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An Audit Report on

Grant Management at the Cancer Prevention and Research Institute of Texas and Selected Grantees

January 2013 Report No. 13-018



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Overall Conclusion

The Cancer Prevention and Research Institute of Texas (CPRIT) should significantly improve the transparency and accountability of its grant management processes. Weaknesses in CPRIT's processes reduce its ability to properly award and effectively monitor its grants. Specifically, CPRIT should address deficiencies in the following areas:

- > Making award decisions.
- > Evaluating grant applications.
- Verifying compliance with matching funds requirements.
- > Processing payments to grantees.
- > Monitoring grantees' expenditures.
- Assessing and measuring research progress.
- Managing contract agreements with grantees.

Making Award Decisions

CPRIT should ensure that all award decisions are free from real or apparent conflicts of interest. The executive director discussed award recommendations with certain members of the oversight committee prior to presenting the recommendations to the full oversight committee. Also, CPRIT's chief scientific officer, chief commercialization officer, and director of scientific review had office locations on the campuses of higher

Cancer Prevention and Research Institute of Texas

In 2007, Texas voters approved a constitutional amendment establishing the Cancer Prevention and Research Institute of Texas (CPRIT), which may receive bond funding of \$300 million on an annual basis to fund its grants and associated operating costs. The total amount of bonds that can be issued for CPRIT cannot exceed \$3.0 billion. From September 1, 2009, through August 31, 2012, approximately \$363.5 million in bond debt was issued to support CPRIT (see Appendix 8 for more information). As of October 1, 2012, the Texas Public Finance Authority had paid debt service that totaled \$30.9 million in principal and interest payments on CPRIT's bond debt.

As of August 31, 2012, CPRIT reported it had awarded 575 grants totaling approximately \$797.8 million, for which it reported disbursing \$104.2 million in reimbursements and \$40.2 million in advance payments (see Appendices 2 and 4 for more information on grants and payments, respectively).

CPRIT awards three categories of grants:

- Prevention Grants These grants fund prevention services such as outreach, screenings, and training of health professionals. CPRIT is statutorily limited to awarding no more than 10 percent of its funds for prevention grants during any year.
- Research Grants These grants support various types of cancer research projects, including basic research, translational research, and clinical applications. In addition, research grants support the recruitment and retention of distinguished researchers, enhancements to research facilities, and the acquisition of major research equipment.
- Commercialization Grants These grants finance the development of products and services for cancer treatments by new or existing businesses.

For fiscal year 2012, CPRIT was appropriated 24 full-time equivalent (FTE) positions. For the quarter ending August 31, 2012, CPRIT had 23.3 FTE employees. CPRIT is governed by an oversight committee that consists of the following 11 members:

- Three members appointed by the Governor.
- Three members appointed by the Lieutenant Governor.
- Three members appointed by the Speaker of the House of Representatives.
- The Comptroller of Public Accounts or the Comptroller of Public Accounts' designee.
- The Attorney General or Attorney General's designee.

education institutions that received CPRIT awards. The chief scientific officer, the chief commercialization officer, and the director of scientific review are responsible for managing the peer review process for grant applications in their respective areas. In addition, auditors identified two members of CPRIT's commercialization review council with financial and personal interests in certain grantees. Specifically:

- > One member of the commercialization review council was also a member of the board of directors for a grantee that received a \$25.2 million research award from CPRIT. According to CPRIT's records, that individual did not participate in the review of the grant application for that grantee.
- > Another member of the commercialization review council provided consulting services to two applicants applying for Texas life sciences incubator commercialization grants. That individual was not listed as participating in the review of grant applications for incubator grants, and neither applicant ultimately submitted a formal application for an incubator grant.

CPRIT also reported that it does not receive financial information about donors to the CPRIT Foundation or the amounts of the donations. Without that information, CPRIT has no assurances that it is not awarding grants to the CPRIT Foundation donors, which could create a conflict of interest. The General Appropriations Acts (81st and 82nd Legislatures) state that an individual; an organization; or an employee, officer, or director of an organization that makes a contribution to the CPRIT Foundation, or a person who has second-degree consanguinity or affinity to an employee of CPRIT, is not eligible to receive grants from CPRIT.

CPRIT's lack of controls for ensuring there are not any business and professional relationships between its peer reviewers and grantees impairs CPRIT's ability to assure the public that its award decisions are not improperly influenced.

