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CANCER PREVENTION & RESEARCH  
INSTITUTE OF TEXAS

**Oversight Committee Meeting Minutes**

February 17, 2016

**1. Meeting Called to Order**

A quorum being present, Presiding Officer Geren, called the Oversight Committee to order at 9:06 a.m.

**2. Roll Call /Excused Absences**

Board Members Present:

Angelos Angelou  
Donald (Dee) Margo  
Pete Geren  
Ned Holmes  
Will Montgomery  
Cynthia Mulrow, M.D.  
Amy Mitchell  
Bill Rice, M.D.  
Craig Rosenfeld, M.D.

**3. Adoption of Minutes from the November 19, 2015, Oversight Committee Meeting (TAB 1)**

**MOTION:**

Presiding Officer Geren called for a motion to approve the minutes of the November 19, 2015, Oversight Committee meeting.

Motion made by Dr. Rosenfeld and seconded by Mr. Montgomery.

**MOTION CARRIED UNANIMOUSLY**

**4. Public Comment**

Presiding Officer Geren stated there were no requests for public comment.

**5. Chief Executive Officer Report (TAB 2)**

Mr. Wayne Roberts, Chief Executive Officer, introduced Dr. James Willson, the new Chief Scientific Officer, whose start date will be March 1, 2016.

Staff has begun collecting data related to recruitment awards, including the number of full-

time employees (FTEs) added with each recruitment award, additional funding (and grants) brought to Texas, and post-grant developments. Mr. Roberts stated the Oversight Committee will hear more about this project.

Mr. Roberts stated that Texas Health and Safety Code § 102.260(c) requires the Chief Executive Officer to report at least annually to the Oversight Committee on the progress and continued merit of each program. He reported that CPRIT's Academic Research Program, Prevention Program, and Product Development Research Program each showed progress and merit in fiscal year 2015, with further details in the Oversight Committee meeting materials.

Mr. Roberts noted the Oversight Committee requested at its November 19, 2015, meeting that staff provide information on options for ensuring compliance with Texas Health and Safety Code § 102.203(e), which limits to 10% the amount of grant funding that may be obligated for cancer prevention grants each year. Currently, Prevention Program grants awarded by CPRIT exceeds the statutory limit by \$2.77 million. This inconsistency can be attributed to three factors, which cause CPRIT to exceed its 10% limit: 1) research program grants being declined after the fiscal year end; 2) increases in the operating budget to support additional grant award processes; and 3) Oversight Committee approval of prevention grants prior to the moratorium that stopped consideration of grant recommendations in other programs for the remainder of fiscal year 2013.

To comply with the statutory directive and resolve the remaining overage, Mr. Roberts presented for the Oversight Committee's consideration three options identified by CPRIT staff to realign prevention grant spending.

Option 1 is a realignment of funding by a one-time reduction of \$2.77 million in fiscal year 2017. This approach would have the disadvantage of slowing the momentum CPRIT has gained following the fiscal year 2013 moratorium. However, this option means that CPRIT remains out of compliance until 2017.

Option 2 is an incremental realignment, spreading the \$2.77 million across the next several years. This approach minimizes the impact on future Prevention projects and allows more time for a natural resolution of the overage as Prevention grantees do not expend the full amount obligated by contracts ending in a given fiscal year. The disadvantage is that CPRIT does not fully resolve the noncompliance issue for several years.

Option 3 is a retroactive realignment by contract and fiscal year amending active fiscal year 2013 through fiscal year 2016 prevention contracts to reduce funding awarded in each fiscal year so that the total prevention funding would equal 10% of the total grant funds awarded in all programs each fiscal year. This option addresses the issue immediately but would significantly disrupt grantee budgets.

Mr. Roberts introduced Ms. Ramona Magid, Senior Program Manager for Prevention, to represent Dr. Rebecca Garcia, Chief Prevention and Communications Officer, who was unable to attend the meeting.

Mr. Roberts was asked if he had a recommendation for the Oversight Committee. Mr. Roberts stated Dr. Garcia's preference would be to have the reduction taken in fiscal year 2019, with the assumption that over time there would be a natural resolution of the overage as Prevention grantees do not expend the full amount obligated by contracts. Mr. Roberts stated that he recommended taking the amount from fiscal year 2017 to demonstrate that the agency took corrective action as soon as the issue was discovered. He feels taking the reduction in 2016 would be too disruptive, but taking the reduction in 2017 would show good intent on behalf of the agency. An Oversight Committee member asked about the wording in the statute regarding the 10% requirement. Mr. Roberts responded that the statute directs CPRIT to adhere to the 10% maximum each year and not at the end of CPRIT's grant process.

An Oversight Committee member asked about the effect of a reduction in 2016. Ms. Magid stated she and Dr. Garcia had worked to restore momentum of the program after the moratorium and that as a result there were currently 35 grant applications in response to Requests for Applications that will close March 3, 2016. This is higher than compared to the previous cycle with 12 starts. She stated that \$14 million is available to fund prevention grants for the balance of fiscal year 2016, and taking the full amount in 2016 would be a reduction of \$2.77 million. An Oversight Committee member noted that it would not affect grants already approved for 2016, but would affect only grants not yet approved for 2016.

