hand but would get the information to the Oversight Committee following the meeting.

An Oversight Committee member commented that more perspective and involvement from individuals living and practicing in non-urban areas would be beneficial to the advisory committee's work and requested that CPRIT add to the Clinical Trials Advisory Committee.

Another Oversight Committee agreed, and explained that it made sense to go out into these non-urban communities and involve more members to make this a more comprehensive effort. Mr. Roberts requested recommendations from the committee for appropriate additions.

After the Oversight Committee's discussion with Dr. Gerber, Dr. Le Beau introduced Dr. Sarah Williams-Blangero, who provided the Geographic Diversity Advisory Committee Annual Report.

Following her report, an Oversight Committee member expressed his strong support for the TREC funding mechanisms and appreciated Dr. Williams-Blangero and the Geographic Diversity Advisory Committee's goals. He recommended that CPRIT increase the ceiling for these awards.

Presiding Officer Dr. Patel and the Oversight Committee members thanked the advisory committee representatives for the presentations.

**FY 2024 Honoraria Policy – Agenda Item 13, Tab 10**

Presiding Officer Dr. Patel recognized Mr. Roberts to present the FY 2024 honoraria policy.

> **MOTION:**
> On a motion made by Dr. Rosenfeld and seconded by Mr. Margo, the Oversight Committee voted unanimously to approve the FY 2024 Honoraria Policy.

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

Presiding Officer Dr. Patel recognized Mr. Roberts to present the Health and Safety Code Section 102.1062 waivers for FY 2024. Mr. Roberts presented the two waivers located behind Tab 11 in the Agenda Packet.

**MOTION:**
On a motion made by Dr. Rosenfeld and seconded by Mr. Margo, the Oversight Committee voted unanimously to approve the Health and Safety Code Section 102.1062 waivers for FY 2024.

**Amendments to 25 T.A.C. Chapters 701 and 703 – Agenda Item 15, Tab 12**

Presiding Officer Dr. Patel recognized assistant general counsel Cameron Eckel to present the proposed administrative rule changes. Ms. Eckel reviewed the final orders and the proposed rule change, located behind Tab 12.

**MOTION:**
On a motion by Dr. Rosenfeld and seconded by Mr. Margo, the Oversight Committee voted unanimously to approve the final orders adopting the rule changes to the Texas Administrative Code Chapters 701 and 703 and to approve the publication of the proposed changes to Chapter 701 in the *Texas Register*.

**Chief Operating Officer Report – Agenda Item 16, Tab 13**

Presiding Officer Dr. Patel recognized Chief Operating Officer Heidi McConnell to present her report.

Following her report, Ms. McConnell responded to an Oversight Committee member's question inquiring about what the lowest interest rate has been. She explained that she believed the interest rate was approximately 0.3% around 2010.

Ms. McConnell provided an update on the CPRIT Conference, noting that there were 400 conference registrants, 55% of whom were CPRIT grantees. She indicated that CPRIT will send out additional reminders about the conference. She reported that an additional exhibitor has signed up since her last update, bringing the total to seven exhibitors.

In response to a question by an Oversight Committee member inquiring whether CPRIT expected companies or academic institutions to be exhibitors, Ms. McConnell responded that a company that is not a current CPRIT grant recipient and does not intend to apply for a grant award may be a conference sponsor or exhibitor. Because every academic institution in the state is a grant recipient or may apply for a CPRIT grant in the future, CPRIT does not consider them for a sponsor or exhibitor.

In response to a question by an Oversight Committee member inquiring if grantees must attend the conference, Ms. McConnell responded that each CPRIT grant program strongly encourages grantees to attend, but does not mandate attendance.

**Contract Approvals – Agenda Item 17, Tab 14**

Presiding Officer Dr. Patel recognized Ms. McConnell to present contract approvals.

Ms. McConnell presented the recommendation for a FY2024 contract with The Perryman Group for $195,000 to perform an economic assessment of the cost of cancer in Texas and for FY2024 contract renewals with Alan Boyds Consultants for $330,000 to perform business due diligence reviews and Business and Financial Management Solutions (BFS) for $121,409 to monitor peer review meetings.

In response to a question by an Oversight Committee member asking about the timing of the most recent economic assessment, Ms. McConnell responded that The Perryman Group performed the economic assessment of the cost of cancer in Texas last year.

> **MOTION:**
> On a motion by Dr. Rosenfeld and seconded by Mr. Margo, the Oversight Committee voted unanimously to approve the contracts with The Perryman Group, Alan Boyds Consultants, and BFS.

**Subcommittee Business – Agenda Item 19, Tab 16**

Presiding Officer Dr. Patel presented the proposed subcommittee assignments for fiscal years 2024 and 2025 located behind Tab 16.

> **MOTION:**
> On a motion by Mr. Margo and seconded by Dr. Cummings, the Oversight Committee voted unanimously to approve the new subcommittee assignments for fiscal years 2024 and 2025.

**Election of Board Officers – Agenda Item 22, Tab 17**

Presiding Officer Dr. Patel presented the Board Governance Subcommittee recommendations for the slate of officers to serve two-year terms ending in August 2025.

> **MOTION:**
> On a motion by the chair and seconded by Dr. Rosenfeld, the Oversight Committee voted unanimously to approve Dr. David Cummings as Presiding Officer, Cindy Payne as Vice Presiding Officer, and Dr. Ambrosio Hernandez as Board Secretary to serve the Oversight Committee for fiscal years 2024 and 2025.

Following the vote, Mr. Roberts presented Presiding Officer Dr. Patel a gavel on behalf of the CPRIT staff in recognition of Dr. Patel's service and leadership.

**Communication Report – Agenda Item 18, Tab 15**

Presiding Officer Dr. Patel recognized Communications Director Mark Loeffler to present his report. Mr. Loeffler updated the committee members on communications activities.

There were no questions for Mr. Loeffler.

**Future Meeting Dates and Agenda Items – Agenda Item 25, Tab 18**

Presiding Officer Dr. Patel stated that the Oversight Committee would not take up standing items 23 and 24. He directed members to tab 18 of the meeting packet for the proposed dates for the Oversight Committee's regular quarterly meetings and subcommittee meetings for FY 2024**.**

The next regular Oversight Committee meeting will occur November 15, 2023.

> **MOTION:**
> On a motion by Dr. Rosenfeld and seconded by Mr. Margo, the Oversight Committee voted unanimously to approve the proposed meeting dates for the regular meetings of the Oversight Committee and the subcommittees for FY 2024.

**Internal Auditor Report – Agenda Item 10, Tab 7**

Returning to Agenda Item 10, Presiding Officer Dr. Patel recognized Daniel Graves to present the internal auditor report. Mr. Graves provided a status update on current internal audit activities.

There were no questions for Mr. Graves.

Presiding Officer Dr. Patel announced the committee would go into closed session at 11:17 a.m. pursuant to Texas Government Code 551.076 to receive an update on the Internal Audit Report over Information Technology General Controls and to discuss the FY 2023 DIR Texas Cybersecurity Framework Assessment and the personnel action related to the Chief Executive Officer and the Chief Scientific Officer. He asked for Mr. Roberts, Dr. Le Beau, Ms. Doyle, Ms. Nelson, Ms. McConnell, Mr. Burgess, Mr. Nance, Ms. Eckel, Ms. Cusick, Mr. Emenike and Mr. Graves to join the members in closed session. Due to technology restrictions, Oversight Committee members Dr. Rice and Mr. Montgomery did not attend the closed session.

The Board reconvened in open session at 12:01 p.m.

> **MOTION:**
> On a motion by Dr. Rosenfeld and seconded by Dr. Hernandez, the Oversight Committee voted unanimously to set the **e**xempt salary for the Chief Scientific Officer position to the legislatively authorized $639,300 effective on or after September 1, 2023.

**MOTION:**
On a motion by Dr. Rosenfeld and seconded by Dr. Hernandez, the Oversight Committee voted unanimously to set the **e**xempt salary for the Chief Executive Officer position to the legislatively authorized $282,277 effective on or after September 1, 2023.

**Adjournment – Agenda Item 22**

**MOTION:**
There being no further business, the Oversight Committee voted unanimously to approve Presiding Chair Dr. Patel's motion to adjourn, which Dr. Hernandez seconded.

The meeting adjourned at 12:02 p.m.

_____ _____

Signature Date

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

# MEMORANDUM

| | |
|---|---|
| **TO:** | OVERSIGHT COMMITTEE MEMBERS |
| **FROM:** | WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER |
| **SUBJECT:** | AGENDA ITEM 5: CHIEF EXECUTIVE OFFICER REPORT |
| **DATE:** | NOVEMBER 6, 2023 |

The Chief Executive Officer Report presented at the November 15 Oversight Committee meeting will include the following items. In addition, attached behind this memo are copies of the August/September 2023 and October 2023 CPRIT Activity Updates for your reference.

**FY 2023 Grant Awards Funds Available and CPRIT Dashboard** (Attachments 1 and 2)

As shown in Attachment 1, if the Oversight Committee approves the Academic Research and Product Development awards at the Program Integration Committee's recommended level of $63.2 million, we will have $209.8 million to award in the remainder of FY 2024.

Attachment 2 is CPRIT's dashboard of metrics that we track on a regular basis.

**Personnel**

CPRIT has filled 44 full-time equivalent positions and has several positions in progress, including an accountant position and grant compliance specialist positions.

**Short Special Presentation**

At the time of this writing, I expect there to be a short special presentation of interest to the Oversight Committee.
Additional items will be added as warranted.

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CPRIT has awarded **1,901** grants totaling **$3.381 billion:**

- 291 prevention awards totaling $354.8 million
- 1,610 academic research and product development research awards totaling $3.03 billion

Of the $3.03 billion in academic research and product development research awards,

- 31.6% of the funding ($955.9 million) supports clinical research projects
- 23.8% of the funding ($720.1 million) supports translational research projects
- 29.4% of funding ($889.4 million) supports recruitment awards
- 12.2% of the funding ($370.1 million) supports discovery stage research projects
- 3.0% of funding ($90.4 million) supports training programs.

CPRIT has seven open Requests for Applications (RFAs)

- 3 Academic Research Recruitment
- 4 Academic Research Projects

**FY 2024 GRANT AWARD FUNDS AVAILABLE**

General Obligation Bond Proceeds

| | Prevention | Academic / Product Development Research | 1% Grant Funding Buffer | Operating Budget | Total Appropriations |
|---|---|---|---|---|---|
| **Available Appropriated Funds** | $ 27,478,429 | $ 251,369,432 | | $ 21,152,139 | $ 300,000,000 |
| **Appropriations Transfer to DSHS** | | $ (3,118,032) | | $ 3,118,032 | |
| **Adjusted Appropriations** | $ 27,478,429 | $ 248,251,400 | | $ 24,270,171 | $ 300,000,000 |
| **Total Available for All Grants** | | | $ 275,729,829 | | |
| **1% of Total Available Grant Funding** | | | $ 2,757,298 | | |
| **Adjusted Grant Award Funding** | 27,478,429 | $ 245,494,102 | | | $ 272,972,531 |

| | Prevention Grants | Academic Research Grants | PD Research Grants | | |
|---|---|---|---|---|---|
| **Total Available for Grant Awards (Total GO Bond Proceeds Less Operating Budget)** | $ 27,478,429 | $ 173,775,980 | $ 74,475,420 | | $ 275,729,829 |
| **Total Available for Grant Awards Incorporating 1% Grant Funding Buffer** | $ 27,478,429 | $ 171,845,871 | $ 73,648,231 | | $ 272,972,531 |
| **Announced Grant Awards** | | | | | |
| | $ - | $ - | $ - | | |
| | $ - | $ - | $ - | | |
| **Announced Grant Award Subtotal** | $ - | $ - | $ - | $ - | $ - |
| **Available Funds as of September 1, 2023** | $ 27,478,429 | $ 171,845,871 | $ 73,648,231 | | $ 272,972,531 |
| **Pending Grants-PIC Recommendations** | | | | | |
| ACR Recruitment Awards (2) | $ - | $ 7,990,000 | $ - | | |
| PDR Company Grant Awards (6) | $ - | $ - | $ 55,206,634 | | |
| **Pending Award Subtotal** | $ - | $ 7,990,000 | $ 55,206,634 | | $ 63,196,634 |
| **Total Recommended Grant Funding Committed** | $ - | $ 7,990,000 | $ 55,206,634 | | $ 63,196,634 |
| **Available Funds as of November 16, 2023** | $ 27,478,429 | $ 163,855,871 | $ 18,441,597 | | $ 209,775,897 |
| **1% Grant Funding Buffer** | $ - | $ 1,930,109 | $ 827,189 | | $ 2,757,298 |
| **Total Remaining Funds** | $ 27,478,429 | $ 165,785,980 | $ 19,268,786 | | $ 212,533,195 |

| **Operating Budget Detail** | | |
|---|---|---|
| Indirect Administration | $ | 4,910,893 |
| Grant Review & Award Operations | $ | 16,058,895 |
| Salary Adjustment | $ | 182,351 |
| Subtotal, CPRIT Operating Costs | $ | 21,152,139 |
| Cancer Registry Operating Cost Transfer | $ | 3,118,032 |
| Total, Operating Costs | | 24,270,171 |

**CPRIT MANAGEMENT DASHBOARD**
**FISCAL YEAR 2023**

| | SEPT | OCT | NOV | DEC | JAN | FEB | MAR | APR | MAY | JUN | JUL | AUG | CUMULATIVE (ANNUAL) | CUMULATIVE (TO DATE) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **ACCOUNTABILITY** | | | | | | | | | | | | | | |
| **Announced Grant Awards** | 25 | | 2 | | | 48 | | | 9 | | | 20 | 104 | |
| **New Grant Contracts Signed** | 10 | 11 | 15 | 13 | 4 | 3 | 5 | 17 | 19 | 3 | 7 | 2 | 109 | |
| **New Grant Contracts In Negotiation** | | | 8 | | | 30 | | | 9 | | | 13 | 60 | |
| **Grant Reimbursements Processed (#)** | 172 | 150 | 124 | 193 | 148 | 149 | 195 | 185 | 196 | 170 | 93 | 134 | 1909 | |
| **Grant Reimbursements Processed ($)** | $ 16,461,776 | $ 18,449,931 | $ 9,059,403 | $ 15,994,971 | $ 25,810,994 | $ 18,838,917 | $ 20,938,739 | $ 25,259,310 | $ 21,928,601 | $ 25,900,748 | $ 17,560,466 | $ 12,357,161 | $ 228,561,017 | |
| **Revenue Sharing Payments Received** | $ 20,611 | $ 1,000 | $ 70,854 | $ 3,100 | $ 41,334 | $ 1,020,317 | $ 115,886 | $ - | $ 260,511 | $ 90,490 | $ 196,472 | $ 102,482 | $ 1,923,057 | $ 9,648,596 |
| **Grants Awarded (#)/ Applications Rec'd (#)** | 18% | 18% | 18% | 18% | 18% | 19% | 19% | 19% | 19% | 18% | 19% | 19% | | |
| **Grantee Compliance Trainings** | 2 | 4 | 3 | 4 | 1 | 3 | 4 | 1 | 2 | 3 | 5 | 2 | 34 | |
| **Grantee Compliance Monitoring Visits** | 0 | 0 | 2 | 4 | 1 | 4 | 2 | 1 | 0 | 3 | 1 | 4 | 22 | |
| **Awards with Delinquent Reimbursement Submission (FSR)** | | | 0 | | | 1 | | | 1 | | | 0 | | |
| **Awards with Delinquent Matching Funds Verification** | | | 3 | | | 13 | | | 1 | | | 0 | | |
| **Awards with Delinquent Progress Report Submission** | | | 4 | | | 0 | | | 0 | | | 0 | | |
| **MISSION** | | | | | | | | | | | | | | |
| **Open RFAs** | 7 | 6 | 6 | 10 | 14 | 10 | 11 | 11 | 11 | 13 | 5 | 5 | | |
| **Prevention Applications Received** | 0 | 0 | 0 | 0 | 0 | 25 | 0 | 0 | 0 | 0 | 0 | 29 | 54 | 1,017 |
| **Product Development Preliminary Applications Received** | 26 | 11 | 9 | 9 | 2 | 0 | 0 | 0 | 43 | 36 | 0 | 0 | 136 | 136 |
| **Product Development Full Applications Received** | 0 | 0 | 14 | 0 | 1 | 0 | 0 | 0 | 0 | 16 | 0 | 0 | 31 | 675 |
| **Academic Research Applications** | 4 | 3 | 0 | 4 | 0 | 7 | 0 | 36 | 0 | 327 | 2 | 0 | 383 | 9,056 |
| **Help Desk Calls/Emails** | 175 | 221 | 132 | 136 | 123 | 91 | 71 | 131 | 221 | 254 | 210 | 116 | 1,881 | |
| **Number of Research Grants Announced (Annual)** | 24 | | 2 | | | 40 | | | 3 | | | | 69 | |
| **Recruited Scientists Contracted** | | | | | | | | | | | | | | 294 |
| **Number of Product Development Grants Announced (Annual)** | 1 | | 0 | | | 0 | | | 6 | | | 0 | 7 | |
| **Life Science Companies Recruited (in TX)** | | | | | | | | | | | | | 2 | 17 |
| **Number of Product Development Jobs Created & Maintained** | | | | | | | | | | | | | | 1,482 |
| **Number of Prevention Grants Announced (Annual)** | | | 0 | | | 8 | | | 0 | | | 9 | 17 | |
| **Total Number of Education, Navigation and Training Services** | | | 162,223 | | | 127,978 | | | 203,636 | | | 173,697 | 667,534 | |
| **Total Number of Clinical Services** | | | 46,301 | | | 40,140 | | | 47,601 | | | 46,527 | 180,569 | |
| **Published Articles on CPRIT-Funded Projects (#)** | | | | | | | | | | | | | 1,116 | |
| **Clinical Studies (#)** | | | | | | | | | | | | | | 273 |
| **Number of Patent Applications** | | | | | | | | | | | | | 39 | |
| **Number of Patents Resulting from Research** | | | | | | | | | | | | | 5 | |
| **TRANSPARENCY** | | | | | | | | | | | | | | |
| **Total Website Hits (Sessions)** | 10,994 | 9,456 | 9,086 | 6,474 | 10,576 | 32,480 | 10,971 | 9,066 | 14,521 | 11,623 | 9,923 | 11,891 | | |
| **Total Unique Visitors to Website (Users)** | 8,280 | 7,276 | 7,070 | 5,081 | 8,142 | 29,224 | 8,115 | 6,508 | 8,317 | 6,608 | 6,433 | 7,173 | | |

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

# MEMORANDUM

| | |
|---|---|
| **TO:** | OVERSIGHT COMMITTEE MEMBERS |
| **FROM:** | WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER |
| **SUBJECT:** | CPRIT ACTIVITIES UPDATE FOR AUGUST & SEPTEMBER 2023 |
| **DATE:** | OCTOBER 9, 2023 |

Topics in this memo address CPRIT activities in August and September, including a recap of the CPRIT Innovations VI Conference, recent milestones in our fight against cancer, a staffing summary, the ARPA-H site selection announcement, outreach efforts, and updates from Compliance, Programs, and Operations.

## CPRIT Innovations VI Conference

Oversight Committee Presiding Officer Dr. David Cummingham officially gaveled in the start of the CPRIT Innovations VI Conference on the morning of October 2 at the Moody Gardens Hotel and Convention Center in Galveston. Nearly 700 scientists, clinicians, entrepreneurs, community organizers, policy makers and honored guests attended the two day conference, which featured 25 plenary and breakout sessions. Conference speakers included luminaries from the cancer research and prevention field, including national cancer leaders, active researchers, prevention program directors, and corporate product development innovators. (You can see the full schedule and speakers at www.texascancerconference.org.) CPRIT grantees also displayed and discussed their scientific abstract posters during two different poster sessions at the conference.

A highlight of this conference was the presentation of the inaugural "Texans Conquer Cancer" awards at the dinner Monday night. CPRIT created this award series to recognize individuals or organizations that have demonstrated outstanding leadership in furthering CPRIT's mission to prevent, detect, treat, and cure cancer in Texas. It was my privilege to present these first awards to four Texas legislators instrumental in the creation of CPRIT in 2007 and its reauthorization in 2019: Secretary of State and former state senator Jane Nelson, former state representative Jim Keffer, former state representative Dr. John Zerwas, and former state senator and current Austin Mayor Kirk Watson. The award recipients regaled the audience with stories of propelling the CPRIT legislation forward through daunting odds in 2007 and the work to keep CPRIT on track in 2013 and reauthorized in 2019.

Another highlight of that evening was the premiere of the CPRIT's Innovation VI Conference Dinner video. Mark Loeffler and Justin Rand created the video on CPRIT's impact, dedicating many hours to interviewing, editing, and finalizing the production. The video kicked off the awards ceremony and set the perfect tone for the night.



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At the end of the evening, each of the award recipients made a point of telling me how much the award and CPRIT's impressive body of work has meant to them. Hearing their remarks about bipartisan commitment and collegiality reinforced the pledge CPRIT has made to adhere to the constitution, the statute and our rules and regulations; to document that adherence; and do so as transparently as possible. Their comments also serve to remind us that CPRIT is a unique agency in that the no one appointing officer can dictate CPRIT policy – only by working together can members set the program priorities and agency policy. This structure was no accident. It puts CPRIT's constitutional mission to fund innovative cancer prevention and treatments at the forefront and reduces disruptive political or personal agendas.

Several Oversight Committee members traveled to Galveston to attend the conference and network with CPRIT grantees. I appreciate your participation and hope the experience was worth your time and was as enjoyable as it was for me.

Many CPRIT employees worked behind the scenes for more than 18 months to design the program, secure the speakers, and to complete the unending administrative work necessary to pull off this incredible event. I would like to specifically recognize Heidi McConnell for leading the effort, as well as the IT staff, the CPRIT communications team, and our dedicated program staff.

We are also grateful for the support of two conference sponsors and nine exhibitors that helped to underwrite some of the conference expenses:

- Scorpius BioManufacturing—Day 1 Conference Lunch Sponsor
- NexPoint—Bag Insert Sponsor
- Agilent Technologies, Inc.—Exhibitor
- Bio-Techne--Exhibitor
- Collaborative Drug Discovery—Exhibitor
- H2Ocean®—Exhibitor
- Levitas Bio—Exhibitor
- Metabolon—Exhibitor
- MilliporeSigma—Exhibitor
- Shimadzu Scientific Instruments—Exhibitor
- The Greater Houston Partnership—Exhibitor

We hope to convene the next CPRIT Innovations Conference in 2025 and will provide an update at a future Oversight Committee meeting.

**Recent Milestones in the Fight Against Cancer**

CPRIT Grantees in the News

- The Greater Houston Women's Chamber of Commerce (GHWCC) recognized Jessica Duckworth as one of its "Breakthrough Women of 2023" at its GHWCC Annual Conference on May 19. Ms. Duckworth, Chief Operating Officer of The Rose and project director of multiple CPRIT awards, is responsible for managing all clinical and support staff, mobile operations, strategic business development, information systems, and new initiatives for The Rose. She is a distinguished leader in the breast imaging industry, as well as a recent breast cancer survivor. As a powerful force in the workplace, she uses her extensive knowledge of breast imaging, and her passion for work and community service, along with her own personal breast cancer journey, to help lead The Rose and support the organization's mission.

  CPRIT awarded The Rose eight CPRIT breast cancer screening and early detection grants since 2010 (PP100096, PP110154, PP120040, PP140171, PP150080, PP170091, PP190043, PP220015) totaling nearly $12 million.

- Invectys, Inc. announced on July 31 that the FDA granted Fast Track designation to IVS-3001, its CAR-T cell immunotherapy. IVS-3001 targets the rarely exploited immune checkpoint and tumor-specific antigen known as HLA-G. In cancer, tumors can use HLA-G to create a protective microenvironment, evading the immune system, and promoting tumor growth. The Fast Track designation to IVS-3001 follows compelling data from the company's Investigational New Drug Application (IND) submission, and recognizes the potential for IVS-3001 to address unmet need in patients with HLA-G positive locally advanced or metastatic clear cell renal cell carcinoma (RCC) who have failed or are intolerant to standard RCC therapies. Fast Track designation is a critical regulatory designation designed to expedite the development and review process for therapies that address unmet medical needs in serious conditions. Houston-based Invectys USA, Inc. received a $14.2 million CPRIT Product Development Research grant (DP200034) in May 2020.

- On August 2, The University of Texas MD Anderson Cancer Center announced that it selected CPRIT Scholar, Christopher Flowers, M.D., an internationally recognized physician-scientist and leader in oncology, as Division Head of Cancer Medicine after a competitive national search, effective September 1. The Division of Cancer Medicine is the largest academic division at MD Anderson, and includes 13 clinical academic departments, three research academic departments with more than 300 faculty and over 2,000 staff.

  MD Anderson recruited Dr. Flowers from Emory University School of Medicine to Texas with a $6 million CPRIT Established Investigator Award (RR190079) in 2019. He is a globally recognized leader in cancer outcome studies, cancer informatics, and early-stage clinical trials focusing on the development of novel therapeutics for B-cell lymphomas. His broader research interests include computer microsimulation models aimed at developing strategies to individualize care for cancer patients and improve systems of care. Dr. Flowers also mentors multiple CPRIT Scholars and grantees in translational cancer research.

- Texas Tech University Health Sciences Center announced August 3 that Yangzom D. Bhutia, D.V.M., Ph.D., an associate professor in the department of cell biology and biochemistry, leveraged research support from the initial CPRIT Texas Regional Excellence in Cancer (TREC) Awards issued in 2021 to secure a $1.76 million peer-reviewed 5-year grant from the National Cancer Institute to develop a unique drug target to treat pancreatic cancer. CPRIT awarded Texas Tech University Health Sciences Center a $6 million TREC grant in August 2021 (RP210154). The TREC award is a multicomponent award designed to strengthen cancer research through supporting investigator-initiated research projects, recruitment of new junior faculty, and research infrastructure at institutions located in regions of Texas that have historically received low levels of peer-reviewed cancer research funding.

- The Biden Cancer Moonshot announced August 3 the inaugural cohort of 11 Cancer Moonshot Scholars, including CPRIT Scholar Todd Aguilera, M.D., Ph.D. The Cancer Moonshot Scholars program, administered through the National Cancer Institute, launched last year to support early-stage cancer researchers, and to help build a cancer research workforce that better represents American diversity. This diverse set of scholars will drive progress in the fight to end cancer as we know it by pursuing projects at institutions across the country. These emerging leaders in cancer research and innovation will use this funding to help increase prevention and early detection efforts for patients from underrepresented populations, create new cancer treatments, and further the nation's expertise in addressing hard-to-treat cancer. The Administration intends to fund up to 30 additional Cancer Moonshot Scholars by 2025.

  Dr. Aquilera, an assistant professor in the department of radiation oncology at The University of Texas Southwestern Medical Center and the Simmons Comprehensive Cancer Center, is working to determine whether evaluating treatment response dynamics by integrating molecular, spatial, and cellular tumor profiles can reveal insights into the immune response, and inform therapy selection and the mechanisms of response to therapy. UT Southwestern recruited Dr. Aguilera from Stanford University to Texas with the help of a $2 million CPRIT First-Time, Tenure-Track Faculty Member Award Scholar Award (RR170051) in 2017.

- On August 7, the Community Crossroads TV station in Victoria featured the CPRIT-funded "Salud en Mis Manos" breast and cervical cancer screening and diagnostic testing program directed by Dr. Lara Savas, associate professor at The University of Texas Health Science Center at Houston School of Public Health. Senior Program Manager Emily Adlparvar, M.P.H., discussed breast health, mammography, and the collaboration with The Rose of Houston to provide mammograms and breast health education to uninsured and medically underserved women in Victoria.

  CPRIT awarded UTHealth Houston four grants totaling $6.5 million (PP110081, PP160047, PP190061, PP230038) to establish and expand the Salud en Mis Manos program since 2011.

- The Association of American Cancer Institutes announced on August 8 that Amelie Ramirez, DrPH, M.P.H., leader of Salud America! at The University of Texas Health Science Center at San Antonio, has won the 2023 Cancer Health Equity Award. The award recognizes exceptional leadership in promoting health equity, mitigating cancer disparities, and advocating for diversity and inclusion at a cancer center. Dr. Ramirez conducts research and interventions to reduce Latino cancer disparities. She aims to reduce lung cancer with Quitxt, a bilingual text-message service funded by CPRIT that helps Latino young adults quit smoking. She currently directs Salud America! national multimedia program to empower its vast network of over 500,000 community and school leaders to drive healthy policy and system changes to promote health equity and support for Latino families. CPRIT has awarded UTHealth San Antonio and Dr. Ramirez three CPRIT Prevention grants (PP140176, PP170099, PP180092) in 2014, 2017, and 2018, totaling $4.2 million.

- On August 10 Molecular Templates, Inc. announced key milestones for 2023. The Austin-based company reported accelerating enrollment across all clinical programs, initiation of first-in-human Phase I study for MT-8421 in the third quarter of 2023, resuming MT-0169 screening and enrollment following the FDA's removal of partial clinical hold on patient enrollment, and advancing the Bristol Myers Squibb research collaboration across multiple targets. Molecular Templates received two CPRIT Product Development Research grants (CC121020, DP160071) in 2011 and 2016 totaling $25.8 million to advance MT-3724 into human clinical testing and to move MT-4019ND through clinical studies in patients with refractory multiple myeloma.

- The *Baytown Sun* newspaper featured "All for Them," a CPRIT-funded school-based HPV vaccination project led by Dr. Paula Cuccaro, assistant professor of Health Promotion and Behavioral Sciences at The University of Texas Health Science Center Houston's School of Public Health, on August 10. The All For Them initiative provides free vaccination clinics at middle and high schools in six public school districts: Aldine ISD, Crowley ISD, Fort Worth ISD, Goose Creek CISD, Houston ISD and Spring ISD. The clinics in medically underserved schools offer all childhood and adolescent vaccines — including the HPV vaccine, which protects against six types of cancer.

  CPRIT has awarded UTHealth Houston three prevention awards totaling nearly $4 million since 2017 (PP170046, PP20017, PP230033) to establish and expand the All For Them comprehensive school-based approach to increase HPV vaccination through public schools.

- Rice University announced August 10 that associate research professor of chemistry Carolyn Nichol, Ph.D., received a competitive Science Education Partnership Award (SEPA) from the National Institutes of Health to address race-based cancer health disparities by increasing underrepresented minority student populations' engagement and participation in biosciences education. This new program should improve the participation of underrepresented students in cancer research.

  The 5-year, $1.04 million SEPA award will support Nichol's Cancer Health Activism Network for Greater Equity (CHANGE) project in bringing together cutting-edge cancer

research with insight on race-based health care disparities from the social sciences in a series of transformative high school biology lessons aligned with both state and national standards. "Our goal is to affect students' interest in bioscience careers and studies by working with their teachers," Dr. Nichol explained. "We're recruiting high school biology teachers to do research in university labs on projects led by leading cancer research faculty at Rice and Texas Southern University who are CPRIT Scholars."

- Medicenna Therapeutics, Inc. announced two key hires in August, appointing Brent Meadows as its Chief Business Officer on August 14 and Jeff Caravella as Chief Financial Officer on August 28. Mr. Meadows brings over 25 years of business development, commercial strategy and marketing experience at large pharma and biotech companies, including Johnson & Johnson, Bristol-Myers Squibb, Shire/Baxalta, and Regeneron. He will be responsible for leadership of Medicenna's business development and corporate strategy, including structuring, negotiating and executing key alliances and partnerships with Medicenna's Phase 3 ready glioblastoma asset, bizaxofusp, and its pipeline of clinical and pre-clinical Superkines. Mr. Caravella will lead Medicenna's financial strategy to support the company's growth as Medicenna initiates a Phase 2 study with MDNA11 and expands its executive team. CPRIT awarded a $14.1 million New Company Product Development Award grant (DP150031) in 2015 to Houston and Toronto-based Medicenna to conduct two clinical trials for glioblastoma multiforme patients to test bizaxofusp's (formerly MDNA55) safety, effectiveness, and dosage.

- On August 16, The University of Texas Southwestern Medical Center announced that CPRIT Scholar, Qing Zhang, Ph.D., associate professor of pathology, is the recipient of the 2024 American Society for Investigative Pathology Outstanding Investigator Award. The recognition honors midcareer investigators who have demonstrated excellence in experimental pathology research. Dr. Zhang is also the Chief Scientific Officer for the Breast Cancer Research Program at the Simmons Comprehensive Cancer Center.

  UT Southwestern recruited Dr. Zhang from the University of North Carolina Lineberger Comprehensive Cancer Center to Texas with the help of a $4 million CPRIT Recruitment of Rising Stars Scholar Award (RR190058) in 2019. Dr. Zhang studies how cancer cells sense low oxygen tension, and adapt to the harsh living environment in oxygen-deprived conditions, which makes them more aggressive and more resistant to radiation or chemotherapy, especially in breast and kidney cancer patients. Dr. Zhang and his team have pioneered proteomic and genomic approaches to identify new signaling molecules in oxygen-sensing signaling pathways, which have yielded potential therapeutic targets in cancer.

- On August 17, The University of Texas MD Anderson Cancer Center honored faculty members with the institution's most prestigious endowed faculty awards. Jennifer Wargo, M.D., professor, department of surgical oncology and director of the Platform for Innovative Microbiome and Translational Research, received The Jack and Beverly Randall Prize for Excellence in Cancer Research, established in 2011 to encourage innovative ideas and the novel thinking necessary to end cancer. Han Liang, Ph.D., professor and Deputy Department Chair, Bioinformatics and Computational Biology, was one of two awardees of the R. Lee

Clark Prize, which recognizes MD Anderson faculty in clinical research and basic/translational research. The prize honors the dedication to scholarship, service and social responsibility embraced by the late R. Lee Clark, M.D., MD Anderson's first President. Both Dr. Wargo and Dr. Liang have been principal investigators in CPRIT Academic Research grants (RP200574 and RP140462).

- Merck reported on August 18 that a drug acquired from Dallas-based Peloton Therapeutics in 2019 helped delay disease progression in patients with advanced renal cell carcinoma. Merck said a pre-planned, interim analysis found the drug, Welireg, to be significantly better than another kidney cancer therapy, everolimus, on the trial's main goal of preventing disease progression. The study enrolled 740 adults with advanced renal cell carcinoma that had progressed after treatment with two specific kinds of targeted cancer therapy. According to Merck, analysis of the report findings indicates that a statistically significant percentage of patients responded in some way to Welireg. Peloton received a $3.2 million CPRIT Company Recruitment grant (R1009) in 2010 to develop Welireg.

- The August 31 edition of the *Daily Texan* highlighted Drs. Navkiran Shokar and Mike Pignone of The University of Texas at Austin Dell Medical School and the $3 million CPRIT grant for the first Colorectal Cancer Screening Coordinating Center (PP230060).

  The five-year grant will provide funds to spearhead the Coordinating Center for Colorectal Cancer Screening Across Texas (CONNECT), which aims to mitigate health disparities and increase the number of Texans screened for colorectal cancer. "That's why it's called CONNECT," Shokar said. "The vision behind it is truly to connect to anyone that's in the pathway for screening, including the people that are receiving screening."

  CPRIT awarded UT Austin and Dr. Pignone $4.5 million since 2017 (PP170082, PP200066, PP210045) to create and disseminate Dr. Pignone's mailed stool testing program for colorectal cancer prevention in underserved communities in Texas. CPRIT awarded Texas Tech University Health Sciences Center El Paso three prevention awards totaling over $10 million since 2011 (PP110156, PP140164, PP170068, PP210005) to establish and expand colorectal cancer screening and diagnostic testing during Dr. Shokar's tenure at Texas Tech University HSC El Paso.

- OncoNano announced September 6 a clinical trial supply agreement with Regeneron for the use of Libtayo (cemiplimab), a PD-1 inhibitor, in the combination stage of the first human trial of OncoNano's ONM-501, a dual-activating STING (STimulator of INterferon Genes) agonist and lead therapeutic development candidate. The ONM-501 first-in-human trial is a multicenter Phase 1a/b dose escalation and dose expansion study of intratumoral ONM-501 as monotherapy and in combination with Libtayo in patients with advanced solid tumors and lymphomas.

  The Southlake-based company is developing a new class of products that exploit pH as a biomarker to diagnose and treat cancer. CPRIT awarded OncoNano three product development grants (DP140072, DP190066, DP200081) since 2014.

- Perimeter Medical Imaging AI Inc. updated stakeholders on September 7 regarding the clinical development of its ongoing clinical trial evaluating the use of Perimeter B-Series OCT combined with its proprietary ImgAssist AI software during breast conservation surgery. Based on feedback from the U.S. Food and Drug Administration ("FDA"), the Company has reached alignment on key elements of the ongoing clinical trial, including the introduction of an interim analysis, which the company expects in the second quarter of 2024. Perimeter also announced the appointment of veteran MedTech sales executive Adam Hodges as vice president, sales and marketing. Mr. Hodges brings more than 20 years of commercialization experience in the medical device industry to his new post. Most recently, he was vice president of sales at SIA Health, leading the commercial acceleration of DuraSorb, which Integra LifeSciences acquired in December 2022.

  The Houston and Toronto based commercial-stage technology company received a $7.5 million CPRIT product development grant (DP190087) in 2019, to develop ultra-high-resolution, real-time, advanced imaging tools for cancer surgery.

- The American Chemical Society announced September 7 that it will recognize CPRIT Scholar John L. Wood, Ph.D., with the Ernest Guenther Award in the Chemistry of Natural Products. Dr. Wood, the Robert A. Welch Distinguished Professor of Chemistry, chair of the department of chemistry and biochemistry, and co-director of the Baylor University Synthesis and Drug-Lead Discovery Lab, will be honored at the awards ceremony in April 2024 in conjunction with the Society's spring meeting in New Orleans.

  The prestigious award recognizes Dr. Wood's outstanding achievements in the analysis, structure elucidation and chemical synthesis of natural products that have medicinal properties. Dr. Wood and fellow chemist Daniel S. Romo, Ph.D., co-direct the Baylor Synthesis and Drug-Lead Discovery Laboratory, which focuses on the development and application of chemo- and site-selective methods for the derivatization of biologically and pharmacologically important natural products and other bioactive small molecules. Since derivatization for structure-activity relationship (SAR) studies and reaction optimization play fundamental roles in drug discovery, the laboratory's high-throughput capabilities drive collaboration and discovery among an interdisciplinary group of researchers extending beyond Baylor to both the national and international levels.

  Baylor University recruited Dr. Wood to Texas from Colorado State University in 2013 with a $4.3 million CPRIT Recruitment of Established Investigator grant (R1309.) He has received numerous honors and awards throughout his career, including a Fellowship in the Royal Society of Chemistry, Honorary Member of the Sociedad Argentina de Inestigacion en Quimica Organica, and the American Chemical Society Arthur C. Cope Scholar Award.

- Rice University President Reginald DesRoches and Texas Medical Center President and CEO Bill McKeon joined other university leaders at a ceremony on September 12 at Rice's Bioscience Research Collaborative. The event simultaneously kicked off the Rice Biotech Launch Pad - the first in a series of 'moonshot' programs that Rice will unveil in 2023 - and

celebrated the 61st anniversary of President John F. Kennedy's 1962 speech at Rice Stadium announcing what became the Apollo program.

The Biotech Launch Pad is a medical innovation and commercialization initiative focused on slashing the time it takes to translate Rice-discovered technologies into medical treatments that significantly impact people's lives. Federal grants and philanthropic gifts will support the accelerator, which will include about 15,000 square feet of space for Rice health and medical technology startup companies. CPRIT Scholar Omid Veiseh, Ph.D., an associate professor of bioengineering at Rice will serve as the Rice Biotech Launch Pad Director. He explained, "We're going to measure this accelerator's success not based on the number of spinouts that we have, but in terms of the impact that we can make on patients' lives. We're going to measure it based on clinical trials launched through discoveries made here at Rice."

Rice recruited Dr. Veiseh to Texas from the Massachusetts Institute of Technology with a $2 million First-Time, Tenure-Track Faculty Member award (RR160047) in 2016. The Veiseh laboratory utilizes multi-scaled (nano, micro, and macro) fabrication techniques, combined with molecular engineering and cellular and molecular biology, to develop functional platforms of implantable devices tailored for applications in oncology, immunology, regenerative medicine, and disease monitoring. Avenge Bio, a company Veiseh co-founded with biotech entrepreneur and executive Paul Wotton, began a clinical trial for recurrent ovarian cancer in 2022 using a cell-based immunotherapy platform releasing the IL2 cytokine developed from technology discovered in Dr. Veiseh's lab only four years earlier.

- The Joe R. and Teresa Lozano Long School of Medicine at The University of Texas Health Science Center at San Antonio and the University College at The University of Texas at San Antonio announced September 14 the launch of the first known program in the U.S. to combine medicine and artificial intelligence. A Doctor of Medicine (M.D.) from UT Health San Antonio and a Master of Science in Artificial Intelligence (MSAI) from UT San Antonio will form a five-year M.D./M.S. program enabling physicians to lead in the practical use of artificial intelligence to improve diagnostic and treatment outcomes. The UT San Antonio MSAI is a multidisciplinary degree program with three tracks: data analytics, computer science, and intelligent and autonomous systems.

  Ambika Mathur, dean of The UTSA Graduate School, and CPRIT grantee, Robert R. Hromas, M.D., dean of UT Health San Antonio's Long School of Medicine spearheaded this first-of-its-kind M.D./M.S. program, which has been several years in the making. Researchers and clinicians already use AI in multiple areas in medicine, including customizing patient treatment plans, robotic surgeries, image analysis in screening for cancer, and drug dosing. UT Health San Antonio and UT San Antonio have several research programs underway to improve health care diagnostics and treatment with the help of AI.

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

- **SQUID Untangles the Complexity of Tumors.** As reported in the August 1 issue of *Genome Biology*, CPRIT-supported researchers at Baylor College of Medicine and the Dan

L. Duncan Comprehensive Cancer Center report a breakthrough that could change the way clinicians understand and treat tumors.

Scientists have long known that tumors are composed of cancer cells and other non-malignant cells that may influence tumor growth and response to therapies. Researchers commonly analyze the RNA (or DNA) of tumors in bulk, with the results yielding an average of the RNAs present in all these cells. Profiling the tumor this way is essentially blind to the chemoresistant component, making it hard to pinpoint and treat the resistant cells effectively. The team led by Pavel Sumazin, Ph.D., assistant professor of pediatrics, with contributions by Tsz-Kwong Man, Ph.D., aimed to make a method known as single-cell RNA sequencing (scRNA-seq), which can look at individual cells, more accessible and affordable for doctors and patients.

Dr. Sumazin's team introduced a new technique called Single-cell RNA Quantity Informed Deconvolution (or SQUID). SQUID is an innovative computational tool that further analyzes regular RNA test results, revealing if chemoresistant cells are present in the tumor sample, and to the chemotherapies they are likely to be sensitive. Clinicians receive a clearer picture of a tumor's make-up and can target both the easy-to-treat cells and the chemoresistant ones, potentially improving the outcome for patients.

In the future, a physician could run a standard bulk RNA test on a tumor, which costs approximately $100, and then use SQUID to gain additional insights typically only available from more expensive tests. Dr. Sumazin plans future studies that will extend SQUID use for other conditions beyond cancer.

CPRIT awarded Dr. Sumazin an individual investigator research grants for childhood and adolescent cancer in 2023 (RP230120), and multi-investigator research award funding as investigator for Project 1 (RP180674) totaling $1.37 million. Dr. Man is the recipient of an individual investigator research award in computational biology (RP200135).

- **CPRIT Scholars Team-Up to Solve the Molecular Structure of Immune Response Proteins.** CPRIT Scholars at The University of Texas Health Science Center at San Antonio and the Mays Cancer Center have teamed up to use leading-edge cryogenic-Electron Microscopy technologies to explain the structures of human proteins involved in the innate immune response to pathogens. As published online on August 8 in *Nature Communications*, the team led by Shaun K. Olsen, Ph.D., an associate professor in the department of biochemistry and structural biology, report seminal new data that may inform the development of novel therapies for a variety of disease, including cancer.

  The human body increases production of a protein, ISG15, when exposed to pathogens like viruses or bacteria. ISG15 acts like an alarm system, helping to kick-start the cells' defenses against invaders. It works with other proteins through processes that involve adding or removing small "tags" (like the ISG15 protein itself) to other proteins. This tagging process is critical for many cell functions. Because proteins like ISG15 often dysregulate in cancer, researchers often use them as therapeutic targets.

Despite its biological importance, scientists do not understand one part of this process - how a protein called Uba7 helps activate ISG15 and passes it to another protein, UBE2L6. There was no detailed picture or model of how Uba7 works at the tiniest molecular level. But Dr. Olsen's research team, using advanced imaging tools at the Cryo-EM Facility and other institutional structural biology shared resources, captured these details, seeing for the first time how Uba7 interacts with ISG15 and UBE2L6.

With this new understanding, researchers have clearer insights into how these proteins work together in cells, and how their functions dysregulate in diseases like cancer. With this new "picture" of Uba7 and its partners, scientists may design drugs that fix these problems, helping to restore a healthy immune response.

In addition to Dr. Olsen (RR200030, Recruitment of Rising Star, $4 million), CPRIT Scholars Dr. Patrick Sung (RR180029, Recruitment of Established Investigator, $6 million) and Dr. Elizabeth Wasmuth (RR220068, Recruitment of First-Time, Tenure-Track Faculty, $2 million) contributed to this study.

- Plus Therapeutics, Inc. reported positive data from the ReSPECT-LM clinical study evaluating the company's lead radiotherapeutic, rhenium (186Re) obisbemeda, for the treatment of leptomeningeal metastases at the Society for Neuro Oncology/American Society of Clinical Oncology Central Nervous System Cancer Conference held in San Francisco August 10 - 12. Researchers did not observe any dose limiting toxicities and did not reach a maximum tolerated dose or maximum feasible dose. Most adverse events were mild (Grade 1, 58.7%) or moderate (Grade 2, 24%), with the majority not related to treatment. Currently, 5 of the 10 treated patients remain alive with a median overall survival of ten months. The FDA approved continued dose escalation.

  CPRIT awarded Austin-based Plus Therapeutics a three-year $17.6 million product development grant (DP220039) August 2022 to fund ReSPECT-LM study. The FDA previously granted Fast Track designation to rhenium (186Re) obisbemeda for the treatment of leptomeningeal metastases.