Evaluating Grant Applications

CPRIT should ensure that its policies and procedures for evaluating grant applications are up to date and consistently followed. In addition, CPRIT should maintain records of all reviews that are performed.

Auditors could not verify that CPRIT consistently followed its process for withdrawing grant applications from the peer review process. CPRIT did not have reliable data to support grant applications that were withdrawn (see Chapter 1-B for more information).

Auditors identified the following significant issues for three grant applications tested:

➤ The Statewide Clinical Trials Network of Texas (CTNeT) received a \$25.2 million research grant from CPRIT even though CTNeT did not exist at the time the grant was awarded. The CTNeT grant was the largest single grant that CPRIT had awarded as of June 2012. CPRIT originally awarded the grant to the University

of Texas M.D. Anderson Cancer Center in June 2010. Subsequent to the award, CTNeT was formed and registered to become a Texas-based non-profit company in August 2010 and CPRIT executed a grant agreement with CTNeT in September 2010. It is unclear what allowed CPRIT to transfer the award from the University of Texas M.D. Anderson Cancer Center to CTNeT. CPRIT also did not have documentation to support that the scientific review council recommended the original application for a grant.

- CPRIT awarded a \$20.0 million commercialization grant to the Houston-Area Translational Research Consortium (HATRC) and the Institute for Applied Cancer Science (IACS). Neither the HATRC grant application nor the IACS research proposal received scientific, due diligence, or intellectual property reviews. CPRIT reported that it rescinded the award in May 2012 after IACS requested to resubmit its research proposal for commercialization and scientific reviews.
- CPRIT awarded an \$11.0 million commercialization grant to Peloton Therapeutics Inc. (Peloton, formerly Damascus Pharmaceuticals), whose application did not receive scientific, commercialization, due diligence, or intellectual property reviews.

Auditors reviewed the peer review scores for 218¹ (5.9 percent) of the 3,698 grant applications CPRIT reported receiving from September 2009 through June 2012 through the CPRIT Application Receipt System. Auditors identified four applications for which the peer review scores were not consistent with receiving a grant recommendation. CPRIT also did not have documentation to support the factors that peer reviewers used in making grant recommendations to CPRIT's executive director.

In addition, CPRIT did not document its review of recruitment grant applications or maintain records of those reviews in its Peer Review Management Information System. Recruitment grants are for the recruitment of investigators with the ability to make outstanding contributions to the field of cancer research, promote inquiry into new areas, foster collaboration, and stimulate growth in the field. Select scientific review council members manually review the recruitment grant applications; however, the only documentation maintained was a one-page summary statement that recommends the award of a recruitment grant. As of August 2012, CPRIT had awarded 60 recruitment grants totaling \$184.9 million.

By not ensuring that <u>all</u> grant applications are properly evaluated and documented, CPRIT weakens its ability to ensure that its award decisions best align with the agency's mission.

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¹ Auditors reviewed 159 research grant applications, 49 prevention grant applications, and 10 commercialization grant applications.

Verifying Compliance with Matching Funds Requirements

CPRIT should verify the accuracy and availability of the matching funds its grantees report. The Texas Constitution, Article III, Section 67 (a)(3)(i), requires that before CPRIT awards a grant, the grantee must have funds equal to one-half the amount of the grant dedicated to the research that is the subject of the grant. CPRIT requires grantees to certify the amount of matching funds available for research at (1) the time of contract execution and (2) on an annual basis thereafter. However, CPRIT did not verify the accuracy and availability of the matching funds reported. In addition, during site visits to five grantees, auditors identified two methodologies, permitted by CPRIT, that allow a grantee to report funds that were not used on a CPRIT-funded research project as matching funds. Specifically:

- > During interviews with auditors, staff at the University of Texas M.D. Anderson Cancer Center, the University of Texas Southwestern Medical Center, and the Baylor College of Medicine reported that the matching funds those institutions reported to CPRIT were based on the total amount of funding available to them for cancer research, excluding CPRIT funding. However, those reported matching funds were not dedicated to CPRIT-funded research projects. As of August 2012, those three institutions had received a combined 331 awards totaling \$402.4 million.
- ➤ CTNeT, which received a \$25.2 million research grant, did not dedicate \$12.6 million in matching funds as required. Instead, CPRIT accepted certifications that the University of Texas M.D. Anderson Cancer Center and the Baylor College of Medicine would fulfill CTNeT's matching funds requirements for the first and second year of the grant agreement term, respectively. However, CTNeT did not receive those reported matching funds. For the first year of the CTNeT grant, CTNeT reported that the CPRIT grant accounted for 98.0 percent of its total revenue.