An Oversight Committee member asked if the Prevention Program's goal to cover the majority of the state with prevention grants would be impacted by taking the full reduction in the remaining cycle of 2016. Ms. Magid said that it could affect that goal.

Another Oversight Committee member noted that the majority of research grant funding by CPRIT has been along the IH35 corridor, but prevention grants tend to include rural West Texas and Border areas.

Another Oversight Committee member pointed out that if all historical grants were taken into consideration instead of only active grants, there would be only two counties (Coryell and Hopkins, covering a total population of approximately 100,000), which never have been covered by prevention grants.

In response to an Oversight Committee member question about recent efforts to inform people about CPRIT funding opportunities, Ms. Magid stated that she and Dr. Garcia made several trips into areas of the state that had no or few projects serving them. As a result, some that were visited have started grant applications.

Presiding Officer Geren proposed that the committee approve a "one-third/two-thirds" approach to the \$2.77 million reduction; taking one-third in the remaining part of fiscal year 2016, one-third in the first half of fiscal year 2017, and one-third in the second half of fiscal year 2017. He stated this would show good faith and spread out the reduction over a period of time.

In a response to questions about the possible response from the Legislature to CPRIT being out of compliance and the agency's attempts to resolve the issue, Presiding Officer Geren stated there is no strict legal guidance to handle this matter. He asked Ms. Kristen Doyle, CPRIT General Counsel, what discretion an agency's governing body has under administrative law to remedy a failure to comply with statutes. Ms. Doyle stated that the non-compliance is an inadvertent violation caused mainly by declinations of research grant awards. By its actions, CPRIT has attempted to be fully compliant, but when declinations come after the close of a fiscal year it affects the denominator for setting a 10% target. There is no specific guidance in statute to address the agency's actions once an overage has been identified. The Oversight Committee taking action to identify and correct the problem as soon as possible communicates the agency's desire to address the problem as well as balancing the Prevention Program priorities.

Staff presented several actions to ensure this doesn't continue to be an issue including awarding less than 10% per year in the Prevention Program to address the possible declinations in other programs after the fiscal year. An Oversight Committee member confirmed with Ms. Doyle that the 10% is a statutory maximum, not an amount that must be achieved. She stated that since it is a maximum, the agency may award less.

Presiding Officer Geren confirmed with Ms. Doyle that it is her opinion that any of the approaches suggested would be consistent with the agency's legal obligations.

Presiding Officer Geren called for a motion to realign the Prevention Program funding to comply with Texas Health & Safety Code § 102.203 by taking one-third of the overage out of the second half of fiscal year 2016 and two-thirds of the overage out of fiscal year 2017 so that the total overage amount will be recouped in those two fiscal years.

An Oversight Committee member asked if, after March 3, 2016, applications in the areas not currently covered by CPRIT grants are not received, can the amount taken from 2016 be increased and the amount from 2017 accordingly decreased. Ms. Doyle stated that the motion as crafted will allow the Chief Operating Officer to determine the amount to be reduced in each year, which will allow for any changes in the applications received.

**MOTION:**

Presiding Officer Geren called for a motion to realign the Prevention Program funding to comply with Texas Health & Safety Code § 102.203 by taking one-third of the overage out of the second half of fiscal year 2016 and two-thirds of the overage out of fiscal year 2017 so that the total overage amount will recoup in those two fiscal years.

Motion made by Mr. Holmes and seconded by Dr. Rosenfeld.

**MOTION CARRIED UNANIMOUSLY**

Request to Amend Minutes of September 10, 2105, meeting

Mr. Roberts presented a request to amend the minutes of the September 10, 2015, meeting to reflect that Mr. Angelou voted to approve an award to The University of Texas at Austin (RR160005) at a time when he held a conflict of interest because of his work with the athletics department of the university. Mr. Angelou self-reported the conflict after becoming aware of the issue and conferring with CPRIT's general counsel. It was determined his work with the university had nothing to do with cancer research or prevention and did not involve anyone applying to receive CPRIT grants. Mr. Angelou's vote did not affect the outcome of the recommendation, which received unanimous approval by the Oversight Committee.

**MOTION:**

Presiding Officer Geren called for a motion to add an addendum to the minutes for the September 10, 2015, meeting to reflect that Mr. Angelou had a conflict of interest with award RR160005 that he inadvertently failed to report and has now brought the conflict to the attention of the Oversight Committee.

Motion made by Mr. Montgomery and seconded by Ms. Mitchell.

**MOTION CARRIED UNANIMOUSLY**

Funding targets for fiscal year 2016

Mr. Roberts discussed the projected funding available for the remainder of fiscal year 2016. To date there was \$72.06 million available for both academic research and product development research awards, and \$14.7 million for prevention awards. The \$72.06 million will increase slightly due to the decision earlier in this meeting on the Prevention Program funding but not significantly enough to affect this funding target discussion.