- **How do Cancers Release the "Molecular Brakes" that Prevent Mutagenesis to Drive Therapy Resistance?** Pivotal new data published in the August 14 issue of *Cancer Cell* from a team of CPRIT-supported investigators led by Ping Mu, Ph.D., provides insights on the process that drives tumor resistance to targeted therapy. Dr. Mu, a CPRIT Scholar, is an assistant professor of molecular biology at The University of Texas Southwestern Medical Center, a member of the Simmons Comprehensive Cancer Center, and a Deborah and W.A. "Tex" Moncrief, Jr. Scholar in Medical Research.

  Cancer researchers have long known that tumor cells can hijack the cellular machinery that maintains integrity of the genome, fostering genomic instability. One such example involves the APOBEC proteins – enzymes that edit messenger RNA or DNA by removing an amino group from cytidine nucleotides that converts them to uridine or thymidine. Scientists

observe an increased mutation pattern of APOBEC-driven mutagenesis across more than 70% of all human cancers. However, the mechanism underlying how tumor cells use the APOBEC-related process to change and adapt, allowing them to resist treatments cancer cells remains largely unknown.

To address this question, Dr. Mu and his colleagues studied prostate cancer cells before and after a common treatment, trying to spot any genetic changes. They found that a gene called SYNCRIP was missing in many of the tumors after treatment. This gene seems to control the APOBEC process, acting as a molecular brake that stops it from causing mutations. Without it, APOBEC can go out of control, causing mutations that help the tumor resist treatment. The team identified several key genes affected by this dysregulated APOBEC process. These drivers for androgen receptor (AR)-targeted therapy resistance in prostate cancer include: BRD7, CBX8, EP300, FOXA1, HDAC5, HSF4, STAT3, and AR.

Collectively, these findings uncovered a cell-intrinsic mechanism that explains how tumors develop numerous mutations so rapidly, and why the mutation pattern varies for different patients with the same cancer types. Moreover, the results raise the possibility that researchers may be able to develop treatments restoring SYNCRIP function, or inhibiting APOBEC proteins to prevent resistance-driving mutations before they develop.

CPRIT Individual Investigator Research Awards totaling $2.9 million to Dr. Mu (RP220473), Tao Wang, Ph.D. (RP190208), and CPRIT Scholar Joshua Mendell, M.D., Ph.D. (RP220309) supported this work. In addition, UT Southwestern recruited Dr. Mu (RR170050) and Bo Li, Ph.D. (RR170079) to Texas with $2 million CPRIT First-Time, Tenure-Track Faculty Member awards. Dr. Mendell received a $4.5 million CPRIT Recruitment of Rising Stars award (R1008) in 2010.

- **CPRIT Researchers Leverage Decades of Advances in Proteomic Sciences to Dissect Tumors.** In the August 14 issue of *Cancer Cell*, the National Cancer Institute released a comprehensive dataset, generated by the Clinical Proteomic Tumor Analysis Consortium (CPTAC), that standardizes genomic, proteomic, imaging, and clinical data from individual studies of more than 1,000 tumors across 10 cancer types. Researchers from around the world will be able to use this publicly available resource to uncover new molecular insights into how cancers develop and progress.

  As reported in the September 11 issue of *Cancer Cell*, CPRIT Scholar, Bing Zhang, Ph.D., co-led an integrated proteogenomic analysis of endometrial carcinoma (EC) identifying new druggable pathways demonstrating the CPTAC dataset's potential as a valuable resource for scientific discovery. EC is the most common gynecologic malignancy in developed nations, with the incidence of EC steadily increasing over the past decade (~1% annually). Unusually, EC-specific mortality has steadily worsened over this interval, attributed to the increasing incidence of aggressive EC histological subtypes, particularly among Black and Hispanic women.

Through four key findings, Dr. Zhang and his colleagues demonstrated the ability of proteogenomic analysis to increase our understanding of EC tumor biology, and identified molecular and imaging markers that researchers should further investigate to guide patient stratification for more precise treatment of EC. The team:

- Developed a targeted assay to precisely measure the concentration of two protein peptides. These proteins help the immune system recognize and attack harmful cells. Appreciating the levels of these proteins may help clinicians decide if a patient will benefit from immunotherapy.
- Determined that a diabetes drug, metformin, may help treat a certain kind of cancer in patients who have a high level of a protein called MYC, even if they do not have diabetes.
- Linked another common mutation in EC – in-frame insertions or deletions within *PIK3R1* - with a spike in AKT activity, a protein often found in cancer. Knowing this may mean that clinicians can treat patients with these cancers with AKT-blocking drugs.
- Observed that computer deep learning accurately predicts EC subtypes and mutations from histopathology images, which may be useful for rapid diagnosis.

Baylor College of Medicine recruited Dr. Zhang to Texas from Vanderbilt University School of Medicine with a $4 million CPRIT Rising Star Scholar Award (RR160027) in 2016.

- **Breaching the Blood-Brain Barrier to Battle Brain Tumors.** Glioblastoma multiforme (GBM) is a particularly aggressive type of brain tumor that has proven challenging to treat, mainly because of difficulties in effectively delivering drugs across a protective barrier in the brain known as the blood-brain-tumor barrier (BBTB). Current strategies to breach this barrier have limited success due to complications, potential toxicity, and inability to precisely target specific regions within the tumor.

  As reported in the August 15 edition of *Nature Communications*, a team of multiple CPRIT-funded investigators has introduced an innovative approach to treat GBM. The team, with lead researchers from The University of Texas at Dallas and The University of Texas Southwestern Medical Center, found that GBM tumors have varied levels of protection by the BBTB. Using a technique that involves laser activation of specialized nanoparticles, they were able to open this barrier temporarily and selectively. By doing so, they improved the delivery of a chemotherapy drug, paclitaxel that researchers previously abandoned for GBM treatment because it did not effectively reach the tumor due to the BBTB. This method not only allowed paclitaxel to better target the tumor but also reduced tumor size significantly and extended the lifespan of the test models.

  This breakthrough suggests that by using such techniques to enhance drug delivery across the BBTB, many potent anti-cancer drugs that researchers previously deemed ineffective for treating brain tumors like GBM could be re-evaluated and repurposed. This could pave the way for more effective treatments for these aggressive tumors in the future.

A CPRIT Individual Investigator grant (RP190278, $900,000) and a CPRIT High Impact/High Risk grant (RP210236, $250,000) to UT Dallas and Dr. Zhenpeng Qin supported this research. Additionally, researchers used magnetic resonance imaging at the CPRIT-funded Small Animal Imaging Core Facility for Cancer Research at UT Dallas (RP180670, $3.6 million.) Two CPRIT Individual Investigator Research Awards (RP180634, $1.2 million; RP110041, $941,314), including one focused on cancers in children, supported Dr. Robert Bachoo's work on brain tumors. Dr. Elizabeth Maher previously received a CPRIT Individual Investigator Research Award focusing on pediatric brain tumors (RP130629, $1 million).

- **A New Look at Epigenetic Therapies Reveals an Unexpected Mode of Action.** As reported in the September 6 issue of *Frontiers of Oncology*, CPRIT-supported researchers are diving deep into how certain proteins, known as Histone deacetylases (HDACs), affect our cells and can contribute to cancer. These proteins control the activity of our genes, and when they act abnormally, they can help cancer grow. Scientists developed drugs, called HDAC inhibitors, to target these problematic proteins. However, they found out that these drugs not only work on the cancer cells but also affect our immune system, which plays a key role in fighting off cancer. The critical question was how these drugs interact with a specific part of our immune system, the T cells, especially when combined with other cancer treatments.

  To address this question, a team of researchers led by Dr. Todd A. Triplett, an affiliate faculty member in the department of oncology at The University of Texas at Austin, Livestrong Cancer Institutes, and CPRIT Scholar Gail Eckhardt, M.D., formerly at UT Austin, and currently the Albert Margaret Alkek Foundation Endowed Chair and associate director for translational research at the Dan L. Duncan Comprehensive Cancer Center at Baylor College of Medicine, studied how a new HDAC inhibitor drug, OKI-179, affected patients' T cells. They observed a temporary boost in the numbers of these immune cells after patients took the drug. But this effect was short-lived, lasting less than a day.

  The research team then combined OKI-179 with anti-PD1 immunotherapy. They found that pausing the HDAC inhibitor treatment while giving the immunotherapy was more effective than giving them both continuously. This suggests that using these drugs effectively in combination can prime the body's defenses to better fight off cancer.

  The University of Texas at Austin recruited Dr. Eckhardt to Texas from the University of Colorado with support from a $6 million CPRIT Established Investigator Scholar Award (RR160093) in 2016.

- **CPRIT TREC Awardees Identify Culturally Sensitive Interventions to Improve Uptake of Cancer Prevention Approaches.** Human papillomavirus (HPV) causes 44,000 cases of cancer every year, including cervical and throat cancers. The HPV vaccine, recommended for people aged 9-45, can prevent 7 of the 13 oncogenic types that cause 90% of HPV-associated cancers. Cervical cancer rates are significantly higher in Hispanics than all other ethnicities. In El Paso, which is mainly Hispanic and a Medically Underserved Area, the cervical cancer rate is higher than both the Texas state average and the national average.

Dr. Eva Moya, professor in the department of social work at The University of Texas at El Paso, led a study to understand why HPV vaccine rates might be lower in heavily Hispanic areas, using El Paso as a case study. The research involved an online survey answered by adults living in El Paso to delve into the factors affecting their decision to get the vaccine.

Most participants in the study were Hispanic and female. The results showed that several factors influenced whether someone would get the HPV vaccine. Circumstances like household size, primary language, community involvement, level of trust in the government, and beliefs about health and sickness all played a role. More specifically, where participants got their information about HPV and how safe they believed the vaccine to be also determined if they would get vaccinated.

Dr. Moya's findings, reported in the September 14 of *BMC Public Health*, highlight the importance of creating trusted health campaigns and interventions tailored to the specific beliefs and needs of the Hispanic community. By understanding what influences vaccine decisions, health professionals can design better strategies to encourage more people in underrepresented communities to get vaccinated against HPV.

The $5.9 million CPRIT Texas Regional Excellence in Cancer (TREC) grant awarded to UT El Paso in 2021 (RP210153) supported this research. The TREC award supports the development of cancer research programs, including bringing experienced investigators into cancer research, faculty recruitment, and advanced technology for cancer research.

- **In Nanomedicine, Older may be Better!** Nanomedicines, or drugs carried by tiny particles, have shown promise in treating various diseases, including cancer. Some of these drugs have proven more effective and less toxic than their traditional counterparts. For instance, clinicians have effectively used a drug called nanoparticle-albumin-bound paclitaxel (nab-paclitaxel) for certain hard-to-treat cancers since 2005. However, despite these successes, the medical community has been slow to embrace such treatments, largely due to concerns about how the liver processes these tiny drug carriers - a mechanism not yet fully understood. A research team led by CPRIT Scholar Wen Jiang, M.D., Ph.D., associate professor of radiation oncology at The University of Texas MD Anderson Cancer Center, have recently discovered that younger patients might respond less effectively to such treatments, highlighting the need for further investigation into the impact of aging on the body’s ability to respond to the treatment.

  As reported in the September 18 issue of *Nature Nanotechnology*, Dr. Jiang's team conducted experiments on mice of varying ages and found that nanomedicines were more effective in older mice than in younger ones. The reason seems to lie in the liver's efficiency: younger livers are better at filtering the bloodstream. While this is usually beneficial because it helps keep toxins out of the blood, it also means that young livers filter out beneficial treatments, like nanomedicines, more efficiently - potentially making them less effective in younger patients.

A key player in this process is a protein known as MARCO, found in macrophages - cells responsible for filtering out foreign substances, including nanoparticles. As creatures age, the number of liver macrophages that express this protein decreases. This is important because MARCO helps with the uptake of nanoparticles. When researchers blocked MARCO in young mice, the nanomedicines became more effective. This discovery highlights the significance of age in determining the effectiveness of certain treatments and underscores the need for treatments tailored to patients' unique physiological profiles, such as age.

A CPRIT Scholar award to Dr. Jiang (RR180017) supported this research.

**Personnel**

CPRIT has filled 44 full-time equivalent positions and has several positions in progress, including an accountant position and a grant compliance specialist position.

- Two part-time grant compliance specialists joined CPRIT on August 4. Debbie Mitchell has years of experience in auditing and accounting of state and local government. She has worked at CPRIT as a contract employee in compliance since 2020. Martin Rivera has a background in auditing with the state of Texas. He began working at CPRIT as a contract employee in compliance earlier this year.

- Michael Bedford joined CPRIT on September 1 as an IT support specialist. Mr. Bedford has worked at CPRIT as a contract employee in IT since January 2022.

- Amaka Nwachukwu started working at CPRIT in December 2021 as an agency Accountant. Effective September 1, she will now serve as a grant compliance specialist.

**Advanced Research Projects Agency for Health (ARPA-H) Names Texas as the National Headquarters for its Customer Experience Hub**

On September 26 ARPA-H announced that it will headquarter its highly anticipated Customer Experience Hub at Pegasus Park in Dallas. The Customer Experience Hub will drive user testing, adoption, access, and trust of ARPA-H's projects, taking a "human-centered" approach to design products and services that people need and want. It will facilitate and enhance clinical trials, reach representative patient populations, and capture outcomes data for future research. Austin, San Antonio, and Houston will also play a significant role in supporting the Texas hub activities.

Landing one of ARPA-H's three national headquarters in Texas is a major coup for the state. Winning this ARPA-H competition validates Texas' position as a leading bioscience center in America. It is the culmination of a two-year effort by the Coalition for Health Advancement and Research in Texas (CHART) to have a Texas presence for ARPA-H. CPRIT staff, specifically, Deputy Executive Officer and General Counsel Kristen Doyle, Chief Strategic Initiatives and

Intellectual Property Officer Tracey Davies, and I sparked the organization of CHART and were three of the original five members of CHART. Personally, I consider my involvement in this effort as one of the most significant accomplishments of my nearly 50 year career.

In addition to the Customer Service Hub in Texas, ARPA-H also named Boston, Massachusetts, as the Investor Catalyst Hub, and Washington, D.C. as the Stakeholder Engagement (administration) Hub. ARPA-H will use the three locations in a "hub-and-spoke" strategy, forming a health network across the country to advance the agency's mission. Each hub will sustain a network of "spokes" (partners) to support ARPA-H's needs. The sites will form a center for key ARPA-H functions, but with a "light" footprint, housing a small number of ARPA-H team members and meeting facilities, alongside key personnel to support agency objectives. Individual projects will then leverage program-relevant assets - the spokes - throughout the country from the hubs.

The Customer Experience Hub and Investor Catalyst Hub locations were determined by open, nationwide solicitation. The formal selection process began in late March, with responses to the solicitation due April 21. Dallas and Houston submitted separate proposals for the Customer Experience Hub. ARPA-H announced the preliminary selections in May, with in-person pitch days running from late May through June 26. The full proposal submission deadline was July 7. ARPA-H elected to proceed with Dallas after this stage, and Houston joined the Dallas consortium, which also included Austin, San Antonio, Tyler, Lubbock and El Paso, with some 600 additional spokes around the country. It is my understanding that while many other cities submitted proposals to host the Customer Service Hub, the only other finalist was the Research Triangle in North Carolina.

We are thrilled with this news and look forward to working with ARPA-H as appropriate. CPRIT's impact on ARPA-H's first projects is already evident. On the same day that it announced that Texas will be the Customer Experience Hub, ARPA-H also awarded a $45 million cooperative agreement to a Rice University-led team of researchers from seven states to fast-track the development of new sense-and-respond cancer implant technology. CPRIT Scholar Omid Veiseh, a Rice bioengineer, serves as the principal investigator on the massive project to develop and test a new approach to cancer treatment that will dramatically improve immunotherapy outcomes for patients with ovarian, pancreatic and other difficult-to-treat cancers.

**CPRIT Outreach**

Staff outreach activities during August and September include:

- On August 2, Deputy Executive Officer and General Counsel Kristen Doyle, Chief Operating Officer Heidi McConnell, and I met with several cancer advocacy representatives to discuss CPRIT activities and possible future legislative support for CPRIT 3.0.

- Academic Research Program Manager Dr. Myriam Casillas attended a virtual NCI webinar held August 4 on "Research Priorities: Leveraging Health Information Technology to Address Cancer Prevention Disparities in Primary Care."

- Ms. Doyle, Ms. McConnell, and I met with Jorge Varela, a Dallas-based biotech consultant, on August 7 to discuss Nexpoint, a possible new biotech park and company incubator in the Metroplex.

- On August 17 and September 7, Senior Product Development Program Manager Dr. Abria Magee, Ms. Doyle, and I met by videoconference with staff of the Texas-Israel Alliance to discuss CPRIT's participation in their BridgeStar Summit. This summit will bring together representatives from Israel, several Middle East Arab nations, The University of Texas MD Anderson Cancer Center and federal agencies to discuss opportunities for collaboration. Dr. Magee and I will attend the summit, held January 15-19, 2024.

- Dr. Casillas attended a virtual NCI webinar held September 4 on "Exploring the Future of Cancer Immunotherapy."

- Dr. Casillas attended a virtual President's Cancer Panel meeting held September 7.

- Dr. Magee met with Abel Negussie of the independent investment firm Yosemite, a spin off from the Emerson Collective, on September 7. Yosemite focuses on opportunities across the oncology ecosystem, with grantmaking and venture investing as a catalyst for scientific breakthroughs to become viable cancer patient solutions. They discussed potential collaborations, including recruiting peer reviewers.

- Prevention Program Manager Carlton Allen presented a feedback session focused on Goal 5 of Texas Cancer Plan at the Texas HPV Coalition annual meeting on September 6-8 in San Antonio. This presentation outlined the current goal regarding HPV vaccination, reviewed recent data regarding how Texas has improved the vaccination rate, and solicited feedback on strategies to increase the rate and whether objectives were still relevant for the current plan.

- Product Development Program Manager Dr. Michelle Leeuwon attended the International Society for Cell & Gene Therapy North America 2023 Conference held September 8 in Houston and participated in a panel discussion titled "Lab to Market: Collaborative Strategies for Faster Patient Access." Dr. Leeuwon provided an overview of CPRIT's role and funding strategies to accelerate the pace of research and foster an environment of innovation that attracts top-tier talent.

- Dr. Casillas attended a virtual HPV Roundtable webinar held September 12 on "HPV Vaccination: Preventing Oropharyngeal Cancers."

- Ms. Doyle, Dr. Magee, Dr. Leeuwon and I attended the Texas Medical Center's Accelerator for Cancer Therapeutics (ACT) Research Summit on September 14 in Houston to meet with companies and discuss future opportunities for continued research and development. The ACT program, supported by a $5.4 million CPRIT core facilities grant, provides a competitively selected cohort of Texas researchers and startup companies with integrated biotech entrepreneurship training, resources, and mentoring over a nine-month period to help advance innovative cancer therapy discoveries into clinical trials. Many CPRIT grantees have participated in the ACT program and several graduates of the program have applied for and received CPRIT product development grants.

- On September 14, Director of Research Dr. Patty Moore, participated in a meeting that included the Governor's Commission for Women, the State Agency Council, and Partnerships for Children, to announce the 2023 Holiday Wishes Program. Dr. Moore serves as vice chair of the State Agency Council.

- On September 20, Dr. Magee met with several representatives from Keliomics, a biotech company focusing on cancer treatment by keeping human tissues and tumors alive outside the human body. They discussed potential CPRIT funding opportunities.

- On September 21 Chief Scientific Officer Dr. Michelle Le Beau represented CPRIT at the 14th Annual Congressional Childhood Cancer Summit co-chaired by Representatives Michael McCaul (Texas), Ami Bera (California), Michael Kelly (Pennsylvania), and Kathy Castor (Florida) held at the Rayburn Congressional Building in Washington DC. The Summit highlighted the progress made in treating cancer in children and adolescents, as well as the opportunities and imperatives for increased investment in research to improve outcomes for children and adolescents with these diseases. Dr. Le Beau's remarks showcased CPRIT's investments in research, therapeutic development, and prevention in childhood cancers, as well as the impact of the CPRIT model of state-supported cancer research and prevention institutes in addressing the national and state's cancer burden. In addition to remarks from the Representatives, other speakers included Dr. Gayle Vaday from the Department of Defense Congressionally Mandated Medical Research Program, Dr. Carol Thiel of the Pediatric Oncology Branch of the National Cancer Institute, and Gavin Lindberg of The Evan Foundation.

- From September 21 through 23 I attended various panels and presentations of the 2023 Texas Tribune's *Tribfest*. This three-day event includes scores of discussions on topical political and social issues of federal, state, and local interest.

## Compliance Program Update

Submission Status of Required Grant Recipient Reports

As of September 21, four entities had not filed five academic research reports, one product development reports, and two prevention reports. CPRIT's grant accountants and compliance specialists review and process incoming reports and reach out to grantees to resolve filing issues. In most cases, CPRIT does not disburse grant funds until the grantee files the required reports. In some instances, grantee institutions may be ineligible to receive a future award if the grantee does not submit required reports.

Financial Status Report Reviews

CPRIT's compliance specialists performed 271 second-level reviews of grantee Financial Status Reports (FSRs) in August and September. Twenty-four FSRs (9%) needed resubmission due to insufficient or inaccurate documentation sent by the grantee. CPRIT's grant accounting staff completes the first review of the FSRs and supporting documentation before routing them to the compliance specialists for final review and disposition.

Desk Reviews

Compliance specialists performed seven enhanced desk-based financial monitoring reviews in August and September. Desk reviews confirm financial, administrative, and programmatic compliance using data from CGMS/CARS with additional focus on an organization's internal controls, current and previous fiscal audits, and grantee report submission timeliness. Desk reviews also aid in the identification of potential problems and technical assistance issues for follow-up during an onsite visit, as well as areas of non-compliance and grantee performance issues. Compliance specialists are collaborating with four grantees to address desk review findings.

Onsite Reviews

Compliance specialists completed four onsite reviews in August and September. Onsite reviews are the most extensive monitoring activity conducted by CPRIT and include virtual or field visits led by compliance grant monitoring staff. CPRIT monitors 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 compliance with single audits during onsite reviews. Onsite monitoring enables CPRIT compliance staff to assess a grantees' capability, performance, and compliance with applicable laws, rules, and policies. Compliance specialists are collaborating with four grantees to address onsite review findings.

Single Audit Tracking

Compliance specialists track the submission of grantees' independent audit reports and the resolution of issues named in these reports. Grantees spending $750,000 or more in state awards in the grantee's fiscal year must undertake a single independent audit, a program specific audit, or an agreed upon procedures engagement. The grantee sends the independent audit report with findings to CPRIT within 30 days of receipt, but no later than nine months after the grantee's fiscal year end.

Currently, two grantees have not submitted the required 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 more time by the due date of the required audit and CPRIT's CEO approves the request. Compliance staff is actively working with the two grantees to submit the required audit.

Match Expenditures Review

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

Product development grantees, as well as those academic research grantees whose indirect cost rate credit does not fully offset the required match, must supply a detailed match expenditure report that includes the amount and date paid, vendor, description, and budget category. Compliance staff review grantees' match expenditures for appropriateness and allowability and work with CPRIT's grant accountants and the grantee to address any deficiencies. Compliance staff performed two annual match expenditure reviews in August and September. The total amount of match expenses reviewed by compliance staff for FY 2023 is $24,463,852.11. The unallowable match expenses for FY 2023 total $138,658.

Training and Support

CPRIT staff conducted three new Authorized Signing Official (ASO) training webinars in August and September for The University of Texas at El Paso, Texas Tech University Health Sciences Center at El Paso, and ImmuneSensor Therapeutics. The trainings covered grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. Pursuant to Texas Administrative Code §703.22, CPRIT requires new ASOs to complete compliance training within 60 days of the change.

CPRIT staff conducted one new grantee training webinar in August and September for Resilience Texas LLC. New grantee training covers 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 grantees to complete the initial compliance training program prior to receiving disbursement of grant award funds.

**Academic Research Program Update**

Recruitment FY 2024 Review Cycle 1 and 2

CPRIT accepted recruitment applications June 21 through August 20 for the first and second review cycles of FY 2024. CPRIT's Scientific Review Council (SRC) reviewed the applications on September 14. Dr. Le Beau will present the SRC's award recommendations for recruitment awards to the Program Integration Committee (PIC) and the Oversight Committee in November.

| FY 24 Mechanism | Received | Funds Requested | Recommended | Recommended Funds |
|---|---|---|---|---|
| Recruitment of Established Investigators | 2 | $12,000,000 | 1 | $6,000,000 |
| Recruitment of First-Time, Tenure Track Faculty Members | 2 | $ 3,990,000 | 1 | $1,990,000 |
| **TOTAL** | **4** | **$15,990,000** | **2** | **$7,990,000** |

Academic Research FY 2024 Review Cycle 1 (24.1)

CPRIT posted five Individual Investigator RFAs for the first review cycle of FY 2024 on February 17, accepting applications March 15 through June 14. Peer review will take place in October. Dr. Le Beau will present the SRC's recommendations for the cycle 24.1 grants to the PIC and the Oversight Committee in February 2024.

| FY 24 Cycle 1 Mechanism | Received | Funds Requested |
|---|---|---|
| Individual Investigator Research Award (IIRA) | 228 | $233,894,288 |
| IIRA for Computational Systems Biology of Cancer | 18 | $36,108,737 |
| IIRA for Cancer in Children and Adolescents | 35 | $47,815,216 |
| IIRA for Prevention and Early Detection | 15 | $27,050,403 |
| IIRA for Clinical Translation | 19 | $19,850,946 |
| **TOTAL** | **315** | **$364,719,590** |

Academic Research FY 2024 Review Cycle 2 (24.2)

On September 14, CPRIT released several RFAs (listed below) for the second cycle of FY 2024 and will accept applications October 17 – January 16, 2024. Peer review panels will meet

virtually in late April 2024 to consider the applications. Dr. Le Beau will present the SRC's recommendations to the PIC and the Oversight Committee in August 2024.

- **Core Facility Support Awards**
  Supports applications that facilitate the development or improvement of core facilities that will provide valuable services to support and enhance scientifically meritorious cancer research projects. Applicants may request funds to develop a new facility or to enhance the capabilities of an existing facility that will directly support and impact cancer research programs at the institution and in the region. CPRIT will look with special favor on applications that propose a facility that will serve cancer researchers at multiple Texas research institutions, in particular TREC-eligible institutions.
  **Award:** The maximum duration for this award mechanism is 5 years. Applicants may request up to a maximum of $3,000,000 in total costs.

- **High-Impact/High-Risk Research Awards**
  Supports applications that explore the feasibility of high-risk projects that, if successful, would contribute major new insights into the etiology, diagnosis, treatment, or prevention of cancers. Using this mechanism, CPRIT intends to support innovative, developmental projects that focus on exceptionally promising topics that are not yet sufficiently mature to compete successfully for more conventional funding. CPRIT expects the HIHR Research Awards to provide the foundation for individual or multiple investigator peer-reviewed awards upon completion. The goal of this award mechanism is to fund uncommonly great ideas that merit the opportunity to acquire preliminary data.
  **Award:** Applicants may request a total of $250,000 for a period of up to 24 months.

- **Multi-Investigator Research Awards**
  Supports highly integrated programs of collaborative and cross-disciplinary research among multiple Texas investigators and Institutions. CPRIT particularly encourages applications addressing one of the program priorities for academic research adopted by CPRIT's Oversight Committee.
  **Award:** $4,500,000 in total costs for a maximum period of 4 years.

- **Clinical Investigator Award**
  Supports mid-career clinician scientists with specialty training relevant to delivery of cancer care to devote more time to augment their capabilities in clinical cancer research, and to provide mentoring to early-stage investigators in the conduct of clinical research. The CIA will provide protected time from clinical responsibilities to provide physicians with the opportunity to expand clinical research skills, to develop investigator-initiated clinical trials, to develop external relations with industry and pharmaceutical company partners, and to expand partnerships with laboratory-based collaborators to design and conduct correlative studies needed to interpret the outcome of an interventional trial. The CIA initiative will increase the pool of clinical investigators at Texas academic institutions who are conducting patient-oriented studies, who will be able to compete successfully for peer-reviewed grants, and who will mentor the next generation of clinical investigators.
  **Award:** $1,500,000 in total costs for a maximum period of 5 years.

**Product Development Research Program Update**

Product Development FY 2024 Cycle 1 Review (24.1)

On May 1 CPRIT released four FY 2024 Product Development Research RFAs and opened the portal to receive preliminary and full applications on a rolling basis. As described in more detail below, CPRIT received the total number of full applications (15) allocated for the first cycle of FY 2024 by June 30, one month before the August 1 deadline.

- Preliminary Application Review: CPRIT received 79 FY 2024 preliminary applications on a rolling basis between May 1 and June 30. Like the FY 2023 review cycle, five standing review panels evaluated the FY 2024 preliminary applications on a rotating basis. CPRIT issued weekly invitations to submit full applications to companies that presented meritorious preliminary applications, based on application scores as determined by the preliminary application peer review panel.

  As discussed in the section below, CPRIT received the total number of full applications for the 15 review slots for the first review cycle for FY 2024 on June 30. The preliminary review panels had completed reviews of 45 preliminary applications and issued invitations to 19 companies to submit a full application for FY 2024 by June 30. Because there are no more spots available for full application review, CPRIT returned 34 preliminary applications to applicants without review. Should the applicants submit these unreviewed applications in future cycles, they will not count against the resubmission limit.

  The table below provides information about the FY 2024 preliminary applications.

| 24.1 RFA | Preliminary Applications | | | Total Prelim Request | Full Application Invites |
|---|---|---|---|---|---|
| | Submitted | Reviewed | Returned - no review | | |
| TTC | 34 | 23 | 11 | $353 M | 10 |
| TDDC | 4 | 2 | 2 | $27 M | 1 |
| TNTC | 9 | 5 | 4 | $39 M | 2 |
| Seed | 32 | 15 | 17 | $48 M | 6 |
| **TOTAL** | **79** | **45** | **34** | **$467 M** | **19** |

TTC = Texas Therapeutics Company
TDDC = Texas Device and Diagnostic Company
TNTC – Texas New Technologies Company

  Full Application Review (July and August): In addition to the 19 invitations issued by June 30, CPRIT allowed four companies that submitted full applications in the FY 2023 cycle to resubmit their full applications for review in the FY 2024 cycle. (CPRIT did not review these four full applications in FY 2023 because of time and resource limitations.)

  The FY 2024 RFAs notified applicants that CPRIT would continually monitor the number of submissions and would stop accepting full applications before the August 1 deadline if we received more than 15 applications. By 4:00 p.m. CST on June 30, CPRIT received its 15th

and 16th full application submittal (including the four FY 2023 full applications.) Accordingly, we closed the portal for full application submission at 5:00 p.m. on June 30. We separately notified the seven companies with invitations for FY 2024 who had not submitted full applications by June 30 that CPRIT was no longer accepting full applications at this time.

Although we planned for 15 spots, Dr. Smith decided to increase the number of review slots by one (16 full application review panels) to accommodate the 16th full application received by CPRIT on June 30. As a result, unlike the FY 2023 review cycle, CPRIT will not return any full applications to applicants without a review, and we will not carry over submitted but unreviewed full applications into the FY 2025 cycle.

The table below provides information about the FY 2024 cycle 1 full applications.

| 24.1 RFA | Invited Apps | Submitted Apps | Budget Request | Apps in Due Diligence | Budget Request |
|---|---|---|---|---|---|
| TTC | 12 | 8 | $112.8M | 3 | $41.8M |
| TDDC | 2 | 2 | $9.0M | 1 | $5.4M |
| TNTC | 2 | 1 | $12.6M | 1 | $12.6M |
| Seed | 7 | 5 | $15.0M | 3 | $9.0M |
| **TOTAL** | **23** | **16** | **$149.4M** | **8** | **$68.8M** |

- Panel Presentations, Due Diligence Review and Budget Negotiation (August – October): Prior to panel presentations, one company withdrew from consideration because of unexpected clinical results. The remaining 15 companies presented their full applications to review panels in August and September. Based upon the review panels' recommendations, eight companies proceeded to due diligence review. The review panels will meet in early October to evaluate the due diligence reports and to finalize panel award recommendations.

  Using the same process we successfully employed for the FY 2023 review cycle, Chief Product Development Officer Dr. Ken Smith is negotiating the proposed project budgets to identify ways to decrease CPRIT-funded project expenses while maintaining the goals and objectives of the recommended projects. As we learned from the FY 2023 review process, this is a crucial step to ensuring that CPRIT can fund as many meritorious projects as possible with the estimated $74 million allocated for FY 2024 Product Development awards.

- Final Recommendations (November): The Product Development Review Council (PDRC) will meet in late October to recommend companies for product development awards. Dr. Smith will present the companies recommended for product development awards to the Program Integration Committee and the Oversight Committee in November.

- Looking Ahead: If CPRIT does not award all product development award funds allotted for FY 2024 in this first cycle, the product development program expects to reopen the RFAs in

December or January for a second round of awards for Oversight Committee approval in May or August 2024.

## Prevention Program Update

Prevention FY 2024 Review Cycle 1 (24.1)

The Prevention Program released two prevention RFAs on May 5 for the first cycle of FY 2024. CPRIT received 29 proposals totaling $46.7 million by the August 30 deadline. Peer review will take place October – December, with Ms. Magid presenting the PRC's recommendations to the PIC and the Oversight Committee in February 2024.

| Cycle 24.1 Mechanism | Applications | Funds Requested |
|---|---|---|
| Primary Prevention of Cancer | 13 | $19,384,419 |
| Cancer Screening and Early Detection | 16 | $27,272,619 |
| **TOTAL** | **29** | **$46,657,038** |

## Advisory Committees

- The Clinical Trials Advisory Committee met September 15.
- The Advisory Committee on Childhood Cancers met September 18.
- The Geographic Diversity Advisory Committee met October 2.
- The Product Development Advisory Committee will meet October 12.

## Texas Cancer Plan

Prevention Program Manager Carlton Allen is leading the revision of the *Texas Cancer Plan*. The *Texas Cancer Plan* aims to reduce the cancer burden across the state and improve the lives of Texans. As the statewide call to action for cancer research, prevention, and control, it identifies the challenges and issues that affect our state and presents a set of goals, objectives, and strategies to help inform and guide communities in the fight against cancer. The report provides a coordinated, prioritized, and actionable framework that will help guide efforts to mitigate the cancer burden.

The Texas legislature charged CPRIT by statute with facilitating the development of the *Texas Cancer Plan*. CPRIT releases a new version every six years, with the first plan developed under its leadership issued in 2012. The most recent version, released in 2018, reflects changes, progress, and advances in cancer prevention and control efforts since 2012.

CPRIT's strategic direction and funding opportunities align with the *Texas Cancer Plan*. However, the overall outcome and success of efforts to reduce the state's cancer burden will depend on the cooperation, collaboration, and resources of many Texas stakeholders.

Mr. Allen is engaging an array of stakeholders to gather input to enhance the plan's effectiveness. He is also working with the Texas Cancer Registry and Behavioral Risk Factor Surveillance System to gather updated data on screening and treatment statistics. CPRIT is collaborating with the Department of State Health Services to facilitate data integration. To ensure the *Texas Cancer Plan* reflects the state's needs, CPRIT will host town halls and forums to elicit open feedback and encourage community involvement. We will continue to update you on the progress of this project.

## Operations and Finance Update

Internal Auditor

CPRIT's internal auditor, Weaver and Tidwell, completed the purchasing compliance internal audit of CPRIT's procurement processes and procedures. Ms. McConnell and CPRIT's contract specialist Don Brandy have been working on the audit.

Financial Audit

CPRIT recently received audit delegation authority from the State Auditor's Office to proceed with the renewal of the McConnell & Jones contract to conduct the audit of the agency's FY 2023 financial statements. Ms. McConnell and CPRIT accountant Michelle Huddleston have primary responsibility for completing this audit. McConnell & Jones will deliver the final audit to the agency in early December and the Audit Subcommittee will review it at a to-be-scheduled special meeting in December. Once McConnell & Jones initiates the audit in October, Oversight Committee members will receive the Related Party and Fraud Risk questionnaires that are a standard part of this audit every year.

## Upcoming Subcommittee Meetings

Listed below are the subcommittee meetings in advance of the November 15 Oversight Committee meeting. We will send instructions for signing onto the Microsoft Teams platform along with the subcommittee agenda and meeting materials one week prior to each meeting.

| | |
|---|---|
| Board Governance | November 2 at 10:00 a.m. |
| Audit | November 6 at 10:00 a.m. |
| Prevention | November 7 at 12:00 p.m. |
| Academic Research | November 8 at 12:00 p.m. |
| Product Development | November 9 at 10:00 a.m. |

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CPRIT has awarded **1,901** grants totaling **$3.381 billion:**

- 291 prevention awards totaling $354.8 million
- 1,610 academic research and product development research awards totaling $3.03 billion

Of the $3.03 billion in academic research and product development research awards,

- 31.6% of the funding ($955.9 million) supports clinical research projects
- 23.8% of the funding ($720.1 million) supports translational research projects
- 29.4% of funding ($889.4 million) supports recruitment awards
- 12.2% of the funding ($370.1 million) supports discovery stage research projects
- 3.0% of funding ($90.4 million) supports training programs.

CPRIT has seven open Requests for Applications (RFAs)

- 3 Academic Research Recruitment
- 4 Academic Research Projects

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

# MEMORANDUM

| | |
|---|---|
| **TO:** | OVERSIGHT COMMITTEE MEMBERS |
| **FROM:** | WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER |
| **SUBJECT:** | CPRIT ACTIVITIES UPDATE FOR OCTOBER 2023 |
| **DATE:** | NOVEMBER 1, 2023 |

Topics in this memo address CPRIT activities in October, including preparations for the upcoming November 15 Oversight Committee meeting, recent milestones in our fight against cancer, a staffing summary, outreach efforts, FY 2025 program priorities and updates from Compliance, Programs, and Operations.

## Planning for the November 15 Oversight Committee Meeting

The Oversight Committee will meet in person on Wednesday, November 15, in the Barbara Jordan Building. The meeting will begin at 8:30 a.m. We will have a full agenda with two grantee presentations, grant award recommendations, the FY 2025 Oversight Committee Program Priorities, and several internal audit reports. Please notify me as soon as possible if you are unable to attend the November 15 meeting or have schedule constraints that require you to arrive at the meeting after 8:30 a.m. or leave prior to 12:30 p.m. Immediately following the meeting, CPRIT staff invites you to attend our Thanksgiving lunch at the CPRIT office.

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

Attached is a draft meeting agenda. CPRIT will post the final agenda for the Oversight Committee meeting by November 7. Oversight Committee members will receive an electronic copy of the agenda packet by November 8. Hard copies of the agenda and proposed award packet will be available at the meeting.

## Recent Milestones in the Fight Against Cancer

CPRIT Grantees in the News

- Dr. Jane Montealegre, associate professor in the Department of Behavioral Science at The University of Texas MD Anderson Cancer Center discussed the CPRIT-funded HPV vaccine



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project as a guest contributor to the St. Jude Childrens Research Hospital newsletter. The University of Texas Medical Branch at Galveston project, directed by Dr. Abbey Berenson, professor in the department of Obstetrics and Gynecology and Pediatrics, Director, Center for Interdisciplinary Research in Women's Health, partners with schools to increase HPV vaccine coverage in rural communities along the US-Mexico border.

CPRIT awarded UTMB $7 million since 2016 (PP160097, PP190023, PP200057, PP230043) to establish and expand the School-Based Human Papillomavirus Vaccination Project in the Rio Grande Valley.

- The September 5 edition of the journal *Health Promotion Practice* featured a commentary by Dr. Amelie Ramirez, exploring the milestones and remaining challenges in Latino health promotion. Dr. Ramirez, professor and chair of the Department of Population Health Sciences, director of the Institute for Health Promotion Research at The University of Texas Health Science Center at San Antonio, and associate director of cancer outreach and engagement at Mays Cancer Center, also discussed these issues on the Health Promotion Practice podcast.

  CPRIT awarded The University of Texas Health Science Center at San Antonio $1.3 million since 2014 to establish and expand tobacco cessation services among young adult rural, low-income, and Spanish-speaking tobacco users as well as for primary care and cancer patients at UT Health San Antonio (PP140176, PP170099, PP180092).

- On September 20, Columbia University announced that it will award the 2023 Louisa Gross Horwitz Prize to Zhijian "James" Chen, Ph.D., professor of molecular biology at The University of Texas Southwestern Medical Center and Simmons Comprehensive Cancer Center, in recognition of his groundbreaking work on innate immunity. Nearly half of the scientists honored with the Horwitz Prize over the past 56 years subsequently received the Nobel Prize.

  Dr. Chen, who holds the George L. MacGregor Distinguished Chair in Biomedical Science, received the Breakthrough Prize in Life Sciences in 2019, He is also an elected member of the National Academy of Sciences (2014) and the National Academy of Medicine (2022). He has discovered pathways and proteins that trigger immune and stress responses, including a signaling pathway involving a novel DNA sensor – cyclic GMP-AMP (cGAMP) synthase, or cGAS – which activates an interferon response that plays a critical role in immune defense against pathogens and malignant cells, as well as in autoimmune diseases such as lupus. Dr. Chen is a multi-CPRIT grantee, receiving nearly $11 million in CPRIT research grants since 2011 (RP110430, RP120718, RP150498, RP180725). In addition, a Dallas-based clinical stage biotechnology company, ImmuneSensor Therapeutics Inc., created to commercialize Dr. Chen's CPRIT-funded research, is developing a new class of drug called STING agonists that target this cellular pathway to activate the patient's immune system to fight cancers. ImmuneSensor received a $16.2 million CPRIT Texas Company Product Development Award in 2022 (DP220030).

- CPRIT Scholar Daisuke Nakada, Ph.D., professor in the Department of Molecular and Human Genetics at Baylor College of Medicine, was one of the six faculty members honored on September 18 with the 2023 Michael E. DeBakey Excellence in Research Award. His research focuses on the molecular and cellular mechanisms that regulate the biology of hematopoietic stem cells (HSCs), the parent cells of blood cells, and leukemia. Dr. Nakada developed an efficient method to edit the genomes of HSCs. Researchers used this method to develop new mouse models of hematological malignancies and to investigate the genetic interactions in both mouse and human acute myeloid leukemia models, setting the research conducted by the Nakada lab at the forefront of HSC leukemia stem cell biology. Baylor College of Medicine recruited Dr. Nakada from the University of Michigan with a $2 million CPRIT First-Time, Tenure-Track Faculty Member grant (R1201) in 2011.

- On September 26, the Advanced Research Projects Agency for Health (ARPA-H) awarded its second research cooperative agreement to a team of investigators led by CPRIT Scholar Omid Veiseh, Ph.D., an associate professor of bioengineering at Rice University, and CPRIT Grantee Weiyi Peng, Ph.D., an assistant professor of biology and biochemistry at the University of Houston. The $45 million award involving collaborators at eight other institutions and agencies focuses on developing sense-and-respond implant technology that could reduce U.S. cancer-related deaths by more than 50%.

  The award will fast-track the development and testing of a first-of-its-kind approach to cancer treatment that aims to dramatically improve immunotherapy outcomes for patients with ovarian, pancreatic, and other difficult-to-treat cancers. The sense-and-respond implantable device technology works through a minimally invasive procedure to implant a small device that continuously monitors patients' cancers and adjusts their doses in real time. Referred to as the THOR technology for "targeted hybrid oncotherapeutic regulation," Dr. Peng explains that "By integrating a self-regulated circuit, the THOR technology can adjust the dose of immunotherapy reagents based on a patient's responses. With this new feature, researchers expect THOR to achieve better efficacy and minimize immune-related toxicity. We hope this personalized immunotherapy will revolutionize treatments for patients with peritoneal cancers that affect the liver, lungs and other organs." The THOR cooperative agreement includes funding for a first-phase clinical trial of the implant to treat recurrent ovarian cancer slated to begin in the fourth year of THOR's 5 1/2-year project.

  Rice recruited Dr. Veiseh to Texas from the Massachusetts Institute of Technology with a $2 million First-Time, Tenure-Track Faculty Member award (RR160047) in 2016. CPRIT awarded University of Houston and Dr. Peng a $250,000 High Impact-High Risk grant (RP200520) in 2020.

- Gail Tomlinson, M.D., Ph.D., division director of pediatric hematology-oncology at The University of Texas Health Science Center at San Antonio, received a $400,000 Hyundai Hope Scholar Grant Award on September 26 to study new mechanisms to treat liver tumors, including those resistant to conventional therapies. Hyundai also presented Dr. Tomlinson's genetics team in the division of pediatric oncology a $100,000 Hyundai Impact Grant Award to expand the availability of genetic testing at University Hospital's pediatric clinic.

CPRIT has awarded UT Health San Antonio and Dr. Tomlinson three CPRIT research grants (RP101195-C1, RP120715-AC, RP220137) and two prevention grants (PP120089, PP160011) since 2010.

- ImmunoGenesis announced on September 28 that it dosed the first patient in the company's Phase 1a/1b clinical trial of its lead candidate, IMGS-001, at The University of Texas MD Anderson Cancer Center. IMGS-001 is an antibody engineered with cytotoxic function designed to treat cold, immune-excluded tumors, which are resistant to existing immunotherapy. The Phase 1a/1b first-in-human, open-label, multicenter study (NCT06014502) consists of a dose escalation and expansion portion to evaluate the safety, pharmacokinetics, and preliminary anti-tumor activity of IMGS-001 in adult patients with locally advanced or metastatic solid tumors refractory to standard-of-care treatment. Anticipated tumor types in the dose escalation portion of the study include ovarian, colorectal and triple-negative breast cancer. CPRIT awarded Houston-based ImmunoGenesis, a clinical-stage immuno-oncology biopharmaceutical company re-envisioning the treatment of immune-excluded tumors, a $15.45 million CPRIT Product Development Research grant (DP200094) in August 2020.

- The National Institutes of Health recognized CPRIT Scholars Ravikanth Maddipati, M.D., and Julea Vlassakis, Ph.D., October 3 with the 2023 Director's New Innovator Award. This coveted $1.5 million, 5-year grant is from the NIH Common Fund High-Risk, High-Reward Program – an initiative that supports early-career investigators pursuing highly innovative research, with the potential to have a broad impact on biomedical, behavioral, or social sciences.

  The University of Texas Southwestern Medical Center recruited Dr. Maddipati from the University of Pennsylvania to Texas in 2019 with a $2 million First-Time, Tenure-Track Faculty Member CPRIT recruitment award (RR190029). He is an expert in diseases of the pancreas and the management of patients at high-risk for the development of pancreatic cancer.