Processing Payments to Grantees

CPRIT should establish requirements to help ensure the appropriateness of advance payments and reimbursements it makes to grantees. Specifically:

- > Advance payments. CPRIT's policies and procedures specify that CPRIT will distribute funds on a reimbursement basis. However, it made advance payments that totaled \$40.2 million to 10 grantees from September 2008 through August 2012.
- ➤ Reimbursements. CPRIT relies on quarterly financial status reports and supporting documentation that grantees submit for reimbursement payments. However, CPRIT did not always obtain sufficient documentation from grantees to support the appropriateness of the reported expenditures. For 85 (84.1 percent) of the 101 reimbursements tested, or \$9.4 million in reimbursements, CPRIT did not obtain documentation such as time sheets, invoices, contracts, and bill

records to support the reimbursed expenditures. For those 85 reimbursements, grantees typically provided CPRIT with spreadsheets that summarized the expenditures.

Monitoring Grantees' Expenditures

CPRIT should improve its processes for monitoring grantee expenditures. CPRIT requires grantees to submit quarterly financial reports on research expenditures associated with awarded grants. In addition, CPRIT established a desk review process to assess grantees' financial controls and reported expenditures. However, CPRIT did not ensure that all grantees submitted financial reports in a timely manner, did not maintain a complete record of all the financial reports it received from grantees, and had not performed any desk reviews of 487 grants totaling approximately \$683 million as of June 2012.

Assessing and Measuring Research Progress and Compliance with Grant Milestones

CPRIT should ensure that grantees submit all required annual progress reports by required due dates, and it should review those reports and document those reviews. While CPRIT developed monitoring tools for tracking the due dates and submissions of annual progress reports, CPRIT lacked documentation to support that it followed up with grantees for past due reports. For a sample of 20 grant agreements that auditors reviewed, CPRIT had not received 12 (60 percent) of 20 annual progress reports that were due from September 2011 through June 2012. CPRIT's records indicated that it had started following up with grantees about past due reports beginning in May 2012. In addition, CPRIT has not developed review criteria for evaluating and measuring a grantee's reported progress. Although CPRIT used its peer reviewers to evaluate the eight annual progress reports it received, the peer reviewers did not document whether a grantee's reported progress met grant milestones or whether any problems had been identified that could affect the grantee's ability to complete the research project. CPRIT reported that it received emails from the peer reviewers indicating that a review was complete and that no issues had been reported by reviewers.

CPRIT should improve its management of the CTNeT research grant and other administrative practices.

Auditors identified significant weaknesses in CPRIT's award decision and management of the \$25.2 million research grant to CTNeT (see Chapter 3 for more information about this grant). Specifically:

> CTNeT's grant application did not receive a favorable peer review score. CPRIT evaluated grant applications on a scale of 1 to 9, with 1 being the highest. The CTNeT grant application received a peer review score of 4.64. Auditors reviewed the peer review scores for 44 other applications and identified 9 applications that were not awarded grants that received peer review scores ranging from 3.93 to 4.40.

- > CPRIT has a role in CTNeT's business operations. CPRIT's oversight committee chair, vice-chair, and executive director interviewed and hired CTNeT's chief operating officer before the contract was executed. In addition, CPRIT's executive director, chief scientific officer, and a member of CPRIT's commercialization review council are members of CTNeT's board of directors.
- ➤ CPRIT made \$6.8 million in advance payments to CTNeT even though its grant agreement with CTNeT allowed only reimbursement payments.
- > CTNeT did not comply with matching funds requirements and annual progress reporting requirements.

CPRIT's relationship with CTNeT and its lack of enforcing contract requirements impair CPRIT's ability to ensure that CTNeT is properly using grant funds and complying with grant requirements.

CPRIT also should improve certain procurement and payment practices for vendors and other professional services.