At the Oversight Committee meeting in November 2015, staff was instructed to begin the discussion on setting targets for funding between the three programs. As applications for funding continue to increase, it is possible that recommendations from the review panels might exceed available monies. The Oversight Committee will need to meet to begin a discussion among the committee members and agency staff where various permanent approaches could be proposed and reasoned through. Currently, staff estimates there is enough funding for the awards anticipated to be approved by the Oversight Committee in May 2016; however, these estimates do not include any additional recruitment applications, which could result in more proposed awards than available funding. Mr. Roberts recommended a two-prong approach to target setting which would include a temporary target for the remainder of fiscal year 2016, and a more in-depth discussion to set a permanent target for following fiscal years. The meeting materials contain options for the remainder of fiscal year 2016. Mr. Roberts stated that staff would know the amount of funding needed by the May 2016 meeting. Mr. Roberts recommended that CPRIT assertively move forward with establishing funding target guidance for fiscal year 2017 and beyond.

An Oversight Committee member asked about the status of the expected overage in Academic Research proposed awards. Mr. Roberts responded that there is sufficient funding for the \$70.3 million in awards that Dr. Margaret Kripke, Chief Scientific Officer, is

projecting, based upon a historical evaluation of the request for applications (RFAs) that are coming forward. That projection does not take into account additional recruitment recommendations that could occur. Mr. Roberts suggested that Dr. Kripke work with the Scientific Review Council to more accurately predict the funding needed. An Oversight Committee member asked if the RFAs are issued with a cap on the award amount. Dr. Kripke stated the RFAs do have a cap. The current round of RFAs include core facilities awards, high-impact high-risk awards, and multi-investigator research awards. They each have a different cap. The high-impact high-risk awards are limited to \$200,000 over a two year period—very small amounts that she does not recommend reducing. A multi-investigator award could be several million dollars, with a cap of \$1.5 million per year and \$7.5 million over a five year period. She stated the total amount of the proposed awards will not be known until after the Scientific Review Council meeting. The core facility awards are capped at \$6 million over a five year period. Therefore, it is likely that funding must be limited; one or more of the very large awards could be deferred to the August 2016 Oversight Committee meeting.

An Oversight Committee member requested clarification on whether the caps are on individual awards or on aggregate funding of awards. Dr. Kripke stated that the cap is on aggregate funding and is the amount available for spending on programmatic issues. Until recently, there was no need to prioritize which grants would receive funding because there was enough funding to approve all grants recommended by the Scientific Review Council. Mr. Roberts added that the Scientific Review Council is asked to rank the projects, then the Program Integration Committee (PIC) is charged with culling the awards to meet the funding available, if necessary. If the PIC is unable to prioritize sufficiently, ultimately, the final authority is with the Oversight Committee. He also stated that it is preferred that the prioritization take place at the Review Council level since they are the science experts, though each Review Council can only take into account their own program when prioritizing.

Mr. Roberts confirmed for an Oversight Committee member that the funding for the Academic Research and Program Development Research program grants come from the same allocation which means if more funds are expended for Academic Research, less will be spent on Product Development Research.

Presiding Officer Geren noted that guidelines given to staff on how to prioritize and allocate those funds is one of the important decisions the Oversight Committee must make. For the May meeting, the Oversight Committee needs to give the staff guidance on how to prioritize the grants for the remainder of fiscal year 2016. At a special workshop meeting, the Oversight Committee will consider more fully the options for guidance in future years.

In response to an Oversight Committee member question about possibly deferring award approvals to a September 2016 meeting, Ms. Doyle stated that awards can be deferred only in the fiscal year in which they are recommended, which ends August 31. If an award is to be deferred to the next fiscal year, the Review Council would need to defer their recommendation.

An Oversight Committee member asked if product development research awards had caps and if the Product Development Review Council considered the amount of the application in any way. Ms. Doyle responded that there is a \$20 million cap on product development research awards and the Product Development Review Council does look at the amounts being requested. She stated the cap is a CPRIT operational cap, not a statutory cap. While there is normally a restriction on communications between the Chief Product Development Officer and potential grantees, the Chief Executive Officer may grant an exception to that restriction to allow staff to have budget discussions with applicants before the May meeting to determine if their budgets could be adjusted to stay within available funding.

An Oversight Committee member asked if a choice had to be made between a core facility award and a multi-investigator award, which would be chosen. Dr. Kripke responded it would depend more on whether the application was coming from an institution that had not received significant CPRIT funds, as a less funded institution would most likely receive priority. Mr. Roberts added that the Oversight Committee's program priorities would also be considered when recommending an award. Both of these considerations occur prior to weighing a core facility versus a multi-investigator award.

Another Oversight Committee member inquired why an award recommendation cannot be carried over to the next fiscal year. Ms. Doyle responded that it is a statutory requirement that the recommendation be acted upon within the fiscal year the review council makes the recommendation. Legally, staff can give direction to a review council and this has happened with recruitment awards and product development research awards to ensure sufficient funding is available. Dr. Kripke commented that deferring grants can also require them to be updated and the process becomes complicated, along with taking available funds from the next fiscal year.