  Rice University recruited Dr. Vlassakis to Texas from the University of California, Berkley with a $2 million First-Time, Tenure-Track Faculty Member CPRIT recruitment award (RR210028). She designs and applies micro and nanoscale single-cell and single molecule technologies to study proteins and their interactions with other macromolecules. The over-arching goal of the Vlassakis lab is to advance treatment for Ewing sarcoma and other pediatric cancers by identifying molecular markers for targeted therapies.

- On October 9, the National Academy of Medicine (NAM) announced the election of Jennifer A. Wargo, M.D., M.MSc., to its membership. Election to the Academy is one of the highest honors in the fields of health and medicine and recognizes individuals who have demonstrated outstanding professional achievement and commitment to service.

Dr. Wargo is the R. Lee Clark Endowed Professor of Surgical Oncology and Genomic Medicine, and founder and director of the Platform for Innovative Microbiome and Translational Research at The University of Texas MD Anderson Cancer Center. As noted by NAM President Dr. Victor J. Dzau, Dr. Wargo has made fundamental and practice-changing contributions to our understanding of the response and resistance of melanoma to targeted therapy and immunotherapy. She pioneered the role of the tumor and gut microbiome in tumor biology and therapeutic response, and translated these paradigmatic discoveries into novel clinical trials. CPRIT research grants totaling $1.15 million (RP150030, RP200574) support Dr. Wargo's work.

- The October 9 edition of the *Laredo Morning Times* (LMTonline) featured the CPRIT-funded Hep C – C.A.R.E. (Colonias Advancing & Restoring Esperanza) Hepatitis C screening and navigation project, directed by Dr. Roberto Villarreal of University Health System in partnership with the City of Laredo Health Department. The Hepatitis C virus (HCV) is the major risk for hepatocellular cancer, and most HCV positive patients are baby boomers (born 1945-1965). Although baby boomers treated by the University Health System had more than twice the prevalence of HCV when compared to national estimates, the HCV screening rate is much lower for this age group. The project's goal is to decrease liver cancer incidence and mortality among baby boomers through outreach, education, screening, and navigation to prevention and care.

  CPRIT awarded University Health System $1.7 million (PP210016) in 2021 to support the Hep C – C.A.R.E. project. This is an expansion of the University Health System's $1.2 million CPRIT-funded project "Hepatitis Viral Infection and Systematic Treatment Program (HepVISTA)" project awarded in 2017 (PP170024) to increase HCV screening of low income Hispanic baby boomers and reduce disparities in the prevention of liver cancer in Bexar County.

- On October 11, Perimeter Medical Imaging, Inc., a commercial-stage medical technology company, announced that patient randomization is underway at Mayo Clinic in Florida. This is the most recent clinical site the company has initiated as part of an ongoing multi-center, randomized, two-arm pivotal clinical trial evaluating the investigational Perimeter B-Series OCT combined with its proprietary ImgAssist AI software. The Houston and Toronto based commercial-stage technology company received a $7.5 million CPRIT product development grant (DP190087) in 2019 to develop ultra-high-resolution, real-time, advanced imaging tools for cancer surgery.

- Hummingbird Bioscience, a data-driven precision biotherapeutics company discovering and developing transformative biologic medicines for hard-to-treat diseases, announced October 19 that Endeavor BioMedicines acquired exclusive worldwide rights to Hummingbird Bio's antibody-drug conjugate (ADC), HMBD-501. The license agreement provides Endeavor with exclusive rights to HMBD-501, a next-generation HER3-targeted ADC with an exatecan payload optimized for safety and efficacy. Under the terms of the license, Hummingbird Bio will be eligible to receive upfront and milestone payments up to $430 million, plus royalties on net sales.

CPRIT awarded the company, based in San Diego, Houston, and Singapore, a $13.1 million Company Relocation grant (DP190027) in 2019.

- Rice University announced October 30 that the National Institutes of Health awarded a five-year $6.5 million grant to a Rice- led collaboration of engineers, oncologists, and international global health partners from three continents. The team, including CPRIT grantee Dr. Rebecca Richards-Kortum, will establish the Center for Innovation and Translation of POC Technologies for Equitable Cancer Care (CITEC) in the Texas Medical Center. CITEC will advance the development of home-based and point-of-care health technologies to improve cancer detection in low-resource settings. Baylor College of Medicine will serve as clinical core for CITEC.

  CITEC is one of six technology research and development centers around the country that comprise the Point of Care Technology Research Network and will parlay the momentum of the original network established in 2007 by the National Institute of Biomedical Imaging and Bioengineering.

  Dr. Richards-Kortum is Rice's Malcolm Gillis University Professor, a professor of bioengineering and electrical and computer engineering and director of the Rice 360: Institute for Global Health Technology. CPRIT awarded Dr. Richards-Kortum $2.7 million in individual investigator research grants (RP100932, RP160460) in 2010 and 2015.

- The McWilliams School of Biomedical Informatics at The University of Texas Health Science Center at Houston announced a funding landmark on October 31. Between August and October 2023, fifteen faculty members received 16 grants totaling more than $31 million. Four CPRIT-funded faculty members serve as principal investigator (PI) or multiple principal investigator (MPI) on 11 of the 16 awards. Each grant includes medical artificial intelligence (AI) innovations and advancements in research or healthcare. Granting institutions included the National Institutes of Health, National Library of Medicine, National Human Genome Research Institute, and the National Science Foundation.

  Of the 16 announced awards, CPRIT Scholar Dr. Xiaoqian Jiang is a PI/MPI on five awards (totaling $20 million). UT Health Houston recruited Dr. Jiang to Texas from the University of California San Diego with a $4 million CPRIT Rising Star grant (RR180012) in 2018. CPRIT Scholar Hongfang Liu serves as the PI for two new awards (totaling $4.7 million). Dr. Liu joined UT Health Houston from the Mayo Clinic in 2023 with a $6 million CPRIT Recruitment of Established Investigators grant (RR230020). Two other CPRIT-funded researchers, Dr. Zhongming Zhao and Dr. Cui Tao, serve as PIs/MPIs on four of the recently announced awards (totaling $14.8 million). CPRIT awarded UT Health Houston and Dr. Zhao $8.4 million in core facility and training grants (RP180734, RP210045) since 2018. Dr. Tao received a $1.4 million CPRIT Individual Investigator Research Award for Cancer in Children and Adolescents (RP220244) in 2022.

Notable CPRIT-Supported Research and Prevention Accomplishments

- **Expanding the Therapeutic Applications of Gene Editing Technology.** The Nobel-prize winning CRISPR-Cas9 gene editing technology has revolutionized biological research due to its capacity to edit nucleic acids. CPRIT Scholar Yang Gao, Ph.D., assistant professor of biosciences at Rice University, has clarified the detailed three-dimensional structure of one of the smallest known CRISPR-Cas13 systems that uniquely targets RNA rather than DNA. This system modifies or shreds RNA, acting as an intermediary in translating genetic information into protein blueprints. Dr. Gao's innovative work, published in *Nature Communications* September 20, not only reveals the unique functioning of this protein but also enables its re-engineering to enhance precision, opening new doors for therapeutic applications.

  Unlike the DNA-targeting CRISPR-Cas9 systems, Cas13-associated systems focus on RNA, serving vital roles in RNA knockdown and transcriptome modulation due to their high efficiency and programmable RNA targeting. These attributes make Cas13 a promising tool for in vivo applications. However, issues related to non-specific RNA cleavage by the activated Cas13 enzyme when delivered using adeno-associated virus vectors hinders the therapeutic potential. This non-specific activity may disrupt the transcriptome and lead to undesired cell death, posing significant challenges for clinical applications.

  Dr. Gao’s team utilized cryogenic electron microscopy (cryo-EM) to delve into the compact form of Cas13 (Cas13bt3), capturing its structure in a fully active state. They uncovered that Cas13bt3 operates differently compared to other members of its protein family, employing a unique mechanism to bind its target RNA. Unlike other Cas13 proteins that resemble scissors with two initially separated domains that come together upon activation, Cas13bt3's "scissors" are pre-assembled. It uses a binding element contained on two loops of the protein to maintain the domains together, facilitating a more precise and efficient RNA targeting.

  With a better understanding of the protein’s mechanics, the research team engineered Cas13bt3 variants that exhibited reduced off-target activity while maintaining robust target cleavage capabilities. These optimized systems demonstrated enhanced targeting precision in cell cultures, benefiting from the protein’s relatively small size (700 amino acids) compared to other Cas family members (1200 amino acids). This smaller size facilitates better delivery to cells and access to target sites, making Cas13bt3 an attractive candidate for therapeutic applications, particularly for combating RNA viruses and potentially for treatments in cancer and other diseases. For example, scientists may use these RNA-targeting systems in the future to fight viruses, which generally encode their genetic information using RNA rather than DNA.

  This research is an elegant example of how insights into the structure of proteins guide protein engineering efforts needed to improve the tool’s specificity, while still maintaining high sensitivity – in this case high “on-target” RNA editing activity – for therapeutic applications for cancer and other diseases.

Rice University recruited Dr. Gao to Texas with a $2 million First-Time, Tenure-Track Faculty grant (RR190046) in 2019. Baylor College of Medicine received a $5.38 million CPRIT Core Facility Support Awards grant (RP190602) in August 2019 to add new technologies to the two cryo-EM Cores in the Texas Medical Center.

- **Parsing the effects of "Dueling Hormones" on Breast Cancer Proliferation and Metastasis**. CPRIT Scholar Suzanne D. Conzen, M.D., and her team at The University of Texas Southwestern Medical Center have made a significant breakthrough in understanding the complex and paradoxical effects of hormones on breast cancer, specifically early-stage Invasive Lobular Breast Cancer (ILC). Published in the journal *Cancers* on September 22, their research examines the intricacies of how hormonal activities influence ILC, which accounts for approximately 15% of breast cancer cases and is known for its unique pattern of late metastatic spread. Dr. Conzen's previous work on ER+ infiltrating ductal cancer (IDC) had revealed the inhibitory effects of glucocorticoid receptor (GR) activity on tumor growth, providing a foundation for the current study.

  ILC cells, distinct in their growth in multiple distinct areas and late metastatic tendencies, have been a subject of interest due to their perplexing behavior in the presence of estrogen receptor (ER) activity, a known catalyst for cell proliferation. Dr. Conzen's hypothesis centered around the glucocorticoid receptor (GR), a nuclear hormone receptor that responds to stress, speculating that its activation might play a role in ILC's unique biology. The GR, when activated by the human stress hormone, forms a duplex within another GR molecule, and translocates to the nucleus where it activates various genes associated with stress response, cell survival, and inflammation. Dr. Conzen hypothesized that while GR activation might reduce tumor cell proliferation, it could simultaneously enhance ILC's propensity to metastasize.

  To validate this hypothesis, Dr. Conzen's team utilized ER+ ILC cell culture models and an in vivo intraductal mouse mammary gland model of ILC. Their findings confirmed that GR activation indeed slows DNA replication and tumor growth, yet concurrently promotes a metastatic phenotype. The increased expression of integrin genes, enhanced adhesion to extracellular matrix proteins, and augmented mesothelial cell clearance all served as evidence for the conclusion. The in vivo studies further established a connection between GR expression and increased bone metastases, even in the presence of slowed primary mammary tumor growth.

  These groundbreaking results present a nuanced understanding of ILC biology, revealing how GR-mediated gene expression contributes to its low primary tumor proliferative rate and high tendency for late metastasis. This paradoxical behavior of ILC, illuminated by Dr. Conzen's research, opens new avenues for therapeutic interventions, especially considering the low toxicity of GR inhibitors observed in clinical trials. The study highlights the potential of targeting GR activity as a novel approach in managing and treating ILC, providing hope for better clinical outcomes in the future.

UT Southwestern recruited Dr. Conzen to Texas from the University of Chicago with a $6 million Established Investigator award (RR190037) in 2019.

- **Lifting the Fog on Brain Fog.** A recent study led by Dr. Theresa Guise, a CPRIT Scholar at The University of Texas MD Anderson Cancer Center, shows significant advancements in understanding the mechanisms underlying "chemobrain," a term used to describe cognitive impairments experienced by cancer patients during and after chemotherapy. The National Cancer Institute has identified chemobrain as a poorly understood problem for which clinicians have only limited or ineffective management/treatment strategies.

  The research, published in the September 27 issue of *Science Translational Medicine*, builds on existing knowledge that suggests a connection between chemobrain and disruptions in the neuronal ryanodine receptor channel type 2 (RyR2), a critical receptor in the brain associated with learning and memory functions. This receptor is known to regulate calcium ion signaling in neurons, and scientists see evidence of its malfunction in various cognitive disorders, including post-traumatic stress disorder and Alzheimer's disease.

  The researchers conducted their study using a mouse model of breast cancer, administering two chemotherapeutic regimens (doxorubicin or methotrexate plus 5-fluorouracil) to both mice with cancer and healthy mice. Their findings revealed that chemotherapy induced post-translational modifications and increased calcium leakage through the RyR2 receptor, leading to abnormalities in brain glucose metabolism and neurocognitive dysfunction. However, when researchers treated the mice with S107, a stabilizer for the ryanodine receptor calcium release channel, it prevented RyR2 leakiness, and significantly reduced cognitive deficits. Notably, researchers also observed these protective effects of S107 in the cancer-free mice subjected to chemotherapy, underscoring the potential of this treatment approach.

  Through proteomics analysis, the study further revealed the downstream effects of leaky RyR2 channels, exposing dysregulation in proteins crucial for synaptic structures and neurotransmission. This disruption in neuronal calcium homeostasis due to RyR2 leakage emerged as a potential central mechanism contributing to chemobrain. The research not only enhances the understanding of chemobrain's underlying biological processes but also proposes RyR2 as a promising therapeutic target for preventing and managing these cognitive impairments associated with cancer therapy.

  MD Anderson recruited Dr. Guise to Texas from Indiana University School of Medicine with the support of a $6 million CPRIT Established Investigator award (RR190108) in 2019.

- Antibiotics have played a transformative role in healthcare, significantly prolonging human life since their widespread adoption in the 20th century. However, their excessive and improper application in both human medicine and livestock farming has led to a rise in antibiotic-resistant bacteria and the emergence of multidrug-resistant organisms. Addressing this issue necessitates a deep understanding of the mechanisms, genetic mutations, and changes in bacterial behavior that contribute to antibiotic resistance.

Fourier transform infrared spectroscopy (FTIR) is a sophisticated analytical technique that researchers use to analyze the molecular composition of bacterial cells, providing detailed profiles of their biomolecules. A team of international researchers, led by CPRIT Scholar Dr. Vanderlei S. Bagnato at Texas A&M Engineering Experiment Station, developed a novel approach that combines FTIR with machine learning algorithms to enhance the analysis and categorization of absorption spectra from *Staphylococcus aureus* samples. Their work, detailed in the September 30 edition of the journal *MDPI Antibiotics*, highlights the potential of this method in determining bacterial antibiotic resistance.

The data from their research shows that FTIR spectral analysis in the infrared regime can ascertain whether a bacterial sample is antibiotic-resistant, as well as identifying the specific antibiotic to which the bacteria have developed resistance. This is a significant advancement in the field, providing a more comprehensive understanding of how bacterial resistance develops and which antibiotics are most implicated in this process.

By integrating machine learning algorithms with FTIR spectral analysis, the researchers have created a powerful tool with the potential to revolutionize how scientists approach the challenge of antibiotic resistance. This methodology offers a more efficient and accurate means of identifying resistant bacterial strains and understanding the dynamics of antibiotic resistance. It can inform the development of new drugs and strategies to combat the growing issue of antibiotic resistance, ultimately leading to more effective treatments and better patient outcomes.

Texas A&M Engineering Experiment Station recruited Dr. Bagnato to Texas with the support of a $6 million Recruitment of Established Investigators grant (RR220054) in 2022.

- On October 3, Medicenna Therapeutics presented new preclinical data characterizing MDNA223, an anti-PD1-IL-2 BiSKIT (Bifunctional SuperKine for ImmunoTherapy), at the 2023 American Association for Cancer Research Special Conference in Cancer Research: Tumor Immunology and Immunotherapy held in Toronto, Canada. The sum of encouraging preclinical data on MDNA223 highlights the potential of Medicenna's BiSKIT platform to broadly deliver effective therapy to otherwise challenging-to-treat 'cold' tumors.

  CPRIT awarded a $14.1 million New Company Product Development Award grant (DP150031) in 2015 to Houston and Toronto-based Medicenna to conduct two clinical trials for glioblastoma multiforme patients to test bizaxofusp's (formerly MDNA55) safety, effectiveness, and dosage.

- **New research reveals how inherited mutations in BRCA1 affect cancer susceptibility in women.** In the October 5 issue of *Molecular Cell*, a team of scientists at The University of Texas Health Science Center at San Antonio and the Mays Cancer Center unveiled a major discovery regarding the BRCA1 gene, a well-known tumor suppressor gene linked to breast and ovarian cancer susceptibility. This breakthrough, coming thirty years after the initial identification of the gene, clarifies how a substantial number of BRCA1 mutations lead to cancer in women. The insights gleaned from this research will guide the development of

targeted drugs for breast and ovarian cancers and enhance risk assessment for women at increased risk of these cancers.

Dr. Weixing Zhao and his colleagues conducted an in-depth analysis of BRCA1, a large and multifunctional protein, to better understand its crucial role in genome repair. The BRCA1 protein operates in tandem with its partner protein, BARD1, to prevent cancer, but scientists debate the exact mechanisms of its protective actions. A specific function of BRCA1, known as E3 ligase activity, has been under scrutiny since its discovery in 1999. This activity enables BRCA1 to tag certain proteins with ubiquitin moieties, marking them for degradation and playing a key role in DNA repair and other cellular processes. However, previous research using a mutated form of BRCA1 (I26A) suggested that E3 ligase activity might not be essential for cancer prevention, a hypothesis that contradicted the prevalence of patient mutations within the E3 ligase domain.

Despite the publication of over 200 papers utilizing the BRCA1-I26A variant, no conclusive evidence existed proving the variant's lack of E3 ligase activity in a physiological context. Dr. Zhao's team addressed this gap by generating highly purified full-length BRCA1-BARD1 and its cellular substrates, establishing in vitro ubiquitylation reactions to study the protein's activity. This innovative approach allowed them to explore the modulation of the enzyme's activity, assess the impact of various mutations, and challenge the prevailing belief that E3 ligase activity is not vital for BRCA1's tumor-suppressing function. Contrary to previous assumptions, the BRCA1-I26A variant retained significant E3 ligase activity, and the team identified a truly inactive mutant, demonstrating the critical role of this enzymatic activity in multiple stages of DNA repair.

This groundbreaking research not only resolves longstanding questions about the role of BRCA1's E3 ligase activity in tumor suppression but also paves the way for novel therapeutic strategies targeting BRCA1-related pathways. By revealing the mechanisms behind BRCA1's protective functions, the study offers a renewed understanding of the gene's tumor-suppressing capabilities, with significant implications for cancer treatment and risk assessment.

A CPRIT High Risk/High Impact Research Award (RP210102) to UT Health San Antonio and Dr. Zhao in 2021 supported this research.

- Researchers at Texas Tech University Health Sciences Center, led by Dr. Yangzom D. Bhutia, have conducted a comprehensive study on the role of SLC38A5, a neutral amino acid transporter, in the growth and proliferation of Pancreatic Ductal Adenocarcinoma (PDAC) cells. PDAC cells, known for their high demand for nutrients such as sugars, amino acids, and lipids, utilize these components to fuel their rapid growth and spread. Amino acids play a crucial role in connecting glucose, lipid, and nucleotide metabolism, serving as intermediaries in these vital biochemical pathways.

  The team employed CRISPR/Cas9-mediated knockdown techniques to delve into the function of SLC38A5 in both cell lines and mouse models. Their findings, published in

*Scientific Reports* on October 6, reveal that SLC38A5 is markedly overexpressed in PDAC cells, and this overexpression correlates with poorer overall survival rates in PDAC patients. This establishes a clear link between the increased expression or activity of SLC38A5 and the aggressive nature of pancreatic cancer, underscoring the transporter's role in promoting tumor growth.

In addition to establishing the prevalence of SLC38A5 in PDAC cells, the researchers analyzed the transporter's functionality within these cancer cells. Through a combination of metabolomics and RNA-sequencing, the team conclusively demonstrated that SLC38A5 plays a critical role in the growth and proliferation of PDAC cells. This novel insight adds a valuable layer to the understanding of pancreatic cancer's metabolic mechanisms and highlights SLC38A5 as a potential target for therapeutic intervention.

The study was part of a broader initiative at Texas Tech University Health Sciences Center, supported by a $6 million CPRIT Texas Regional Excellence in Cancer grant (RP210154) awarded in August 2021. The grant facilitates research into new anti-cancer drugs and cancer immunotherapies, as well attracting and supporting outstanding junior faculty in West Texas dedicated to developing innovative cancer treatments.

- On October 23, Hummingbird Bioscience presented positive clinical data for the dose escalation part of the HMBD-001 Phase I/IIa trial (NCT05057013) at the European Society for Medical Oncology Congress 2023. The trial is evaluating HMBD-001 as a monotherapy across various tumor types in the UK. As of the data cut-off on September 8, the trial enrolled 23 heavily pre-treated patients across various tumor types where HER3 may play an important role. The dose escalation trial cleared six monotherapy cohorts with no dose-limiting toxicities and there were no treatment discontinuations due to related adverse events.

  CPRIT awarded the company, based in San Diego, Houston, and Singapore, a $13.1 million Company Relocation grant (DP190027) in 2019.

**Personnel**

CPRIT has filled 44 full-time equivalent positions and has several positions in progress, including an accountant position and grant compliance specialist positions.

**88th Texas Legislature, 3rd Called Session**

The 30-day third called session of the 88th Texas Legislature convened on October 9 and will adjourn no later than November 7. Currently there are no issues affecting CPRIT.

**CPRIT Outreach**

Staff outreach activities during October include:

- On October 5, I met with Representative Mike Scofield to discuss the process that led to the successful recruitment of the ARPA-H Customer Experience Hub to Texas and miscellaneous legislative issues.

- I met with governmental affairs staff of Baylor College of Medicine on October 11 to provide an update of CPRIT activities and to discuss various legislative issues.

- Program Manager for Academic Research Dr. Myriam Casillas attended a virtual Global Cancer Research and Control Seminar Series held October 12.

- On October 16 Chief Scientific Officer Dr. Michelle Le Beau, Director of Research Dr. Patty Moore, Deputy Executive Officer and General Counsel Kristen Doyle, and I received a videoconference briefing on The University of Texas MD Anderson's Institute for Data Science in Oncology.

- On October 16, Senior Program Manager for Product Development Dr. Abria Magee met with Dr. Barbara Mroczkowski, program director for the NCI Experimental Therapeutics (NExT) program. NExT focuses primarily on therapies that have the potential to provide an important advance or meet a critical need but are unlikely to initially attract private sector investment because they are too high risk or may only be of potential benefit to a small patient population. NExT has provided matching funds support to Allterum, a CPRIT-funded company.

- On October 17 Oversight Committee member Dee Margo attended an event hosted by Texas Tech University Health Sciences Center El Paso to announce two new CPRIT grants that will enhance preventive cervical care in the El Paso Borderplex region, and support research focused on an aggressive form of acute myeloid leukemia. Dr. Michelle Le Beau participated in the event through a video recording emphasizing the vital important of research addressing the increased cancer burden in the Borderplex region, and the partnership of Texas Tech El Paso and CPRIT in the fight against cancer.

- On October 19 Ms. Doyle and I attended the launch event celebrating the Customer Experience Hub of the Advanced Research Projects Agency Network for Health (ARPANET-H) at Pegasus Park in Dallas. At the event ARPANET-H announced a new initiative that is soliciting proposals focusing on clinical trial readiness with a goal of enabling 90 percent of all eligible Americans to take part in a clinical trial within a half hour of their home. We will be promoting this initiative with our grantees and providing our own comments from the CPRIT office.

- Dr. Moore was an invited presenter at The University of Texas at Dallas Research Days Series on October 23. She discussed CPRIT's history and its unique role in the fight against

cancer. Dr. Moore also reviewed UT Dallas' current CPRIT funding portfolio and funding opportunities.

- On October 23, Dr. Magee met with faculty member Danny Diaz with the Institute for Foundations of Machine Learning (IFML) at The University of Texas at Austin to discuss potential product development award opportunities to spin out IFML technology. IFML is developing frameworks for machine learning and key foundational tools for the next decade of AI innovation.

- Dr. Moore spoke at the National Council of University Research Administrators Region V Conference on October 24.

- Program Manager for Product Development Dr. Michelle Leeuwon attended The University of Texas Southwestern Medical Center Innovation Days on October 25 and met with several researchers, including Dr. Tao Wang (AI-assisted T-cell receptor design technology), Dr. Jason Park (OncoSeer, a company collaborating with UT Southwestern to develop multi-marker blood tests for patients undergoing immune checkpoint inhibitor therapy), Dr. Kathryn O'Donnel (novel monoclonal antibody technology), and Dr. Jing Wang (malignant lymph node identification AI algorithms.)

- On October 25 Texas Healthcare & Bioscience Institute (THBI) recognized me with the THBI Luminary award for my efforts in fostering innovations for potential medical breakthroughs in preventions and cures and promoting cancer research in Texas. Several current and former Oversight Committee members and CPRIT senior staff attended the awards dinner.

- Chief Operating Officer Heidi McConnell, Ms. Doyle and I attended the Texas Economic and Technology Briefing on October 26 hosted by RSM (a national provider of audit, tax and accounting services focused on the middle market), the U.S. Chamber of Commerce, and the Texas Association of Business. The briefing included presentations on artificial intelligence and technology advancements in the current economic climate.

- Dr. Le Beau participated as an invited panelist at the Precision Oncology and Diagnostics Conference held October 26-27 in Chicago. Her session, "Challenges and Opportunities in Multi-Cancer Early Detection (MCED) Tests," focused on the current state of this disruptive new technology, as well as the challenges in implementing the approach in the health care system in a cost-effective and equitable manner. MCED tests are primarily blood-based tests that can detect the presence of multiple cancer types through the identification and analysis of circulating cell-free DNA, and other markers.

- Ms. Doyle and I held several discussions over the month about the feasibility of CPRIT support for an outside effort to create a bio filling center in College Station.

- Program Manager for Prevention Carlton Allen joined the American Indian Cancer Foundation's Indigenous Cancer Solutions Texas Coalition. This coalition works with

individuals, clinics, and organizations throughout Texas to develop and implement the Indigenous Cancer Solutions Comprehensive Cancer Control Plan. The Coalition's goals include increasing appropriate cancer screening through recommended screening cancer guidelines in Indigenous communities and reducing the rate of late-stage diagnosis.

**Program Priorities for FY 2025**

The three program subcommittees will discuss program priorities for FY 2025 in their upcoming subcommittee meetings in preparation for the Oversight Committee's vote to adopt the priorities at the November 15 meeting.

**Compliance Program Update**

Submission Status of Required Grant Recipient Reports

As of October 27, seven entities had not filed seven academic research reports, and one product development report. CPRIT's grant accountants and compliance specialists review and process incoming reports and reach out to grantees to resolve filing issues. In most cases, CPRIT does not disburse grant funds until the grantee files the required reports. In some instances, grantee institutions may be ineligible to receive a future award if the grantee does not submit required reports.

Financial Status Report Reviews

CPRIT's compliance specialists performed 186 second-level reviews of grantee Financial Status Reports (FSRs) in October. Twenty-four FSRs (13%) needed resubmission due to insufficient or inaccurate documentation sent by the grantee. CPRIT's grant accounting staff completes the first review of the FSRs and supporting documentation before routing them to the compliance specialists for final review and disposition.

Desk Reviews

Compliance specialists performed six enhanced desk-based financial monitoring reviews in August and September. Desk reviews confirm financial, administrative, and programmatic compliance using data from CGMS/CARS with additional focus on an organization's internal controls, current and previous fiscal audits, and grantee report submission timeliness. Desk reviews also aid in the identification of potential problems and technical assistance issues for follow-up during an onsite visit, as well as areas of non-compliance and grantee performance issues. Compliance specialists are collaborating with three grantees to address desk review findings.

Single Audit Tracking

Compliance specialists track the submission of grantees' independent audit reports and the resolution of issues named in these reports. Grantees spending $750,000 or more in state awards in the grantee's fiscal year must undertake a single independent audit, a program specific audit, or an agreed upon procedures engagement. The grantee sends the independent audit report with findings to CPRIT within 30 days of receipt, but no later than nine months after the grantee's fiscal year end.

Currently, two grantees have not submitted the required 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 more time by the due date of the required audit and CPRIT's CEO approves the request. Compliance staff is actively working with the two grantees to submit the required audit.

Training and Support

CPRIT staff conducted a series of Annual Compliance Training webinars on October 25-26 for 120 grantee staff. Training is specific to each program area (Academic Research, Product Development Research, and Prevention) and allows for an interactive experience and opportunity to focus on topics relevant to each program. The trainings covered grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. This was the third training series offered this year for the annual compliance training requirement which requires the Authorized Signing Official (ASO) and at least one other employee from each grantee organization to attend an annual compliance training by December 31 of each year.

## Academic Research Program Update

Recruitment FY 2024 Review Cycle 1 and 2

CPRIT accepted recruitment applications June 21 through August 20 for the first and second review cycles of FY 2024. CPRIT's Scientific Review Council (SRC) reviewed the applications on September 14. Dr. Le Beau will present the SRC's award recommendations for recruitment awards to the Oversight Committee November 15.

| FY 24 Mechanism | Received | Funds Requested | Recommended | Recommended Funds |
|---|---|---|---|---|
| Recruitment of Established Investigators | 2 | $12,000,000 | 1 | $6,000,000 |
| Recruitment of First-Time, Tenure Track Faculty Members | 2 | $ 3,990,000 | 1 | $1,990,000 |
| **TOTAL** | **4** | **$15,990,000** | **2** | **$7,990,000** |

Academic Research FY 2024 Review Cycle 1 (24.1)

CPRIT posted five Individual Investigator RFAs for the first review cycle of FY 2024 on February 17, accepting applications March 15 through June 14, 2023. Peer reviewers met in October to evaluate the 315 applications. Dr. Le Beau will present the SRC's recommendations for the cycle 24.1 grants to the PIC and the Oversight Committee in February 2024.

| FY 24 Cycle 1 Mechanism | Received | Funds Requested |
|---|---|---|
| Individual Investigator Research Award (IIRA) | 228 | $233,894,288 |
| IIRA for Computational Systems Biology of Cancer | 18 | $36,108,737 |
| IIRA for Cancer in Children and Adolescents | 35 | $47,815,216 |
| IIRA for Prevention and Early Detection | 15 | $27,050,403 |
| IIRA for Clinical Translation | 19 | $19,850,946 |
| **TOTAL** | **315** | **$364,719,590** |

Academic Research FY 2024 Review Cycle 2 (24.2)

On September 14, CPRIT released several RFAs (listed below) for the second cycle of FY 2024 and will accept applications October 17 – January 16, 2024. Peer review panels will meet virtually in late April 2024 to consider the applications. Dr. Le Beau will present the SRC's recommendations to the PIC and the Oversight Committee in August 2024.

- **Core Facility Support Awards**
  Supports applications that facilitate the development or improvement of core facilities that will provide valuable services to support and enhance scientifically meritorious cancer research projects. Applicants may request funds to develop a new facility or to enhance the capabilities of an existing facility that will directly support and impact cancer research programs at the institution and in the region. CPRIT will look with special favor on applications that propose a facility that will serve cancer researchers at multiple Texas research institutions, in particular TREC-eligible institutions.
  **Award:** The maximum duration for this award mechanism is 5 years. Applicants may request up to a maximum of $3,000,000 in total costs.

- **High-Impact/High-Risk Research Awards**
  Supports applications that explore the feasibility of high-risk projects that, if successful, would contribute major new insights into the etiology, diagnosis, treatment, or prevention of cancers. Using this mechanism, CPRIT intends to support innovative, developmental projects that focus on exceptionally promising topics that are not yet sufficiently mature to compete successfully for more conventional funding. CPRIT expects the HIHR Research Awards to provide the foundation for individual or multiple investigator peer-reviewed awards upon completion. The goal of this award mechanism is to fund uncommonly great ideas that merit the opportunity to acquire preliminary data.
  **Award:** Applicants may request a total of $250,000 for a period of up to 24 months.

- **Multi-Investigator Research Awards**
  Supports highly integrated programs of collaborative and cross-disciplinary research among multiple Texas investigators and Institutions. CPRIT particularly encourages applications addressing one of the program priorities for academic research adopted by CPRIT's Oversight Committee.
  **Award:** $4,500,000 in total costs for a maximum period of 4 years.

- **Clinical Investigator Award**
  Supports mid-career clinician scientists with specialty training relevant to delivery of cancer care to devote more time to augment their capabilities in clinical cancer research, and to provide mentoring to early-stage investigators in the conduct of clinical research. The CIA will provide protected time from clinical responsibilities to provide physicians with the opportunity to expand clinical research skills, to develop investigator-initiated clinical trials, to develop external relations with industry and pharmaceutical company partners, and to expand partnerships with laboratory-based collaborators to design and conduct correlative studies needed to interpret the outcome of an interventional trial. The CIA initiative will increase the pool of clinical investigators at Texas academic institutions who are conducting patient-oriented studies, who will be able to compete successfully for peer-reviewed grants, and who will mentor the next generation of clinical investigators.
  **Award:** $1,500,000 in total costs for a maximum period of 5 years.

**Product Development Research Program Update**

Product Development FY 2024 Cycle 1 Review (24.1)

On May 1 CPRIT released four FY 2024 Product Development Research RFAs and opened the portal to receive preliminary and full applications on a rolling basis. CPRIT received the total number of full applications (15) allocated for the first cycle of FY 2024 by June 30, one month before the August 1 deadline.

- Preliminary Application Review: CPRIT received 79 FY 2024 preliminary applications on a rolling basis between May 1 and June 30. Like the FY 2023 review cycle, five standing review panels evaluated the FY 2024 preliminary applications on a rotating basis. CPRIT issued weekly invitations to submit full applications to companies that presented meritorious preliminary applications, based on application scores as determined by the preliminary application peer review panel.

  CPRIT received the total number of full applications for the 15 review slots for the first review cycle for FY 2024 on June 30. The preliminary review panels completed reviews of 45 preliminary applications and issued invitations to 19 companies to submit a full application for FY 2024 by June 30. Because there were no more spots available for full application review, CPRIT returned 34 preliminary applications to applicants without review. Should the applicants submit these unreviewed applications in future cycles, they will not count against their resubmission limit.

The table below provides information about the FY 2024 preliminary applications.

| 24.1 RFA | Preliminary Applications | | | Total Prelim Request | Full Application Invites |
|---|---|---|---|---|---|
| | Submitted | Reviewed | Returned - no review | | |
| TTC | 34 | 23 | 11 | $353 M | 10 |
| TDDC | 4 | 2 | 2 | $27 M | 1 |
| TNTC | 9 | 5 | 4 | $39 M | 2 |
| Seed | 32 | 15 | 17 | $48 M | 6 |
| **TOTAL** | **79** | **45** | **34** | **$467 M** | **19** |

TTC = Texas Therapeutics Company
TDDC = Texas Device and Diagnostic Company
TNTC – Texas New Technologies Company

- Full Application Review (July and August): In addition to the 19 invitations issued by June 30, CPRIT allowed four companies that submitted full applications in the FY 2023 cycle to resubmit their full applications for review in the FY 2024 cycle. (CPRIT did not review these four full applications in FY 2023 because of time and resource limitations.)

  The FY 2024 RFAs notified applicants that CPRIT would continually monitor the number of submissions and would stop accepting full applications before the August 1 deadline if we received more than 15 applications. By 4:00 p.m. CST on June 30, CPRIT received its 15th and 16th full application submittal (including the four FY 2023 full applications.) Accordingly, we closed the portal for full application submission on June 30. We separately notified the seven companies with invitations for FY 2024 who had not submitted full applications by June 30 that CPRIT was no longer accepting full applications at this time.

  Although we planned for 15 spots, Dr. Smith increased the number of review slots to accommodate the 16th full application received by CPRIT on June 30. As a result, unlike the FY 2023 review cycle, CPRIT did not return any full applications to applicants without a review, and we will not carry over submitted but unreviewed applications into future cycles.

- Panel Presentations, Due Diligence Review and Budget Negotiation (August – October): Prior to panel presentations, one company withdrew from consideration because of unexpected clinical results. The remaining 15 companies presented their full applications to review panels in August and September. Based upon the review panels' recommendations, eight companies proceeded to due diligence review. The review panels met in September and October to evaluate the due diligence reports and to finalize panel award recommendations. Following the meetings, the panels recommended seven companies for product development awards.

  Using the same process we successfully employed for the FY 2023 review cycle, Chief Product Development Officer Dr. Ken Smith negotiated the proposed project budgets to identify ways to decrease CPRIT-funded project expenses while maintaining the goals and objectives of the recommended projects. As we learned from the last cycle, this is a crucial

step to ensuring that CPRIT can fund as many meritorious projects as possible with the estimated $74 million allocated for FY 2024 Product Development awards.

The table below provides information about the FY 2024 cycle 1 full applications.

| 24.1 RFA | Invited Apps | Submitted Apps | Budget Request | Apps in Due Diligence | Budget Request |
|---|---|---|---|---|---|
| TTC | 12 | 8 | $112.8M | 3 | $41.8M |
| TDDC | 2 | 2 | $9.0M | 1 | $5.4M |
| TNTC | 2 | 1 | $12.6M | 1 | $12.6M |
| Seed | 7 | 5 | $15.0M | 3 | $9.0M |
| **TOTAL** | **23** | **16** | **$149.4M** | **8** | **$68.8M** |

- Final Recommendations (October and November): The Product Development Review Council (PDRC) met October 24 to develop a final ranked list of the seven companies recommended for product development awards. Dr. Smith will present the companies recommended for product development awards to the Program Integration Committee and the Oversight Committee at the November 15 Oversight Committee meeting.

- Looking Ahead: If CPRIT does not award all product development award funds allotted for FY 2024 in this first cycle, the product development program expects to reopen the RFAs in December or January for a second round of awards for Oversight Committee approval in May or August 2024.

The Texas Resource Guide

For the past several months, a joint effort of the product development program staff, IT staff, and communications staff, led by Dr. Magee, created *The Texas Resource Guide* for biotech companies in Texas or considering relocating to Texas. CPRIT debuted a beta version of the guide at the *CPRIT Innovations Conference* in early October. It features a compilation of detailed information about service providers and other entities that support early stage and developing life science companies in Texas. We expect to finalize the "look and feel" for the landing page and improve the navigation process by early November. Currently, the guide includes 196 entities; we will regularly update the guide with more information.

Other Activities

Dr. Magee and Dr. Leeuwon met with 19 active CPRIT-funded companies for on-site visits in Houston and Dallas during October. The team received high-level project overviews from the companies, including updates on pending project goals and objectives and expected next steps. The product development program will use this information to augment the ongoing CPRIT company portfolio project. Dr. Magee met with the following Houston-based companies: Allterum, Asylia Therapeutics, 7 Hills Pharma, Hummingbird Bioscience, Immunogenesis, Invectys, InformAI, Instapath, Iterion, Marker Therapeutics, OmniNano, OncoResponse,

PranaThoracic, Pulmotect, and Xerient. Dr. Leeuwon met with three Dallas-based companies: ImmuneSensor, OncoNano, and Perimeter. The CPRIT team plans more on-site visits in 2024.

**Prevention Program Update**

Prevention FY 2024 Review Cycle 1 (24.1)

The Prevention Program released two prevention RFAs on May 5 for the first cycle of FY 2024. CPRIT received 29 proposals totaling $46.7 million by the August 30 deadline. Peer review will take place November 2023 – January 2024, with Ms. Magid presenting the Prevention Review Council's recommendations to the PIC and the Oversight Committee in February 2024.

| Cycle 24.1 Mechanism | Applications | Funds Requested |
|---|---|---|
| Primary Prevention of Cancer | 13 | $19,384,419 |
| Cancer Screening and Early Detection | 16 | $27,272,619 |
| **TOTAL** | **29** | **$46,657,038** |

**Advisory Committees**

- The University Advisory Committee will meet November 3.

**IP Database Project**

Now under the direction of Product Development Program Manager Dr. Leeuwon, CPRIT compiled and transferred all IP reporting files to WellSpring, our database vendor, in October. WellSpring will populate CPRIT's hosted IP database (called Sophia) with the transferred files. Once this task is complete, CPRIT and Wellspring will finalize the database fields and update the reporting forms. We requested that grantees temporarily pause submitting their regular IP reports to minimize redundant effort. We expect to have a functional database for internal review in early 2024.

**Operations and Finance Update**

The audit of the CPRIT's FY 2023 financial statements, performed by the McConnell & Jones audit team, is underway. Chief Operating Officer Heidi McConnell and CPRIT accountant Michelle Huddleston have primary responsibility for completing this audit. McConnell & Jones will deliver the final audit to the agency in early December. The Audit Subcommittee will hold a special meeting (not yet scheduled) in December to review the audit with staff.

Thank you for completing the Related Party and Fraud Risk questionnaires and submitting the completed forms to the audit team.

Ms. Huddleston is finalizing the agency's Annual Financial Report (AFR), which CPRIT must complete by November 20. CPRIT will send the AFR to the Office of the Comptroller of Public Accounts, State Auditor's Office, Governor's Office, Legislative Budget Board, Legislative Reference Library, and Texas State Library.

The Governor's Office and Legislative Budget Board released instructions for completing the FY 2024 Operating Budget on October 16. State agencies must complete an operating budget in every even-numbered year. In odd-numbered years, agencies complete Legislative Appropriations Requests in preparation for an upcoming legislative session. The FY 2024 Operating Budget is due December 1. Ms. McConnell and CPRIT Operations Specialist Dan Limas are working on completing this document.

**Upcoming Subcommittee Meetings**

Listed below are the subcommittee meetings in advance of the November 15 Oversight Committee meeting. We will send instructions for signing onto the Microsoft Teams platform along with the subcommittee agenda and meeting materials one week prior to each meeting.

| | |
|---|---|
| Board Governance | November 2 at 10:00 a.m. |
| Audit | November 6 at 10:00 a.m. |
| Prevention | November 7 at 12:00 p.m. |
| Academic Research | November 8 at 12:00 p.m. |
| Product Development | November 9 at 10:00 a.m. |

******

CPRIT has awarded **1,901** grants totaling **$3.381 billion:**

- 291 prevention awards totaling $354.8 million
- 1,610 academic research and product development research awards totaling $3.03 billion

Of the $3.03 billion in academic research and product development research awards,

- 31.6% of the funding ($955.9 million) supports clinical research projects
- 23.8% of the funding ($720.1 million) supports translational research projects
- 29.4% of funding ($889.4 million) supports recruitment awards
- 12.2% of the funding ($370.1 million) supports discovery stage research projects
- 3.0% of funding ($90.4 million) supports training programs.

CPRIT has seven open Requests for Applications (RFAs)

- 3 Academic Research Recruitment
- 4 Academic Research Projects

**Kirk Dorius, JD**

**Chief Executive Officer**
**Atom Mines, LLC**

Mr. Kirk Dorius serves as CEO and General Counsel for Atom Mines specializing in production of stable Ytterbium-176 needed to produce the radioisotope Lutetium-177 for radiotherapies. Mr. Dorius has been an entrepreneur and consultant in the nuclear medicine and nuclear energy industries since 2010 and previously worked as a patent attorney with national firms and as a mechanical engineer with a missile defense contractor. He also served as president of the Pointsman Foundation, a nonprofit organization advancing domestic production and use of stable isotopes and radioisotopes for a range of medical treatments, diagnostics, and research.

Mr. Dorius has particular expertise in isotope separation, molten salt reactors, and intellectual property law. He studied mechanical engineering at Utah State University and patent law at the University of New Hampshire. Atom Mines has received a CPRIT grant to scale up production of 176-Yb for prostate cancer therapies using Magnetically Activated and Guided Isotope Separation (MAGIS) technology developed by Dr. Mark Raizen at The University of Texas at Austin.