CPRIT should strengthen its vendor procurement and payment practices to ensure that the services and costs for grant management services and virtual management company services are reasonable and necessary. Specifically:

- ➤ The costs for a five-year contract for grant management services increased from \$15.7 million to \$21.2 million (35.2 percent) within the first three years of the contract. The cost increases were based on amendments to the contract that increased the workload of the grant management services contractor and the development of a grant management system.
- > The costs for the first two years of a four-year contract for virtual management company services increased from \$1.5 million to \$4 million, approximately 166.7 percent. The cost increases were based on amendments to include services management, an entrepreneur-in-residence program, salaries for additional executive positions that were added to the contractor's staff, and other direct costs.

CPRIT also did not consistently obtain sufficient documentation to support the appropriateness of honorarium payments it made to its peer reviewers. From September 2009 through June 2012, honorarium payments to peer reviewers were approximately \$6.7 million. In addition, CPRIT lacked documentation to justify increases in honorarium payments to officers of its peer review committees. Also, auditors identified honorarium payment amounts for certain peer reviewers that may be significantly higher than the payment amounts that the National Cancer Institute pays its peer reviewers.

Auditors communicated other, less significant issues to CPRIT's management separately in writing. Those issues were related to administrative reporting discrepancies, the forms grantees use for reporting, reporting practices for certain

grantees' payment practices, performance feedback to grantees, executing grant agreements, and management of peer reviewer rosters.

The Legislature should consider amending statutory requirements to improve the transparency and accountability of CPRIT.

The Legislature should consider statutory requirements to:

- > Allow peer reviewers to provide their grant recommendations to the executive director and members of the CPRIT oversight committee at the same time.
- Clarify what funds can be used and the intended use of matching funds reported by grantees.
- Clarify whether contributions made by non-profit foundations affiliated with grantees are appropriate.
- ➤ Prohibit an interlocking directorate between CPRIT and the CPRIT Foundation.
- Prohibit CPRIT employees from serving on a grantee's board of directors and related foundations.
- ➤ Clarify the positions of the oversight committee's presiding officer and other officers, including the responsibilities and specific term of service for those positions.
- > Allow members of the oversight committee to affirmatively vote to approve the executive director's recommendations.
- > Remove the Attorney General and the Comptroller of Public Accounts from CPRIT's oversight committee so that their statutory duties and responsibilities would not be impaired.
- Allow the executive director to provide CPRIT's oversight committee, along with grant recommendations, documentation of the other factors that the executive director considered when making grant recommendations.
- > Require the CPRIT Foundation to make its records, books, and reports available to the public.

Summary of Management's Response

CPRIT management generally agreed with the recommendations in this report. CPRIT's detailed management responses are presented immediately following each set of recommendations in the Detailed Results section of this report.

Summary of Information Technology Review

Auditors did not assess the reliability of the data provided by CPRIT's Peer Review Management Information System and the CPRIT Application Receipt System. Both information systems are proprietary systems supported by CPRIT's grant management services contractor and were physically located outside of Texas. CPRIT had not examined the controls over those two systems. As a result, CPRIT had not obtained assurances that the data and reports from those two systems were sufficiently reliable to support management decisions for awarding and managing grants. Auditors were unable to determine whether the data in CPRIT's Peer Review Management Information System and the CPRIT Application Receipt System were sufficiently reliable for purposes of this audit.

Auditors assessed the reliability of accounting data based upon prior audit work performed for the Uniform Statewide Accounting System (USAS) and determined that the data in that system was reliable for purposes of this audit. Auditors also performed a general controls review of logical security of CPRIT's applicable networks and network folders and determined that data maintained on the CPRIT network was reasonably secured.

Summary of Objectives, Scope, and Methodology

The objectives of this audit were to:

- ➤ Determine whether CPRIT has processes and related controls to help ensure that grantees perform in accordance with the terms of their grants.
- ➤ Determine whether CPRIT has processes and related controls to help ensure that grants are awarded in accordance with state law, rules, and CPRIT policies and procedures.

The scope of this audit covered the period from September 1, 2008, through June 30, 2012. Auditors collected financial information related to the revenues and expenditures of the CPRIT Foundation and conducted interviews with the CPRIT Foundation management and staff. However, the CPRIT Foundation was not audited as part of this audit of CPRIT.

The audit methodology included collecting information and documentation related to CPRIT, performing selected tests and other procedures, analyzing and evaluating the results of the tests, and conducting interviews with CPRIT management and staff. Auditors also performed site visits at five grantees. Those visits included performing physical inspections of laboratories and equipment purchases, testing samples of research expenditures and matching funds certifications, and conducting interviews with grantee staff. See Appendix 1 for detailed methodology information.