An Oversight Committee member asked for confirmation that over the next year the committee will consider whether to allocate more funding to Product Development Research awards that would otherwise have gone to Academic Research awards. Presiding Officer Geren stated that, in order to provide guidance to staff, the Oversight Committee would consider funding targets more broadly than just whether current funding for product development research is the appropriate amount and will include how CPRIT policies can best serve the people of Texas.

Presiding Officer Geren noted Mr. Roberts' recommendation that the Oversight Committee meet in a workshop session in May to discuss funding targets.

## **6. Chief Scientific Officer Report and Grant Award Recommendations(TAB 3)**

Dr. Margaret Kripke, Chief Scientific Officer reported on the activities of the Academic Research Program:

- Academic Research Grants Currently Under Review
  - 208 applications received

- New Requests for Applications (RFAs)
  - Academic Research request for applications will be posted February 19, 2016 and will be due by May 19, 2106, to be brought before the Oversight Committee at their November 2016 meeting.

Proposed Academic Research Grant Awards

Presiding Officer Geren noted that the grant award recommendations were in the meeting materials handout titled “Proposed Grant Awards.”

Dr. Kripke reported that 12 applications went before the Scientific Review Council and eight were recommended to the Program Integration Committee (PIC). Of those eight, two (RR160028 and RR160030) declined the recruitment offers after the PIC had acted. Therefore, six awards are presented for approval by the Oversight Committee: three established investigator awards, one rising star award, and two first-time faculty awards. Total award funding being requested for recruits is \$26 million. One of the first-time faculty awards and one of the established investigator awards are in computational biology, addressing a program priority set by the Oversight Committee.

An Oversight Committee member asked if Dr. Kripke felt there should be any priority for attracting outstanding researchers to a new medical school, as opposed to an established facility with large departments. Dr. Kripke said no consideration has been given to whether the recruits were going to established or new facilities, though some candidates are faculty recruitments for the new medical school at The University of Texas at Austin.

**Academic Research Grant Award Recommendations**

<b>REC 16.4</b>				
<b>App ID</b>	<b>Candidate</b>	<b>Mechanism</b>	<b>Organization</b>	<b>Budget Request</b>
RR160029	Xiaodong Cheng	Recruitment of Established Investigators	The University of Texas M. D. Anderson Cancer Center	\$6,000,000
RR160023	Daniel Leahy	Recruitment of Established Investigators	The University of Texas at Austin	\$6,000,000
RR160027	Bing Zhang	Recruitment of Rising Stars	Baylor College of Medicine	\$4,000,000

\*Note: Grant applicant RR160028 withdrew after the Program Integration Committee met.



REC 16.5-6				
App ID	Candidate	Mechanism	Organization	Budget Request
RR160034	Luke Andrew Gilbert	Recruitment of First-Time, Tenure-Track Faculty Members	The University of Texas Southwestern Medical Center	\$2,000,000
RR160031	Filippo G. Giancotti	Recruitment of Established Investigators	The University of Texas M. D. Anderson Cancer Center	\$6,000,000
RR160032	Traver Hart	Recruitment of First-Time, Tenure-Track Faculty Members	The University of Texas M. D. Anderson Cancer Center	\$2,000,000

\*Note: Grant applicant RR160030 withdrew after the Program Integration Committee met.

#### COMPLIANCE CERTIFICATION

Mr. Vince Burgess, Chief Compliance Officer, presented his report on the review process for the grant awards being recommended to the Oversight Committee. He noted that two applications were withdrawn, RR160028 and RR160030, after he submitted his report in the meeting materials. He certified that recommended awards complied with applicable statutory and administrative requirements for the three academic recruitment award slates being presented for approval at this meeting.

#### CONFLICT OF INTEREST NOTIFICATIONS

Presiding Officer Geren noted that Mr. Angelou had reported a conflict of interest with application RR160023 submitted by The University of Texas at Austin.

#### MOTION:

Presiding Officer Geren called for a motion to approve the Program Integration Committee recommendation for a recruitment grant to The University of Texas at Austin, RR160023.

Motion made by Mr. Montgomery and seconded by Mr. Holmes.

**MOTION CARRIED UNANIMOUSLY**

Presiding Officer Geren noted for the record that Mr. Angelou abstained from voting.

#### MOTION:

Presiding Officer Geren called for a motion to approve the Program Integration Committee's recommendations for recruitment grant awards to The University of Texas

M.D. Anderson Cancer Center, The University of Texas Southwestern Medical Center and the Baylor College of Medicine.

Motion made by Mr. Montgomery and seconded by Mr. Holmes.

**MOTION CARRIED UNANIMOUSLY**

Presiding Officer Geren noted for the record that the Oversight Committee did not consider RR160028 and RR160030 because the applications were withdrawn.