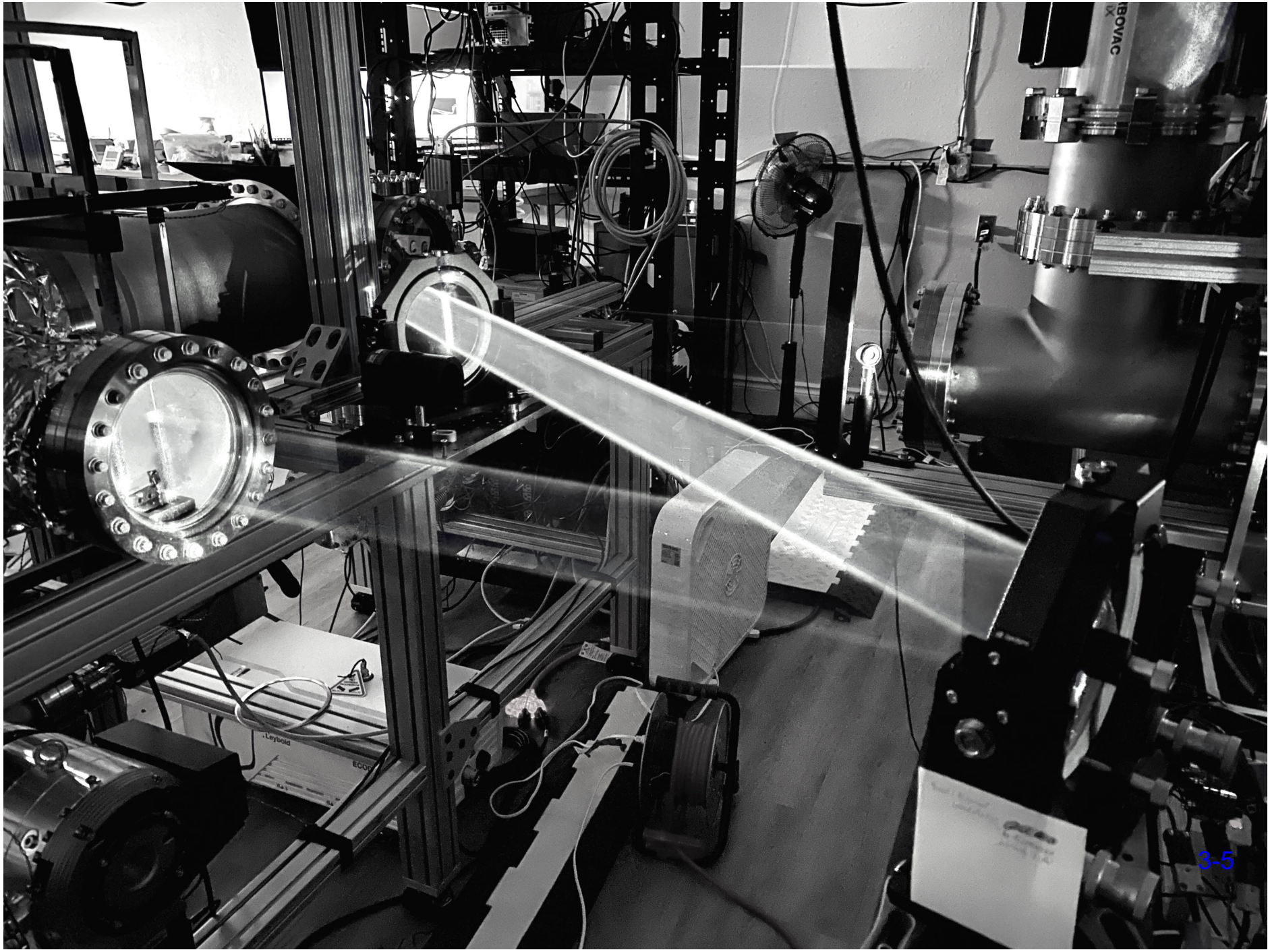
# Enrichment of Stable Ytterbium-176 for Production of No-carrier-added Lutetium-177 for Radiotherapies

Presentation to the CPRIT Oversight Committee
November 15, 2023

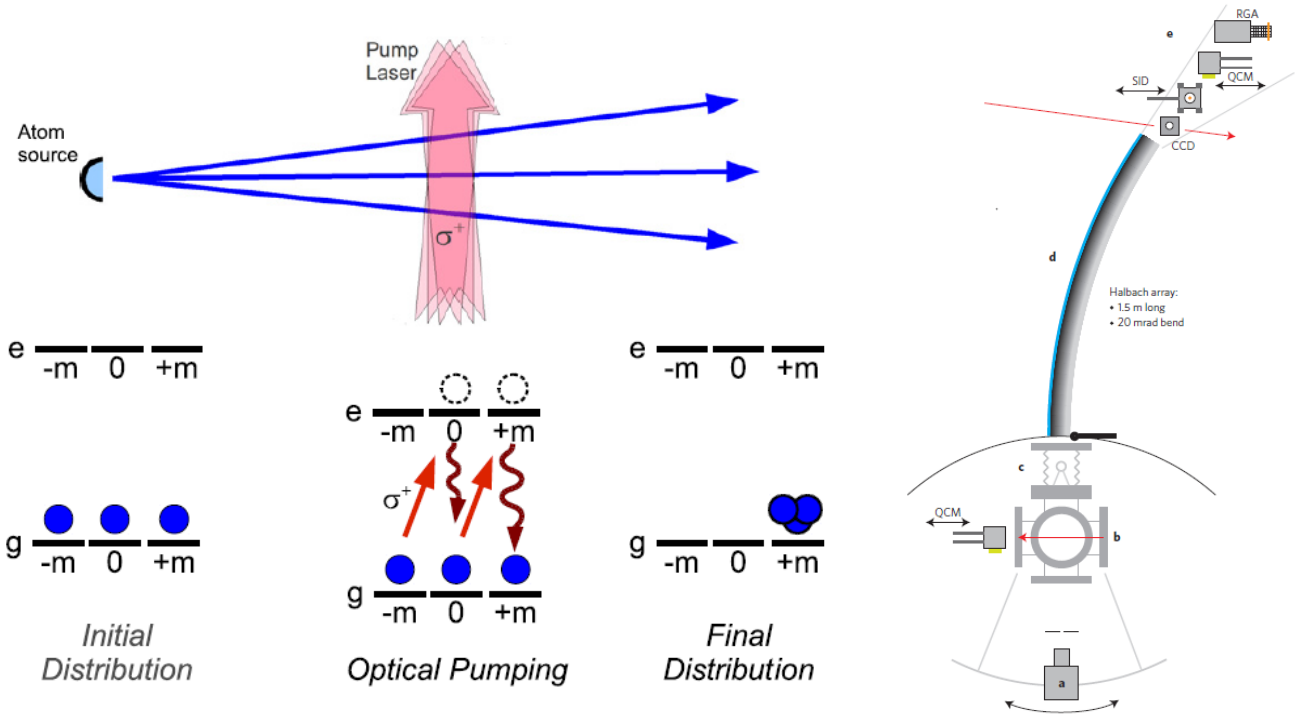
Kirk Dorius - CEO
Atom Mines
kirkdorius@atommines.com


STUDIO
A
DANGER
HIGH VOLTAGE LASER
CONTAINMENT SYSTEM


STUDIO
B
ON
DANGER
CLASS IV LASER
VISIBLE AND INVISIBLE
LASER RADIATION
AVOID EYE AND SKIN EXPOSURE
WEAR PROTECTIVE EYEWEAR
RESTRICTED
AREA
AUTHORIZED
PERSONNEL
ONLY
STOP


3-5

# MAGIS Isotope Separation




•MAGIS is efficient, achieving a high degree of separation with low energy input.

•MAGIS excites selected isotopes with a tuned laser and then uses magnetic fields to separate the excited isotopes.

3-6

# Magnetically-Activated and Guided Isotope Separation (MAGIS)

MAGIS offers a domestic reliable supply of 176Yb and other isotopes for medicine.

(12) **United States Patent**
**Raizen et al.**

(10) **Patent No.: US 8,672,138 B2**
(45) **Date of Patent: Mar. 18, 2014**

(54) **ISOTOPE SEPARATION BY MAGNETIC ACTIVATION AND SEPARATION**

(71) Applicant: **Board of Regents, The University of Texas System**, Austin, TX (US)

(72) Inventors: **Mark G. Raizen**, Austin, TX (US); **Bruce G. Klappauf**, Austin, TX (US)

(73) Assignee: **Board of Regents The University of Texas System**, Austin, TX (US)

(56) **References Cited**

U.S. PATENT DOCUMENTS

| | | | |
|---|---|---|---|
| 848,600 | A | 3/1907 | von Pirani |
| 3,953,731 | A | 4/1976 | Forsen |
| 4,081,677 | A | 3/1978 | Dawson |
| 4,149,077 | A | 4/1979 | Yamashita et al. |
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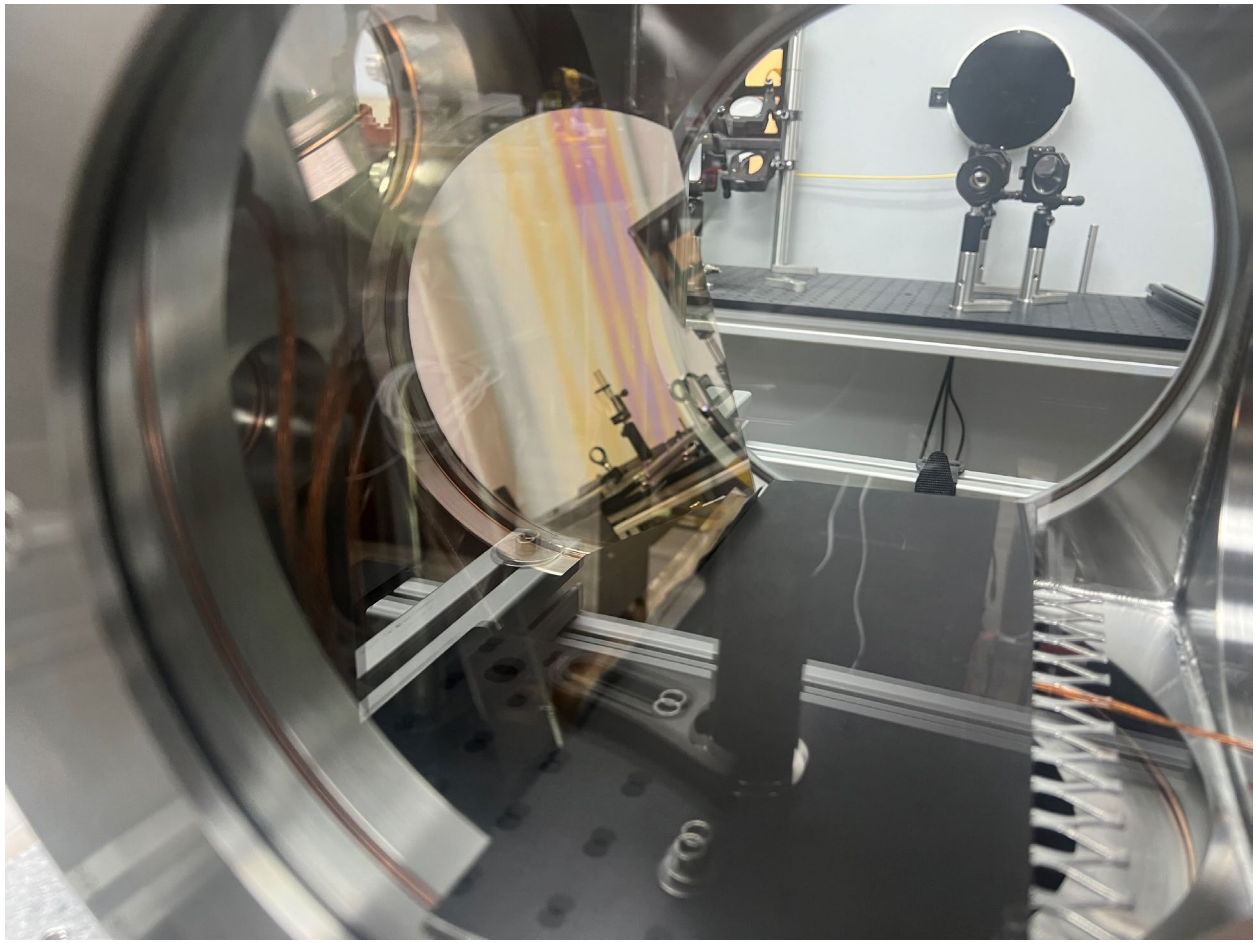
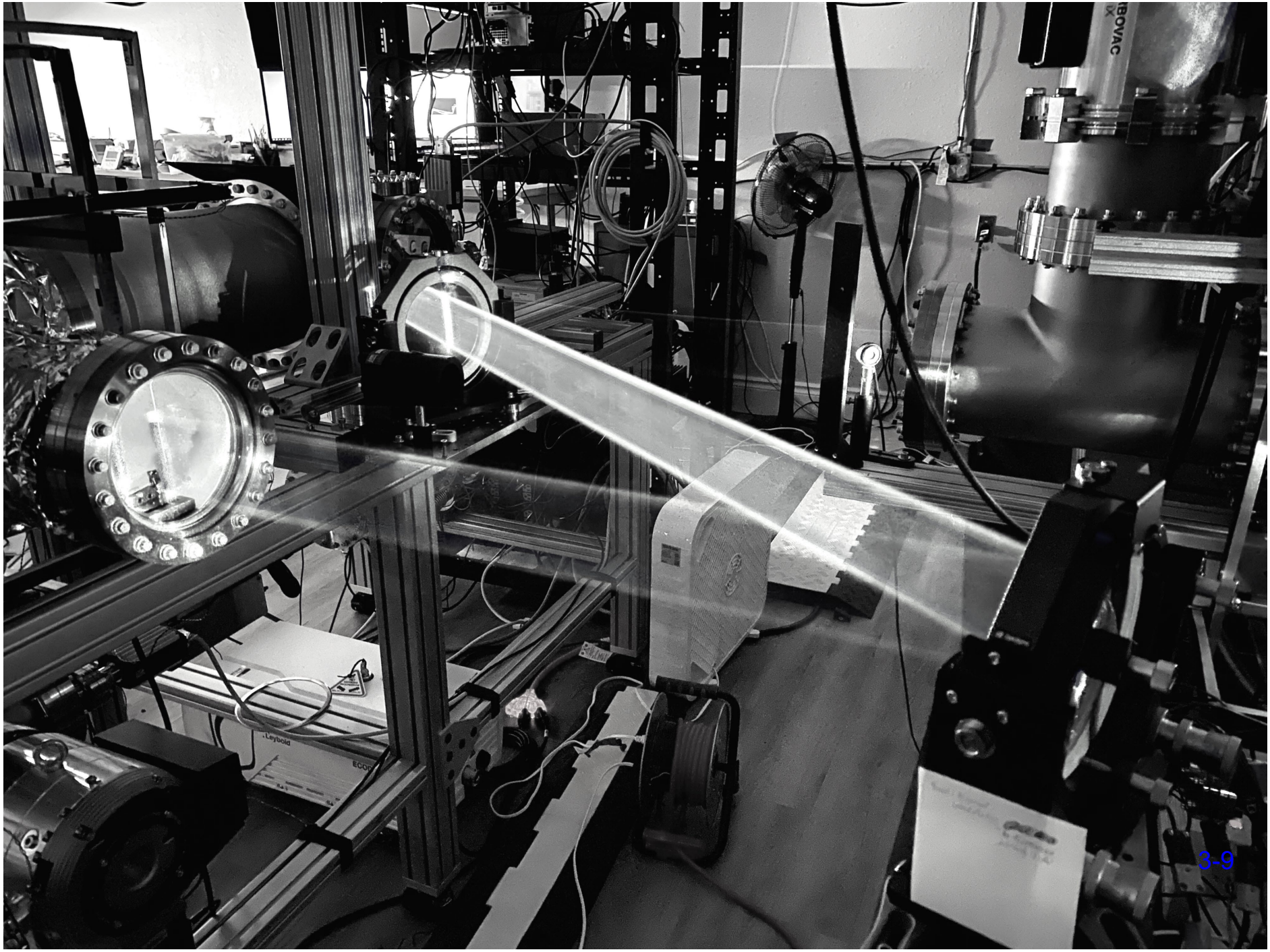
| 7,323,651 | B2 | 1/2008 | Jeong et al. |
| 2011/0278203 | A1 | 11/2011 | Raizen et al. |

FOREIGN PATENT DOCUMENTS

3-7

# Stripes of Collected Yb-176

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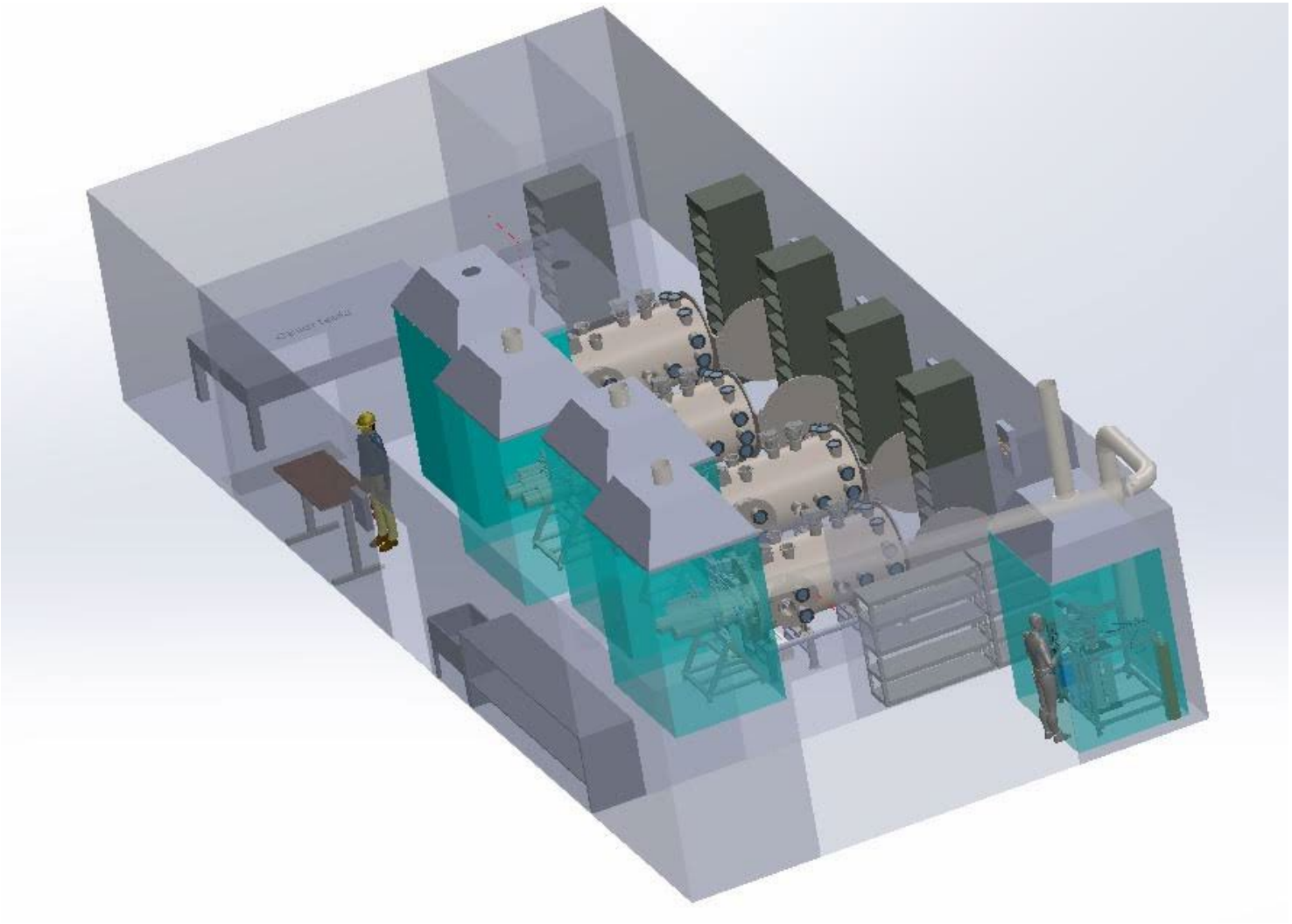
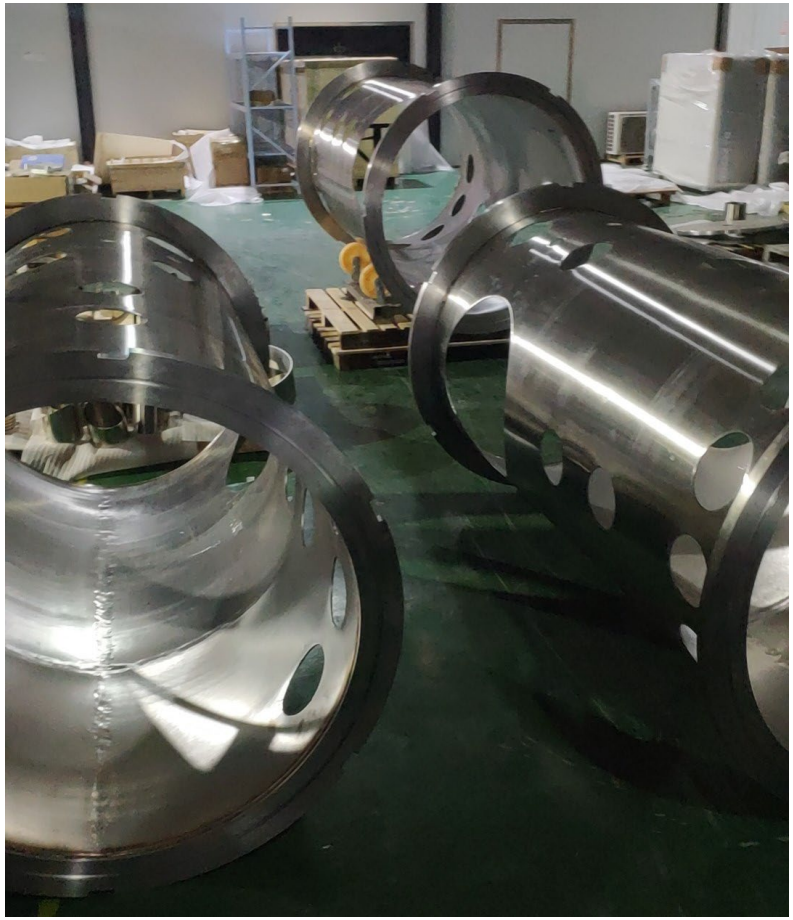


# CPRIT Funding for Commercial Scale-up

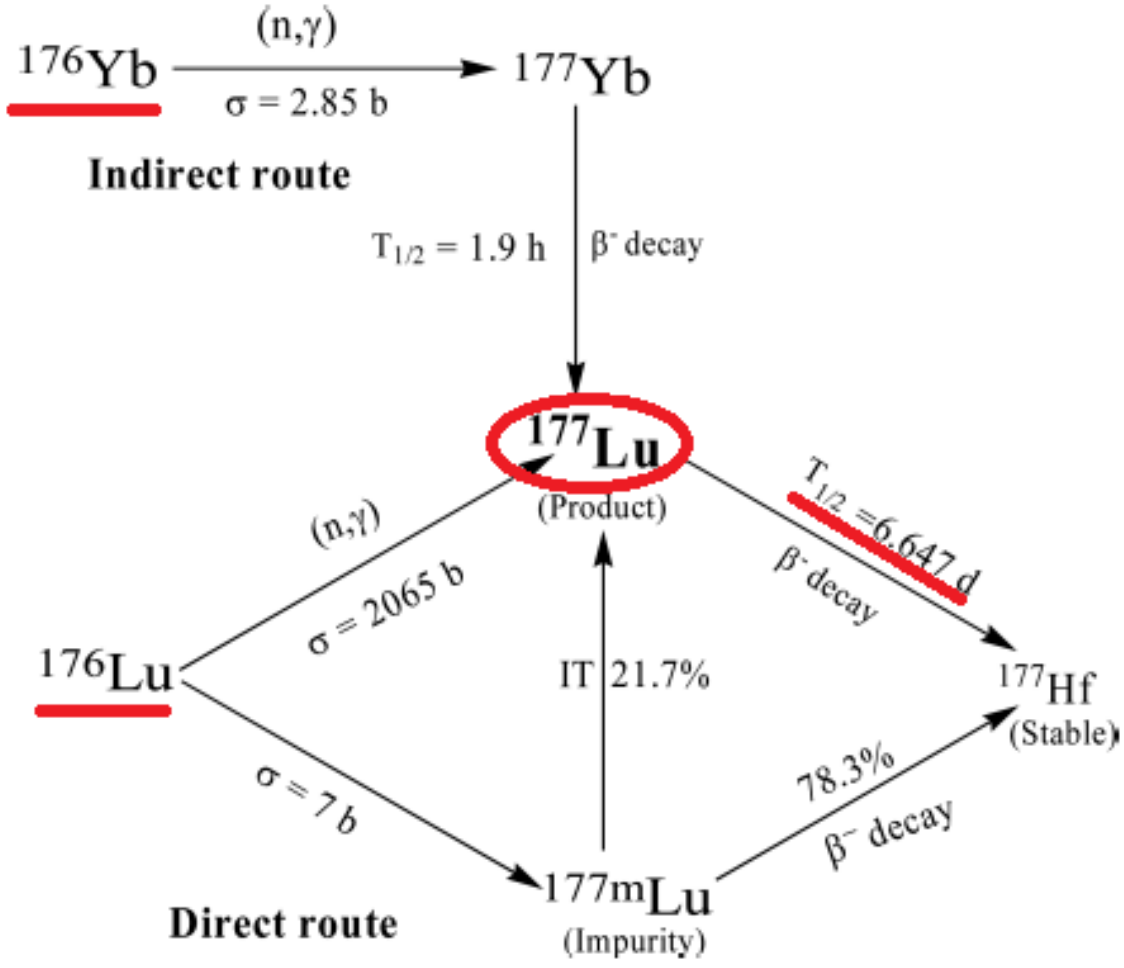


# MAGIS Can Separate Over 130 Isotopes of Over 30 Elements

| | Element | Stable Isotopes |
|---|---|---|
| 1 | Li | 6,7 |
| 2 | Mg | 24,25,26 |
| 3 | Ar | 36,38,40 |
| 4 | K | 39,40,41 |
| 5 | Ca | 40,42,43,44,46,48 |
| 6 | Cr | 50,52,53,54 |
| 7 | Fe | 54,56,57,58 |
| 8 | Ni | 58,60,61,62,64 |
| 9 | Cu | 63,65 |
| 10 | Zn | 64,66,67,68,70 |
| 11 | Ga | 69,70 |
| 12 | Kr | 78,80,82,83,84,86 |
| 13 | Rb | 85,87 |
| 14 | Sr | 84,86,87,88 |
| 15 | Mo | 92,94,95,96,97,98,100 |

| | Element | Stable Isotopes |
|---|---|---|
| 16 | Ag | 107,109 |
| 17 | Cd | 106,108,110,111,112,113, 114,116 |
| 18 | In | 113,115 |
| 19 | Xe | 124,126,128,129,130,131, 132,134,136 |
| 20 | Ba | 130,132,134,135,136,137, 138 |
| 21 | Nd | 142,143,144,145,146,148, 150 |
| 22 | Gd | 152,154,155,156,157,158, 160 |
| 23 | Dy | 156,158,160,161,162,163, 164 |
| 24 | Er | 162,164,166,167,168,170 |
| 25 | Yb | 168,170,171,172,173,174, 176 |
| 26 | Hg | 196,198,199,200,201,202, 204 |
| 27 | Tl | 203,205 |
| 28 | Si | |
| 29 | Sn | |
| 30 | Ge | |
| 31 | Pb | |

# Production of Lu-177 for Cancer Beta-therapies




Kirk Dorius - CEO
Atom Mines
kirkdorius@atommines.com
256-763-1590

Dr. Omid Veiseh, Ph.D., is an Associate Professor and CPRIT Scholar in Cancer Research in the Department of Bioengineering at Rice University. He leads an interdisciplinary translational research program to engineer and commercialize next-generation cell-based therapeutics for various human diseases. His team leverages the latest techniques in synthetic biology, immunoengineering, and materials science to develop innovative cell-based platforms for real-time and feedback-regulated production of biologics. Over the course of his career, he has authored or co-authored more than 75 peer-reviewed publications, including those in Nature, Nature Biotechnology, Nature Materials, Nature Medicine, and Nature Biomedical Engineering, and is an inventor on more than 40 pending or awarded patents. He is also a serial entrepreneur who has co-founded Sigilon Therapeutics (Nasdaq: SGTX), Avenge Bio, Sentinel Bio, and Curada Bio. These companies collectively have attracted ~ $500M in private and public investment capital. In September of 2023, he was named the Director of Rice University's Biotech Launch Pad, a new initiative with a mission to accelerate the translation of Rice University discoveries and technologies into clinical practice to provide rapid patient access to leading-edge therapeutic products.

RICE

# Biotech Launch Pad

## Building an Ecosystem for Innovation at Rice, Houston, and Beyond…….

Omid Veiseh, Ph.D.

https://biotechlaunchpad.rice.edu/

www.veisehlab.rice.edu

# What if nanorobotic surgery could be delivered through a pill

# The Problem

**Academic Researchers**

*Attempt to discover and develop transformative technologies*

**Industry / Investors**

*Seek low-risk investments with strong return on investment*


**Most transformational technologies (~90%) fail to develop because of the gap between researchers and industry stakeholders** 3,13



Icons sourced from Flaticon

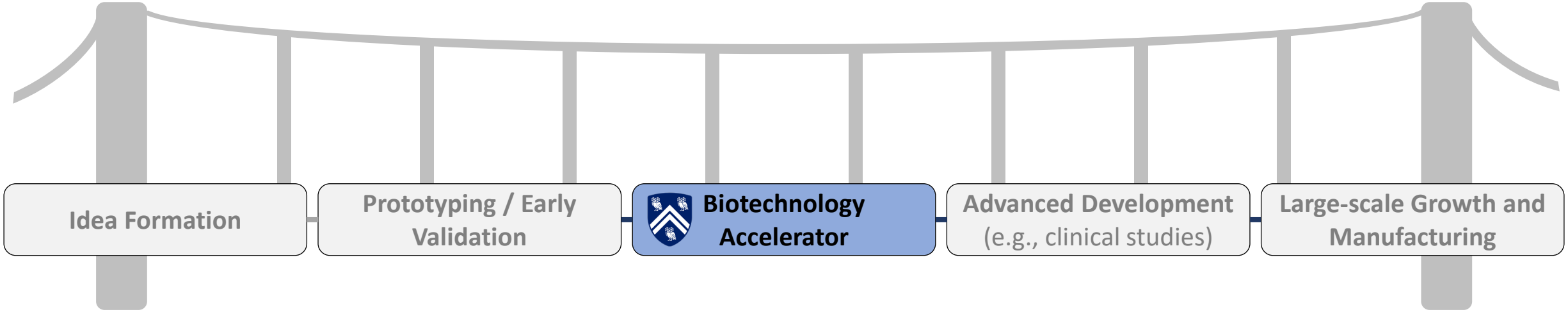
# The Solution: The [Donor] Biotechnology Accelerator

**Academic Researchers**

*Attempt to discover and develop transformative technologies*

**Industry / Investors**

*Seek low-risk investments with strong return on investment*



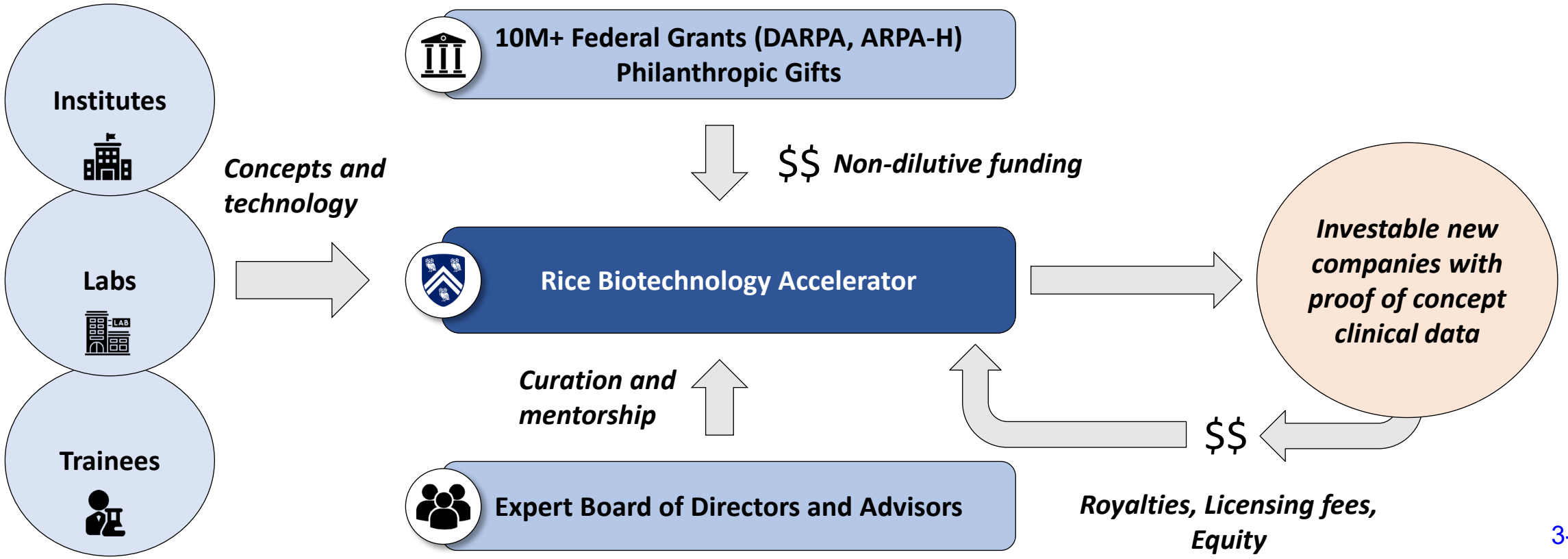

**The Rice University Biotechnology Accelerator will bridge the gap to develop transformative technologies with major impacts**



Icons sourced from Flaticon

# Biotechnology Accelerator Structure

**Our Aim** Translate Rice's most promising health technologies into cures ("From concept to clinic in 5 years")




3-21

# Criteria for Accelerator Programs

**Identify: Source high impact problems to labs, institutes, and trainees to create transformational technology platforms / intellectual property**

**Triage:** Prioritize concepts to solve high impact problems based upon criteria listed below

| Criteria | Commentary |
|---|---|
| **Significant Patient Benefit** | • Must have potential to address considerable unmet need |
| **Transformational Technology** | • Platform can benefit multiple therapeutic areas<br>• High-risk / high-reward projects of greater interest<br>• Me-too approaches are low priority |
| **Strong Competitive Position** | • Must be highly differentiated<br>• 5 years of work can provide substantive validation of concept |
| **Strategic alignment** | • Unfair advantage to Rice and Houston's offerings |

3-22

# Leadership Team (AKA "The Matchmakers")

## Faculty Director

**Omid Veiseh**

## Executive Director

**Paul Wotton**

## Leadership Council

**Rebekah Drezek**

**Jacob Robinson**

**Ashok V., Ph.D.**

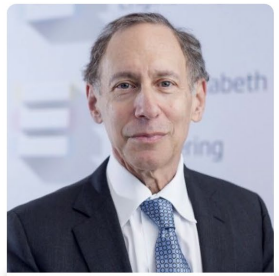
**Yael Hochberg, Ph.D.**

**Paul Cherukuri**

3-23

# External Advisory Board

**Pierre Jacquet, M.D., Ph.D.**
L.E.K., MANAGING DIRECTOR AND VICE CHAIRMAN



**Robert Langer, Sc.D.**
DAVID H. KOCH INSTITUTE FOR INTEGRATED RESEARCH AT THE MASSACHUSETTS INSTITUTE OF TECHNOLOGY, PROFESSOR

**Dennis Lee, Ph.D.**
BILL AND MELINDA GATES FOUNDATION, SENIOR PROGRAM OFFICER IN THE ACCELERATOR, GLOBAL HEALTH

**Ferran Prat, Ph.D., J.D.**
MD ANDERSON CANCER CENTER, SENIOR VICE PRESIDENT OF RESEARCH ADMINISTRATION AND INDUSTRY RELATIONS

**Jason Bock, Ph.D.**
CTMC, FOUNDER & CEO

**Albert Cha, M.D., Ph.D.**
FRAZIER LIFE SCIENCES, MANAGING PARTNER

**Rima Chakrabarti, M.D.**
KDT VENTURES, PARTNER

**John Flavin, MBA**
PORTAL INNOVATIONS, FOUNDER & CEO

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COMMUNITY HEALTH CHOICE, PRESIDENT AND CEO

**Gavin Britz, M.D**
HOUSTON METHODIST

**Ravi Ghanta, M.D.**
BAYLOR COLLEGE OF MEDICINE

**Amir Jazaeri, M.D.**
MD ANDERSON

**Raghu Kalluri, M.D., Ph.D.**
MD ANDERSON

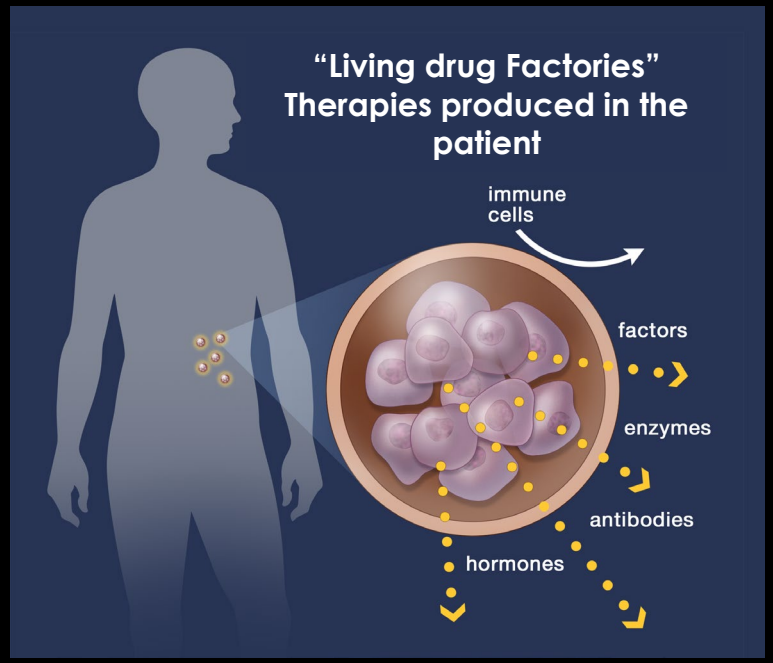
**Katy Rezvani, M.D., Ph.D.**
MD ANDERSON

**Sunil Sheth, M.D.**
UT HEALTH MCGOVERN MEDICAL SCHOOL

3-24

# What if medicines could be generated in our bodies?

Veiseh Lab




## Technology Approach

Encapsulate and implant cells that produce therapeutic enzymes, factors, antibodies, hormones etc.

## Goal

Production of medicine within one's own body, when the body needs it

## Patient Benefits

- Improve outcomes over standard of care for biologic therapy
- Programable Durability
- Deliver protein serum levels at constant rate
- A therapeutic for previously untreatable diseases e.g., short half-life proteins
- Locally deliver higher protein concentration

3-25

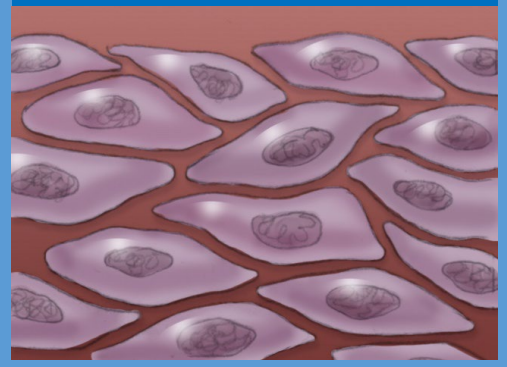
Diabetes Cancer Neurological Disorders Autoimmune disease

# "Living Drugs"- Therapies produced in the patient on as needed basis

Veiseh Lab

## Components Of The Veiseh Lab Platform

Cell Line engineering



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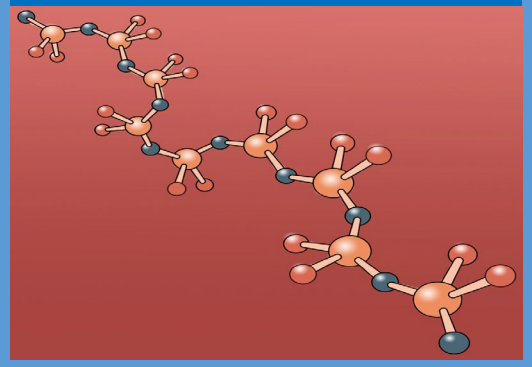
Novel polymer Chemistry



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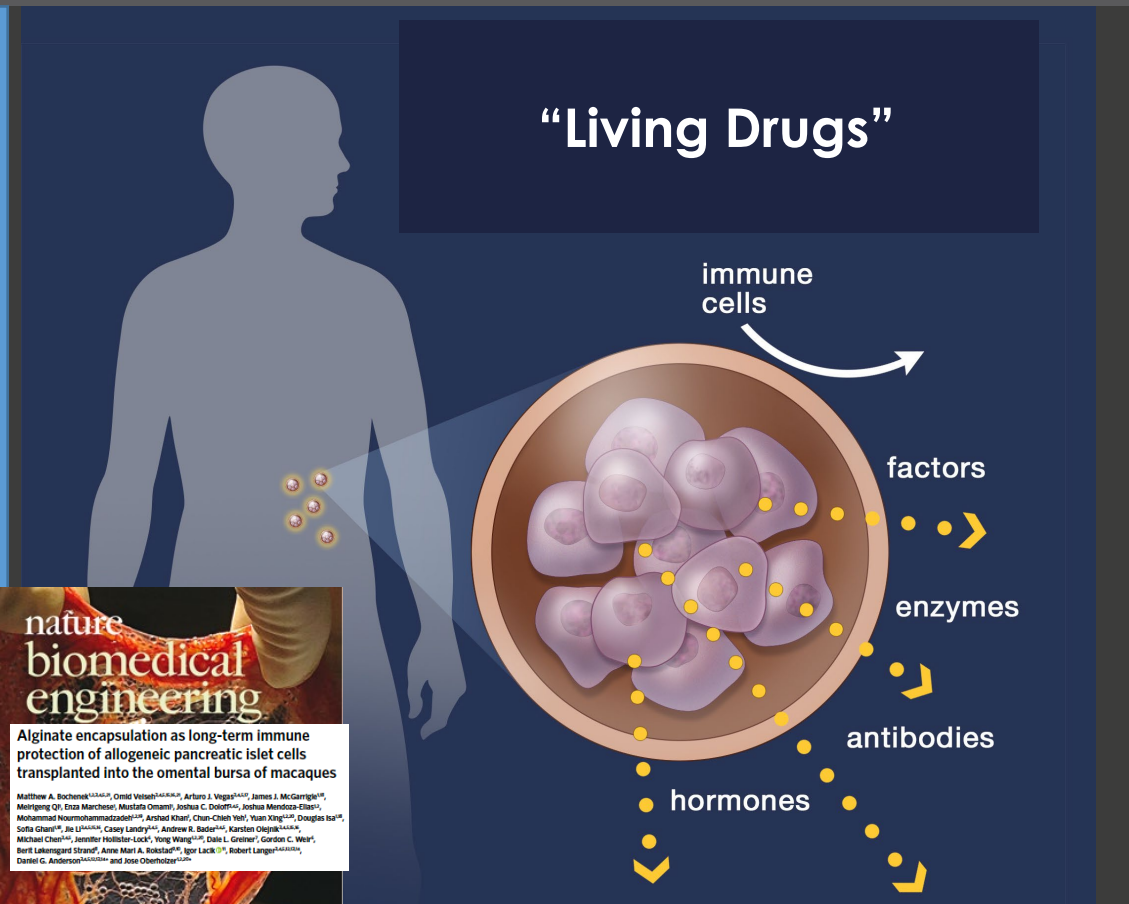
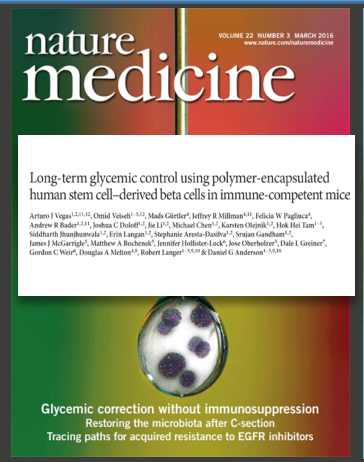
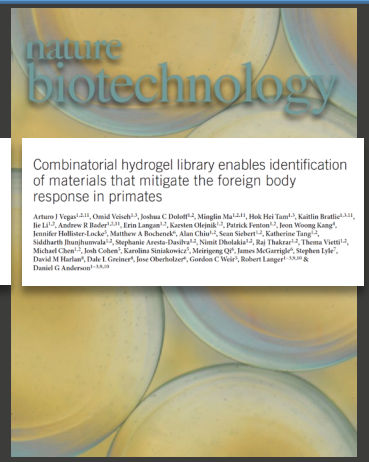
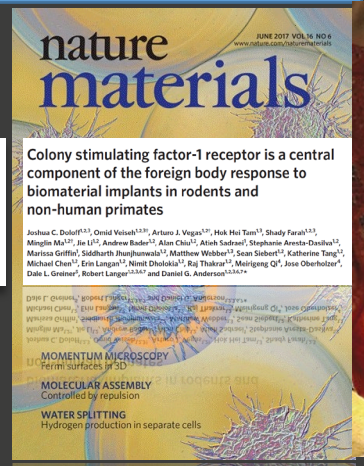










Veiseh Lab Spinout Companies

sigilon therapeutics

AVENGE BIO

Murada Bio

3-26

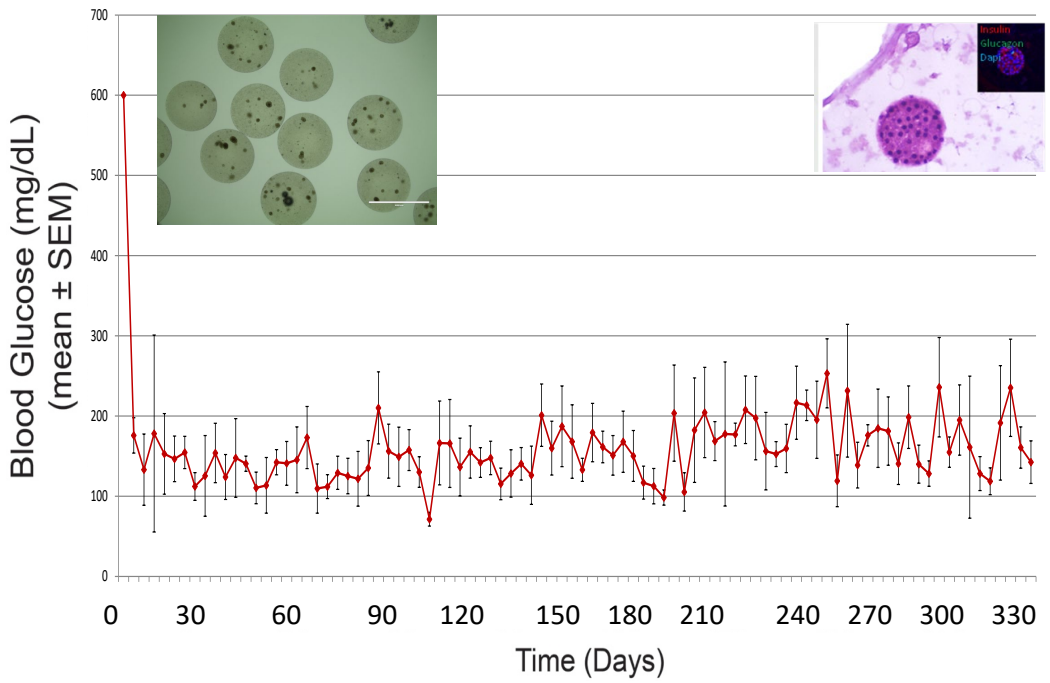
www.veisehlab.rice.edu

# What if we could replace insulin injections for diabetic patients with a drug factory?

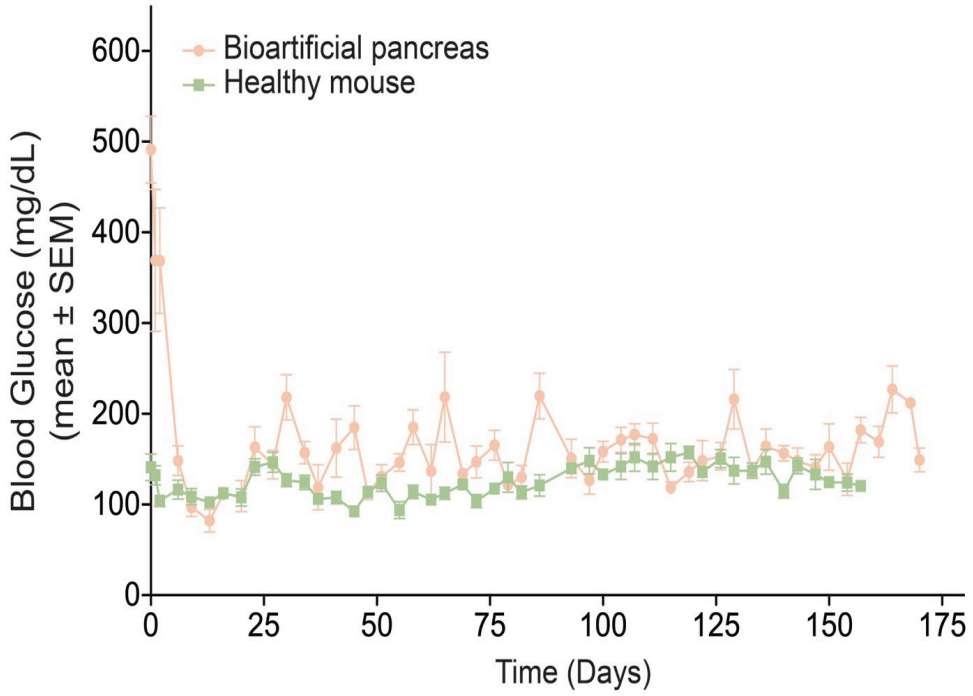
Veiseh Lab

- Two different sources of xenogeneic islet cells encapsulated using immunomodulatory hydrogels cells are viable and functional after > 6 months
- Data generated in a rigorous fibrosis model: C57BL/6 mouse