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Detailed Results

Chapter 1

CPRIT Should Improve the Transparency and Accountability Associated with Its Grant Decisions

Auditors identified significant issues that weaken the ability of the Cancer Prevention and Research Institute of Texas (CPRIT) to ensure the transparency and accountability associated with its grant decisions. Specifically:

- Auditors identified business and professional relationships among certain grantees and CPRIT's management, CPRIT's commercialization review council, and donors who contributed to the CPRIT Foundation.
- Two commercialization grant applications and a research grant application tested were not evaluated according to CPRIT's policies and procedures. CPRIT's executive director² recommended those three grant applications for grants, but peer review councils did not recommend them for grants. Those three grant applications were awarded a total of approximately \$56.3 million in grants.
- CPRIT allowed grantees to report funds as matching funds when the grantees did not spend those funds on CPRIT-funded research projects, which is not consistent with the Texas Constitution requirement for matching funds. The Texas Constitution requires grantees to have matching funds that are (1) equal to one-half of the grant amount they receive and (2) dedicated to the research that is the subject of the grant they receive.

CPRIT should correct these issues to assure the Legislature and the public that its grant decisions are not improperly influenced and are based on a thorough assessment of a grant application's scientific merit, commercialization prospects (if applicable), and compliance with matching funds requirements in statute and CPRIT rules.

² In this report, references to the CPRIT executive director, chief commercialization officer, and chief scientific officer are references to the individuals who were in those positions during the scope of this audit (September 2008 to June 2012). Those individuals have resigned from CPRIT.

Chapter 1-A

CPRIT Should Ensure That All Grant Decisions Are Free from Real or Apparent Conflicts of Interest

Auditors identified business and professional relationships that could impair or influence the independence and professional judgment of CPRIT's decision makers. Specifically:

- The CPRIT executive director discussed grant recommendations with the oversight committee chair and vice-chair before presenting those recommendations to the full oversight committee. This creates a situation in which some members of the oversight committee may have influenced the executive director's grant recommendations. In addition, some members of the oversight committee had information related to grant applications that other members did not have in order to make award decisions.
- CPRIT leased office space from two grantees: Rice University and the University of Texas Southwestern Medical Center. That office space was for CPRIT's chief commercialization officer, chief scientific officer, and director of scientific review.
- CPRIT's executive director, chief scientific officer, two members of the commercialization review council, and the virtual management company services contractor had business and professional relationships with grant applicants and grantees.
- CPRIT did not have processes to prevent it from awarding grants to applicants that made contributions to the CPRIT Foundation. The CPRIT Foundation received contributions from non-profit foundations affiliated with higher education institutions that received grants. It is important to note that auditors did not perform a detailed comparison between donors that made contributions to the CPRIT Foundation and applicants for CPRIT grants.
- Some members of CPRIT's commercialization review council, which serve as peer reviewers, had residences in Texas. This is inconsistent with the portion of CPRIT's strategic plan that called for prevention and scientific peer reviewers to live and work outside of Texas to minimize the potential for conflicts of interests.

In addition, CPRIT's policies allowed peer reviewers who had conflicts of interest to participate in the peer review process as long as they did not review the specific grant applications with which they had a conflict of interest. However, those peer reviewers can review the applications of other applicants that may be competing for the same grant funds. CPRIT also did not maintain consistent and reliable documentation to show that peer reviewers recused

themselves from the peer review process when they reported having conflicts of interest.

The CPRIT executive director discussed certain grant recommendations with individual members of the oversight committee before presenting those recommendations to the full oversight committee.

By discussing grant recommendations with some members of the oversight committee, the executive director created a situation in which grant recommendations may have been influenced by those committee members. Emails concerning grant recommendations for the Texas life sciences incubator commercialization grant and multi-investigator research grants that were going to be presented at the March 29, 2012, oversight committee meeting indicated the following:

The chief commercialization officer, the chief scientific officer, the
executive director, and a member of the oversight committee discussed the
grant recommendations for the Texas life sciences incubator

Grant Recommendation Factors

Texas Health and Safety Code, Section 102.251, requires the CPRIT executive director to give priority to grant applications that:

- Could lead to immediate or long-term medical and scientific breakthroughs in prevention or cures for cancer;
- Strengthen science in cancer research;
- Ensure a comprehensive coordinated approach to cancer research;
- Are interdisciplinary or interinstitutional;
- Address federal or other major research sponsors' priorities in emerging scientific or technology fields in the area of cancer prevention or cures for cancer;
- Are matched with funds available by a private or nonprofit entity and institution or institutions of higher education;
- Are collaborative between any combination of private and nonprofit entities, public or private agencies or institutions in this state, and public or private institutions outside this state:
- Have a demonstrable economic development benefit to the state of Texas;
- Enhance research superiority at institutions of higher education resources; and
- Expedite innovation and commercialization that will drive a substantial increase in high-quality jobs, and increase higher education research capabilities.