**MOTION:**

Presiding Officer Geren entertained a motion to delegate contract negotiation authority to the Chief Executive Officer and CPRIT staff, and to authorize the Chief Executive Officer to sign the contracts on behalf of CPRIT.

Motion made by Mr. Montgomery and seconded by Mr. Holmes.

**MOTION CARRIED UNANIMOUSLY**

**7. Chief Prevention and Communications Officer Report (TAB 4)**

Presiding Officer Geren called on Ramona Magid, Senior Program Manager for Prevention to present for Dr. Rebecca Garcia, Chief Prevention and Communications Officer, who was unable to attend.

Prevention Program

Ms. Magid reported:

- 11 awards are currently going through the contract process.
- Applications for FY2016 Cycle 2 are due on March 3, 2016.
- Staff traveled to the Rio Grande Valley to meet with various representatives of a new medical school, local hospitals and clinics, and a CPRIT grantee.

Ms. Magid reported that in addition to the impact on the health of the people in Texas, prevention grants impact the healthcare system by fostering greater collaborations, reducing wait times for diagnostic testing, reducing the number of people lost to follow-up, implementing patient reminder systems, enhancing electronic medical records, and training community health care workers to educate and navigate people through the medical system.

Communications

Mr. Roberts stated that Dr. Garcia's Communications report was in the meeting materials but that Dr. Garcia would like to call specific attention to the comments regarding the CPRIT Innovations in Cancer Prevention and Research Conference held in November 2015. He noted that 823 people registered for the conference. According to the survey,

in terms of the location for future conferences, 39% preferred Austin, 24% Houston, 18% San Antonio, and 17% Dallas. The projected actual revenue for the conference is \$245,950 and the projected actual expenses are \$227,748, making the net revenue collected from the conference projected to be approximately \$18,000 which will be available for the next conference.

## **8. Chief Product Development Officer Report (TAB 5)**

Mr. Michael Lang, Chief Product Development Officer, reported on the activities of the Product Development program, including:

- Product Development Research Application Review Process Updates
- Product Development Review Council (PDRC) Membership
- Early Translational Research Awards (ETRA) – Business Plan Review
- Company Connections and other Activities of the Chief Product Development Officer
- Product Development Research Program Strategy
- Equity Ownership Policy
- Company Specific Issues

Mr. Lang stated that at their last meeting on November 19, 2015, the Oversight Committee approved a \$20 million grant award to Ruga Corporation (Ruga) subject to three contingencies. Ruga has successfully addressed those contract contingencies. However, after conferring with the Product Development Review Council, Mr. Lang stated it is his opinion that the requirement related to hiring a new Chief Executive Officer is no longer necessary as the company has had a Chief Executive Officer for over two years who is a medical doctor with the appropriate background for the position. After discussion with company representatives and a detailed analysis of the license agreement, he stated that he is satisfied that the 15% royalty rate is applicable only in the event that Ruga sublicenses the technology, is typical of drug industry licensing, and unlikely to be an impediment to future funding. Another concern was that a manufacturing company might ask for an additional royalty, which was successfully addressed by having several company options that will not be able to request a secondary royalty. A third concern was location of the Ruga team, which is currently in San Francisco. The current management team has committed to relocate to Texas upon approval of the award and all new hires will be based in Texas.

Mr. Lang recommended the Oversight Committee delegate authority to CPRIT's Chief Executive Officer to execute the award contract with Ruga Corporation that does not include a contingency requiring hiring of a new Chief Executive Officer (CEO) for Ruga. Mr. Lang stated that, while the primary investigator did function briefly as the CEO, Ruga has had a qualified CEO in place for a couple of years now.

Dr. Geren noted that the Ruga contract and contingencies were discussed at the February 11, 2016, Product Development Subcommittee meeting and the subcommittee recommends approval.

An Oversight Committee member asked for clarification and confirmation that under no circumstances will any manufacturing company have a royalty. Mr. Lang stated that Ruga's Chief Executive Officer has affirmed that no manufacturing company will be afforded a royalty.

Another Oversight Committee member asked about the confusion over the hiring of a Chief Executive Officer for Ruga. Mr. Lang responded that it was due to a miscommunication which probably occurred during the transition period between the resignation of his predecessor at CPRIT and his employment, a period of several months during which this award was being considered.

**MOTION:**

Presiding Officer Geren entertained a motion to authorize the Chief Executive Officer and staff to execute a contract with Ruga Corporation consistent with the Oversight Committee discussion regarding the company's activities to address the contract contingencies.

Motion was made by Mr. Montgomery and seconded by Mr. Holmes.

**MOTION CARRIED UNANIMOUSLY**

Mr. Lang then presented an overview on two subjects to provide a common context for future discussions on target funding. He presented basic information on the cancer research and development landscape and the cancer venture capital investment landscape in Texas. He next presented a high level analysis of the CPRIT portfolio.