Rat donor islets into Mice




hES derived islet cells into Mice




3-27

Vegas, A. and Veiseh, O. *Nature Medicine* (2016), Langer R. *Mol Frontiers J* 92-98 (2017);


sigilon
therapeutics™

# Advancing Potential Functional Cures for Patients With Chronic Diseases

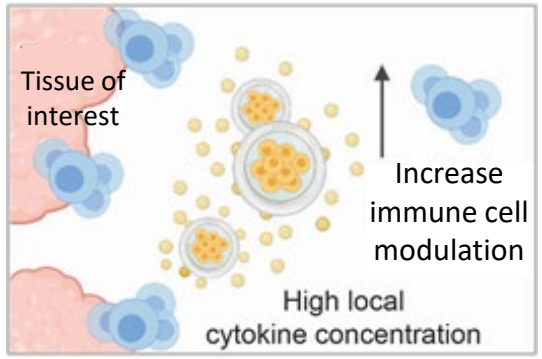
sigilon
therapeutics

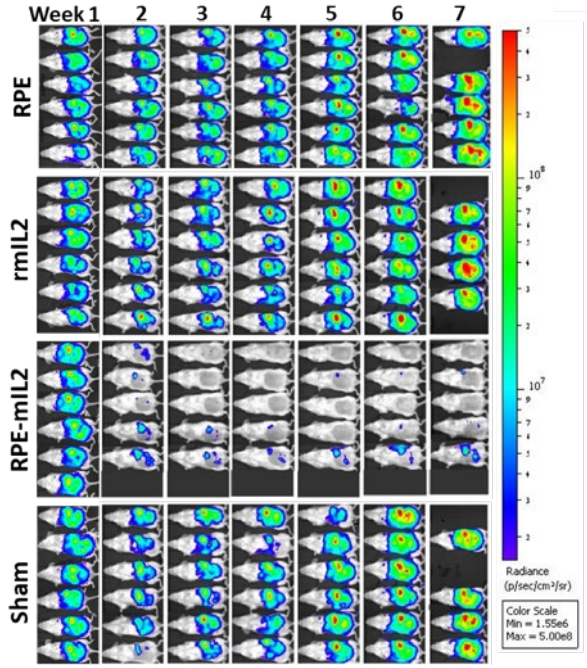
A wholly owned subsidiary of Eli Lilly and Company

# What if we could train our immune systems to eradicate cancer?

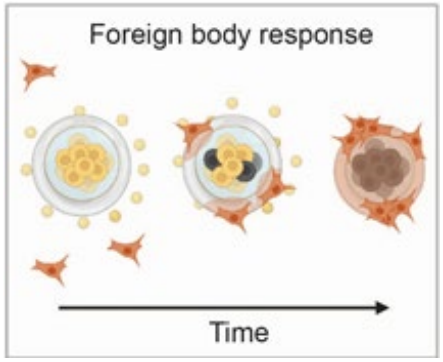
AVENGE BIO

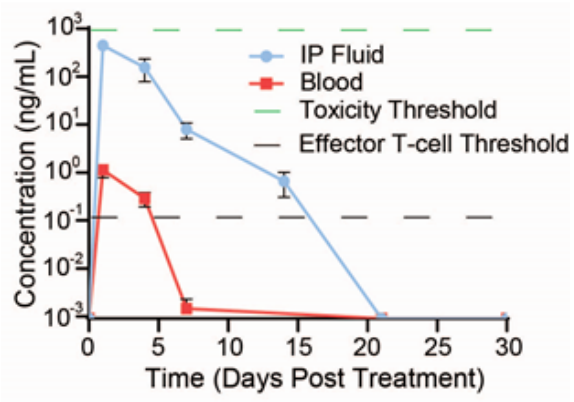
## 1. High local IL-2 concentration eliminates ovarian cancer tumor burden

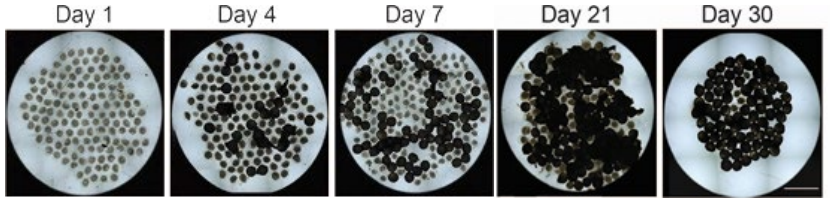


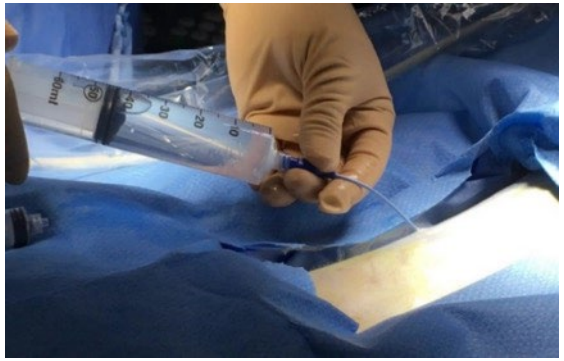

## 2. Programmable therapy duration allows for spatial and temporal control

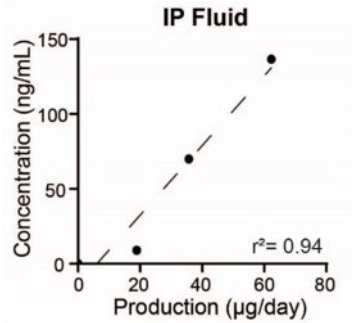


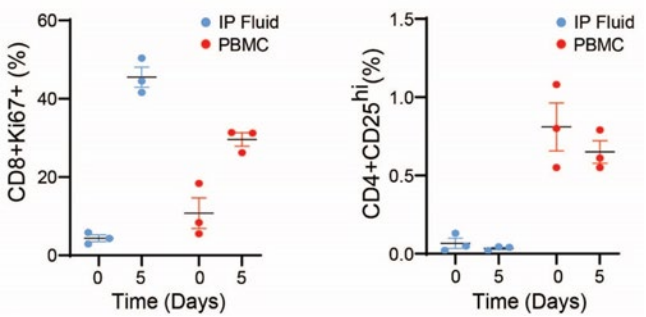




## 3. Demonstrated to be safe and effective in non-human primates






3-29

*Nash et al. Science Advances. 2022*

# Cytokine factories deliver potent, persistent, and regulated dosing to tumor containing cavity (i.e. intraperitoneal, plural, and resection cavity)

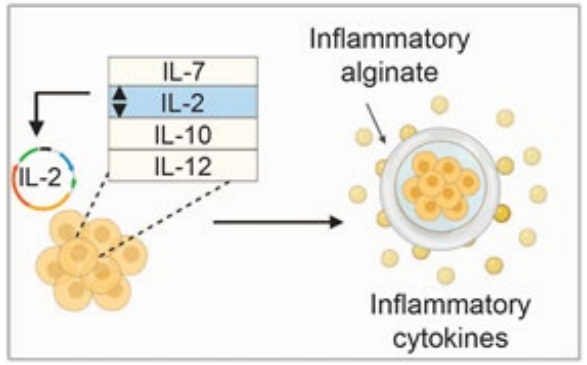
Veiseh Lab

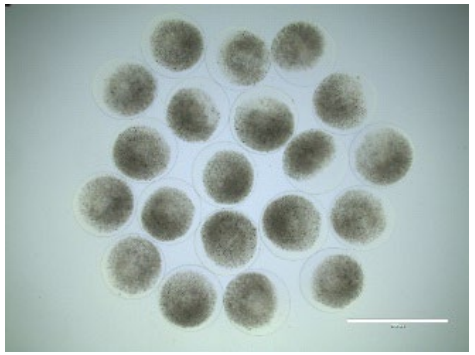
SCIENCE ADVANCES | RESEARCH ARTICLE

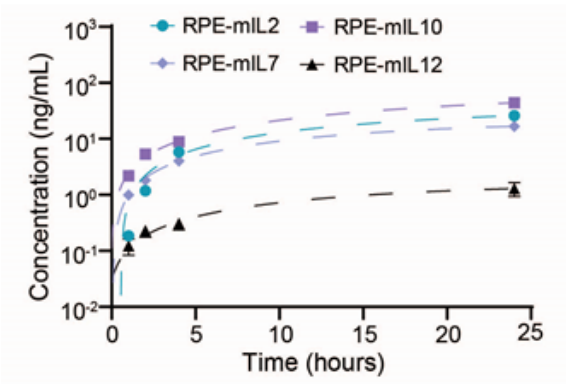
CELL BIOLOGY

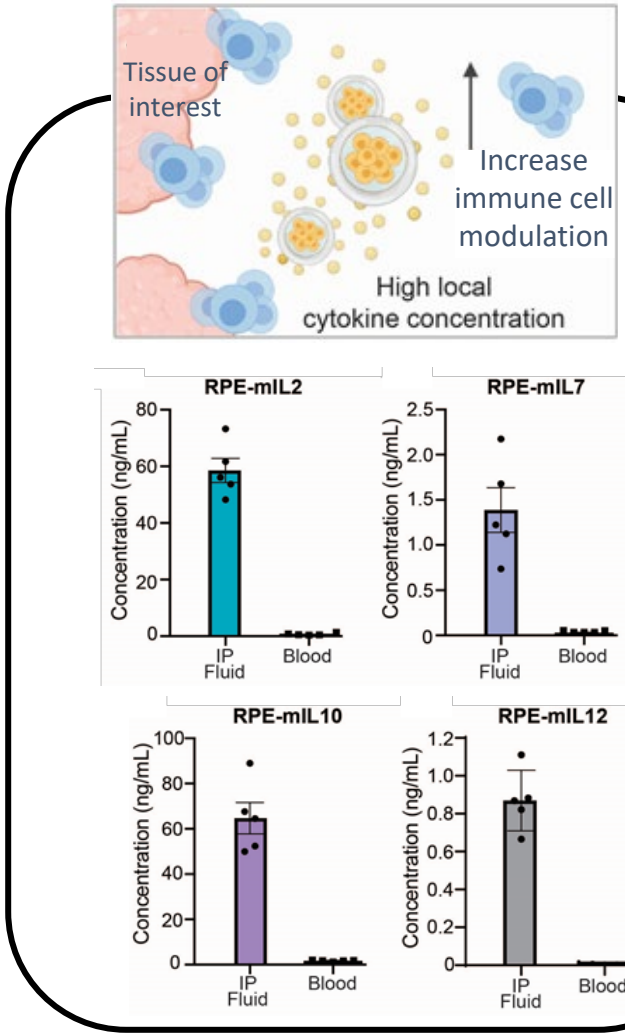
## Clinically translatable cytokine delivery platform for eradication of intraperitoneal tumors

Amanda M. Nash[1], Maria I. Jarvis[1], Samira Aghlara-Fotovat[1], Sudip Mukherjee[1], Andrea Hernandez[1], Andrew D. Hecht[1], Peter D. Rios[2], Sofia Ghani[2], Ira Joshi[2], Douglas Isa[2], Yufei Cui[1], Shirin Nouraein[1], Jared Z. Lee[3], Chunyu Xu[4], David Y. Zhang[1], Rahul A. Sheth[5], Weiyi Peng[4], Jose Oberholzer[2,6], Oleg A. Igoshin[1], Amir A. Jazaeri[7], Omid Veiseh[1]*



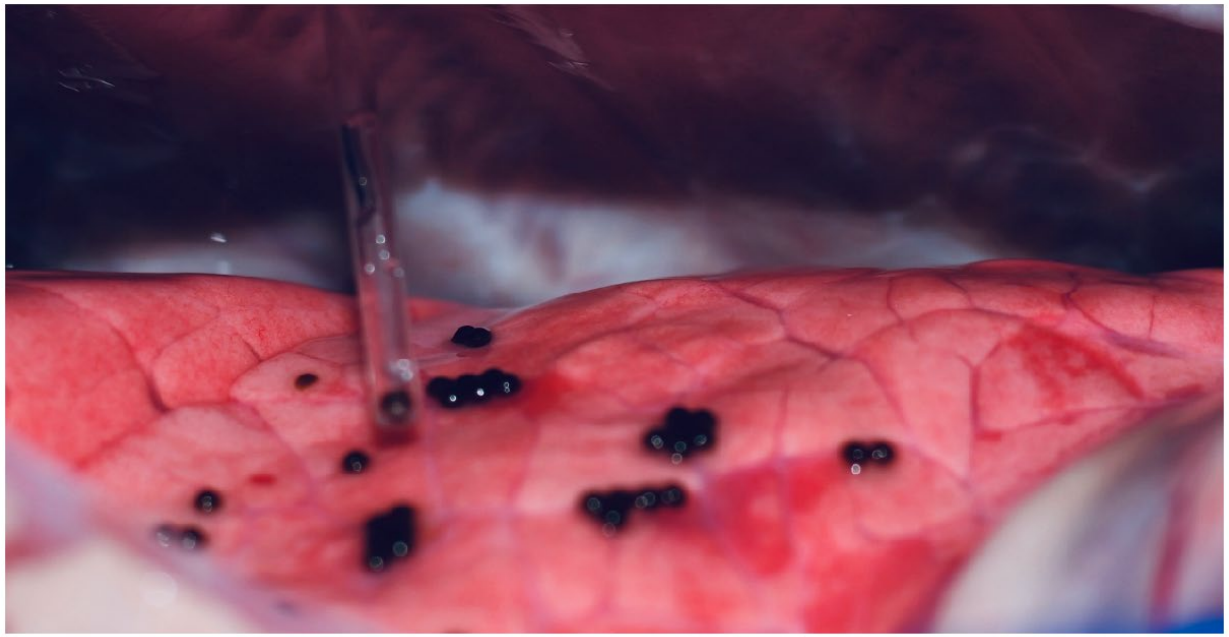


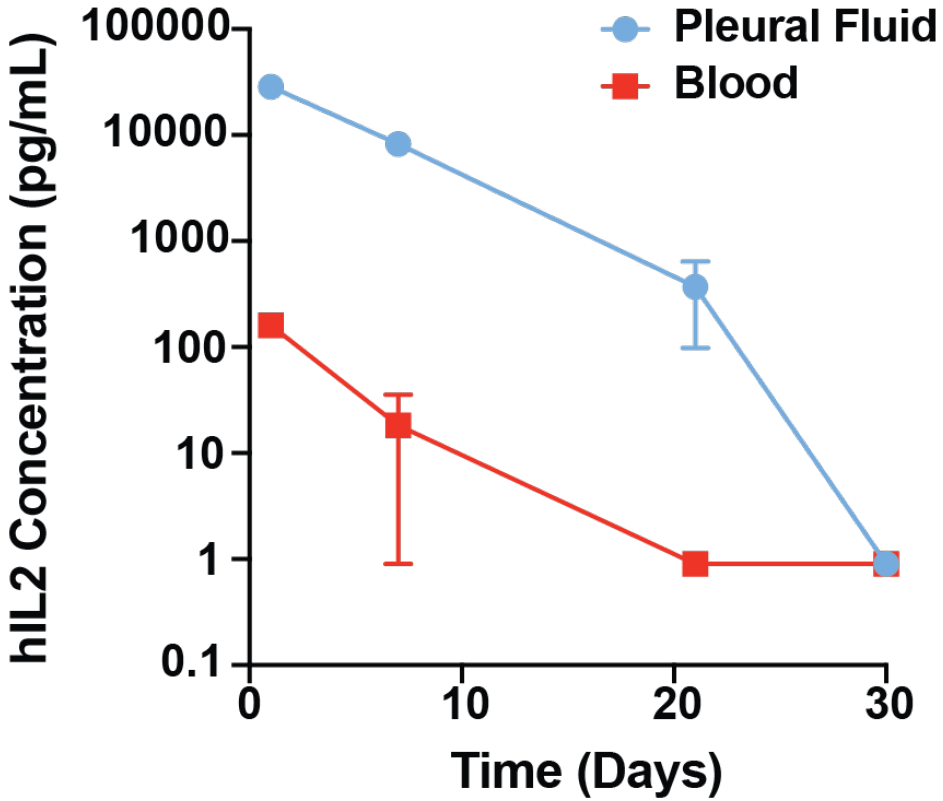

3-30

# Proof of Concept in the Pleural Cavity

Intrapleural capsule administration with catheters



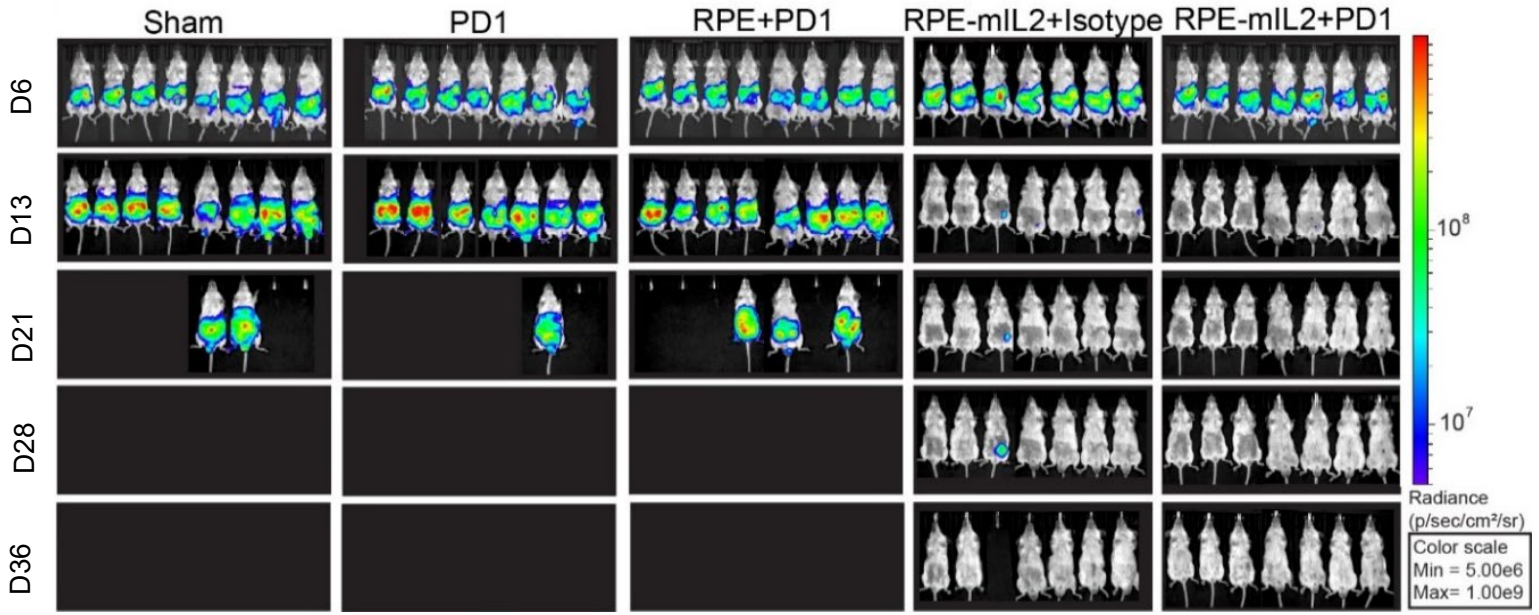
Interleukin 2 Pharmacokinetics

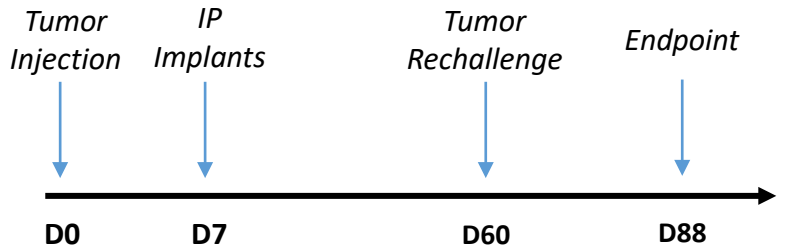


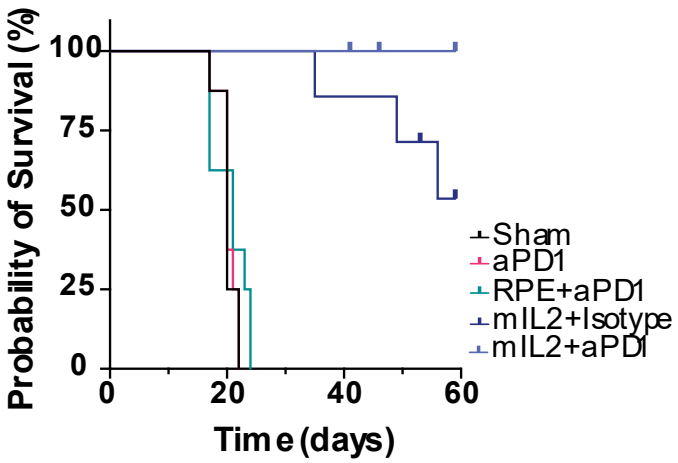

3-31

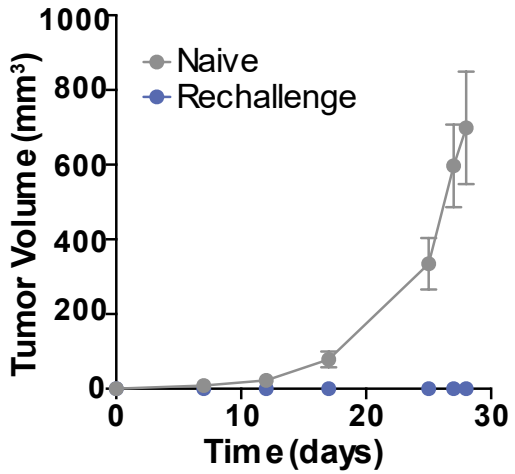
# RPE-mIL2 reduces tumor burden in models of mesothelioma and leads to protection against tumor recurrence

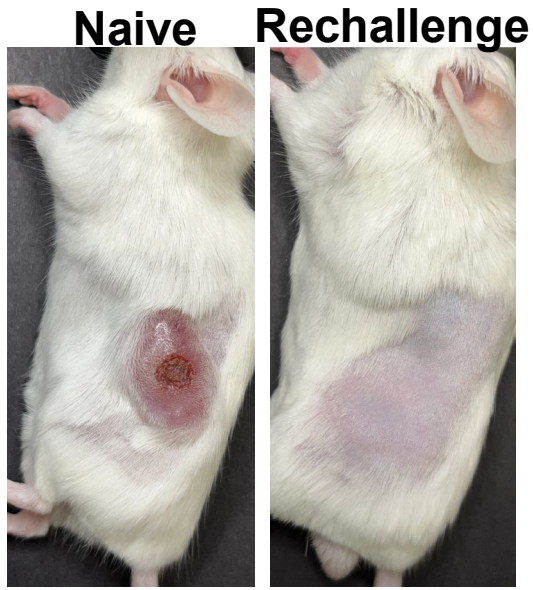
Veiseh Lab




3-32

# Technology transfer and clinical translation (Trial# NCT05538624)

AVENGE BIO

## Avenge Bio Announces Closing of $45 Million Series A Financing

Funding to advance lead program into the clinic for treatment of ovarian cancer


**Avenge Bio Announces FDA Clearance of the AVB-001 IND for the Treatment of Ovarian Cancer, a Novel Cellular Therapy Leveraging the LOCOcyte™ Immunotherapy Platform**

*Avenge Bio expects to initiate a Phase 1 clinical trial in the second half of 2022 for patients with metastatic peritoneal cancers with an initial focus on platinum-resistant ovarian cancer*

**https://clinicaltrials.gov/ct2/show/NCT05538624**

3-33

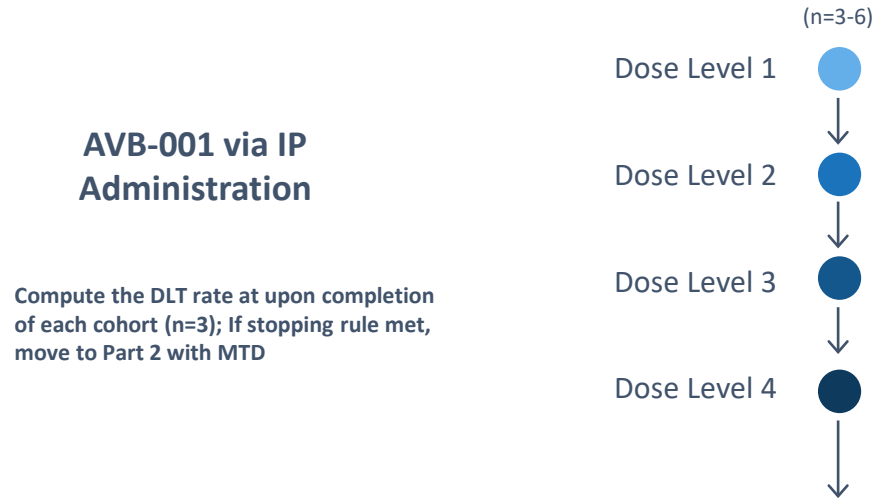


*Nash et al. Science Advances. 2022*

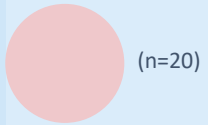
# AVB-1A-101: Phase 1/2, Open-Label First-In-Human Clinical Trial

**Study Design** This is a Phase 1/2, multi-center, Dose Escalation and Expansion Study of AVB-001, an intraperitoneally administered, cell generated human IL-2 immunotherapy in subjects with platinum resistant/refractory ovarian cancer

**Part 1** Dose Escalation (3+3 design): **Adults with high-grade platinum resistant/refractory epithelial ovarian cancer (EOC)** that are recurrent or progressive after best standard of care (N = up to 24)




**Part 2** Dose Expansion: **Adults with high-grade platinum resistant/ refractory high grade EOC** (N = up to 20)




## Key Study Objectives

### Part 1

- **Evaluate tolerability and toxicity of AVB-001 after IP administration of one of four single doses**
- **Determination of maximum tolerated dose (MTD)/Phase 2 dose (RP2D)**
- **Evaluate preliminary efficacy of AVB-001 on measures of tumor progression (secondary)**
- **Assess baseline/on-treatment immunological changes in blood and peritoneal envt. (exploratory)**

### Part 2

- **Further evaluate tolerability and toxicity of AVB-001 after IP administration at MTD/RP2D in target population**
- **Evaluate Objective Response Rate (ORR) per RECISTv1.1**
- **Evaluate efficacy of AVB-001 on other measures of disease progression (secondary)**
- **Assess baseline/on-treatment immunological changes in blood and peritoneal envt. (exploratory)**

3-34

# Technology transfer and clinical translation (Trial# NCT05538624)

Veiseh Lab

Avenge Bio Receives FDA Fast Track Designation for AVB-001, a Novel Cell Therapy Leveraging the LOCOcyte™ Immunotherapy Platform

NEWS PROVIDED BY
Avenge Bio, Inc. →
02 Oct, 2023, 08:00 ET

AVENGE BIO

## Avenge Bio secures FDA orphan drug designation for mesothelioma therapy

Pleural mesothelioma represents 85% of new mesothelioma cases, followed by peritoneal mesothelioma and pericardium or tunica vaginalis mesothelioma.

June 16, 2023

3-35

*Nash et al. Science Advances. 2022*

# New Fed Agency, ARPA-H, Fast-Tracks Rice Led Effort, $45M

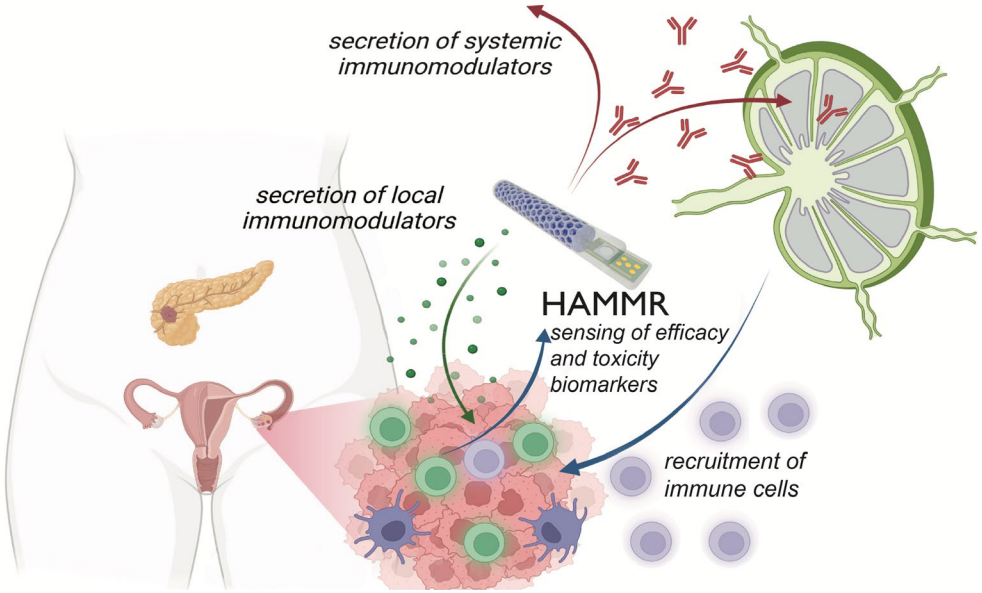
*Develop a Sense-and-Respond Cancer Therapy Implant Technology*

## Project THOR: Targeted Hybrid Oncotherapeutic Regulation

Principle Investigator: Omid Veiseh, Ph.D. Bioengineering

Funding: $45M over 5.5 years to develop and test in the clinic

- **19 investigators,** Engineers, Scientists, Clinicians, and Industry partners dedicated to developing this groundbreaking cancer therapy platform over the next five years.
- **Develop HAMMR**, a small device that can be implanted adjacent to tumors through a minimally invasive procedure.
- **Real-time Adaptive Therapy:** By continuously monitoring the tumor's environment, producing tailored immunotherapy drugs, and adjusting doses in real time, HAMMR can safely and effectively eliminate cancer.
- **The impact** is to reduce cancer-related deaths by more than 50%.




**Partners**

RICE

THE UNIVERSITY OF TEXAS MD Anderson Cancer Center Making Cancer History®

Carnegie Mellon University

JOHNS HOPKINS UNIVERSITY

Stanford University

UNIVERSITY of HOUSTON

Georgia Institute of Technology

# We're only limited by our imagination…….

## Rice engineers set sights on implantable 'living pharmacy'

**$33M, DARPA**

JADE BOYD – MAY 13, 2021

POSTED IN: CURRENT NEWS, FEATURED STORIES

### *Five Rice labs join DARPA-funded effort to make an implant to counter jet lag*

Five Rice University engineering laboratories are part of a $33 million national effort to develop a wireless, fully implantable device that can control the body's circadian clock, halving the time it takes to recover from jet lag and similar disruptions to the body's sleep/wake cycles.

Jade Boyd - Mar. 12, 2020

POSTED IN: **RICE NEWS > Current News > 2020**

**$22M, DARPA**

## 'Smart' wound-healing patch: DARPA awards $22 million grant

### *Team combining AI, bioelectronics, regenerative medicine to regrow muscle tissue*

Rice University neuroengineers and bioengineers are part of a national team that's developing "smart" technology that combines artificial intelligence, bioelectronics and regenerative medicine to regrow muscle tissue for wounded soldiers.

Mike Williams - Dec. 2, 2022

POSTED IN: **RICE NEWS > Current News > 2022**

**$3M Gates**

## HIV 'drug factory' implant promises once-a-year therapy

### *Bioengineer Omid Veiseh receives grant from Bill & Melinda Gates Foundation*

A Rice University laboratory, with a boost from the Bill & Melinda Gates Foundation, will develop a once-a-year treatment for patients infected with HIV and other infectious diseases.

## Rice, Baylor developing implants to heal heart attack injuries

### *Project aims to reduce heart failure with 'drug factories' as small as the head of a pin*

HOUSTON – (Aug. 8, 2022) – The inventors of Rice University's tiny, cancer-killing "drug factory" implants are teaming with surgeons from Baylor College of Medicine to create a version of the technology that can heal injuries caused by heart attacks.

January 5, 2022 08:00 AM EST *Updated January 7, 11:48 AM* | Financing, Startups

## Taking notes from MD Anderson and Rice University, Avenge Bio uncloaks with $45M and a slate of immunotherapies

## Rice U. pursues end game for diabetes

### *National Institutes of Health supports effort to advance cell implants that make insulin on demand*

HOUSTON – (Oct. 8, 2018) – Rice University bioengineer Omid Veiseh ultimately wants patients with Type 1 diabetes to forget about it.

That's the goal his lab has declared with funding support from the National Institutes of Health. The agency has awarded Veiseh's lab a prestigious four-year, $2.8 million R01 grant to design hydrogel-encapsulated cells that, when placed into a patient, sense blood glucose levels and produce insulin on demand.

## Feds fund $45M Rice-led research that could slash US cancer deaths by 50%

### *ARPA-H fast-tracks development of new cancer implant technology*

3-37

The Advanced Research Projects Agency for Health (ARPA-H) has awarded $45 million to rapidly develop sense-and-respond implant technology that could slash U.S. cancer-related deaths by more than 50%.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

# MEMORANDUM

| | |
|---|---|
| **TO:** | OVERSIGHT COMMITTEE MEMBERS |
| **FROM:** | VINCE BURGESS, CHIEF COMPLIANCE OFFICER |
| **SUBJECT:** | COMPLIANCE PROGRAM UPDATE |
| **DATE:** | NOVEMBER 6, 2023 |

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

As of October 27, seven entities had not filed seven academic research reports, and one product development report. CPRIT's grant accountants and compliance specialists review and process incoming reports and reach out to grantees to resolve filing issues. In most cases, CPRIT does not disburse grant funds until the grantee files the required reports. In some instances, grantee institutions may be ineligible to receive a future award if the grantee does not submit the required reports.

## Financial Status Report Reviews

CPRIT's compliance specialists performed 477 second-level reviews of grantee Financial Status Reports (FSRs) in August, September, and October. Forty-five FSRs (9%) needed resubmission due to insufficient or inaccurate documentation sent by the grantee. CPRIT's grant accounting staff completes the first review of the FSRs and supporting documentation before routing them to the compliance specialists for final review and disposition.

## Desk Reviews

CPRIT staff performed 15 enhanced desk-based financial monitoring reviews in August, September, and October. Desk reviews are intended to confirm financial, administrative, and programmatic compliance using data from CGMS/CARS with additional focus on an organization's internal controls, current and previous fiscal audits, and grantee report submission timeliness. Desk reviews also aid in the identification of potential problems and technical



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

assistance issues for follow-up during an onsite visit, as well as areas of non-compliance and grantee performance issues. Compliance specialists are collaborating with three grantees to address desk review findings.

Onsite Reviews

CPRIT completed four onsite reviews in August, September, and October. Onsite reviews are the most extensive monitoring activity conducted by CPRIT and include virtual or field visits led by compliance grant monitoring staff. 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 compliance with single audits are all monitored during onsite reviews. Onsite monitoring enables CPRIT compliance staff to assess a grantees' capability, performance, and compliance with applicable laws, rules, and policies. Compliance specialists are collaborating with two grantees to address onsite review findings.

Single Audit Tracking

Compliance specialists track the submission of grantees' independent audit reports and the resolution of issues named in these reports. Grantees who spend $750,000 or more in state awards in the grantee's fiscal year must undertake a single independent audit, a program specific audit, or an agreed upon procedures engagement. The grantee sends the independent audit report with findings to CPRIT within 30 days of receipt, but no later than nine months after the grantee's fiscal year end.

Grantees are unable to receive reimbursements or advances if they are delinquent in filing the required audit and corrective action plan unless an extension is requested and approved. Compliance staff is actively working with the two grantees to submit the required audit.

Training and Support

CPRIT staff conducted three new Authorized Signing Official (ASO) training webinars in August, September, and October for the University of Texas at El Paso, Texas Tech University Health Sciences Center at El Paso, and ImmuneSensor Therapeutics. The trainings covered grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. Pursuant to Texas Administrative Code §703.22, CPRIT requires new ASOs to complete compliance training within 60 days of the change.

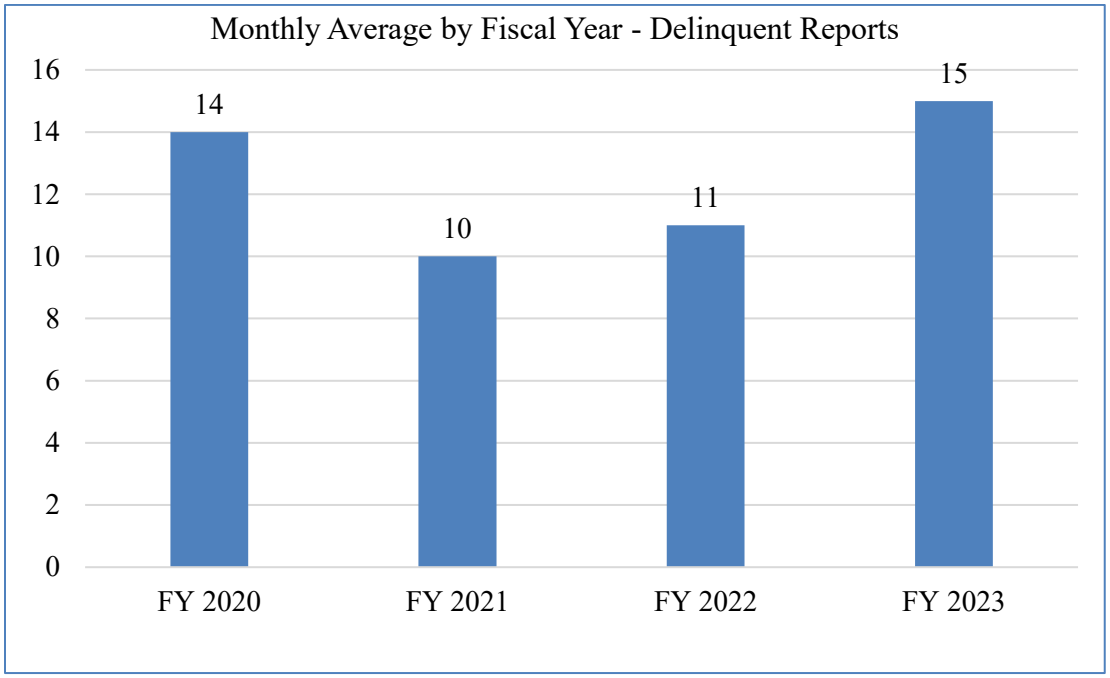
CPRIT staff conducted a series of Annual Compliance Training webinars on October 25-26 for 120 grantee staff. Trainings are specific to each program area (Academic Research, Product Development Research, and Prevention) and allow for an interactive experience and opportunity to focus on topics relevant to each program. The trainings covered grant reporting requirements, administrative rule changes, grant closeout, and an overview of the compliance program including fraud, waste, and abuse reporting. This was the third training series offered this year for the annual compliance training requirement which requires the Authorized Signing Official

(ASO) and at least one other employee from each grantee organization to attend an annual compliance training by December 31 of each year.

FY 2023 Compliance Program Activities Summary

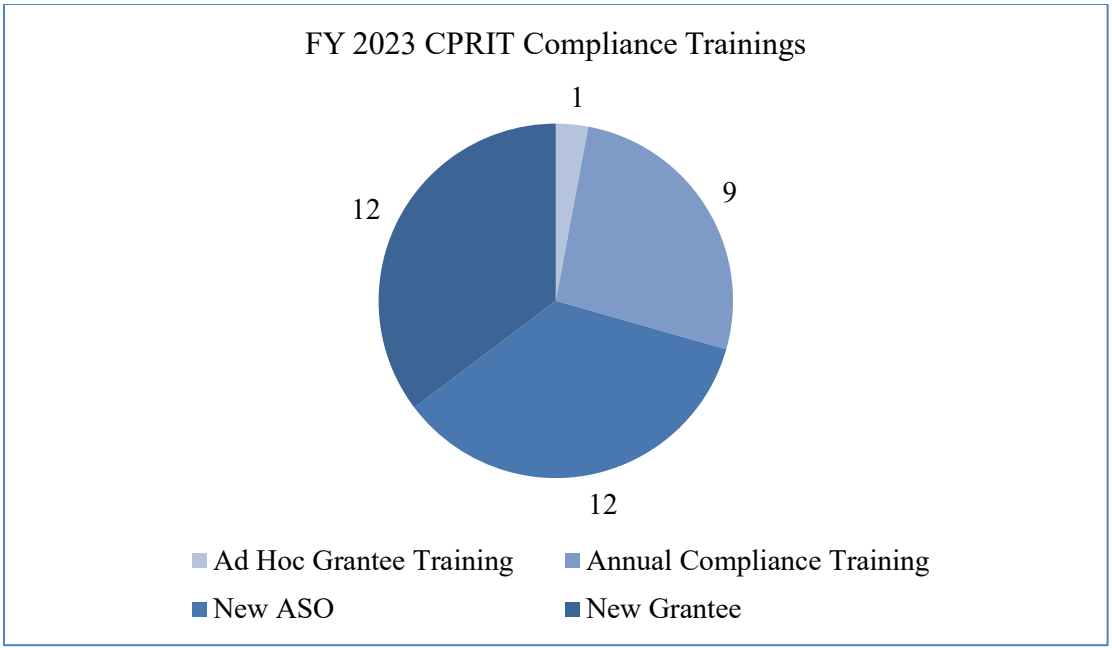
CPRIT's Compliance Program functions are designed to actively support the integrity and transparency of CPRIT's agency processes. FY 2023 Compliance Program highlights include:

- Grant Recipient Report Monitoring –The number of delinquent reports in FY 2023 averaged 15 reports per month. CPRIT staff meet weekly to review and discuss delinquent reporting and actively work with grantees to submit required reports timely. The average number of delinquent reports for the past four fiscal years are represented in the chart below:




- Second-level Reviews of Financial Status Reports (FSRs) – The Compliance team performed a second-level review of 2,097 FSRs in FY 2023. FSRs are grantee expenditure reports that detail how project costs from the previous quarter were incurred. CPRIT's grant accounting staff completes the initial review of the FSRs and supporting documentation before routing them to the compliance specialists for final review and disposition.

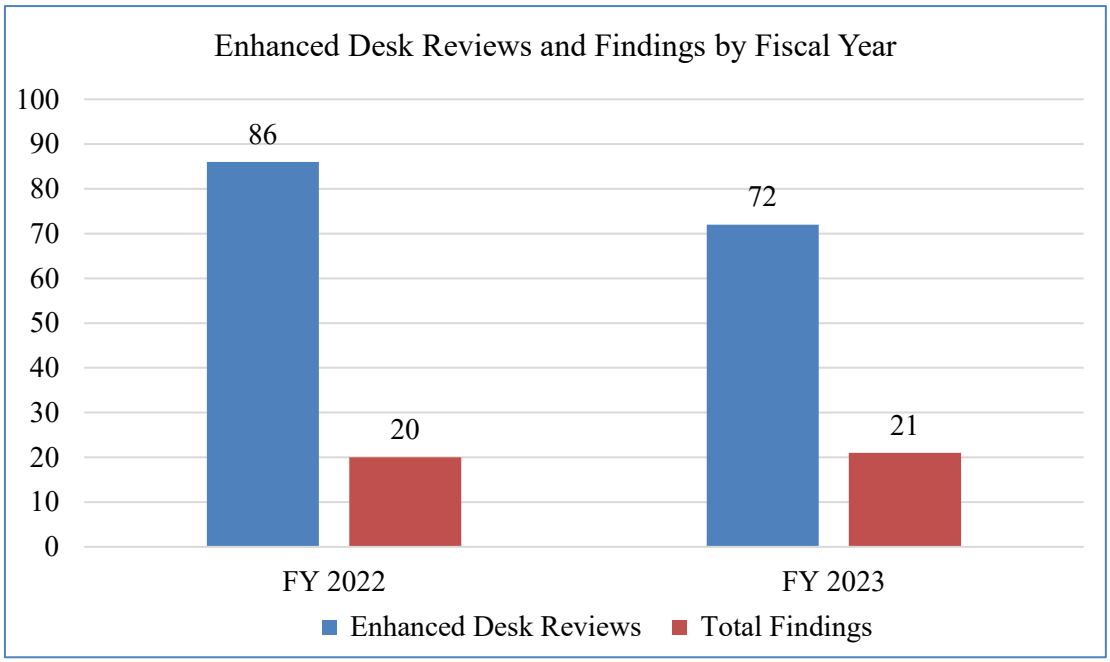
- Training and Education – In FY 2023, CPRIT staff provided 34 grantee trainings including annual compliance trainings, new grantee trainings, and trainings for new Authorized Signing Officials (ASOs). The number of trainings increased 55% from FY 2022. Over 650 grantee staff attended these training opportunities provided to our active grantees.