In addition, CPRIT's rules specify that priority for funding for cancer research and cancer prevention applications will be given to proposals that use money from the Cancer Prevention and Research Fund or the proceeds of general obligation bonds issued on behalf of CPRIT to obtain additional cancer research and prevention funding from other sources.

Sources: Texas Health and Safety Code, Section 102.251, and Title 25. Texas Administrative Code, Section 703.6(a)(7).

- commercialization grant in emails dated on March 12, 2012; March 13, 2012; and March 14, 2012. Those emails included information regarding whether individual grants or a joint grant should be recommended to Rice University (specifically, the Houston-Area Translational Research Consortium) and the University of Texas M.D. Anderson Cancer Center (specifically, the Institute of Applied Cancer Science).
- The executive director, the oversight committee chair, and the oversight committee vice-chair discussed grant recommendations for multi-investigator research grants in emails dated March 9, 2012; March 10, 2012; and March 14, 2012. Those emails included information on how to allocate the number of grant recommendations to the University of Texas Southwestern Medical Center.

Texas Health and Safety Code, Section 102.251(a)(2), requires the CPRIT executive director to submit recommendations to the oversight committee and requires that those recommendations be substantially based on the recommendations made by CPRIT's peer review councils and, to the extent possible, other factors as defined in statute (see text box for additional information).

The CPRIT chief commercialization officer, chief scientific officer, and director of scientific review had offices in space that CPRIT leased from grantees.

CPRIT's chief commercialization officer, chief scientific officer, and director of scientific review maintained satellite office locations as part of their employment with CPRIT. The director of scientific review worked alongside the chief scientific officer in the same satellite office location. Specifically:

- CPRIT leased office space on the campus of Rice University for its chief commercialization officer.
- CPRIT leased office space on the campus of the University of Texas Southwestern Medical Center for the chief scientific officer and director of scientific review.

While the chief commercialization officer, the chief scientific officer, and the director of scientific review are not involved in making or approving grant recommendations, leasing space for their offices from grantees creates a risk that grant recommendations related to those grantees could be improperly influenced.

The CPRIT executive director, chief scientific officer, certain members of the commercialization review council, and an employee of a contractor providing services to CPRIT had business and professional relationships with grantees.

Grant application evaluation scores, summary statements, and general background information on selected grantees revealed the following relationships that may have impaired CPRIT's independence and influenced certain grant recommendations:

- The CPRIT executive director, chief scientific officer, and a member of CPRIT's commercialization review council are members of the board of directors of the Statewide Clinical Trials Network of Texas (CTNeT). While they were appointed to the CTNeT board after CPRIT awarded a grant to CTNeT, their membership on the CTNeT board gives the appearance that the grant recommendation for CTNeT may have been improper. Auditors identified other concerns with the grant that CPRIT awarded to CTNeT (see Chapter 3 for additional information).
- CPRIT allowed a member of its commercialization review council to provide consulting services to CPRIT's virtual management company services contractor (see Chapter 4-A for more information on the virtual management services contractor). The commercialization review council member provided consulting services to two organizations that wanted to apply for Texas life sciences incubator commercialization grants. CPRIT reported that the commercialization review council member did not participate in the peer review of grant applications for incubator commercialization grants and, based on data provided by CPRIT, neither of the applicants that received consulting services ultimately submitted a

grant application. However, there is a risk that there have been other instances in which members of CPRIT's peer review councils have assisted grant applicants.

The president of a company that provides virtual management company services to CPRIT was reported as a collaborator on a grant application that the Houston-Area Translational Research Consortium submitted to CPRIT for a Texas life sciences incubator commercialization grant.

The CPRIT Foundation receives contributions from non-profit foundations affiliated with CPRIT grant applicants and CPRIT grantees.