An Oversight Committee member asked for more information on the low-risk, high-risk ventures. Mr. Lang stated that the pharmaceutical companies have been highly studied. Many compounds are screened to identify those that are seemingly good drug candidates and about 4-5% of drug candidates that start the process actually get approved by the Food and Drug Administration (FDA). He explained that it is a multi-step process and there's attrition at various stages of the process. The preponderance of the failures happen in the first part of the process, before a full investment has been made. Because of the biological complexity involved, the attrition rate in pharmaceutical development is higher than in many other industries.

An Oversight Committee member asked where CPRIT investments fall on the spectrum of drug discovery to FDA approval, i.e., low, middle, high risk. Mr. Lang responded that CPRIT investments are mostly in the middle. Most drug FDA approvals are in the large pharmaceutical companies. Most of CPRIT investments are in the pre-clinical stage and can be expected to be sold to a large pharmaceutical company for final development.

An Oversight Committee member asked for information that categorizes companies by stage of development to be considered in the workshop on funding guidance. Mr. Lang said he has that information developed and will share it with the Oversight Committee prior to the workshop.

Another Oversight Committee member asked if within the US cancer research and development landscape devices and diagnostics are taking off and if CPRIT focuses too much on those instead of other promising areas that are coming up. Mr. Lang noted that in cancer there has been a revolution in diagnostics in the last 10 years. Molecular diagnostics are advancing cancer treatment significantly. The Oversight Committee member asked if the infrastructure that is needed to develop diagnostics and devices differs from the infrastructure needed for drug development. Mr. Lang responded that some of the infrastructure is the same, but much is different because the technologies are substantially different. He stated medical devices have been responsible for a significant impact in cardiovascular disease, but much less so in cancer due to the nature of the disease that has historically not lent itself to device therapies.

There were no further questions for Mr. Lang.

**9. University Advisory Committee – Annual Report (Tab 9) (*Agenda Item 12 taken out of order*)**

Presiding Officer Geren introduced Dr. Mary Ann Ottinger, Vice-Chair of the University Advisory Committee (UAC) and Associate Vice-Chancellor for Research at the University of Houston, to present the UAC's annual report to the Oversight Committee.

Dr. Ottinger noted that the UAC annual report is in the meeting materials.

There were no questions for Dr. Ottinger.

**10. Advisory Committee on Childhood Cancer – Annual Report (Tab 8) (*Agenda Item 11 taken out of order*)**

Presiding Officer Geren introduced Dr. Susan Blaney, Chair of the Advisory Committee on Childhood Cancer (ACCC) and Deputy Director of the Texas Children's Cancer Hematology Center and Executive Vice-Chair of the Department of Pediatric Oncology at Baylor College of Medicine. Dr. Blaney presented the ACCC annual report to the Oversight Committee. The report is also in the meeting materials.

Dr. Blaney also noted that the ACCC membership subcommittee discussed the instance in which an institution is a member, should it have more than one member, and if so, who? The committee decided that current members should maintain membership, but that input should be increased from across the pediatric oncology community in underserved areas of Texas. Therefore, ACCC proposes that non-member institutions nominate a non-voting member to serve on the advisory committee. Criteria would then be developed for non-voting members to ultimately become members. The subcommittee would also like to include ad hoc members as appropriate, increase the term of membership to three years with a limit of two terms, initiate membership rotation over the next year for continuity, and

modify the by-laws as appropriate.

An Oversight Committee member asked if the \$10 million dollars in peer review funding to CPRIT-funded investigators was for the last year or the life of CPRIT. Dr. Blaney responded it was for the last year.

An Oversight Committee member asked if all members of the ACCC are from academic institutions. Dr. Blaney responded that currently, except for advocates, there is only one practicing pediatric oncologist on the committee with the remainder from academic institutions, which is why they recommend expanding the membership.

An Oversight Committee member asked if there are certain diseases that should be prioritized or de-prioritized by CPRIT—possibly that funding for diseases with very high cure rates should be decreased and funding for some incurable cancers be increased. Dr. Blaney responded that the answer is multifaceted. While many childhood cancers are now 80% curable, the non-targeted cures come with significant long-term side effects that lead to higher morbidity in adulthood. That means much research still needs to be dedicated to minimizing the toxicity of current therapies.

There were no further questions for Dr. Blaney. Presiding Officer Geren stated that the process for considering the recommendations coming from the advisory committees was unclear and stated it would be helpful to the Oversight Committee if staff put together a response to each of their recommendations. Dr. Kripke responded that, in the past, the advisory committees' comments were discussed in the Research Subcommittee of the Oversight Committee. Staff would then discuss point by point with the advisory committee to let them know which recommendations could be implemented and how, or why CPRIT could not implement a recommendation, so that there is continual dialogue. Going forward, Presiding Officer Geren stated he would like to have a summarization of the recommendations and CPRIT responses presented to the full Oversight Committee.