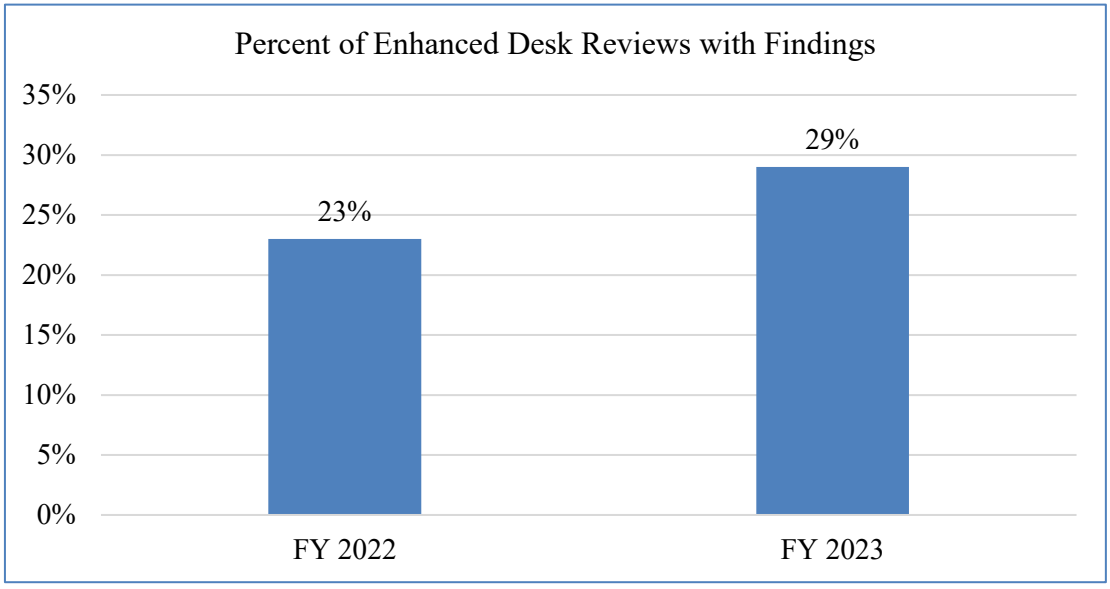



- Annual Compliance Attestation – CPRIT requires grantees to submit an annual attestation form, demonstrating compliance with statutory and administrative grant requirements, CPRIT's policies and procedures, grant contract terms, and the Texas Grant Management Standards. Grantees have until December 31 to submit the completed attestation. As part of the annual attestation process, product development grantees must submit documentation demonstrating compliance with the Texas Location Criteria, pursuant to Texas Administrative Code §701.19. The Compliance team reviewed and processed 50 attestations submitted by grantees.

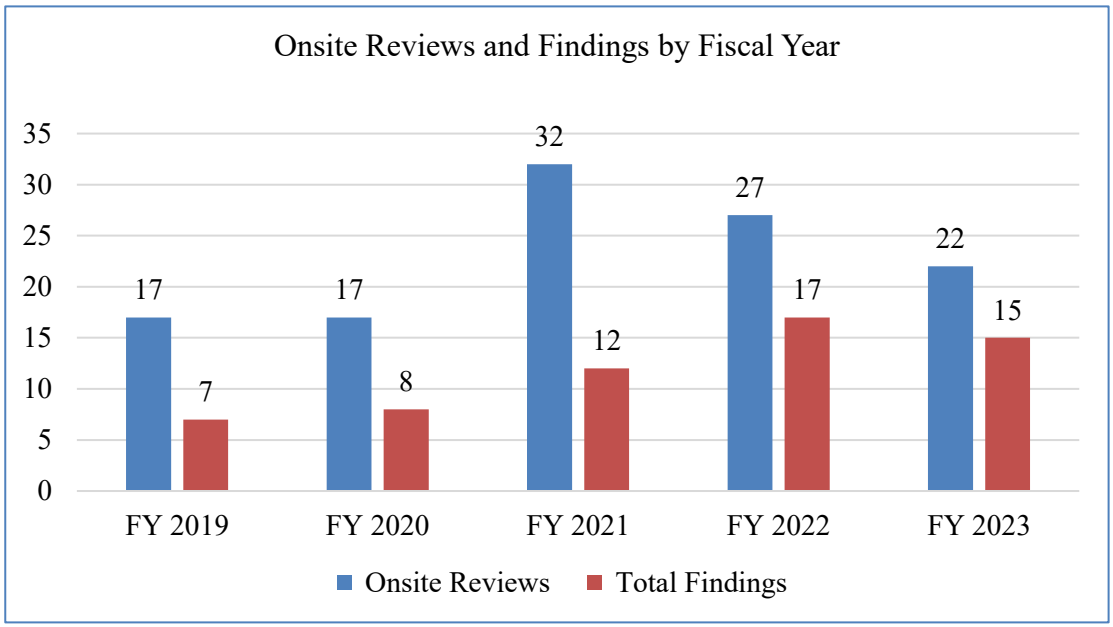
- Single Audit Reviews – Compliance specialists track the submission of grantees' independent audit reports and the resolution of issues named in these reports. Grantees who spend $750,000 or more in state awards in the grantee's fiscal year must undertake a single independent audit, a program specific audit, or an agreed upon procedures engagement. The Compliance team reviewed 40 audits and Agreed Upon Procedures (AUP) reports and worked with one grantee to remediate audit findings.

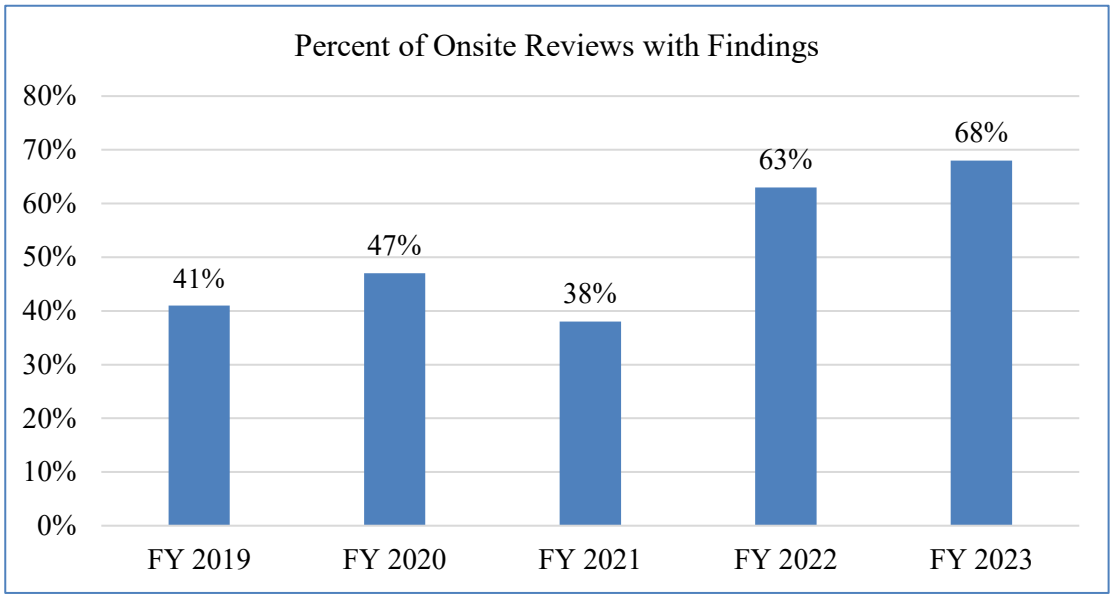
- Compliance Monitoring Reviews (Enhanced Desk and Onsite) – The Compliance team performed 94 compliance reviews (72 enhanced desk reviews, 22 onsite reviews) during FY 2023. Twenty-one of the 72 enhanced desk reviews contained findings. Of these 21 reviews that contained findings, 86% had findings related to timeliness of report submission by the grantee.




For FY 2023, 15 of the 22 onsite reviews contained findings. Seven of the 15 reviews that contained findings (47%) were related to timeliness of report submission by the grantee.

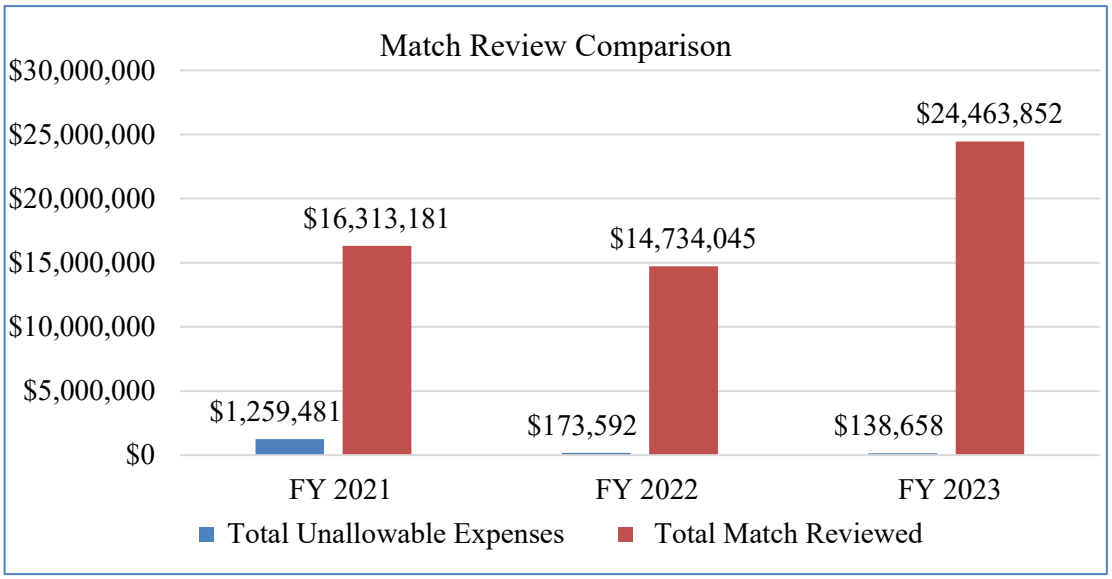


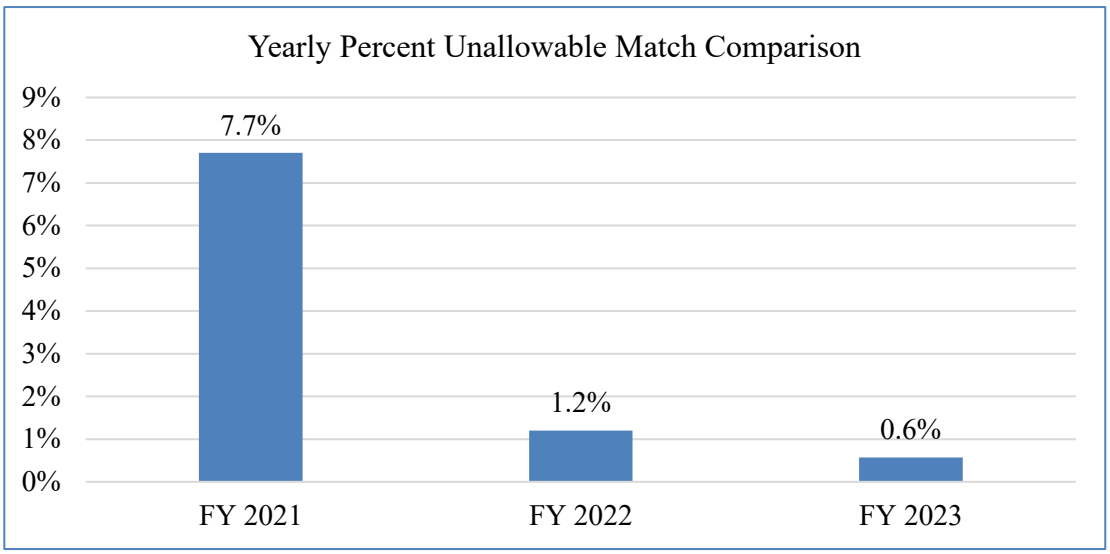




- Match Expenditures Review – CPRIT requires academic research and product development research grantees to show that they have available unused funds equal to at least one-half of the CPRIT grant award that the grantee will spend on the CPRIT-funded project. This obligation, often referred to as "CPRIT's matching funds requirement," requires the grantee to first certify that it has available matching funds, and then at the end of the grant year, to verify that the grantee spent the matching funds on the project. CPRIT's statute allows an institution of higher education to use its federal indirect cost rate as a credit toward the required 50% match.
  Product development grantees plus those academic research grantees whose indirect cost rate credit does not fully offset the required match must supply a detailed match expenditure report that includes the amount and date paid, vendor, description, and

budget category. Compliance staff review grantees' match expenditures for appropriateness and allowability and work with CPRIT's grant accountants and the grantee to address any deficiencies.

Compliance staff performed 20 annual match expenditure reviews for FY 2023. The total amount of match expenses reviewed by compliance staff for FY 2023 was $24,463,852.11. The amount of unallowable expenses was $138,658.00.




Due to an increased number of Product Development grantees over the last year, the total amount of match expenses reviewed in FY 2023 has increased by $9,729,806.92 (20 reviews completed in FY2023 versus 15 reviews in FY 2022). In FY 2023, there was an overall decrease in unallowable match expenses of $34,933.67.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

**MEMORANDUM**

| | |
|---|---|
| **TO:** | OVERSIGHT COMMITTEE MEMBERS |
| **FROM:** | MICHELLE LE BEAU, PH.D., CHIEF SCIENTIFIC OFFICER |
| **SUBJECT:** | ACADEMIC RESEARCH PROGRAM UPDATE |
| **DATE:** | NOVEMBER 15, 2023 |

**FY2024 Cycle 1 RFAs**

The following FY24.1 RFAs were posted on February 17, 2023. The CPRIT Application Receipt System (CARS) opened for applications on March 15, 2023 and closed on June 14, 2023. Virtual Peer Review was conducted in October 2023. Dr. Le Beau will present the Scientific Review Council's recommendations to the PIC and the Oversight Committee in February 2024.

- **Individual Investigator Research Awards (IIRA)**
  Supports applications for innovative research projects addressing critically important questions that will significantly advance knowledge of the causes, prevention, and/or treatment of cancer. Areas of interest include laboratory research, translational studies, and/or clinical investigations. Competitive renewal applications accepted.
  Award: Up to $350,000 per year. Exceptions permitted if extremely well justified; maximum duration: 3 years.

- **Individual Investigator Research Awards for Computational Systems Biology of Cancer (IIRACSBC)**
  Supports applications for innovative mathematical and/or computational research projects addressing questions that will advance current knowledge in the (a) mechanisms that tie altered gene expression and downstream molecular mechanisms to functional cancer phenotypes; and/or (b) mechanisms that tie tumor morphology to functional cancer phenotypes and/or mechanisms that tie treatment sequence and combination to evolving functional cancer phenotypes (that emerge as a result of treatment selection).
  Award: Up to $400,000 in total costs per year for up to 3 years. Exceptions permitted if extremely well justified.

- **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



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are all acceptable. CPRIT expects the outcome of the research to reduce the incidence, morbidity, or mortality from cancer in children and/or adolescents in the near or long term. Competitive renewal applications accepted.
Award: Up to $350,000 per year. Applicants who 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 which propose clinical and population-based projects designed to develop effective prevention and early detection interventions to reduce cancer risk, mortality, and morbidity among Texans. Projects that propose such research collaborations with existing CPRIT Prevention Program awardees including the CPRIT funded *Texas Collaborative Center for Hepatocellular Cancer* (https://www.bcm.edu/research/labs-and-centers/research-centers/texas-collaborative-center-for-hepatocellular-cancer) are strongly encouraged.
  Award: Up to $400,000 per year. Exceptions permitted if extremely well justified; maximum duration: 5 years.

- **Individual Investigator Research Awards for Clinical Translation (IIRACT)**
  Supports applications that propose innovative cancer clinical studies that are hypothesis driven and involve patients enrolled prospectively on a clinical trial. Areas of interest include clinical studies of new or repurposed drugs, hormonal therapies, immune therapies, surgery, radiation therapy, stem cell transplantation, combinations of interventions, or therapeutic devices. A clinical trial must be planned to begin when the contract is awarded.
  Award: Up to $500,000 per year. Maximum duration: 4 years. Exceptions permitted if extremely well justified.

**Table 1: Application Submission data for FY2024 Cycle 1**

| Mechanism | Submitted | Total Funding Requested |
|---|---|---|
| Individual Investigator Research Award (IIRA) | 228 | $233,894,288 |
| Individual Investigator Research Awards for Computational Systems Biology of Cancer (IIRACSBC) | 18 | $36,108,737 |
| Individual Investigator Research Awards for Cancer in Children and Adolescents (IIRACCA) | 35 | $47,815,216 |
| Individual Investigator Research Awards for Prevention and Early Detection (IIRAP) | 15 | $27,050,403 |
| Individual Investigator Research Awards for Clinical Translation (IIRACT) | 19 | $19,850,946 |
| **Total** | **315** | **$364,719,590** |

**FY2024 Cycle 2 RFAs**

The following FY24.1 RFAs were posted on September 14, 2023. The CPRIT Application Receipt System (CARS) opened for applications on October 17, 2023 and will close on January 16, 2024. Virtual Peer Review will be conducted in late April 2024. Dr. Le Beau will present the Scientific Review Council's recommendations to PIC and the Oversight Committee in August 2024.

**Core Facility Support Awards (R-24.2 CFSA)**

Supports applications that facilitate the development or improvement of core facilities that will provide valuable services to support and enhance scientifically meritorious cancer research projects. Funds may be requested to develop a new facility or to enhance the capabilities of an existing facility that will directly support and impact cancer research programs at the institution and in the region. CPRIT will look with special favor on applications that propose a facility that will serve cancer researchers at multiple Texas research institutions, in particular TREC-eligible institutions.
**Award:** The maximum duration for this award mechanism is 5 years. Applicants may request up to a maximum of $3,000,000 in total costs.

**High-Impact/High-Risk Research Awards (R-24.2 HIHR)**

Supports applications that explore the feasibility of high-risk projects that, if successful, would contribute major new insights into the etiology, diagnosis, treatment, or prevention of cancers. Using this mechanism, CPRIT intends to support innovative, developmental projects that focus on exceptionally promising topics that are not yet sufficiently mature to compete successfully for more conventional funding. The HIHR Research Awards are expected to provide the foundation for individual or multiple investigator peer-reviewed awards upon completion. The goal of this award mechanism is to fund uncommonly great ideas that merit the opportunity to acquire preliminary data.
**Award:** Applicants may request a total of $250,000 for a period of up to 24 months.

**Multi-Investigator Research Awards (R-24.2 MIRA)**

Supports highly integrated programs of collaborative and cross-disciplinary research among multiple Texas investigators and Institutions. Applications responding to this

RFA that address one of the program priorities for academic research adopted by CPRIT's Oversight Committee are particularly encouraged.
**Award:** $4,500,000 in total costs for a maximum period of 4 years.

**Clinical Investigator Award (R-24.2 CIA)**

Supports mid-career clinician scientists with specialty training relevant to delivery of cancer care to devote more time to augment their capabilities in clinical cancer research, and to provide mentoring to early-stage investigators in the conduct of clinical research. The CIA will provide protected time from clinical responsibilities to provide physicians with the opportunity to expand clinical research skills, to develop investigator-initiated clinical trials, to develop external relations with industry and pharmaceutical company partners, and to expand partnerships with laboratory-based collaborators to design and conduct correlative studies needed to interpret the outcome of an interventional trial. The CIA initiative will increase the pool of clinical investigators at Texas academic institutions who are conducting patient-oriented studies, who will be able to compete successfully for peer-reviewed grants, and who will mentor the next generation of clinical investigators.
**Award:** $1,500,000 in total costs for a maximum period of 5 years.

**FY2024 Recruitment Update**

Table 2 displays an overview of the status of CPRIT recruitment applications received for the first and second cycles of FY2024. The CPRIT Application Receipt System (CARS) opened for applications on June 21, 2023 and closed on August 20, 2023. The Scientific Review Council reviewed these applications on September 14, 2023, and recommended applications will be presented to the Oversight Committee in November 2023.

**FY2024**

**Table 2: Recruitment Application Submission data for Cycle 24.1 and 24.2**

| Mechanism | Number Received | Funds Requested | # SRC Recommended | SRC Recommended Funds |
|---|---|---|---|---|
| Recruitment of Established Investigators | 2 | $12,000,000 | 1 | $6,000,000 |
| Recruitment of First-Time, Tenure-Track Faculty Members | 2 | $3,990,000 | 1 | $1,990,000 |
| **TOTAL** | **4** | **$15,990,000** | **2** | **$7,990,000** |

CANCER PREVENTION & RESEARCH
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**MEMORANDUM**

| | |
|---|---|
| **TO:** | OVERSIGHT COMMITTEE MEMBERS |
| **FROM:** | RAMONA MAGID, CHIEF PREVENTION OFFICER |
| **SUBJECT:** | PREVENTION PROGRAM UPDATE |
| **DATE:** | NOVEMBER 15, 2023 |

## FY 2024 Review Cycle 1 (24.1)

The Prevention Program released two RFAs, *Primary Prevention of Cancer and Cancer Screening and Early Detection*, on May 5, 2023, for the first cycle of FY 2024. CPRIT received 29 proposals totaling $46,657,038 by the August 30 deadline. Three applications were research projects or not responsive to the RFAs and were administratively withdrawn. The remaining twenty-six applications requesting a total of $42,666,078 will undergo peer review on December 5 and 6 by teleconference. The Prevention Review Council will meet in January 2024. Ms. Magid will present the Prevention Review Council's recommendations to the PIC and the Oversight Committee in February 2024.

| Mechanism | Apps Received | Funds Requested |
|---|---|---|
| Cancer Screening and Early Detection | 14 | $24,274,025 |
| Primary Prevention of Cancer | 12 | $18,392,053 |
| **TOTAL** | **26** | **$42,666,078** |

## Proposed FY 2025 Requests for Applications

CPRIT is recommending the release of three Requests for Applications for FY 2025.

## Dissemination of CPRIT- funded Cancer Prevention and Control Interventions

The RFA solicits applications from currently or previously funded CPRIT projects that have demonstrated exemplary success and have materials, policies, and other resources that have been successfully implemented and evaluated and could be scaled up and/or applied to other systems and settings. The goal is to expand successful models for the delivery of prevention interventions across the state through adaptation or replication.



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Applicants to this RFA should outline specific implementation strategies they will utilize with targeted recipients to replicate or adapt projects to other settings or populations. Implementation strategies are described as the processes, activities, and resources that are used to integrate interventions into usual settings. Core implementation components can be staff selection, preservice and in-service training, ongoing consultation and coaching, staff and program evaluation, and systems interventions. Priority will be given to those projects that identify and assist potential target partners/audiences in preparing to implement the intervention and/or preparing to apply for grant funding.

**Funding Amount and Duration:** up to 3 years, $450K maximum

## Primary Prevention of Cancer

The **Primary Prevention of Cancer** RFA solicits applications for eligible projects up to 36 months in duration that will deliver multilevel, evidence-based interventions that improve cancer-related health behaviors. Interventions may address tobacco use, obesity, physical inactivity, unhealthy eating, alcohol use, HPV vaccination, Hepatitis B vaccination, and environmental/occupational cancer exposures. Sun safety education may be addressed if combined with another behavioral intervention to reduce risk.
The following are required components of the project:

- **Evidence-Based**: CPRIT's primary prevention grants are intended to fund culturally appropriate effective and efficient systems of delivery of preventive services based on the existing body of knowledge about and evidence for cancer prevention.
- **Multilevel Interventions:** Health behaviors have multiple levels of influences, often including individual, group, organization, and community determinants. Influences on behaviors interact across these different levels and multilevel interventions are the most effective in changing behavior.
- **Geographic Area to be Served:** Preventive service delivery to nonmetropolitan/medically underserved area (MUA) counties must be included in the defined service area. Service to urban counties that are not medically underserved is allowable if the project proposes to also serve nonmetropolitan counties that are medically underserved.
- **Community Partner Networks:** Applicants are strongly encouraged to coordinate and describe a collaboration of community partners that can deliver services to the most counties and the most people possible in a selected service region.

**Funding Amount and Duration:**
The amount of funding that applicants may request is dependent on the primary focus of the project and on the type of project – New, Initial Expansion or Maintenance Expansion. Use the table below to determine the maximum amount of funding and the maximum number of years that may be requested.

| Project Type | Maximum Amount of Funding | Maximum Duration |
|---|---|---|
| **New Project** | $1 million | 3 years |
| **Initial Expansion** | $1 million | 3 years |
| **Initial Expansion – vaccination/tobacco cessation** | $1.5 million | 3 years |
| **Maintenance Expansion** | $2 million | 5 years |
| **Maintenance Expansion – vaccination/tobacco cessation** | $2.5 million | 5 years |

## Screening and Early Detection

The Screening and Early Detection RFA solicits applications for eligible projects up to 5 years in duration that will deliver evidence-based clinical services in cancer screening for breast, cervical, colorectal, liver, and lung cancers according to established and current national guidelines and criteria. Nonmetropolitan (rural) and/or medically underserved populations must be included in the defined service area.
The following are required components of the project:

- **Evidence-Based**: CPRIT's secondary prevention grants are intended to fund effective and efficient systems of delivery of early detection services based on the existing body of knowledge about and evidence for screening for both primary and secondary cancers in ways that far exceed current performance in a given service area.
- **Comprehensive Projects:** Comprehensive projects include a continuum of services and systems and policy changes and comprise the following: Public and professional education and training, outreach, delivery of screening and diagnostic services, follow-up navigation to treatment services for those diagnosed with cancer and precancer, data collection and tracking, and systems improvement.
- **Geographic Area to be Served:** Preventive service delivery to nonmetropolitan/medically underserved area (MUA) counties must be included in the defined service area. Service to urban counties that are not medically underserved is allowable if the project proposes to also serve nonmetropolitan counties that are medically underserved.
- **Clinical Service and Community Partner Networks:** Applicants are encouraged to coordinate and describe a collaboration of clinical service providers and community partners that can deliver outreach, education, clinical, and navigation services to the most counties and the most people possible in a selected service region.

**Funding Amount and Duration:**
The amount of funding that applicants may request is dependent on the primary focus of the project and on the type of project – New, Initial Expansion or Maintenance Expansion. Use the table below to determine the maximum amount of funding and the maximum number of years that may be requested.

| Project Type | Maximum Amount of Funding | Maximum Duration |
|---|---|---|
| New project | $1.5 million | 3 years |
| Initial Expansion Project | $2 million | 3 years |
| Maintenance Expansion Project | $2.5 million | 5 years |

**Other Activities**

Mr. Carlton Allen, Program Manager for Prevention, has joined the American Indian Cancer Foundation's (AICF) Indigenous Cancer Solutions Texas Coalition. This coalition aims to work with individuals, clinics, and organizations throughout Texas to develop and implement the Indigenous Cancer Solutions Comprehensive Cancer Control Plan. The Coalition's goals include increasing appropriate cancer screening through recommended screening cancer guidelines in Indigenous communities and reducing the rate of late-stage diagnosis.

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# MEMORANDUM

**TO:** OVERSIGHT COMMITTEE MEMBERS

**FROM:** KEN SMITH, PH.D., CHIEF PRODUCT DEVELOPMENT OFFICER

**SUBJECT:** PRODUCT DEVELOPMENT PROGRAM UPDATE

**DATE:** NOVEMBER 8, 2023

Product Development FY 2024 Cycle 1 Review (24.1)

On May 1 CPRIT released four FY 2024 Product Development Research RFAs and opened the portal to receive preliminary and full applications on a rolling basis. CPRIT received the total number of full applications (15) allocated for the first cycle of FY 2024 by June 30, one month before the August 1 deadline.

- Preliminary Application Review: CPRIT received 79 FY 2024 preliminary applications on a rolling basis between May 1 and June 30. Like the FY 2023 review cycle, five standing review panels evaluated the FY 2024 preliminary applications on a rotating basis. CPRIT issued weekly invitations to submit full applications to companies that presented meritorious preliminary applications, based on application scores as determined by the preliminary application peer review panel.

  CPRIT received the total number of full applications for the 15 review slots for the first review cycle for FY 2024 on June 30. The preliminary review panels completed reviews of 45 preliminary applications and issued invitations to 19 companies to submit a full application for FY 2024 by June 30. Because there were no more spots available for full application review, CPRIT returned 34 preliminary applications to applicants without review. Should the applicants submit these unreviewed applications in future cycles, they will not count against their resubmission limit.

  The table below provides information about the FY 2024 preliminary applications.

| 24.1 RFA | Preliminary Applications | | | Total Prelim Request | Full Application Invites |
|---|---|---|---|---|---|
| | Submitted | Reviewed | Returned - no review | | |
| TTC | 34 | 23 | 11 | $353 M | 10 |
| TDDC | 4 | 2 | 2 | $27 M | 1 |
| TNTC | 9 | 5 | 4 | $39 M | 2 |
| Seed | 32 | 15 | 17 | $48 M | 6 |
| **TOTAL** | **79** | **45** | **34** | **$467 M** | **19** |

TTC = Texas Therapeutics Company; TDDC = Texas Device and Diagnostic Company; TNTC – Texas New Technologies Company



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- Full Application Review (July and August): In addition to the 19 invitations issued by June 30, CPRIT allowed four companies that submitted full applications in the FY 2023 cycle to resubmit their full applications for review in the FY 2024 cycle. (CPRIT did not review these four full applications in FY 2023 because of time and resource limitations.)

  The FY 2024 RFAs notified applicants that CPRIT would continually monitor the number of submissions and would stop accepting full applications before the August 1 deadline if we received more than 15 applications. By 4:00 p.m. CST on June 30, CPRIT received its 15th and 16th full application submittal (including the four FY 2023 full applications.) Accordingly, we closed the portal for full application submission on June 30. We separately notified the seven companies with invitations for FY 2024 who had not submitted full applications by June 30 that CPRIT was no longer accepting full applications at this time.

  Although we planned for 15 spots, I increased the number of review slots to accommodate the 16th full application received by CPRIT on June 30. As a result, unlike the FY 2023 review cycle, CPRIT did not return any full applications to applicants without a review, and we will not carry over submitted but unreviewed applications into future cycles.

- Panel Presentations, Due Diligence Review and Budget Negotiation (August – October): Prior to panel presentations, one company withdrew from consideration because of unexpected clinical results. The remaining 15 companies presented their full applications to review panels in August and September. Based upon the review panels' recommendations, eight companies proceeded to due diligence review. The review panels met in September and October to evaluate the due diligence reports and to finalize panel award recommendations. Following the meetings, the panels recommended seven companies for product development awards.

  Using the same process we successfully employed for the FY 2023 review cycle, I negotiated the proposed project budgets to identify ways to decrease CPRIT-funded project expenses while maintaining the goals and objectives of the recommended projects. This is a crucial step to ensuring that CPRIT can fund as many meritorious projects as possible with the estimated $74 million allocated for FY 2024 Product Development awards.

  The table below provides information about the FY 2024 cycle 1 full applications.

| 24.1 RFA | Invited Apps | Submitted Apps | Budget Request | Apps in Due Diligence | Budget Request |
|---|---|---|---|---|---|
| TTC | 12 | 8 | $112.8M | 3 | $41.8M |
| TDDC | 2 | 2 | $9.0M | 1 | $5.4M |
| TNTC | 2 | 1 | $12.6M | 1 | $12.6M |
| Seed | 7 | 5 | $15.0M | 3 | $9.0M |
| **TOTAL** | **23** | **16** | **$149.4M** | **8** | **$68.8M** |

- Final Recommendations (October and November): The Product Development Review Council (PDRC) met October 24 to develop a final ranked list of the seven companies recommended for product development awards. I discussed the PDRC's proposed awards with the Program Integration Committee (PIC) on November 1. Following my recommendation, the PIC voted to defer one award recommendation for possible action at a future FY 2024 PIC meeting. I will present the six companies proposed for awards at the November 15 Oversight Committee meeting.

- Looking Ahead: If CPRIT does not award all product development award funds allotted for FY 2024 in this first cycle, the product development program expects to reopen the RFAs in December or January for a second round of awards for Oversight Committee approval in May or August 2024.

The Texas Resource Guide

For the past several months, a joint effort of the product development program staff, IT staff, and communications staff, led by Senior Program Manager for Product Development Dr. Abria Magee, created *The Texas Resource Guide* for biotech companies in Texas or considering relocating to Texas. CPRIT debuted a beta version of the guide at the *CPRIT Innovations Conference* in early October. It features a compilation of detailed information about service providers and other entities that support early stage and developing life science companies in Texas. Currently, the guide includes 199 entities; we will regularly update the guide with more information.

Other Activities

Dr. Magee and Program Manager for Product Development Dr. Michelle Leeuwon met with 19 active CPRIT-funded companies for on-site visits in Houston and Dallas during October. The team received high-level project overviews from the companies, including updates on pending project goals and objectives and expected next steps. The product development program will use this information to augment the ongoing CPRIT company portfolio project. Dr. Magee met with the following Houston-based companies: Allterum, Asylia Therapeutics, 7 Hills Pharma, Hummingbird Bioscience, Immunogenesis, Invectys, InformAI, Instapath, Iterion, Marker Therapeutics, OmniNano, OncoResponse, PranaThoracic, Pulmotect, and Xerient. Dr. Leeuwon met with three Dallas-based companies: ImmuneSensor, OncoNano, and Perimeter. The CPRIT team plans more on-site visits in 2024.

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# MEMORANDUM

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|---|---|
| **TO:** | OVERSIGHT COMMITTEE MEMBERS |
| **FROM:** | WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER |
| **SUBJECT:** | PROGRAM PRIORITIES FOR FY 2025 |
| **DATE:** | NOVEMBER 8, 2023 |

**Summary and Recommendation**

I recommend that the Oversight Committee approve the program priorities for fiscal year 2025 as presented behind this memo. Texas Health and Safety Code § 102.107 requires the Oversight Committee to set priorities for the grant programs annually. Each program officer discussed the priorities proposed for fiscal year 2025 with their respective subcommittee in meetings earlier this month. The FY 2025 program priorities are the same as the priorities adopted by the Oversight Committee last November for fiscal year 2024.

**Priorities** for **FY 2025**

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

The Oversight Committee reviews its priorities annually and adjusts as circumstances change to incorporate the latest information concerning cancer-related advances in prevention, academic research, and product development research. In January 2018, the Oversight Committee decided to approve program priorities at November meetings to provide CPRIT staff more lead time for preparing and releasing RFAs. Adopting the 2025 program priorities at the November 15, 2023, Oversight Committee meeting allows the priorities to guide the fiscal year 2025 RFA process.

Each of the program subcommittees discussed the program priorities proposed for fiscal year 2025. The Prevention, Product Development Research, and Academic Research Subcommittees recommend proposed fiscal year 2025 priorities for their respective programs unchanged from the priorities adopted for fiscal year 2024.

In addition to the priorities specific to each grant program, the proposed fiscal year 2025 program priorities also reflect priorities across CPRIT's three programs. These overarching priorities, which also remain the same as those adopted for fiscal year 2024, inform the Program



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Integration Committee on balancing the portfolio across the academic research, prevention, and product development research programs.

CPRIT staff will use the newly adopted program priorities to develop RFAs for the fiscal year 2025 CPRIT grant review cycles.

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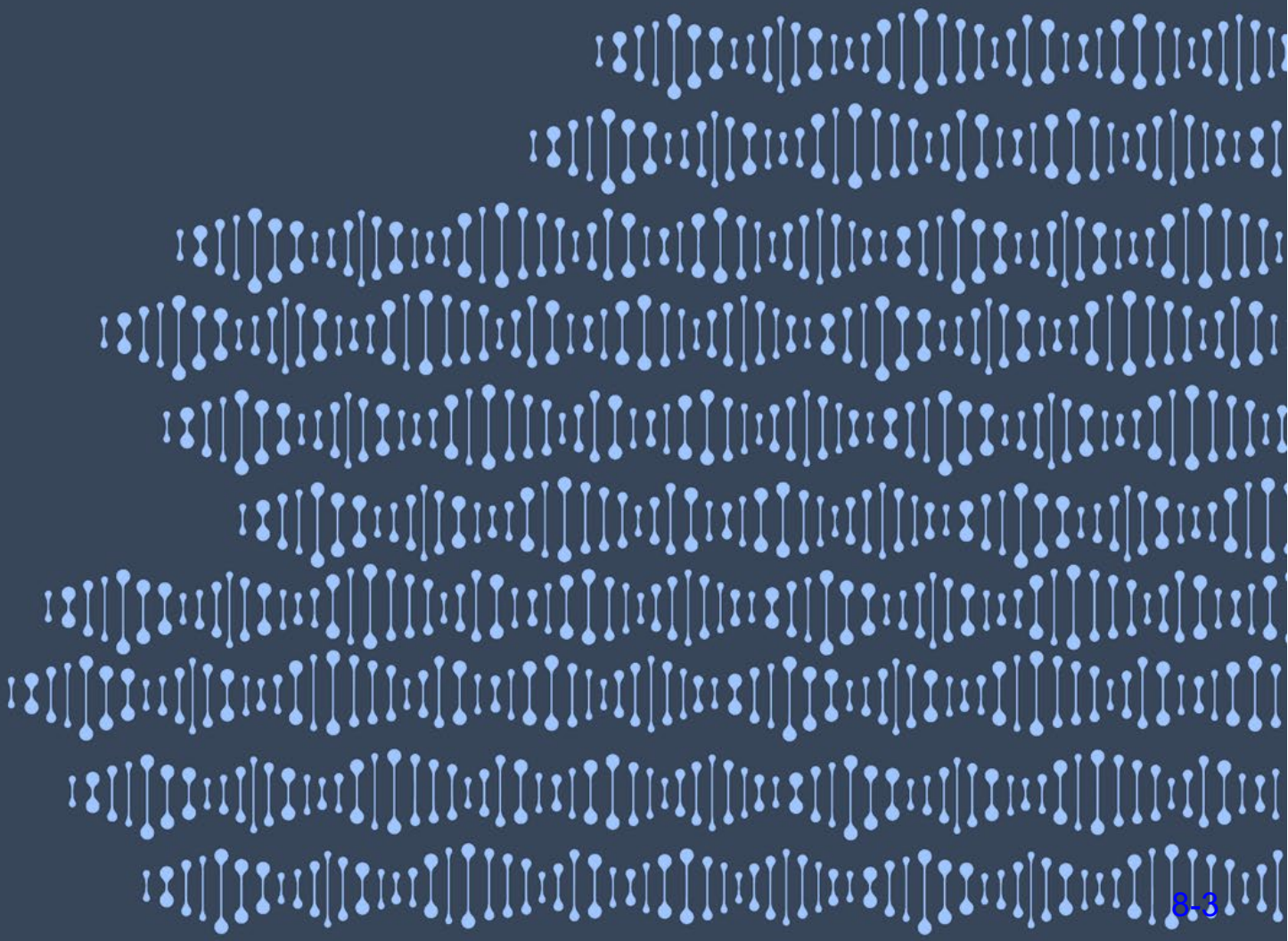
# Proposed Program Priorities For FY 2025



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## ABOUT CPRIT'S PROGRAM PRIORITIES PROJECT

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

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

CPRIT Purpose

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

Program Priorities Legislative Mandate

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

## PROCESS TO DEVELOP PROGRAM PRIORITIES

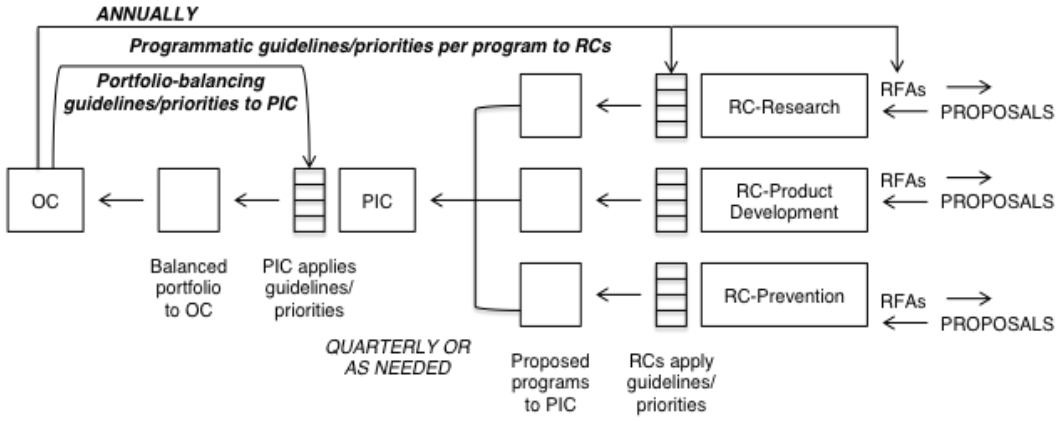
The Oversight Committee initially approved the program priorities in November 2014 after a six-month process that included public input. The fiscal year 2015 program priorities were subsequently incorporated into the RFAs released by each program. The Oversight Committee continues to annually approve priorities for each program every year, most recently adopting the program priorities for fiscal year 2024 at the November 15, 2022, meeting.

## SCOPE OF PROGRAM PRIORITIES PROJECT

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

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

Priorities and CPRIT's Grant Making Process




## CPRIT'S LONG TERM VISION

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

Innovative projects funded by CPRIT will result in:

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

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

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

## PRIORITIES WITHIN EACH OF CPRIT'S PROGRAMS

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

Established key principles essential to executing CPRIT's purpose guide each of CPRIT's three programs. The main principle underlying all three programs is that each will continue to ensure only applications with scientific merit move 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 across Texas.

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 oncology 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 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 ensure 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 in all regions of the state
- Reducing cancer disparities in cancer incidence and mortality

| Academic Research Program Priorities |
| --- |
| • Recruitment of outstanding cancer researchers to Texas<br>• Investment in core facilities<br>• A broad range of innovative, investigator-initiated research projects<br>• Implementation research to accelerate adoption and deployment of evidence-based prevention, early detection, risk assessment and interventions<br>• Computational oncology and analytic methods<br>• Childhood and adolescent cancers<br>• Hepatocellular cancer<br>• 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 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 in all regions of the state to populations with obstacles to cancer prevention, detection, diagnostic testing, treatment, and survivorship services 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 continuum of primary, secondary, and tertiary cancer prevention

| Prevention Program Priorities |
|---|
| • Populations disproportionately affected by cancer incidence, mortality, or cancer risk prevalence<br>• Geographic areas of the state disproportionately affected by cancer incidence, mortality, or cancer risk prevalence<br>• Populations with obstacles to cancer prevention, detection, diagnostic testing, treatment, and survivorship services<br>• Program assessment to identify best practices, use as a quality improvement tool, and guide future program direction |

**Product Development Research Program**

Background

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

Developing novel cancer treatments, diagnostics, and devices results from a series of research and development activities. As a product moves through the development process, the risk of failure decreases as the product successfully 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) have a higher investment risk and a harder time attracting private capital. CPRIT invests in these early stage companies where private capital is hardest to obtain, typically referred to as the technology "valley of death," where promising ideas die for lack of funding. Subject matter experts review company proposals to identify the most promising projects. CPRIT's investment in early stage companies increases the number of cancer therapies in development in Texas, which stimulates the Texas life sciences ecosystem.

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

Established Principles

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

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

CPRIT's Product Development Research Program also catalyzes 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;
- Commercializing technologies developed at Texas institutions; and
- Promoting company formation.

| Product Development Research Program Priorities |
|---|
| • Funding novel projects that offer therapeutic or diagnostic benefits; i.e., disruptive technologies<br>• Funding projects addressing large or challenging unmet medical needs<br>• Investing in early stage projects when private capital is least available<br>• Stimulating commercialization of technologies developed at Texas research entities<br>• Supporting new company formation in Texas or attracting promising companies to Texas that will recruit staff with life science expertise, especially C-level executives<br>• 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. Scientists need funds for research and development activities taking place between the stages of discovery science - traditionally funded by grants from federal sources and foundations - and late term development and commercialization of drugs, devices, diagnostic tests, and biologicals – often 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 across Texas.

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 risk assessment, prevention, early detection, and interventions that could translate into implementation prevention research. | Fund the continuum of cancer research - population, basic, translational, and clinical research - that could develop new discoveries into practical advances | Increase the cancer research infrastructure across Texas by investing in researcher recruitment, training grants and core facilities. |
| **Prevention Program Implementation** | Implement programs that place innovative, evidence-based approaches into practice and continue to fund effective approaches. | Harness emerging technologies that expedite the development of early cancer detection, risk assessment, and interception to implement novel prevention services | Implementing systems change, developing partnerships and collaborations, training of community and healthcare providers, and creating new jobs. |
| **Product Development Research Program Implementation** | Fund new technologies and methods for early cancer detection and prevention. | Fund early-stage companies that are bridging the gap between basic research and product development. | Grow the life sciences industry and infrastructure in Texas while creating new employment opportunities. |

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

# MEMORANDUM

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| **TO:** | OVERSIGHT COMMITTEE MEMBERS |
| **FROM:** | CAMERON ECKEL, ASSISTANT GENERAL COUNSEL |
| **SUBJECT:** | APPOINTMENTS TO THE SCIENTIFIC RESEARCH AND PREVENTION PROGRAMS COMMITTEE |
| **DATE:** | NOVEMBER 6, 2023 |

## Summary and Recommendation

The Chief Executive Officer has appointed nine experts to CPRIT's Scientific Research and Prevention Programs Committee. CPRIT's statute requires Oversight Committee approval for the appointments. At their November 2 meeting, the Board Governance subcommittee reviewed the appointees to the Academic Research, Prevention, and Product Development Research peer review panels and recommends approval by the Oversight Committee.

## Discussion

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

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

The Board Governance Subcommittee reviewed the nine appointees at its November 2 meeting and recommends their approval by the Oversight Committee.