## **11. Scientific Research and Prevention Program Committee Appointments (TAB 6)** *(Agenda Item 9 taken out of order)*

Mr. Roberts presented the nomination of Dr. Karen Patricia Williams to the Scientific Research and Prevention Program Committee. Mr. Roberts also stated that Dr. Neil Spector and Dr. Robert Sarisky have been appointed to the Product Development Review Council but do not require Oversight Committee action because they are current members of the Scientific Research and Prevention Program Committee.

Presiding Officer Geren noted that the Nominations Subcommittee had recommended approval of Dr. Williams' proposed nomination.

### **MOTION:**

Presiding Officer Geren called for a motion to approve appointment of Dr. Karen Patricia Williams to the Scientific Research and Prevention Program Committee.

Motion was made by Dr. Rosenfeld and seconded by Mr. Montgomery.

**MOTION CARRIED UNANIMOUSLY**

**12. Health & Safety Code § 102.1062 Waiver (TAB 7) (*Agenda Item 10 taken out of order*)**

Mr. Roberts presented the proposed conflict of interest waiver for FY 2016 for Program Integration Committee member Dr. John Hellerstedt, Commissioner of the Department of State Health Services.

**MOTION:**

Presiding Officer Geren called for a motion to approve the proposed conflict of interest waiver for Dr. Hellerstedt.

Motion was made by Dr. Rosenfeld and seconded by Mr. Holmes.

**MOTION CARRIED UNANIMOUSLY**

**13. Chief Operating Officer Report (Tab 10)**

Ms. Heidi McConnell, Chief Operating Officer, presented a report on CPRIT's fiscal year 2016 1<sup>st</sup> quarter financial overview, fiscal year 2016 1<sup>st</sup> quarter performance measures, and debt issuance history. She highlighted that, in terms of revenue, CPRIT collected \$171,000 in conference fee registrations in November which was added to about \$35,000 collected previously. CPRIT is still receiving conference registration payments. She also highlighted the debt issuance history. At the beginning of fiscal year 2015, CPRIT requested that the Texas Public Finance Authority issue \$55.4 million in commercial paper notes on CPRIT's behalf to provide funds for CPRIT's fiscal year 2016 operating costs and grant award payments. The amount issued on CPRIT's behalf since the prior year totals \$300 million in General Obligation Commercial Paper Notes, which includes \$69.8 million for anticipated grant award expenses.

There were no questions for Ms. McConnell.

**14. Internal Auditor Services Contract ( Tab 11)**

Ms. McConnell presented the staff recommendation to contract with Weaver and Tidwell for CPRIT's internal audit service contract for fiscal year 2016 in the amount of \$232,500, including three one-year renewal options through the end of fiscal year 2019.

There were no questions for Ms. McConnell.

**MOTION:**

Presiding Officer Geren called for a motion to approve Weaver and Tidwell to perform internal audit services for fiscal year 2016.

Motion made by Mr. Holmes and seconded by Mr. Angelou.

**MOTION CARRIED UNANIMOUSLY**

### **15. Chief Compliance Officer Report (TAB 12)**

Mr. Vince Burgess, Chief Compliance Officer, reported on the activities of the Compliance program. He noted that CPRIT has made an effort to increase internal communications and work with grantees to ensure that grantee reports are filed on time. Though a certain percentage of the approximately 500 reports due each month is expected to be missing or delinquent, statistics show a continued downward trend in terms of delinquent reports. The 13 delinquent reports on January 29, 2016, included 2 that were single audit determinations forms, 2 that were progress reports, 2 matching forms, and 7 financial status reports (FSRs). Mr. Burgess reported that 6 or 7 of the delinquencies were the result of a new grant being executed, which results in the system immediately showing subsequent reports due.

Mr. Burgess stated that at the November 19, 2016, Oversight Committee meeting staff was asked to perform an analysis of the reporting required by grantees. A report was presented to the Board Governance Subcommittee and prepared for the Audit Subcommittee. He stated that the report was located in the meeting materials along with a matrix of all required reports with associated information on who files, due dates, and applicable Texas Administrative Code and/or the Uniform Grant Managements Standards reference. Mr. Burgess said that the most common feedback from grantees concerns the amount of documentation required on the FSRs. Much of this need comes from State Auditor recommendations, internal audit recommendations, and financial audit findings indicating CPRIT had not required sufficient documentation. Therefore, CPRIT requires documentation for any expenses of \$750 and over in some budget categories. For other budget categories, CPRIT requires full documentation.

An Oversight Committee member asked if staff requests clarification or questions regarding why the state asks for more documentation. Mr. Roberts responded findings are mostly derived from the January 2013 State Auditor's Office audit where 52 recommendations were made. Ten were directed to the Legislature. At the time, Mr. Roberts directed staff to accept all of the other recommendations unless they prohibited CPRIT from doing its job effectively. Additionally, Ms. Doyle stated that most of the 52 recommendations were incorporated by the Legislature into the CPRIT statutes.

An Oversight Committee member asked if the multiple reports due at the fiscal year end could be combined into one. Ms. Doyle responded that some of the year end reports cover different information from the annual reports. She stated that at one time all the different information was submitted as part of the annual progress report. Using this approach was difficult when disseminating the information to the various individuals that reviewed differing parts of the report. It was also difficult to remedy the problems arising from some parts of the report not being fully completed before submission. It has been determined it is no more difficult for the grantees to submit the information in separate reports, though it does



make their reporting requirements appear greater.

**16. Proposed Amendments to 25 T.A.C. Chapters 702 and 703 and Authorization to Publish in *Texas Register* (Tab 13)**

Ms. Kristen Doyle presented the proposed rule changes for 25 T.A.C. Chapters 702 and 703, which affect professional conflicts of interest, limitation on the use of grantee funds, and financial status report reimbursement reviews. Mr. Holmes, Chair of the Board of Governance Subcommittee, noted that the subcommittee recommended the Oversight Committee approve publication of the changes in the *Texas Register*.

**MOTION:**

Presiding Officer Geren called for a motion to approve the proposed rule changes for publications in the *Texas Register* for public comment.

Motion made by Mr. Montgomery and seconded by Dr. Rosenfeld.

**MOTION CARRIED UNANIMOUSLY**

**17. Final Order Approving Amendments to 25 T.A.C. Chapter 703 (Tab 14)**

Ms. Doyle presented for final approval by the Oversight Committee the amendments to 25 T.A.C. Chapter 703, which affect grant applications, matching funds, the prevention cap, no cost extension approval, tobacco-free policy waivers, grantee report due dates and the report approval process. These rule changes were preliminarily approved at the November 2015 Oversight Committee meeting. They were published in the *Texas Register* and public comments from two institutions were received and addressed.

**MOTION:**

Presiding Officer Geren called for a motion to approve the final order adopting CPRIT's rule changes and to direct staff to file the order with the Secretary of State.

Motion made by Mr. Montgomery and seconded by Mr. Holmes.

**MOTION CARRIED UNANIMOUSLY**

**18. Subcommittee Business (*Agenda Item 19 taken out of order*)**

Presiding Officer Geren noted for the record that there was nothing to discuss under this standing item regarding subcommittee business.

**19. Compliance Investigation Pursuant to Health & Safety Code § 102.2631 (*Agenda Item 22*)**

Presiding Officer Geren noted for the record that there was nothing to discuss under this standing item.

**20. Future Meeting Dates and Agenda Items (*Agenda Item 24 taken out of order*)**

The next regular Oversight Committee meeting will be May 18, 2016, at 10:00 a.m.

**Special Presentation Honoring Dr. Margaret Kripke**

Presiding Officer Geren recognized Dr. Margaret Kripke's retirement from CPRIT effective March 16, 2016. Mr. Roberts presented Dr. Kripke with a certificate from the Governor of Texas in appreciation of her service to Texas. Presiding Officer Geren proposed a resolution honoring Dr. Kripke for her service as Chief Scientific Officer for CPRIT.

**MOTION:**

Presiding Officer Geren called for a motion to approve the proposed resolution honoring Dr. Kripke for her service as Chief Scientific Officer for CPRIT.

Motion made by Dr. Rice and seconded by Mr. Montgomery.

**MOTION CARRIED UNANIMOUSLY**

- 21. Proposed Settlement – Peloton Therapeutics (*Agenda Item 21 taken out of order*)**
- 22. Public Information Act and Open Meeting Act Update Training (Tab 15) (*Agenda Item 18 taken out of order*)**
- 23. Personnel – Chief Executive Officer Annual Evaluation (*Agenda Item 20 taken out of order*)**
- 24. Consultation with General Counsel (*Agenda Item 23 taken out of order*)**

Presiding Officer Geren announced the Oversight Committee would go into closed session to take up out of order and together: Item 18, Public Information Act and Open Meeting Act Update Training; Item 20, Personnel – Chief Executive Officer Annual Evaluation; Item 21, Proposed Settlement – Peloton Therapeutics; and Item 23, Consultation with General Counsel; and will seek legal advice in closed session.

Pursuant to Texas Open Meetings Act Section 551.071 and 551.074, the Oversight Committee went into closed session to consult with legal counsel and discuss personnel matters. The following CPRIT staff were asked to join the Oversight Committee in the closed session: Kristen Doyle, Wayne Roberts, and Cameron Eckel.

Presiding Officer Geren convened in closed session at 12:33 p.m.

Presiding Officer Geren reconvened the open meeting at 2:03 p.m.

**MOTION:**

Presiding Officer Geren called for a motion to authorize the Chief Executive Officer to negotiate and execute a settlement with Peloton Therapeutics consistent with the guidance and terms discussed during closed session.

Motion made by Mr. Holmes and seconded by Mr. Margo.

**MOTION CARRIED UNANIMOUSLY**

**25. Adjourn**

**MOTION:**

There being no further business, Presiding Officer Geren made a motion to adjourn.

Motion was seconded by Mr. Montgomery.

**MOTION CARRIED UNANIMOUSLY**

Meeting adjourned at 2:05 p.m.

*Cory M. Mitchell*  
Signature

5/18/16  
Date