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CANCER PREVENTION & RESEARCH
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**Scientific Research and Prevention Program Committee ("Peer Reviewer") Appointments**
**November 2023**

| CPRIT Program | Name | Organization | Title | Expertise |
|---|---|---|---|---|
| Academic Research | Xuefeng Wang, Ph.D. | Department of Biostatistics & Bioinformatics Moffitt Cancer Center Tampa, FL | Vice Chair and Associate Member | Statistical Genomics, Biostatistics, Bioinformatics, Biomarker Discovery |
| Prevention | Matthew (Mateo) P. Banegas, Ph.D., MPH, MS | Department of Radiation Medicine and Applied Sciences University of California San Diego | Associate Professor and Co-Director of the Center for Health Equity Education and Research (CHEER) | Health services research, cancer prevention and control |
| Prevention | Patricia I. Moreno, Ph.D. | Department of Public Health Sciences at the University of Miami Miller School of Medicine | Assistant Professor, Lead of Evidence-Based Survivorship Supportive Care at the Sylvester Comprehensive Cancer Center. | Survivorship, health disparities, quality of life |
| Product Development Research | Paul de Figueiredo, Ph.D. | Department of Molecular Microbiology and Immunology, School of Medicine, University of Missouri | Roy Blunt NextGen Professor | Immunology, immunotherapy, high-throughput screening, immunomodulators |
| Product Development Research | Diana Bytnar Fordyce, Ph.D. | Fordyce-Bytnar Consulting LLC | Partner, Independent Pharmaceutical Regulations Consultant | regulatory strategies, labeling, FDA Meetings, CTD section reviews and gap analyses |



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| CPRIT Program | Name | Organization | Title | Expertise |
|---|---|---|---|---|
| Product Development Research | M. N. V. Ravi Kumar, Ph.D. | The Center for Convergent Bioscience and Medicine, University of Alabama | Distinguished Research Professor Founding Director, | Drug delivery, drug targeting, toxicology |
| Product Development Research | David P. Rotella, Ph.D. | Montclair State University | Margaret and Herman Sokol Professor of Chemistry | Organic chemistry, medicinal chemistry |
| Product Development Research | Feng Tian, Ph.D. | CovalaBio Inc. San Diego, USA | Co-founder and president | Protein engineering, antibody-drug conjugate, drug development |
| Product Development Research | Semen O. Yesylevskyy, Ph.D. | Department of Physics of Biological Systems, Institute of Physics, Kyiv, Ukraine | Leading researcher | Computer modeling, molecular dynamics simulation |

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

# MEMORANDUM

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| **TO:** | OVERSIGHT COMMITTEE MEMBERS |
| **FROM:** | CAMERON ECKEL, ASSISTANT GENERAL COUNSEL |
| **SUBJECT:** | APPOINTMENTS TO ADVISORY COMMITTEES REQUIRING OVERSIGHT COMMITTEE APPROVAL |
| **DATE:** | NOVEMBER 6, 2023 |

## Summary

At its November 2 meeting, the Board Governance subcommittee reviewed Presiding Officer Dr. David Cummings' proposed appointment to the Clinical Trials Advisory Committee (CTAC). The subcommittee recommends that the Oversight Committee approve the appointment.

## Discussion

Texas Health & Safety Code § 102.155 allows the Oversight Committee to create ad hoc committees of experts to advise the Oversight Committee. The presiding officer of the Oversight Committee is responsible for appointing experts to serve on CPRIT's advisory committees. The appointments must be approved by the Oversight Committee.

The primary purpose of the CTAC is to advise the Oversight Committee on important issues of clinical trials. The CTAC gives their expert opinion on the impact of current CPRIT mechanisms supporting clinical trials; gives advice on opportunities to increase CPRIT's impact on translating basic discoveries to clinical trials; and advises on mechanisms that would address barriers to patient enrollment in therapeutic clinical trials.

The Board Governance subcommittee reviewed the appointment to the CTAC at its November 2 meeting and voted to recommend approval to the Oversight Committee.



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**Advisory Committee Appointments**
**November 2023**

| Advisory Committee | Nominee | Institution |
|---|---|---|
| Clinical Trials Advisory Committee | Martha P. Mims, M.D., Ph.D.<br>Professor of Medicine<br>Section Chief,<br>Hematology/Oncology | Baylor College of Medicine |



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CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

# MEMORANDUM

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| **TO:** | OVERSIGHT COMMITTEE CHAIR DAVID CUMMINGS |
| **FROM:** | WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER |
| **SUBJECT:** | SECTION 102.1062 WAIVER—DR. LEEUWON FY 2024 |
| **DATE:** | NOVEMBER 8, 2023 |

## Waiver Request and Recommendation

I request that the Oversight Committee approve a conflict of interest waiver for FY 2024 for Dr. W. Michelle Leeuwon, Program Manager for Product Development, pursuant to Health & Safety Code Section 102.1062 "Exceptional Circumstances Requiring Participation." Dr. Leeuwon's husband is a professor of chemistry at Texas A&M University and a principal investigator (PI) on two active CPRIT academic research grants.

It is unlikely that Dr. Leeuwon will participate in any activities related to academic research grant applications or grant awards. Although Dr. Leeuwon is not involved in the academic research grant application or reporting process in her capacity as program manager for product development, the waiver ensures transparency regarding her relationship with a PI at a grantee institution. I recommend approval because together with the waiver's proposed limitations, adequate protections are in place to mitigate factors other than merit and the established grant criteria affecting the award and management of grant funds.

## Background

Dr. Leeuwon's husband, Dr. Wenshe Liu, is a professor of chemistry at Texas A&M University. In that role, he serves as a PI for an active CPRIT academic research grant award, RP230345 (approved February 2023) and for an award, RP230449 (approved August 2023) that is currently in contract negotiation. He previously served as PI for another CPRIT academic research grant (RP170797) that is no longer active.

Texas Health & Safety Code § 102.106(c)(3) finds a professional conflict of interest exists when a relative within the second degree of affinity or consanguinity of the individual involved in the CPRIT review process is an employee of a grant recipient or grant applicant.[1] Texas A&M University is a current grant recipient and frequent grant applicant.

[1] CPRIT's administrative rule §702.13(c) classifies this type of professional conflict of interest as one that raises the presumption that the existence of the conflict may affect the impartial review of all other grant applications submitted pursuant to the same grant mechanism in the grant review cycle. A person involved in the review process that holds one of the conflicts included in the § 702.13(c) "super conflict" category must recuse himself/herself from participating in the "review, discussion, scoring, deliberation and vote on all grant applications competing for the same grant mechanism in the entire grant review cycle, unless a waiver has been granted…"



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Texas Health & Safety Code § 102.1061 requires a CPRIT employee with this professional conflict of interest to recuse herself from an application that comes before the employee for review or other action and not access information regarding the matter. In her role as program manager for product development, Dr. Leeuwon neither participates in the review of any CPRIT grant applications nor does she make grant award decisions. As far as decisions related to Dr. Liu's current grant awards, it is highly unlikely that Dr. Leeuwon would be involved with matters related to her husband's grants because other CPRIT programmatic staff, such as the director of research and the program manager for academic research, are responsible for day-to-day management of academic research grants.

**Exceptional Circumstances**

To approve a conflict of interest waiver, the Oversight Committee must find that there are exceptional circumstances justifying the conflicted individual's participation in the review process. This conflict of interest waiver is different than most waivers I have requested in that Dr. Leeuwon is not involved in the academic research grant application or reporting process in her capacity as program manager for product development. However, in the unlikely event that the academic research program requires Dr. Leeuwon's assistance with the review process and/or grantee reports in the future, this waiver will ensure her ability to do so consistent with the limitations listed below. The waiver consideration and approval process also promotes transparency regarding Dr. Leeuwon's close relationship with a PI at a CPRIT grantee institution.

**Proposed Waiver and Limitations**

In granting the waiver of the conflict of interest set forth in Health & Safety Code Section 102.106(c)(3), I recommend that the Oversight Committee permit Dr. Leeuwon to perform all duties assigned as program manager for product development subject to the limitations stated below:

1. Dr. Leeuwon will notify the Chief Product Development Officer and/or the Chief Scientific Officer, as appropriate, prior to taking any action that would directly affect a grant award that includes Dr. Wenshe Liu as part of the grantee team;
2. Prevent Dr. Leeuwon from accessing application review data for any applications under review that include Dr. Wenshe Liu as part of the grantee team;
3. The Chief Product Development Officer and/or the Chief Scientific Officer, as appropriate, in conjunction with the Chief Executive Officer, Chief Compliance Officer and Deputy Executive Officer and General Counsel, can review the circumstances and determine whether Dr. Leeuwon should recuse herself from involvement in regular job duties.

**Important Information Regarding this Waiver and the Waiver Process**

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

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

# MEMORANDUM

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|---|---|
| **TO:** | OVERSIGHT COMMITTEE MEMBERS |
| **FROM:** | KRISTEN PAULING DOYLE, DEPUTY EXECUTIVE OFFICER & GENERAL COUNSEL<br>CAMERON L. ECKEL, ASSISTANT GENERAL COUNSEL |
| **SUBJECT:** | CHAPTERS 701 RULE CHANGES PROPOSED FOR FINAL ADOPTION |
| **DATE:** | NOVEMBER 6, 2023 |

## Summary and Recommendation

The Board Governance Subcommittee convened on November 2 to review the final order adopting rule amendments to Chapter 701. Once the Oversight Committee approves the final order adopting the changes to T.A.C. § 701.25, CPRIT will submit the amendment to the Secretary of State and the change 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. CPRIT published the proposed amendments in the September 1, 2023, edition of the *Texas Register*. CPRIT received no public comments regarding the proposed rule changes to Chapter 701.

The change to § 701.25 amends CPRIT's electronic signature policy to include grant applicants so that the convenience and responsibilities associated with electronic signatures are available to grant applicants as well as grant recipients.

The Board Governance Subcommittee met on November 2 to discuss adoption of the proposed rule changes to Chapter 701 with CPRIT staff. The subcommittee voted to recommend that the Oversight Committee approve adoption of the rule change.

## Next Steps

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



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The Cancer Prevention and Research Institute of Texas (“CPRIT” or “the Institute”) adopts the amendments to 25 Tex. Admin. Code § 701.25 without changes to the proposed amendments as published in the September 1, 2023, issue of the Texas Register (48 TexReg 4773); therefore, the rule will not be republished. The amendments relate to CPRIT’s electronic signature policy.

Reasoned Justification

CPRIT amends its electronic signature policy to include grant applicants so that the convenience and responsibilities associated with electronic signatures are available to grant applicants as well as grant recipients.

Summary of Public Comments and Staff Recommendation

CPRIT received no public comments regarding the proposed amendments to § 701.25; CPRIT staff recommends moving forward with adoption of the amendments.

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

Certification

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

To be filed with the Office of Secretary of State on November 17, 2023.

<rule>

§701.25.Electronic Signature Policy.

A Grant Recipient's use of the Institute's electronic Grant Management System or a Grant Applicant's use of the Institute's electronic Application Receipt System to create, exchange, execute, submit, and verify legally binding Grant Contract documents and Grant Award reports or a Grant Application shall be pursuant to an agreement between the Institute and the Grant Recipient or Grant Applicant regarding the use of binding electronic signatures. Such agreement shall include at least the following minimum standards:

(1) The Grant Recipient or Grant Applicant agrees that by entering the Authorized Signing Official's password in the electronic Grant Management System or Application Receipt System at certain specified points, the Grant Recipient or Grant Applicant electronically signs the Grant Contract document or related form or Grant Application . The Grant Recipient or Grant Applicant further agrees that the electronic signature is the legal equivalent of the Authorized Signing Official's manual signature.

(2) The Institute may rely upon the electronic signature rendered by entering the Authorized Signing Official's password as evidence that the Grant Recipient or Grant Applicant consents to

be legally bound by the terms and conditions of the Grant Contract or related form or Grant Application as if the document was manually signed.

(3) The Grant Recipient or Grant Applicant shall provide prompt written notification to the Institute of any changes regarding the status or authority of the individual(s) designated by the Grant Recipient or Grant Applicant to be the Grant Recipient's or Grant Applicant's Authorized Signing Official. The notice must be provided to an individual designated by the Institute.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

# MEMORANDUM

**TO:** OVERSIGHT COMMITTEE MEMBERS

**FROM:** HEIDI MCCONNELL, CHIEF OPERATING OFFICER

**SUBJECT:** CHIEF OPERATING OFFICER REPORT

**DATE:** NOVEMBER 7, 2023

## CPRIT Financial Overview for FY 2023, Quarter 4

FY 2023, Quarter 4 Operating Budget

In the fourth quarter of FY 2023, CPRIT has encumbered or expended 79% of the $5.2 million Indirect Administration budget and 99% of the $16.2 million Grant Review and Award Operations budget. The Grant Review and Award Operations budget includes the majority of the agency's vendor contracts which support grant award and administration, including the $9.9 million contract for grant management support services with GDIT.

CPRIT received $389,444 in revenue sharing payments during the fourth quarter. Total revenue sharing payment deposits from CPRIT's inception exceeds $9.6 million through the end of August 2023.

FY 2023, Quarter 4 Performance Measure Report

CPRIT completed reporting on the two quarterly and three annual key performance measures to the Legislative Budget Board for FY 2023. The results are:

- A total of 848,103 people served through CPRIT prevention and control grants, exceeding the 700,000-person served goal;
- Two company relocations, exceeding the goal of one relocation;
- Being within range of the 141.0 annual age-adjusted mortality rate at 140.5;
- A total of 1,091 published articles on CPRIT-funded research, exceeding the 1,000-article target; and
- A total of 3,551 jobs created or maintained, exceeding the 3,000-job target.

Debt Issuance History

The Texas Public Finance Authority (TPFA) issued $59.2 million in commercial paper notes on CPRIT's behalf in June 2023 and another $14.6 million in general obligation bond proceeds in August 2023 during the fourth quarter bringing the total debt issued to $298.3 million in FY 2023. The long-term bond transaction that took place on August 29, 2023, also included refunding $350 million in commercial paper notes issued between July 2022 and June 2023.



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# Cancer Prevention and Research Institute of Texas
## Quarterly Financial Report
### As of August 31, 2023

**Indirect Administration (B.1.1.)**

| | | 2023 Appropriated | 2023 Budgeted | % of Total Budget | Actual Expenditures & Grant Encumbrances (FYTD) | Remaining Budget | Percent Expended | Estimated Expenditures (YTD) | Lapse/Overspent |
|---|---|---|---|---|---|---|---|---|---|
| 1001 | Salaries and Wages | $ 1,847,425 | $ 1,824,970 | | $ 1,734,826 | 90,144 | 95% | $ 1,734,826 | $ 90,144 |
| 1002 | Other Personnel Costs | 38,785 | 47,056 | | 47,056 | 0 | 100% | 47,056 | 0 |
| 2001 | Professional Fees and Services | 1,038,960 | 1,227,490 | | 1,207,030 | 20,460 | 98% | 1,207,030 | 20,460 |
| 2003 | Consumable Supplies | 24,000 | 24,000 | | 4,037 | 19,963 | 17% | 4,037 | 19,963 |
| 2004 | Utilities | 58,600 | 58,600 | | 27,939 | 30,661 | 48% | 27,939 | 30,661 |
| 2005 | Travel | 45,000 | 45,000 | | 44,576 | 424 | 99% | 44,576 | 424 |
| 2006 | Rent-Building | 11,000 | 11,000 | | 3,295 | 7,705 | 0% | 3,295 | 7,705 |
| 2007 | Rent-Machine and Other | 39,172 | 39,172 | | 22,812 | 16,360 | 58% | 22,812 | 16,360 |
| 2009 | Other Operating Expenses | 1,807,951 | 1,897,359 | | 972,341 | 925,018 | 51% | 972,341 | 925,018 |
| | **Subtotal - Indirect Administration (B.1.1.)** | **$ 4,910,893** | **$ 5,174,647** | **1.74%** | **$ 4,063,912** | **$ 1,110,735** | **79%** | **$ 4,063,912** | **$ 1,110,735** |

**Grant Review and Award Operations (A.1.3.)**

| | | 2023 Appropriated | 2023 Budgeted | % of Total Budget | Actual Expenditures & Grant Encumbrances (FYTD) | Remaining Budget | Percent Expended | Estimated Expenditures (YTD) | Lapse/Overspent |
|---|---|---|---|---|---|---|---|---|---|
| 1001 | Salaries and Wages | $ 3,505,873 | 4,035,375 | | $ 4,035,375 | $ (0) | 100% | $ 4,035,375 | $ (0) |
| 1002 | Other Personnel Costs | 45,000 | 112,944 | | 112,944 | 0 | 0% | 112,944 | 0 |
| 2001 | Professional Fees and Services | 12,420,663 | 11,913,217 | | 11,913,217 | 0 | 100% | 11,913,217 | 0 |
| 2003 | Consumable Supplies | - | - | | - | - | 0% | - | - |
| 2004 | Utilities | 12,000 | 17,674 | | 17,674 | 0 | 100% | 17,674 | 0 |
| 2005 | Travel | 45,000 | 25,000 | | 22,896 | 2,104 | 92% | 22,896 | 2,104 |
| 2009 | Other Operating Expenses | 70,359 | 221,095 | | 29,368 | 191,726 | 13% | 29,368 | 191,726 |
| | **Subtotal - Grant Operations (A.1.3.)** | **$ 16,098,895** | **$ 16,325,305** | **5.49%** | **$ 16,131,473** | **$ 193,831** | **99%** | **$ 16,131,473** | **$ 193,831** |

**Grants**

| | | 2023 Appropriated | 2023 Budgeted | % of Total Budget | Actual Expenditures & Grant Encumbrances (FYTD) | Remaining Budget | Percent Expended | Estimated Expenditures (YTD) | Lapse/Overspent |
|---|---|---|---|---|---|---|---|---|---|
| 4000 | Grants - Prevention (A.1.2) | $ 27,671,780 | $ 27,718,402 | | $ 26,920,426 | $ 797,976 | 97% | $ 26,920,426 | $ 797,976 |
| 4000 | Grants - Research (A.1.1.) | 248,251,400 | $ 248,251,400 | | 242,119,006 | $ 6,132,394 | 98% | 242,119,006 | 6,132,394 |
| | **Subtotal - Grants** | **$ 275,923,180** | **$ 275,969,802** | **92.77%** | **$ 269,039,432** | **$ 6,930,370** | **97%** | **$ 269,039,432** | **$ 6,930,370** |
| | **Grand Totals** | **$ 296,932,968** | **$ 297,469,753** | **100.00%** | **$ 289,234,817** | **$ 8,234,937** | **97%** | **$ 289,234,817** | **$ 8,234,937** |

# Cancer Prevention and Research Institute of Texas

## Cancer Prevention and Research Institute Fund Account - 5136

## As of August 31, 2023

| | 08/01/2023-08/31/2023 | AY 23 Year to Date as of 08/31/2023 |
|---|---|---|
| **Beginning Balance : 9/01/2022** | | **$ 600,506** |
| **Increases:** | | |
| (1) | $ - | $ - |
| (2) | - | |
| **Total Increases** | **$ -** | **$ 600,506.00** |
| **Reductions:** | | |
| Expenditures - Appropriated | $ - | $ - |
| | $ - | $ - |
| | $ - | $ - |
| **Total Reductions** | **$ -** | **$ -** |
| **Ending Balance: 08/31/2023** | | **$ 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, 2023

| | | 08/01/2023-08/31/2023 | AY 23 Year to Date as of 08/31/2023 |
|---|---|---|---|
| **Beginning Balance : 9/01/2022** | | | **$ 46,621.77** |
| **Increases:** | | | |
| (1) | License Plate Revenue Received | $ 672.82 | $ 6,764.91 |
| | Interest | $ 194.98 | $ 1,758.03 |
| **Total Increases** | | **$ 867.80** | **$ 55,144.71** |
| **Reductions:** | | | |
| | Expenditures - Appropriated | $ - | $ - |
| | | - | - |
| **Total Reductions** | | **$ -** | **$ -** |
| **Ending Balance: 08/31/2023** | | | **$ 55,144.71** |

Note:

Balance forward from 2022 License Plate $46,621.77

# Cancer Prevention and Research Institute of Texas

## Appropriated Receipts - 666

## As of August 31, 2023

| | | 08/01/2023-08/31/2023 | AY 23 Year to Date as of 08/31/2023 |
|---|---|---|---|
| **Beginning Balance : 9/01/2022** | | | **$ 34,246.90** |
| **Increases:** | | | |
| **(1)** | Product Development Application Fees Received | $ 2,000.00 | $ 21,000.00 |
| **(2)** | Conference Registration Fees | $ 74,650.00 | $ 187,797.75 |
| **(3)** | Conference Registration Fees-Credit Card | $ 1,869.22 | $ 4,364.93 |
| **Total Increases** | | **$ 78,519.22** | **$ 213,162.68** |
| **Reductions:** | | | |
| | Conference Expenditures - Appropriated | $ - | $ - |
| | Credit Card Fees Expended | $ - | $ - |
| | Refund-Application Fees | $ - | $ - |
| | Legal Services Expenses (Application Fees) | $ - | $ - |
| **Total Reductions** | | **$ -** | **$ -** |
| **Ending Balance: 08/31/2023** | | | **$ 247,409.58** |

Forward balance for FY 2022 is $34,246.90
Application Fees

# Cancer Prevention and Research Institute of Texas

## Interest & Sinking Fund Account - 5168

## As of August 31, 2023

| | | 08/01/2023-08/31/2023 | AY 23 Year to Date as of 08/31/2023 |
|---|---|---|---|
| **Beginning Balance : 9/01/2022** | | | **$ 4,467,549.58** |
| **Increases:** | | | |
| (1) | Revenue Sharing / Royalties | $ 102,481.91 | $ 1,923,056.43 |
| | | $ - | |
| **Total Increases** | | **$ 102,481.91** | **$ 6,390,606.01** |
| **Reductions:** | | | |
| | Expenditures - Appropriated | $ - | $ - |
| | | $ - | |
| | | $ - | $ - |
| **Total Reductions** | | **$ -** | **$ -** |
| **Ending Balance: 08/31/2023** | | | **$ 6,390,606.01** |

Balance forward from FY 2022 is $4,467,549.58

## Cancer Prevention and Research Institute of Texas
### FY 2023, 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** | 700,000 | 208,524 | 168,118 | 251,237 | 220,224 | 848,103 | 121.16% |
| **Number of Entities Relocating to TX for Cancer Research Related Projects** | 1 | 0 | 1 | 0 | 1 | 2 | 200.00% |
| **Annual Age-adjusted Cancer Mortality Rate** | 141.0 | N/A | N/A | N/A | N/A | 140.5 | 99.65% |
| **Number of Published Articles on CPRIT-Funded Research Projects** | 1,000 | N/A | N/A | N/A | N/A | 1,091 | 109.10% |
| **Number of New Jobs Created and Maintained** | 3,000 | N/A | N/A | N/A | N/A | 3,551 | 118.37% |

## Variance Explanations

| |
|---|
| **Number of People Served by Institute Funded Prevention and Control Activities** |
| CPRIT prevention grantees have continued to be successful at delivering cancer prevention education and clinical services to more people than they anticipated, stretching their CPRIT-grant funds further to serve Texans. They have resumed providing cancer prevention clinical services, such as mammograms and colonoscopies, following COVID-19 precautions which include the use of COVID-19 tests and extra safety precautions. |
| **Number of Entities Relocating to TX for Cancer Research Related Projects** |
| This output is dependent on the number of companies applying for CPRIT Company Awards that can successfully advance through CPRIT's rigorous review and evaluation process, receive an award and relocate operations to Texas. A company must meet 4 of CPRIT's 7 criteria for a relocation to be considered complete. This year two companies who received a CPRIT award were able to complete this process. |
| **Number of Published Articles on CPRIT- Funded Research Projects** |
| The number reflects that CPRIT-funded research projects have yielded numerous results and breakthroughs which grantees have been successful in reporting through scientific publications. |
| **Number of New Jobs Created and Maintained** |
| The number of new jobs created and maintained reported by academic and product development research grantees exceeded the projection because CPRIT has a portfolio with more than 550 active grants and several scientific staff are required for each project. In addition, the measure includes jobs maintained which is proportionally more than double the number of new jobs created in a given year. Grantees conduct CPRIT-funded research projects over multiple years and must maintain the scientific expertise to do so. |
| |
| |
| |
| |
| |
| |

# CPRIT Commercial Paper and G.O. Bond Issuance

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

# CPRIT Commercial Paper and G.O. Bond Issuance

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

# CPRIT Commercial Paper and G.O. Bond Issuance

| Fiscal Year | Amount Appropriated | Dated Issued | Amount Issued | Amount Issued for Fiscal Year | Commercial Paper or GO Bond Issuance | Series | Comments | Interest Rate |
|---|---|---|---|---|---|---|---|---|
| 2020 | | September 16, 2019 | $ 64,300,000 | | Commercial Paper Notes | Series A, Taxable | | Interest rate of 2.10% |
| 2020 | | January 9, 2020 | $ 52,000,000 | | Commercial Paper Notes | Series A, Taxable | | |
| 2020 | | April 23, 2020 | $ 237,720,000 | | G.O. Bonds (Refunding Bonds) | Taxable Series 2020 | Par amount of refunding: Refunded $248.025M of GOCP CPRIT Series A | Fixed Rate Bonds All-In-True Interest Cost 2.644360% |
| 2020 | | April 23, 2020 | $ 115,000,000 | | G.O. Bonds | Taxable Series 2020 | Par amount of new money | Fixed Rate Bonds All-In-True Interest Cost 2.644360% |
| 2020 | | April 23, 2020 | $ 119,750,000 | | G.O. Bonds (Refunding Bonds) | Taxable Series 2020 | Par amount of refunding. Refunded $120.525M of Taxable Series 2011 | |
| | | | | $ 231,300,000 | | | | |
| | | | | | | | | |
| 2021 | $300,000,000 | September 11, 2020 | $ 75,000,000 | | Commercial Paper Notes | Series A, Taxable | | |
| 2021 | | January 14, 2021 | $ 59,000,000 | | Commercial Paper Notes | Series A, Taxable | | |
| 2021 | | April 29, 2021 | $ 68,900,000 | | Commercial Paper Notes | Series A, Taxable | | |
| 2021 | | August 12, 2021 | $ 57,400,000 | | Commercial Paper Notes | Series A, Taxable | | |
| | | | | $ 260,300,000 | | | | |
| | | | | | | | | |
| 2022 | $300,000,000 | September 28, 2021 | $ 87,000,000 | | Commercial Paper Notes | Series A, Taxable | | |
| 2022 | | November 18, 2021 | $ 334,745,000 | | G.O. Bonds (Refunding Bonds) | Taxable Series 2021B | Par amount of refunding: Refunded $347.300M of GOCP CPRIT Series A | Fixed Rate Bonds All-In-True Interest Cost 2.191715% |
| 2022 | | November 18, 2021 | $ 139,565,000 | | G.O. Bonds | Taxable Series 2021B | New money proceeds of $144.800M | Fixed Rate Bonds All-In-True Interest Cost 2.191715% |
| 2022 | | November 18, 2021 | $ 108,005,000 | | G.O. Bonds (Refunding Bonds) | Taxable Series 2021B | Par amount of refunding: Refunded $108.660M of Taxable Series 2014B | Fixed Rate Bonds All-In-True Interest Cost 2.191715% |
| 2022 | | July 14, 2022 | $ 66,300,000 | | Commercial Paper Notes | Series A, Taxable | | Interest rate of 2.30% |
| | | | | $ 298,100,000 | | | | |
| | | | | | | | | |
| 2023 | $300,000,000 | September 20, 2022 | $ 79,500,000 | | Commercial Paper Notes | Series A, Taxable | | Interest rate of 3.15% |
| 2023 | | March 2, 2023 | $ 66,000,000 | | Commercial Paper Notes | Series A, Taxable | | Interest rate of 4.80% |
| 2023 | | April 6, 2023 | $ 79,000,000 | | Commercial Paper Notes | Series A, Taxable | | Interest rate of 5.10% |
| 2023 | | June 15, 2023 | $ 59,200,000 | | Commercial Paper Notes | Series A, Taxable | | Interest rate of 5.40% |
| 2023 | | August 29, 2023 | $ 350,000,000 | | G.O. Bonds (Refunding Bonds) | Taxable Series 2023 | Par amount of refunding | Fixed Rate Bonds All-In-True Interest Cost 5.020317% |
| 2023 | | August 29, 2023 | $ 14,600,000 | | G.O. Bonds | Taxable Series 2023 | Par amount of new money proceeds | Fixed Rate Bonds All-In-True Interest Cost 5.020317% |
| | | | | $ 298,300,000 | | | | |
| | | | | | | | | |
| **TOTAL ISSUED TO DATE** | | | | **$ 2,811,700,000** | | | | |

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

# MEMORANDUM

| | |
|---|---|
| **TO:** | OVERSIGHT COMMITTEE MEMBERS |
| **FROM:** | HEIDI MCCONNELL, CHIEF OPERATING OFFICER |
| **SUBJECT:** | REPORT ON 2023 CPRIT INNOVATIONS IN CANCER PREVENTION AND RESEARCH CONFERENCE VI ON OCTOBER 2-3, 2023, IN GALVESTON, TEXAS |
| **DATE:** | NOVEMBER 7, 2023 |

## Overview

The Innovations VI Conference was held October 2-3, 2023, at the Moody Gardens Hotel, Spa and Convention Center in Galveston. Approximately 633 scientists, clinicians, entrepreneurs, community organizers, policy makers and honored guests attended the two-day conference, which featured 25 plenary and breakout sessions.

A highlight of this conference was the presentation of the inaugural "Texans Conquer Cancer" awards at the dinner on Monday, October 2. CPRIT created the award to recognize individuals or organizations that have demonstrated outstanding leadership in furthering CPRIT's mission to prevent, detect, treat, and cure cancer in Texas. These first awards were made to four Texas legislators instrumental in the creation and funding of CPRIT in 2007 and its reauthorization in 2019:

- Secretary of State and former state senator Jane Nelson,
- Former state representative Jim Keffer,
- Former state representative Dr. John Zerwas, and
- Former state senator and current Austin Mayor Kirk Watson.

## Registration and Attendance

At the conference, there were:

- 280 grantees—136 academic research grantees, 117 prevention grantees, and 27 product development research grantees;
- 102 separate organizations represented; and
- 325 scientific abstract posters displayed.

Conference speakers included luminaries from the cancer research and prevention field, including national cancer leaders, active researchers, prevention program directors, and corporate product development innovators. Approximately 60%, or 41 of the 63 conference speakers or moderators, were CPRIT grantees.



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## Sponsors and Exhibitors

There were two conference sponsors and nine exhibitors.

Sponsors

- NexPoint—Conference Bag Sponsor
- Scorpius BioManufacturing—Day 1 Lunch Sponsor

Exhibitors

- Agilent Technologies, Inc.
- Bio-Techne
- Collaborative Drug Discovery
- H2Ocean
- Levitas Bio
- Metabolon
- MilliporeSigma
- Shimadzu Scientific Instruments
- The Greater Houston Partnership

## Communications

CPRIT's communications team created *The Spark* video to summarize CPRIT's impact on cancer research and prevention in Texas and beyond since CPRIT's first grant was awarded in fall 2009. The video premiered at the Monday, October 2 conference dinner. It is now featured prominently on CPRIT's home page.

During the conference the communications team conducted on-camera interviews with grantees. In addition, CPRIT has video footage of the keynote and plenary presentations as well as the dinner. Justin Rand took professional photographs during major events at the conference. The communications team has also collected candid photos taken by CPRIT staff throughout the conference. The photographs will be curated, and the video footage will be edited. Both will be presented on CPRIT's website, featured in the upcoming 2023 annual report, and utilized in social media postings and other communications opportunities.

## Budget

The estimated conference cost is approximately $378,000 comprised of approximately $231,000 for base meeting expenses such as food and beverage catering and audiovisual services, $99,000 for conference meeting planning and décor, approximately $38,000 for speaker travel and fees, and approximately $11,000 for program printing and other conference expenses.

CPRIT has revenue sources, primarily from conference registrations and exhibitor and sponsorship fees totaling approximately $334,000. The $99,000 meeting planning services contract was budgeted out of FY 2021 agency operating expenses, so this expense will be paid with that funding, not conference revenue.

**Survey Results**

CPRIT released a conference survey on October 19 to 633 conference attendees. The survey closed on November 3 with 85 responses, or a 13.4% response rate.

Generally, the responses were complimentary of the conference with constructive comments about the schedule, the online registration process, and online abstract submission process. CPRIT staff is still evaluating the responses and comments, but here are some highlights:

- 96.5% responded that the conference was good or excellent.
- 81.7% responded that the length of the conference was just right and 17.1% responded that it was too short.
- Overall positive comments about the conference food at meals and breaks.
- 72.7% responded that the poster sessions were good or excellent.
- All of the speakers and sessions were primarily rated good or excellent.

In terms of the schedule, many of the comments about the poster sessions were either that they should not be timed early in the morning before 9 am and should not overlap with meals. Other comments suggested that the first day of the conference begin midday to allow travel in the morning or that it was too long with the awards dinner that evening.

CPRIT staff will fully evaluate all the comments and incorporate many of the suggestions into planning the next conference.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

# MEMORANDUM

| | |
|---|---|
| **To:** | OVERSIGHT COMMITTEE |
| **From:** | HEIDI MCCONNELL, CHIEF OPERATING OFFICER |
| **Subject:** | FY 2024 INTERNAL AUDIT SERVICES CONTRACT APPROVAL |
| **Date:** | NOVEMBER 7, 2023 |

## Recommendation

CPRIT staff recommends the Oversight Committee approve a contract with Weaver and Tidwell for $186,000 to provide internal audit services FY 2024.

The contract cost is a not-to-exceed amount, and payment is based on the delivery of actual services through time and materials expended by the vendor.

The contract with Weaver and Tidwell will require the State Auditor's Office to provide audit delegation authority to CPRIT prior to contract execution.

## Background

CPRIT conducted a competitive solicitation for internal audit services beginning late spring 2023. CPRIT received three proposals by the bid period close on July 27, 2023. CPRIT staff evaluated the proposals and determined that Weaver and Tidwell is the best value in terms of having an experienced public sector audit team in Texas with in-depth experience adhering to the state's internal audit requirements and serving as an internal auditor to a state agency. Weaver and Tidwell is the incumbent vendor.

In FY 2024, the proposed internal audit plan includes audits over internal agency compliance and oversight committee reporting; follow-up audits on the purchasing, communications, and information technology general controls audits; and an internal audit advisory engagement over records management.



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CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

# MEMORANDUM

| | |
|---|---|
| **TO:** | OVERSIGHT COMMITTEE MEMBERS |
| **FROM:** | MARK DALLAS LOEFFLER |
| **SUBJECT:** | COMMUNICATIONS UPDATE |
| **DATE:** | NOVEMBER 6, 2023 |

These are highlights of CPRIT communications team efforts since the August Oversight Committee meeting.

## CPRIT Conference

The 2023 CPRIT Innovations in Cancer Prevention and Research Conference VI was held in Galveston from October 2 to 3. The communications team was involved in many aspects of the conference, from the original bid process, site visits, email and social media promotion, creating and implementing the conference program, updating the website, creating the signage, branding, and graphics for the conference and much more. The team also created a video, "The Spark," to highlight CPRIT's mission during the opening night dinner. During the conference we captured approximately 7 hours of in-depth interviews with CPRIT grantees and conference speakers. These videos will be used to highlight CPRIT and grantee activities. After the conference, the communications team also created the Conference Survey and distributed that to attendees.

## Texas Tech University Health Sciences Center El Paso video

Texas Tech University Health Sciences Center El Paso (TTUHSC) held a media event to highlight a recent CPRIT TREC award on October 17 in El Paso. Oversight Committee Member Dee Margo was there on behalf of CPRIT and communications shot and edited a short video comment from Dr. Le Beau for use during the event.

## Texas Resource Guide

The communications team implemented a Product Development Research program request to create a resource guide for companies in Texas or looking to relocate to Texas. The Texas Resource Guide is now an online resource with listings of capital companies, economic development organizations, core facilities and other resources. The Guide was presented online in time for the 2023 CPRIT Conference and has since moved to a Phase 2 with expanded information. The guide may be found at www.texasresourceguide.org

## ARPA-H Announcement



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The communications team responded to the announcement regarding ARPA-H headquartering in Texas by facilitating a successful interview with the Dallas Morning News and sharing the news and photos of the kickoff event on social media.

**Direct Communication**

The communications team distributed listserv notifications regarding

- Press release for August OC meeting
- FY24.2 Academic Research RFAs
- CPRIT Innovations VI Conference invitation to legislators
- (5) CPRIT conference reminders or promotional messages
- An initial CPRIT conference attendee survey and a follow up reminder
- Proposed changes to current agency rules
- CPRIT grantee training webinars
- The Texas Pediatric Cancer Drug Testing Core (TPC-DTC) at UT Health San Antonio promotional message
- TMCi Accelerator For Cancer Therapeutics applications promotional message
- TAMEST conference discount for CPRIT Scholars promotional message

**Media Relations**

The communications team posted and distributed several media advisories and press releases related to CPRIT programs and news:

- Press Release (September 26, 2023): ARPA-H is coming to Texas
- Media Advisory (September 28, 2023): Cancer conference convenes in Galveston next week
- Press Release (October 2, 2023): CPRIT Innovations VI convenes in Galveston
- Press Release (October 26, 2023): CPRIT CEO Roberts receives THBI Luminary Award at Fall Summit

**Newsclips**

We shared 695 articles and social media posts through CPRIT ENews from August 5 – November 5.

**Social Media Statistics**

*Social Media from August 5 to November 5, 2023*

| Facebook | X | LinkedIn |
|---|---|---|
| **7.96%** post engagement rate | **3.12%** engagement rate | **7.44%** engagement rate |
| **1,276** Fans (**+30**) | **3,535** followers (**+45**) | **3,160** followers (**+260**) |
| Top Post: **16.1%** engagement (9/24) | Top Tweet: **2,887** impressions (9/26) | Top Post: **12,021** impressions (9/26) |

*Website Hits and Visitors August 5 to November 5, 2023*

| Users | New Users | Sessions (Visits) | Pageviews | Engage Rate |
|---|---|---|---|---|
| 24,543 | 23,646 | 38,784 | 70,660 | 46.12% |

## Top Performing Posts

### FACEBOOK: 9/24

#CancerResearch is essential to improve outcomes for patients. This #WorldCancerResearchDay, learn how CPRIT supports research on the causes, prevention and early detection that is fundamental to controlling this disease. #SupportCancerResearch https://www.cprit.texas.gov/

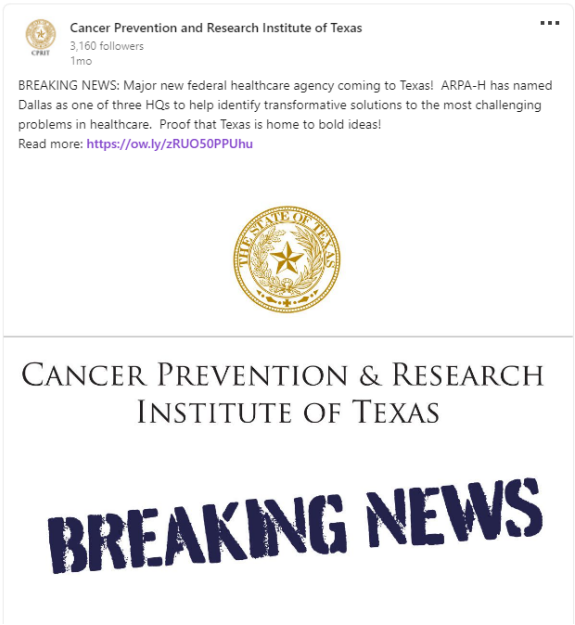

### X: 9/26

BREAKING NEWS: Major new federal healthcare agency coming to Texas! ARPA-H has named Dallas as one of three HQs to help identify transformative solutions to the most challenging problems in healthcare. Proof that Texas is home to bold ideas!
Read more: https://ow.ly/EMcQ50PPUht

**LINKEDIN: 9/26**

BREAKING NEWS: Major new federal healthcare agency coming to Texas! ARPA-H has named Dallas as one of three HQs to help identify transformative solutions to the most challenging problems in healthcare. Proof that Texas is home to bold ideas!
Read more: https://ow.ly/zRUO50PPUhu

Cancer Prevention and Research Institute of Texas' Post



**November 2023 Oversight Committee**
**Internal Audit Status Report**
**As of November 1, 2023**

Weaver and Tidwell, LLP (Weaver) is the outsourced internal auditor of the Cancer Prevention Research Institute of Texas (CPRIT). The Weaver engagement team is led by Daniel Graves, Partner.

***2023 Internal Audit Plan and Schedule***

The tables below reflect the activity to date Weaver has completed for the 2023 Internal Audit Plan.

| 2023 New Internal Audits | | |
|---|---|---|
| **Internal Audit** | **Description** | **Status** |
| Contract Risk Assessment Advisory | The Internal Audit Advisory Project included a review of risks and internal controls in place related to CPRIT's contract risk assessment practices. Activities evaluated included:<br>• Developing a contract risk assessment process<br>• Developing a contract risk assessment matrix in compliance with state requirements | Complete |
| Post-Award Compliance Advisory | The Internal Audit Advisory Project included a review of risks and internal controls in place related to CPRIT's post-award compliance program procedures. Activities evaluated included:<br>• Grantee Risk Assessment<br>• Conversion from UGMS to TxGMS Standards<br>• Enhanced Desk Review (EDR) and Onsite Review documentation | Complete |
| Purchasing Compliance | The Internal Audit included a review of risks and internal controls in place related to CPRIT's purchasing compliance processes. Activities evaluated included:<br>• Purchase Requisitions<br>• Purchase Orders<br>• Open Market Solicitations (Bidding, RFPs and Awards)<br>• Vendor Management<br><br>There were two low risk rated findings identified from the internal audit. For one of the findings, the low risk was accepted by CPRIT management.<br><br>We will perform follow-up procedures in FY 2024 for the one open finding. | Complete |

| | | |
|---|---|---|
| IT General Controls | The Internal Audit included a review of risks and internal controls in place related to CPRIT's IT General Controls practices. Activities evaluated included:<br><br>• User Administration<br>• Change Management<br>• System Development & Acquisition<br>• Incident Management<br>• Job & Interface Monitoring<br>• Vendor Management<br>• Back-up and Recovery<br>• Privacy<br><br>We will perform follow-up procedures in FY 2024 for the eight open findings. | Complete |
| **FOLLOW-UP PROCEDURES** | | |
| Communications Follow-Up<br>• 1 High Finding | Fieldwork for the follow-up procedures to validate remediation of the finding are complete. The one High finding is partially remediated. | Complete |
| Disaster Recovery and Business Continuity Follow-up<br>• 5 recommendations | Fieldwork for the follow-up procedures to validate remediation of the five recommendations are complete. All recommendations have been remediated. | Complete |
| Vendor Contract Compliance Follow-Up<br>• 1 Low Finding | Fieldwork for the follow-up procedures to validate remediation of the one low finding are complete. The one low finding has been remediated and closed. | Complete |

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

We also prepared the FY 2023 Annual Internal Audit Report, as required by the Texas Internal Audit Act. Once approved by the Oversight Committee, the annual report and audit plan will be submitted to the State Auditor's Office, LBB, and Governor's Office

Daniel Graves

Daniel Graves, CPA, Internal Auditor
Partner
Weaver and Tidwell L.L.P.

**Cancer Prevention and Research Institute of Texas**
**Schedule of Audits, Status, and Findings Summary**
**As of Ocotober 31, 2023**

| | | | | | 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 2023** | | | | | | | | | | | | | | | | | |
| Contract Risk Assessment Advisory | 2023 | Completed | May 1, 2023 | N/A | - | - | - | 1 | - | - | - | - | - | - | - | 1 | **Note 1** |
| Post-Award Compliance Program Advisory | 2023 | Completed | September 12, 2023 | N/A | - | - | - | 2 | - | - | - | - | - | - | - | 2 | |
| Purchasing | 2023 | Completed | August 14, 2023 | Strong | - | - | 2 | 2 | - | - | 1 | - | - | - | 1 | 2 | |
| IT General Controls | 2023 | Completed | September 18, 2023 | Satisfactory | | | | | | | | | | | | | |
| 2016 Information Security Follow-Up | 2023 | Completed | September 18, 2023 | Satisfactory | | | | | | | | | | | | | |
| 2018 Communications Follow-Up | 2023 | Completed | N/A | N/A | 1 | 4 | - | 5 | - | 4 | - | 4 | 1 | - | - | 1 | |
| 2020 Disaster Recovery and Business Continuity Follow-up | 2023 | Completed | N/A | N/A | - | - | - | 30 | - | - | - | 30 | - | - | - | - | **Note 2** |
| 2022 Vendor Contract Compliance | 2023 | Completed | N/A | N/A | - | - | 2 | 2 | - | - | 2 | 2 | - | | - | - | |
| **Fiscal Year 2023 Subtotal** | | | | | **1** | **4** | **4** | **42** | **-** | **4** | **3** | **36** | **1** | **-** | **1** | **6** | |

| **Open Items 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** | |
| 2016 Information Security Follow-Up | 2020 | Completed | October 28, 2022 | NA | | | | | | | | | | | | | |
| 2018 Communications Follow-Up | 2020 | Completed | August 7, 2023 | NA | 1 | 4 | - | 5 | - | 4 | - | 4 | 1 | - | - | 1 | **FY 2024** |
| 2020 Disaster Recovery and Business Continuity Follow-up | 2020 | Completed | September 28, 2021 | NA | - | - | - | 30 | - | - | - | 30 | - | - | - | - | |
| Information Technology General Computer Controls | 2021 | Completed | September 24, 2022 | NA | | | | | | | | | | | | | |
| 2022 Vendor Contract Compliance | 2022 | Completed | September 28, 2021 | NA | - | - | 2 | 2 | - | - | 2 | 2 | - | - | - | - | |
| Purchasing | 2023 | Completed | August 14, 2023 | Strong | - | - | 2 | 2 | - | - | - | - | - | - | 2 | 2 | **FY 2024** |
| Information Technology General Computer Controls | 2023 | Completed | September 18, 2023 | Satisfactory | | | | | | | | | | | | | **FY 2024** |
| **Total Findings For Internal Audit Follow-Up** | | | | | **1** | **4** | **4** | **39** | **-** | **4** | **2** | **36** | **1** | **-** | **2** | **3** | |

**Note 1:** The 2023 Contract Risk Assessment and Post-Award Compliance Program findings are recommendations for implementing improvement opportunities. Therefore, they do not have a risk rating associated with them. They are also not included in the Open Items Summary.

**Note 2:** The 2020 Disaster Recovery and Business Continuity Follow-up findings are recommendations for improvement of the DR/BCP documentation. Therefore, they do not have a risk rating associated with them.

**Cancer Prevention and Research Institute of Texas**
**Proposaed Internal Audit Plan**
**Fiscal Year 2024**

| Audit Area | Risk Rating | Summary Procedures | Audit Focus | Estimated Hours |
|---|---|---|---|---|
| **2024 Planned New Internal Audits** | | | | |
| Internal Agency Compliance | High | Internal Audit will include an evaluation of risks and internal controls in place related to CPRIT's Internal Agency Compliance processes. Activities to be evaluated may include Disclosures, Ethics Policy and Compliance, Code of Conduct, and Complaints/Grievances. | Internal Audit | 220 |
| Oversight Committee Reporting | Moderate | Internal Audit will include an evaluation of risks and internal controls in place related to CPRIT's Oversight Committee Reporting processes. Activities to be evaluated may include Legislative Reporting, Management Reporting, Meeting Materials, Monthly Reporting, Management Dashboard, and Ad HOC reporting. | Internal Audit | 280 |
| Records Management Advisory | Moderate | Internal Audit will provide audit advisory servicers to evaluate and assist CPRIT with enhancing the Records Management processes. The advisory audit will include an evaluation of the Data Retention and Records Retention processes. | Internal Audit Advisory | 250 |
| **2024 Planned Internal Audit Follow-up** | | | | |
| Communications | High | Internal Audit will perform follow-up procedures on 2018 Internal Audit findings to ensure corrective action has been taken. | Follow-up | 30 |
| IT General Controls Follow-up | High | Internal Audit will perform follow-up procedures on 2023 Internal Audit findings to ensure corrective action has been taken. | Follow-up | 180 |
| Purchasing Compliance | Low | Internal Audit will perform follow-up procedures on 2023 Internal Audit findings to ensure corrective action has been taken. | Follow-up | 30 |
| **2024 Planned Annual Requirements** | | | | |
| Project Management | NA | Track overall internal audit procedures, coordinate audit activities, and reporting to management. | Project Management | 60 |
| Update Risk Assessment | NA | Perform required annual update of risk assessment | Policy Compliance | 20 |
| Annual and Quarterly Board Reports | NA | Prepare and submit required Annual Internal Audit Report and quarterly reports to the Audit Committee of internal audit activities. | Policy Compliance | 35 |
| | | | **Total 2024 Internal Audit Estimated Hours** | **1,105** |
| | | | **Total 2024 Internal Audit Estimated Fees** | **$ 186,000** |

# Cancer Prevention and Research Institute of Texas

IA# 2023-03 Internal Audit Report over Purchasing Compliance
Report Date: August 14, 2023
Issued: September 22, 2023

weaver
Assurance • Tax • Advisory

# CONTENTS

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

This report presents the results of the internal audit procedures performed for the Cancer Prevention and Research Institute of Texas (CPRIT) during the period May 5, 2023, through August 14, 2023, relating to the purchasing compliance processes.

The objectives of this internal audit were to evaluate the design and effectiveness of CPRIT's purchasing compliance processes as follows:

A. Determine whether internal controls over purchasing compliance processes are designed to ensure that consistent processes are implemented and effectively address the risks within the associated sub-processes and to ensure effective operations.

B. Verify that controls over selected critical processes within purchasing compliance are operating efficiently and effectively, resulting in complete information, appropriate transactions, timely reporting, and active monitoring.

Our procedures included performing interviews with key personnel responsible for purchasing compliance to gain an understanding of the current processes in place, examining existing supporting documentation, and evaluating the internal controls over the processes. We evaluated the existing policies, procedures, and processes in their current state. Our coverage period was from December 1, 2021, through May 31, 2023.

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

Weaver and Tidwell, L.L.P.

WEAVER AND TIDWELL, L.L.P.

Austin, Texas
September 22, 2023

**Cancer Prevention and Research Institute of Texas**
IA #2023-03 Internal Audit Report over Purchasing Compliance
August 14, 2023
Issued: September 22, 2023

## Background

The Cancer Prevention and Research Institute of Texas (CPRIT), is the state agency established to create and expedite innovation in cancer research and enhance the potential for a medical or scientific breakthrough in the prevention of cancer and cures for cancer.

CPRIT advances its mission by awarding merit-based, peer reviewed grants to Texas-based entities and institutions for cancer-related research, product development and the delivery of cancer prevention programs through three programs: Academic Research, Prevention, and Product Development Research. In order to appropriately manage and support the grant making processes, CPRIT utilizes a number of contracts for highly specialized services.

To guide the agency in procuring goods and services to support its mission, CPRIT has a Procurement Plan and Contract Management Guide that details the procurement standards and processes to help ensure that the agency complies with the Texas Comptroller of Public Accounts (Comptroller's Office) requirements. CPRIT procures goods and services for agency use including, but not limited to, the following:

- Office supplies and equipment
- Professional and other services
- ITSAC and Temp contract labor
- Software and hardware contracts

Purchases begin when a purchase request for a commodity or service is submitted to the Purchaser with any necessary background information. The Purchaser determines whether the commodity or service is available through cooperative contracts in place with the Texas Department of Information Resources (DIR), WorkQuest, Texas Correction Industries (TCI), or TxSmartBuy Term Contracts and Texas Multiple Award Schedule (TXMAS) contracts managed by the office of the Texas Comptroller of Public Accounts' Statewide Procurement Division (SPD). If the good or service is available through one of these, the Purchaser initiates a purchase requisition in CAPPS for budget and executive approval of the purchase, and then follows the established procurement procedures for the appropriate purchasing method.

If the commodity or service is not available through one of these purchasing methods, CPRIT initiates a competitive open market purchase using an informal or formal solicitation process based on the estimated purchase price thresholds.

For all open market solicitations, CPRIT utilizes the Centralized Master Bidders List (CMBL) maintained by SPD, along with the CPRIT website, to notify vendors about the solicitations.

**Cancer Prevention and Research Institute of Texas**
IA #2023-03 Internal Audit Report over Purchasing Compliance
August 14, 2023
Issued: September 22, 2023

## Audit Objective and Scope

The audit focused on CPRIT's purchasing compliance processes to obtain goods and services for the agency. We reviewed the procedures in place for appropriate risk and regulatory coverage and compliance to ensure efficient and effective processes related to Purchasing compliance. Key functions and sub-processes within the purchasing compliance process reviewed included:

- Purchase Requisitions
- Purchase Orders
- Open Market Solicitations (Bidding, RFPs and Awards)
- Vendor Management

Our procedures were designed to ensure relevant risks are covered and verify the following:

Purchase Requisitions

- Purchase requisitions were approved by appropriate personnel
- Purchase requisitions were created and approved by separate personnel
- The appropriate method of purchase was selected
- Vendors' existence was validated and approved
- Purchase requisition date preceded that of the Purchase Order
- Purchase requisition and purchase order information agreed

Purchase Orders

- Purchase of goods or services were authorized prior to placing the order with the vendor as evidenced by the purchase requisition
- Quantity and pricing were accurately reflected and entered in the system
- Purchase order modifications were properly authorized
- Open purchase orders were monitored

Open Market Solicitations (Bidding, RFPs and Awards)

- The bidding process was conducted as described in CPRIT's Procurement Plan and Contract Management Guide along with other applicable State of Texas requirements
- Defined and consistent criterion were used to evaluate bids/proposals
- Qualified and appropriate bids were received and evaluated prior to selecting a vendor for award
- Best value was selected for award
- Awards were approved by CPRIT management and/or the Oversight Committee

Vendor Management

- Vendors were properly set up in CAPPS and included contract details
- Vendor performance was monitored and documented
- Vendors selected had complete contract files, including all required forms and supporting documentation

**Cancer Prevention and Research Institute of Texas**
IA #2023-03 Internal Audit Report over Purchasing Compliance
August 14, 2023
Issued: September 22, 2023

The objectives of this internal audit were as follows:

A. Determine whether internal controls over purchasing compliance processes are designed to ensure that consistent processes are implemented and effectively address the risks within the associated sub-processes and to ensure effective operations.

B. Verify that controls over selected critical processes within purchasing compliance are operating efficiently and effectively, resulting in complete information, appropriate transactions, timely reporting, and active monitoring.

Our procedures included interviewing key personnel within the within the agency that have responsibilities in purchasing compliance to gain an understanding of the current processes in place, examining existing documentation, and evaluating the internal controls over the process. We evaluated the existing policies, procedures, and processes in their current state. Our coverage period was from December 1, 2021 through May 31, 2023.

## Executive Summary

Through our interviews, evaluation of internal control design and testing of transactions we identified two findings. The listing of the findings includes those items that have been identified and are considered to be non-compliance issues with documented CPRIT policies and procedures, rules and regulations required by law, or where there is a lack of procedures or internal controls in place to cover risks to CPRIT. These issues could have significant financial or operational implications.

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

| OVERALL ASSESSMENT | Strong |
|---|---|

| SCOPE AREA | RESULT | RATING |
|---|---|---|
| **Objective A:** Determine whether internal controls over the purchasing compliance processes ensure that consistent processes are implemented and effectively address the risks within the associated sub-processes and to ensure effective operations. | We identified 21 controls to be in place in the purchasing compliance process. However, there are opportunities to strengthen the process and control environment, including:<br>• Implementing procedures to ensure that vendors complete the Form 1295. | **Strong** |
| **Objective B:** Verify that controls over selected critical processes within purchasing compliance are operating efficiently and effectively, resulting in complete information, timely reporting, and active monitoring. | Controls appear to be in place; however, not all are consistently executed as designed. We identified the following opportunities for improvement:<br>• Implementing a secondary review or checklist for new vendor set-up to ensure all vendor data is accurately reflected within the CAPPS/ESBD system. | **Strong** |

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## Conclusion

Based on our evaluation, CPRIT has procedures, practices, and controls in place to mitigate risks among the significant purchasing compliance processes. We identified some instances of non-compliance with specific processes in CPRIT's Procurement Plan and Contract Management Handbook. While these instances were minor, the agency could benefit from strengthening the processes, formalizing the procedures performed, and improving the effectiveness of controls within the purchasing compliance processes.

CPRIT should implement procedures to ensure that vendors complete the Form 1295 and provide that to CPRIT prior to completing the award of the procurement.

Additionally, CPRIT should implement a secondary review or checklist for new vendor set up to ensure all vendor information is accurately reflected within the required system.

Follow-up procedures will be performed in fiscal year 2024 to evaluate the effectiveness of remediation efforts taken to address the findings.

# Detailed Procedures Performed, Findings, Recommendations and Management Response

## Detailed Procedures Performed, Findings, Recommendations and Management Response

Our procedures included interviewing key personnel within purchasing compliance who have responsibilities in managing and/or monitoring purchasing to gain an understanding of the current processes in place, examining existing documentation, and evaluating the internal controls over the process. We will evaluate the existing policies, procedures, and processes in their current state. Our coverage period will be from December 1, 2021, through May 31, 2023.

The findings in the report are disclosed in both Objectives A and B. The full finding is presented in Objective A of the report where the control design findings are presented. A separate reference to the finding is made in Objective B where a testing exception occurred.

## Objective A: Design of Internal Controls

Determine whether internal controls over purchasing compliance processes are designed to ensure that consistent processes are implemented and effectively address the risks within the associated sub-processes and to ensure effective operations.

**Procedures Performed:** We conducted interviews with key personnel to gain an understanding of the current processes in place, examined existing documentation, and evaluated the internal controls over the process. We evaluated the existing policies, procedures, and processes in their current state. We documented our understanding of the processes and identified internal controls over the following sub processes:

- Purchase Requisitions
- Purchase Orders
- Open Market Solicitations (Bidding, RFPs and Awards)
- Vendor Management

We evaluated the controls identified against expected controls to determine whether the identified purchasing compliance processes and internal controls are sufficiently designed to mitigate the critical risks associated with the purchasing compliance sub-processes. We identified any risk exposures due to gaps in the existing control structure as well as opportunities to strengthen the effectiveness and efficiency of the existing procedures.

**Results:** We identified 21 controls in place that cover the significant activities within the purchasing compliance processes. We also identified two findings where improvements in the process can be made.

**Cancer Prevention and Research Institute of Texas**
IA #2023-03 Internal Audit Report of Purchasing Compliance
August 14, 2023
Issued: September 22, 2023

| Process Area | Control Coverage | Findings |
|---|---|---|
| **Purchasing Compliance Process** | | |
| Purchase Requisitions | 2 | - |
| Purchase Orders | 3 | - |
| Open Market Solicitations (Bidding, RFPs and Awards) | 3 | **Finding 1** |
| Vendor Management | 13 | **Finding 2** |
| **Total:** | **21** | **2** |

**Finding 1 – Low – Open Market Solicitations**
CPRIT is not obtaining Form 1295 before contract award as required by the State Procurement Guide and CPRIT's Procurement Plan and Contract Management Handbook. We tested all five open market solicitations in the coverage period, and for all five samples, we verified that there were no Form 1295 within the maintained contract files.

**Recommendation**: CPRIT should implement procedures to ensure that vendors complete the Form 1295 and submit it to CPRIT prior to completing the award of the contract.

**Management Response**: CPRIT management agrees that Form 1295 must be completed by any vendor with a contract of $100,000 or more requiring Oversight Committee approval. The completion of the form has been incorporated into the contracting process and is being requested for all new FY 2024 vendor contracts retrospectively as well as for any others initiated this year.

**Responsible Party**: Chief Operating Officer, Purchaser
**Implementation Date**: November 30, 2023

**Finding 2 – Low – New Vendor Setup**
While CPRIT has a new vendor set-up process, CPRIT is inconsistent with the vendor-maintained documentation and the vendor data entered and reflected within the CAPPS system. We tested all five new vendors during our coverage period to verify and ensure that new vendors are set up accurately within the CAPPS system. For one of the five, we obtained vendor set up supporting documentation and were unable to verify that the vendor was set-up accurately in the CAPPS system. The vendor's name and vendor ID did not match the supporting documentation.

Additionally, for one of the vendors we identified that the contract status was labeled incorrectly in the Electronic State Business Daily (ESBD) system. The contract showed "Closed", however we learned that the contract had not been completely processed and should have reflected an "Awarded" status in the system.

**Recommendation**: CPRIT should implement a secondary review or checklist for new vendor set-up to ensure all vendor data is accurately reflected within the CAPPS system. The review, or checklist, should include verification of the vendor's name and vendor identification number. 16-14

**Management Response**: CPRIT management accepts the low risk potentially posed by the identified issues but will not be creating another checklist or validation process. CPRIT acknowledges that these issues are important and should be corrected when identified. However, the consequences of misspelling a vendor name in the CAPPS system (vendors are tracked and payments validated on the vendor number, not name) and marking the status of a contract in ESBD do not materially impact CPRIT's ability to execute a contract or pay a vendor.

## Objective B: Effectiveness of Controls

Verify that controls over selected critical processes within Purchasing Compliance are operating efficiently and effectively, resulting in complete information, appropriate transactions, timely reporting, and active monitoring.

1. **Procedures Performed:** We selected and tested all open market solicitations which included five samples. For each of the selected samples we verified that the bidding and awarding process was conducted as prescribed in CPRIT Procurement Plan and Contract Management Handbook along with applicable State of Texas requirements. The following components were reviewed for completeness:

    - Solicitation drafts
    - Procurement oversight and delegation for solicitations over $100,000 for services and $50,000 for commodities
    - Solicitation notices
    - Signed Form 1295
    - Execution of proposal
    - Proof of services being advertised (CMBL)
    - Evaluation of bids
    - Notice of award

**Results:** For all five open market solicitations selected samples, a signed Form 1295 was not retained within the procurement files.

**Finding 1 – Low – Open Market Solicitations**

2. **Procedures Performed:** We selected and tested all new vendor files for solicitations that occurred between December 1, 2021, through May 31, 2023. For all samples, we verified that the new vendor set up process was conducted as described in CPRIT's Procurement Plan and Contract Management Handbook along with applicable State of Texas requirements. The following were reviewed for completeness:

    - Vendor Information Form, W-9 Form, and any related supporting documentation maintained.
    - Appropriate review and approval performed in CAPPS.
    - New vendor profile in CAPPS matched the information on the forms (Vendor Information and W-9) obtained by the Purchaser.

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**Results:** For one out of the five selected vendors, the vendor was not set-up accurately within the CAPPS system as the vendor's name and vendor ID did not agree with the vendor supporting documentation.

Additionally, for one out of the five samples, we identified that the contract was labeled "Closed". When supporting information was requested, we were notified that the status should have been labeled "Awarded", and the new vendor set up had not been completed.

**Finding 2 – Low – New Vendor Setup**

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# Appendix

**Cancer Prevention and Research Institute of Texas**
IA #2023-03 Internal Audit Report over Purchasing Compliance
August 14, 2023
Issued: September 22, 2023

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

## Report Ratings

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

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

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

| | |
|---|---|
| **Strong** | The area under review meets the expected level. No high risk rated findings and only a few moderate or low findings were identified. |
| **Satisfactory** | The area under review does not consistently meet the expected level. Several findings were identified and require routine efforts to correct, but do not significantly impair the control environment. |
| **Unsatisfactory** | The area under review is weak and frequently falls below expected levels. Numerous findings were identified that require substantial effort to correct. |

## Risk Ratings

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

**High**

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

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

.

**Moderate**

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

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

**Low**

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

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

# Cancer Prevention and Research Institute of Texas

IA# 2023-02 Post Award Grant Compliance Internal Audit Advisory Report
September 12, 2023

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

This report presents the results of the internal audit advisory procedures performed for Cancer Prevention and Research Institute of Texas (CPRIT) during the period May 15, 2023, through September 12, 2023, relating to the post award grant compliance processes.

The objective of our internal audit advisory procedures was to evaluate CPRIT's post-award grant compliance procedures, review the grantee monitoring protocols, and provide recommendations to update protocols. These recommendations included updating protocols to align with changes in state guidelines and identifying opportunities for the grant compliance processes to be more efficient or effective.

To accomplish this objective, we conducted interviews and collaborative work sessions with CPRIT's Compliance personnel, obtained copies of CPRIT's grant compliance program guidelines, and evaluated the execution of grant compliance monitoring performed by CPRIT personnel. Our procedures were completed on September 12, 2023.

The following report summarizes the results of our procedures.

Weaver and Tidwell, L.L.P.

WEAVER AND TIDWELL, L.L.P.

Austin, Texas
October 6, 2023

# Cancer Prevention and Research Institute of Texas

IA# 2023-02 Post Award Grant Compliance Internal Audit Advisory Report
September 12, 2023

## Background

The mission of the Cancer Prevention and Research Institute of Texas (CPRIT) is to invest in the research prowess of Texas universities and research organizations, to create and expand life science infrastructure across the state, and to expedite innovation in research and enhance the potential of breakthroughs in prevention and cures. CPRIT advances its mission by awarding merit-based, peer reviewed grants to Texas-based entities and institutions for cancer-related research, product development and the delivery of cancer prevention programs.

The post-award grant compliance program is an integral process in fulfilling CPRIT's mission. CPRIT's compliance team monitors grant recipients to ensure that grant funds are spent on authorized expenditures and that the grant recipients remain in compliance with the terms and conditions of their contract with CPRIT.

As part of the grant compliance program, CPRIT's compliance team performs a risk assessment of all active grant recipients to assist in determining the nature, timing, and extent of grant monitoring procedures. These procedures include a combination of on-site reviews, desk reviews, and reviews of reimbursement requests from the grantees. These monitoring procedures align with the Texas Grant Management Standards (TxGMS, formerly the Uniform Grant Management Standards – UGMS), Texas Administrative Code, Texas Health and Safety Code, the terms of the grant contract, and CPRIT's Policies and Procedures Guide.

## Audit Advisory Objective and Scope

This internal audit advisory engagement focused on CPRIT's post award grant compliance procedures with the goal of providing recommendations to improve process efficiency and effectiveness. These recommendations included changes to monitoring protocols performed by CPRIT's compliance monitoring team. The CPRIT Chief Compliance Officer also requested the engagement to include the review of the grant recipient risk assessment process and determine if the current process could be simplified.

Our procedures included interviewing compliance personnel, reviews of compliance programs and execution, and conducting collaborative work sessions to update CPRIT compliance program documentation.

## Executive Summary

The outcome of our internal audit advisory procedures resulted in updates to portions of CPRIT's post award grant compliance methodology. The results include a revised risk assessment model to assist in the planning of the specific grant compliance monitoring procedures to be performed by CPRIT's compliance team, as well as changes to the risk assessment model. These changes resulted in a risk assessment model that is based on grant type and historical grant monitoring outcomes instead of grantee attributes, such as: entity age, size, and dollar volume of grant funds received. The result of updated risk assessment should reduce the time spent manipulating large amounts of data input into the risk assessment model, and potentially reducing the frequency of grant monitoring procedures related to specific grant recipients who have had no review findings in prior compliance reviews.

The updates to the methodology also included minor recommended updates to the grant monitoring protocols to more closely align with specific areas of guidance in the TxGMS.

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## Conclusion

CPRIT should evaluate and update the revised risk assessment model with current grant recipient information. The revised risk assessment model represents a shift from a solely grantee attribute focus to a focus on grant type and the outcomes of grant monitoring procedures. Additionally, the CPRIT compliance team should evaluate the proposed updates to the grant monitoring protocols and incorporate the accepted changes into the overall compliance program.

# Detailed Procedures Performed and Results

# Cancer Prevention and Research Institute of Texas

IA# 2023-02 Post Award Grant Compliance Internal Audit Advisory Report
September 12, 2023

## Detailed Procedures Performed and Management Results

Our procedures included interviewing key personnel within the compliance team who have responsibilities in managing and/or monitoring post award grant compliance. We also examined existing documentation for the grantee compliance program We evaluated the existing policies, procedures, and processes in their current state.

## Objective: Post Award Grant Compliance Efficiency and Effectiveness

Evaluate CPRIT's post award grant compliance procedures, review the grantee monitoring protocols, provide recommendations to update protocols for changes in state guidelines, and identify opportunities for the grant compliance processes to be more efficient or effective.

We conducted interviews with key personnel to gain an understanding of the current processes in place, examined existing documentation, and evaluated the processes and procedures for grantee monitoring. We evaluated the existing policies, procedures, and processes over the following sub-processes:

- Grantee Risk Assessment
- Conversion from UGMS to TxGMS Standards
- Enhanced Desk Review (EDR) and Onsite Review documentation

**Grantee Monitoring Decision Template**

**Procedures Performed:** We obtained the current grant recipient risk assessment used by CPRIT to evaluate active grant recipients and conducted interviews with CPRIT personnel who complete the risk assessment. The results of the grantee risk assessment are used by CPRIT to formulate the compliance monitoring plan. The review of the risk assessment and interview was focused on identifying opportunities to improve the efficiency of the risk assessment process.

**Results**: Based on initial discussions with and feedback from CPRIT's compliance team, we developed and drafted an updated risk assessment model. The updated risk assessment model is designed to use the type of grant(s) received by the recipient and the results of prior grant compliance monitoring procedures, if applicable, to determine the type of grant monitoring protocols to be performed for the upcoming fiscal year. This outcomes-based decision model was designed to streamline the data inputs and to focus on the most significant data inputs to complete the assessment.

The current risk assessment model developed by Weaver in 2015 requires the input of 18 data points, whereas the revised model requires only four to seven per grantee. **Updates from UGMS to TxGMS Standards**

**Procedures Performed:** We reviewed changes between the Texas Uniform Grant Management Standards (UGMS) to the Texas Grant Management Standards (TxGMS) and assessed CPRIT's current compliance monitoring procedures to identify opportunities where the compliance monitoring procedures could be updated to more closely align with TxGMS.

**Results**: We identified one revision to CPRIT's compliance monitoring protocols to more closely align with TxGMS guidance. This revision included clarifications and one minor addition to the procedures for the shared use of equipment purchased with grant funds.

**EDR and Onsite Review**

**Procedures Performed:** We sampled eight enhanced desk reviews and five onsite reviews performed in the past fiscal year and reviewed the completed checklists and support documentation to evaluate the performance of the compliance monitoring procedures.

**Results**: We identified opportunities to improve the consistency of the documentation for the performance of compliance monitoring protocols. Through our review of the monitoring checklists, we identified one area of the Onsite Review Checklist and one area of the Enhanced Desk Review checklist where grantee data and information is gathered and were not consistently completed where the field was not applicable to the grant recipient. While this data is not related to specific checklist questions and does not determine compliance with regulations, contracts, or agency policy, it was found to be incomplete in several instances. We provided these fields to the compliance team so that they can more closely monitor their completion.

# Cancer Prevention & Research Institute of Texas

IA #2023-07 Internal Audit Follow-Up Procedures Report over Vendor Contract Compliance
August 15, 2023
Issued: October 27, 2023



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

This report presents the results of the internal audit follow-up procedures performed for the Cancer Prevention and Research Institute of Texas (CPRIT) during the period of July 17, 2023, through August 15, 2023 related to the findings identified in the Internal Audit Report over Vendor Contract Compliance dated October 25, 2022.

The objective of these follow-up procedures was to validate the adequate corrective action has been taking in order to remediate the issues identified in the prior fiscal years' internal audit report.

To accomplish the objective, we conducted discussions and followed-up with written correspondence with key personnel involved in the Vendor Contract Compliance processes. We also reviewed documentation and performed specific testing procedures to validate actions taken.

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

Weaver and Tidwell, L.L.P.

WEAVER AND TIDWELL, L.L.P.

Austin, Texas
August 15, 2023

# Cancer Prevention & Research Institute of Texas

IA #2023-07 Internal Audit Follow-Up Procedures Report over Vendor Contract Compliance
August 15, 2023
Issued: October 27, 2023

## Background

Internal audit procedures were performed over CPRIT's Vendor Contract Compliance process in 2022 and reported to the Oversight Committee. The Internal Audit Report over Vendor Contract Compliance identified two findings:

1) CPRIT did not always receive their peer review panel meeting reports within seven business days of the conclusion of a meeting, the timeframe required in the contract. For four out of the 10 meeting samples that we selected for testing, BFS did not meet the seven-business day requirement.

2) While every requested due diligence report was provided to CPRIT for use in the evaluation of product development research grant applications, ICON did not provide the draft due diligence reports within the timeframes outlined in the terms of the contract. Additionally, the draft due diligence reports excluded minor requirements that, according to the contract, should have been included in the due diligence reports.

The first finding was closed by CPRIT management and Internal Audit due to the fact that the risk was accepted by management.

The 2023 Internal Audit Plan included performing follow-up procedures to determine whether management has implemented corrective actions for the one remaining outstanding internal audit finding identified in the 2022 report.

## Follow-Up Procedures Objective and Scope

The follow-up procedures focused on the remediation efforts taken by CPRIT management to address the one remaining outstanding internal audit finding included in the Internal Audit Report over Vendor Contract Compliance, and to validate that appropriate corrective action had been taken.

We evaluated the corrective action for the outstanding internal audit finding identified in the Internal Audit Report over Vendor Contract Compliance.

Our procedures included conducting discussions and written correspondence with key personnel within the Vendor Contract Compliance process, examining existing documentation, and evaluating if corrective action has been taken. Our coverage period was July 17, 2023, through August 15, 2023.

## Executive Summary

The finding from the 2022 Internal Audit Report over Vendor Contract Compliance include the item that was identified and considered to be non-compliance issues with CPRIT's policies and procedures, rules and regulations required by law, or where there is a lack of procedures or internal controls in place to cover risks to CPRIT.

Through our discussions and written correspondence, review of documentation, observations and testing we determined that the one finding we evaluated for corrective actions was remediated.

# Cancer Prevention & Research Institute of Texas

IA #2023-07 Internal Audit Follow-Up Procedures Report over Vendor Contract Compliance
August 15, 2023
Issued: October 27, 2023

| Risk Rating | Total Findings | Remediated | Closed | Open |
|---|---|---|---|---|
| High | - | - | - | - |
| Moderate | - | - | - | - |
| Low | 2 | 1 | 1 | - |
| **Total** | **2** | **1** | **1** | **-** |

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

| FOLLOW-UP ASSESSMENT | Strong |
|---|---|

| Scope Area | Result | Rating |
|---|---|---|
| **Objective:** Validate that adequate corrective action has been taken in order to remediate the issues identified in the 2022 Internal Audit Report over Vendor Contract Compliance. | We identified that procedures implemented by management fully remediated the one outstanding internal audit finding. | Strong |

## Conclusion

Based on our evaluation, the agency has remediated one outstanding finding from the 2022 Internal Audit Report over Vendor Contract Compliance.

# Detailed Procedures Performed, Findings, Recommendations and Management Response

# Cancer Prevention & Research Institute of Texas

IA #2023-07 Internal Audit Follow-Up Procedures Report over Vendor Contract Compliance
August 15, 2023
Issued: October 27, 2023

## Detailed Procedures Performed, Findings, Recommendations and Management Response

Our procedures included conducting discussions and written correspondence with key personnel within the Vendor Contract Compliance process to gain an understanding of the corrective actions taken to address the one outstanding internal audit finding identified in the 2022 Internal Audit Report over Vendor Contract Compliance, examining existing documentation, and performing testing to validate corrective actions taken. We evaluated the existing policies, procedures, and processes in their current state.

## Objective: Validate Remediation

Validate that adequate corrective action has been taken in order to remediate the outstanding internal audit finding identified in the 2022 Internal Audit Report over Vendor Contract Compliance.

### Vendor Contract Compliance

**Finding 2 – Low – Due Diligence Reports**
While every requested due diligence report was provided to CPRIT for use in the evaluation of product development research grant applications, ICON did not provide the draft due diligence reports within the timeframes outlined in the terms of the contract. Additionally, the draft due diligence reports excluded minor requirements that, according to the contract, should have been included.

**Results: Finding remediated**

CPRIT conducted a re-bid and contracting phase for the ICON contract due to the contract term expiring. ICON did not participate in the re-bid opportunity. Therefore, CPRIT selected a new vendor, Alan Boyd Consultants, to provide their due diligence reports.

As part of the normal contracting cycle, CPRIT modified the terms and conditions in the contract to remove items that were required deliverables and adjusted timelines, as necessary. We obtained and reviewed a copy of the new vendor contract for Alan Boyd Consultants and reviewed a copy of the drafted scope of services for the contract to ensure that the modified terms and conditions have been defined in the contract, as well as conditions of timeliness for the due diligence reports.

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# Appendix

# Cancer Prevention & Research Institute of Texas

IA #2023-07 Internal Audit Report over Vendor Contract Compliance
August 15, 2023
Issued: October 27, 2023

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

## Report Ratings

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

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

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

| | |
|---|---|
| **Strong** | The area under review meets the expected level. No high risk rated findings and only a few moderate or low findings were identified. |
| **Satisfactory** | The area under review does not consistently meet the expected level. Several findings were identified and require routine efforts to correct, but do not significantly impair the control environment. |
| **Unsatisfactory** | The area under review is weak and frequently falls below expected levels. Numerous findings were identified that require substantial effort to correct. |

# Cancer Prevention & Research Institute of Texas

IA #2023-07 Internal Audit Report over Vendor Contract Compliance
August 15, 2023
Issued: October 27, 2023

## Risk Ratings

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

**High**

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

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

.

**Moderate**

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

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

**Low**

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

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

# Cancer Prevention and Research Institute of Texas

IA #2023-06 Internal Audit Follow-up Procedures Report over Communications
Report Date: August 7, 2023
Issued: October 27, 2023

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

This report presents the results of the internal audit follow-up procedures performed for the Cancer Prevention and Research Institute of Texas (CPRIT) during August related to the findings from the Internal Audit Report over Communications dated April 30, 2018.

The objective of these follow-up procedures was to validate that corrective action have been taken to remediate the issues identified in the 2018 Internal Audit Report over Communications.

To accomplish this objective, we conducted interviews with CPRIT personnel responsible for the communication process. We also reviewed documentation and performed specific testing procedures to validate actions taken. Procedures were performed remotely and completed on August 7, 2023.

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

Weaver and Tidwell, L.L.P.

WEAVER AND TIDWELL, L.L.P.

Austin, Texas
August 7, 2023

# Cancer Prevention and Research Institute of Texas

IA #2023-06 Internal Audit Follow-up Procedures Report over Communications

August 7, 2023

Issued: October 27, 2023

## Background

In fiscal year 2018, an internal audit over CPRIT's communication process was completed. The internal audit report identified five findings within the communication process. In 2019, follow-up procedures were performed and identified two of the five findings were remediated. In 2022, follow-up procedures were performed and identified two of the three open findings were remediated.

The 2023 Internal Audit Plan included performing follow-up procedures to validate that CPRIT management has taken steps to address the one open internal audit finding (compliance with state website requirements).

## Follow-Up Objective and Scope

The follow-up procedures focused on the remediation efforts taken by CPRIT management to address the one open finding included in the 2018 Internal Audit Report over Communications and to validate that appropriate corrective action had been taken.

We evaluated the corrective action for the one open internal audit finding identified in the 2018 Internal Audit Report over Communications.

Our procedures included interviewing key personnel responsible for the communication process, examining existing documentation and evaluating if corrective action had been taken. Our coverage period was as of August 2023.

## Executive Summary

The findings from the 2018 Internal Audit Report over Communications include those items that were identified and are considered to be non-compliance issues with CPRIT's policies and procedures, rules and regulations required by law, or where there is a lack of procedures or internal controls in place to cover risks to CPRIT. These issues could have significant financial or operational implications.

Through our interviews, review of documentation, observations and testing, we determined that for the one open finding was partially remediated.

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

| Risk Rating | Total Findings | Previously Remediated | Partially Remediated |
|---|---|---|---|
| High | 1 | - | 1 |
| Moderate | 4 | 4 | - |
| Low | - | - | - |
| **Total** | **5** | **4** | **1** |

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

| SCOPE AREA | RESULT |
|---|---|
| **Objective:** Validate that adequate corrective action has been taken to remediate the findings identified in the 2018 Internal Audit Report over Communications. | We determined that CPRIT management made efforts to remediate the findings from the 2018 Internal Audit Report over Communications. However, management should continue their efforts to remediate the remaining open findings to ensure compliance with state website requirements |

## Conclusion

Based on our evaluation, CPRIT has made progress to remediate the one open finding from the 2018 Internal Audit Report over Communications. CPRIT should complete the final steps identified to ensure that the agency's website is in compliance with all state requirements.

Follow-up procedures should be conducted in Fiscal Year 2024 to validate the effectiveness of the remediation efforts taken to address the remaining open finding.

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

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

Our procedures included interviewing key CPRIT personnel responsible for the communication process to gain an understanding of the corrective actions taken in order to address the open finding identified in the 2018 Internal Audit Report over Communications, examining existing documentation, and performing testing in order to validate the corrective actions. We evaluated the existing policies, procedures, and processes in their current state.

**Finding 4 – High –** CPRIT Website Compliance: In February 2018 CPRIT's Senior Program Manager for Prevention, Staff Attorney and Information Specialist conducted an annual website review to assess compliance with applicable state requirements and identified that CPRIT is not in compliance with the following requirements:

- 1 TAC 206.54(a) - Requirement to include meta data tags on all publications
- 1 TAC 206.54(b) - Requirement to include TRAIL meta data on the homepage
- 13 TAC 3.4(2)(a) - Requirement for accessibility of publications
- 13 TAC 3.2(b) - Requirement for posting the date that each publication is produced or distributed
- 1 TAC 206.51 - Requirement for translation of the website
- 1 TAC 206.55(d) - Requirement for address of the web page with high-value data set.

CPRIT personnel identified the non-compliance prior to this audit and are actively working on addressing these issues with the ongoing implementation of the new agency website.

**Results: Finding partially remediated**

We obtained supporting documentation that supports that 13 TAC 3.4(2)(a) and 1 TAC 206.55(d) were implemented. We verified that CPRIT's website included the high-value data sets and clicked the link to ensure that the user is directed to the appropriate website. Additionally, we reviewed the tool used, Siteimprove, to scan PDF files and publications for accessibility requirements.

We also obtained CPRIT's internal review of their website compliance and identified that the steps to address the following compliance requirements are still in progress:

- 1 TAC 206.54(a) - Requirement to include meta data tags on all publications
- 1 TAC 206.51 - Requirement for translation of the website

**Management Response:** (**1 TAC 206.51**) IT Management has purchased a service called Bablic that uses google AI to translate the website into Spanish and provides a simple UI to review the website before adding a JavaScript plugin to give the user an option to select Spanish translation. A test site was created during the purchasing process to review the plugin's potential, and this phase has been completed. IT Management will do an initial review of the top two-level pages of the translation before going live. The reason for the delay on this is lack of staff with time and Spanish linguistic skills to perform the review. IT Management has recently learned that an IT staff member is very proficient in Spanish and will be doing an initial review this month and then followed up by a fluent speaking staff member to review work. After this is complete the JavaScript snippet will be incorporated on the site, fully resolving this finding. Requirement to include meta data tags on all publications. (**1 TAC 206.54(a)(b)**) Additionally, the Communications team has been adding the required meta data to newly uploaded publications. We are working on the process of creating a procedure and instructions for staff to complete prior to submitting a PDF document for upload on our website.

**Responsible Party:** Information Technology Manager
**Implementation Date:** FY 2023

# Appendix

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

## Report Ratings

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

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

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

| | |
|---|---|
| **Strong** | The area under review meets the expected level. No high risk rated findings and only a few moderate or low findings were identified. |
| **Satisfactory** | The area under review does not consistently meet the expected level. Several findings were identified and require routine efforts to correct, but do not significantly impair the control environment. |
| **Unsatisfactory** | The area under review is weak and frequently falls below expected levels. Numerous findings were identified that require substantial effort to correct. |

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

## Risk Ratings

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

**High**

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

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

**Moderate**

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

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

**Low**

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

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

# Cancer Prevention and Research Institute of Texas

IA #2023-05 Internal Audit Advisory Follow-up Procedures Report over Disaster Recovery and Business Continuity Planning

July 31, 2023

Issued: October 27, 2023

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

This report presents the results of the internal audit follow-up procedures performed for the Cancer Prevention and Research Institute of Texas (CPRIT) during July 2023 relating to the recommendations for improvement from the Advisory Audit Report over Disaster Recovery and Business Continuity Planning (September 2020).

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

To accomplish this objective, we obtained updated disaster recovery and business continuity planning documentation from CPRIT personnel responsible for their maintenance. This documentation was reviewed to verify that the advisory audit improvement opportunities were addressed. Procedures were performed remotely and completed on July 28, 2023.

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

Weaver and Tidwell, L.L.P.

WEAVER AND TIDWELL, L.L.P.

Austin, Texas
July 31, 2023

# Cancer Prevention and Research Institute of Texas

IA #2023-05 Internal Audit Advisory Follow-up Procedures Report over Disaster Recovery and Business Continuity Planning

July 31, 2023

Issued: October 27, 2023

## Background

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

In the 2020 audit advisory report, 30 items were identified to improve and better align CPRIT's planned processes and procedures. In 2021, follow-up procedures were performed and identified 25 of the 30 recommendations had been addressed, with the remaining five recommendations determined to be partially addressed. In 2022, follow-up procedures were performed and identified the previous five recommendations remained partially addressed.

The 2023 Internal Audit Plan included performing follow-up procedures to validate that CPRIT management has taken steps to address the five remaining advisory audit improvement opportunities.

## Follow-Up Objective and Scope

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

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

Our procedures included interviewing key personnel responsible for DR/BCP, examining existing documentation and evaluating if corrective action has been taken. Our coverage period was as of July 31, 2023.

## Executive Summary

Through our review of updated DR/BCP documentation, we determined that the five recommendations that were partially remediated as part of the fiscal year 2022 follow-up procedures have been fully remediated.

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

| SCOPE AREA | RESULT |
|---|---|
| **Objective:** Validate that adequate corrective action has been taken to address recommendations identified in the 2020 Disaster Recovery and Business Continuity Planning Advisory Audit Report. | We determined that CPRIT has fully addressed the recommendations for improvement from the 2020 Disaster Recovery and Business Continuity Planning Advisory Audit Report. |

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# Cancer Prevention and Research Institute of Texas

IA #2023-05 Internal Audit Advisory Follow-up Procedures Report over Disaster Recovery and Business Continuity Planning

July 31, 2023

Issued: October 27, 2023

## Conclusion

Based on our evaluation, CPRIT has remediated the recommendations from the 2020 Disaster Recovery and Business Continuity Planning Advisory Audit Report. With the findings remediated, CPRIT should ensure regular maintenance and testing of Disaster Recovery and Business Continuity Planning and Procedures to facilitate timely and appropriate responses in the event of a business disruption.

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

# Cancer Prevention and Research Institute of Texas

IA #2023-05 Internal Audit Advisory Follow-up Procedures Report over Disaster Recovery and Business Continuity Planning
July 31, 2023
Issued: October 27, 2023

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

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

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

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

| DR/BC Component | Total Criteria | Open Improvement Opportunities | | Fully Remediated |
|---|---|---|---|---|
| | | Count | Type | Content Addition |
| Incident Evaluation | 31 | 2 | R | 2 |
| Incident Management | 30 | 1 | OA | 1 |
| Disaster Recovery | 37 | 1 | R | 1 |
| Business Resumption | 23 | 1 | R | 1 |
| **Total** | **121** | **5** | | **5** |

R – Required elements by SORM or DIR
OA – Other authoritative guidance

**Results:** **Recommendations are fully addressed**

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# Cancer Prevention and Research Institute of Texas

Fiscal Year 2023 Annual Internal Audit Report

August 31, 2023

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# Cancer Prevention and Research Institute of Texas

Fiscal Year 2023 Annual Internal Audit Report
August 31, 2023

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

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

The Cancer Prevention and Research Institute of Texas (CPRIT or the agency) will post this report which includes the Fiscal Year 2023 Internal Audit Plan on its website at www.cprit.texas.gov. CPRIT's Oversight Committee reviewed and approved the Annual Internal Audit Report as part of their regular meeting held on November 15, 2023. In accordance with Texas Government Code, Section 2102.015, CPRIT will post this report on its website within 30 days of the Oversight Committee's approval.

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

## II. Internal Audit Plan for Fiscal Year 2023

The internal audits planned and performed for fiscal year 2023 were selected to address the agency's highest risk areas, based on the risk assessment update conducted in 2023, which included input from CPRIT management. The audits conducted during fiscal year 2022 are listed below.

| Internal Audit | Report Date | Current Status |
|---|---|---|
| Purchasing Compliance | September 22, 2023 | This audit is complete.<br><br>Follow-up Procedures to address the one finding are included in the FY 2024 Internal Audit Plan. |
| IT General Controls | September 18, 2023 | This audit is complete.<br><br>Follow-up Procedures to address the audit findings are included in the FY 2024 Internal Audit Plan. |
| Information Security Follow-Up | September 18, 2023 | Follow-up procedures were completed as part of the IT General Controls audit. |
| Communications Follow-Up | August 7, 2023 | This follow-up is complete.<br><br>Follow-up procedures to address the one remaining open finding are included in the FY 2024 Internal Audit Plan. |
| Vendor Contract Compliance Follow-Up | August 15, 2023 | This audit is complete.<br><br>All findings have been remediated. |

# Cancer Prevention and Research Institute of Texas

Fiscal Year 2023 Annual Internal Audit Report
August 31, 2023

## III. Consulting Services and Non-audit Services Completed

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

| Audit Advisory | Report Date | Current Status |
|---|---|---|
| Contract Risk Assessment Advisory | April 11, 2023 | This audit advisory engagement is complete.<br><br>Advisory procedures are complete. The procedures included developing a contract risk assessment process and developing a contract risk assessment matrix in compliance with state requirements for CPRIT's Management to adopt and implement. |
| Post-Award Compliance Program Advisory | September 12, 2023 | This audit advisory engagement is complete.<br><br>The advisory procedures are complete. The procedures included recommendations for updating CPRIT's risk assessment of grant recipients and grant compliance monitoring protocols. |
| Disaster Recovery and Business Continuity Planning Advisory Follow-Up | July 31, 2023 | This audit advisory engagement is complete.<br><br>All open recommendations were implemented by CPRIT. |

## IV. External Quality Assurance Review

In accordance with professional standards, and to meet the requirements of the Texas Internal Auditing Act, Internal Audit is required to undergo an external quality assurance review at least once every three years. Weaver's review was issued in September 2022.

EideBailly
CPAs & BUSINESS ADVISORS

**Report on Firm's System of Quality Control**

September 19, 2022

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

We have reviewed the system of quality control for the accounting and auditing practice of Weaver & Tidwell, L.L.P. (the firm) applicable to engagements not subject to PCAOB permanent inspection in effect for the year ended May 31, 2022. Our peer review was conducted in accordance with the Standards for Performing and Reporting on Peer Reviews established by the Peer Review Board of the American Institute of Certified Public Accountants (Standards).

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

**Firm's Responsibility**

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

**Peer Reviewer's Responsibility**

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

**Required Selections and Considerations**

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

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

**Opinion**

In our opinion, the system of quality control for the accounting and auditing practice of Weaver & Tidwell, L.L.P. applicable to engagements not subject to PCAOB permanent inspection in effect for the year ended May 31, 2022, has been suitably designed and complied with to provide the firm with reasonable assurance of performing and reporting in conformity with applicable professional standards in all material respects. Firms can receive a rating of *pass*, *pass with deficiency(ies)* or *fail*. Weaver & Tidwell, L.L.P. has received a peer review rating of *pass*.

Eide Bailly LLP

Eide Bailly LLP

## V. Internal Audit Plan for Fiscal Year 2024

The Internal Audit Plan was submitted to the Audit Subcommittee of the CPRIT Oversight Committee. The Audit Subcommittee approved the plan on November 6, 2023, and the Oversight Committee subsequently approved the plan on November 15, 2023. Below is the Fiscal Year 2024 Internal Audit Plan submitted to the agency's Oversight Committee based on the results of the 2023 Internal Audit Risk Assessment Update. The approved internal audit plan was submitted to the State Auditor's Office upon approval from CPRIT's Oversight Committee.

| Fiscal Year 2024 Internal Audit Plan | | |
|---|---|---|
| **Audit Area** | **2023 Risk Rating** | **Estimated Hours** |
| Internal Agency Compliance | **High** | 220 |
| Oversight Committee Reporting | **Moderate** | 280 |
| Records Management Advisory | **Moderate** | 250 |

Planned follow-up procedures for fiscal year 2024 to verify and communicate with Management the remediation efforts of prior Internal Audit Recommendations.

| Fiscal Year 2024 Follow-up Procedures | | |
|---|---|---|
| **Audit Area** | **2022 Risk Rating** | **Estimated Hours** |
| Purchasing Compliance | **Low** | 30 |
| Communications | **High** | 30 |
| IT General Controls Follow-up | **High** | 180 |

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

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

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

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

The 2023 Internal Audit Risk Assessment Update resulted in 10 Significant Activities rated as "High" risk. Seven of the 10 Significant Activities are not included in the Fiscal Year 2024 Internal Audit Plan. Those activities are as follows:

1. Pre-Award Grant Management
2. Post-Award Grant Monitoring
3. Information Security
4. Commodity and Service Contracts
5. Procurement and P-Cards
6. Disaster Recovery and Business Continuity Planning
7. Governance

## VI. External Audit Services Procured in FY 2023

CPRIT engaged McConnell & Jones, LLP, a certified public accounting and consulting firm, as their external auditors for FY 2023.

## VII. Reporting Suspected Fraud, Waste and Abuse

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

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