The CPRIT Foundation provided auditors information indicating that, from April 2009 through August 2012, it received contributions of approximately \$3.7 million (see Appendix 6 for more information on the CPRIT Foundation). That information shows approximately \$2.1 million of the reported contributions was from non-profit foundations.

Several of the non-profit foundations identified are associated with higher education institutions that have received grants from CPRIT. For example, non-profit foundations associated with institutions such as the University of Texas Southwestern Medical Center, Texas A&M University, Texas A&M University Health Science Center, and Texas Tech University have made contributions to the CPRIT Foundation. Those higher education institutions have received grants from CPRIT (see Appendix 2 for list of grants awarded by CPRIT). Table 1 on the next page shows the top 11 non-profit foundations that made contributions to the CPRIT Foundation from April 2009 through August 2012.

Table 1

Donor		Contribution
O'Donnell Foundation ^a		\$1,600,00
Southwestern Medical Foundation		52,50
Texas A&M University HSC Foundation		37,50
The Methodist Hospital System - Foundation		35,0
Texas Tech University System Foundation		35,0
Mary Crowley Cancer Foundation		35,00
Texas Tech University System - Foundation		35,0
Texas Tech System Admin. Foundation		30,00
Astellas USA Foundation		30,0
Serafy Foundation		30,00
Texas A&M Foundation		30,00
	Total	\$1,950,00

[&]quot;The executive director for the O'Donnell Foundation was the registered agent for CTNeT and was a member of CTNeT's board of directors as of June 2012. See Chapter 3 for more information on CTNeT.

Source: The CPRIT Foundation.

In accordance with the General Appropriations Acts (81st and 82nd Legislature), the CPRIT Foundation provides up to approximately \$86,000 in supplemental funding for the salary of CPRIT's executive director and \$488,000 in supplemental funding for the salary of CPRIT's chief scientific officer. When organizations associated with grant applicants or grantees contribute to the CPRIT Foundation, this creates the risk that the contributions may influence the executive director and chief scientific officer in the grant recommendation process.

In addition to supplementing salaries, the CPRIT Foundation functions as an auxiliary organization of CPRIT, providing administrative support, public affairs, strategic communications, and marketing services. That support is provided under the management of an "interlocking directorate" (i.e., the chair, vice-chair and one other member of the CPRIT oversight committee also serve as members of the CPRIT Foundation's board of directors). This effectively establishes the CPRIT Foundation as a blended component unit of CPRIT for financial reporting purposes, though it is not subject to the legislative appropriations process. The CPRIT Foundation's annual report is available at http://www.cpritfoundation.org/about-us/annual-reports (see Appendix 7 for more information about the CPRIT Foundation).

CPRIT did not have processes to prevent it from awarding grants to applicants that made contributions to the CPRIT Foundation.

CPRIT reported that it had not requested or received financial information concerning donors to the CPRIT Foundation or the amounts of their contributions. However, without that information, CPRIT has no assurances that it is not awarding grants to donors that made contributions to the CPRIT Foundation, which would create an apparent conflict of interest. The General Appropriations Acts (81st and 82nd Legislatures) state that an individual; an organization; or an employee, officer, or director of an organization that makes a contribution to the CPRIT Foundation, or a person who has second-degree consanguinity or affinity to an employee of CPRIT, is not eligible to receive grants from CPRIT.

CPRIT rules allow peer reviewers who self-report a conflict of interest to participate in the peer review process as long as they do not participate in the review of the grant application for which they have a conflict.

CPRIT's rules prohibit peer reviewers with a conflict of interest from participating in the review, discussion, deliberation, or vote on a grant application for which they have a conflict of interest. However, peer reviewers may review the applications of other applicants that may be competing for the same grant funds. This increases the risk that peer reviewers could influence the evaluation of the competing applications as a result of their conflicts of interest. The total amount CPRIT can award each year is limited to \$300 million.

CPRIT did not consistently follow its process for identifying and recusing peer reviewers who had conflicts of interest when required.

While CPRIT had a process that allowed its peer reviewers to self-

report conflicts of interest, CPRIT did not consistently follow that

reviewed a sample of pre-meeting and post-meeting certifications

for peer reviews performed from September 2009 through June

process (see text box for additional information). Auditors

Pre-meeting and Post-meeting Certification

CPRIT reported that peer reviewers are required to self-report any potential conflicts of interest concerning a grant application prior to participating in the review of that application. The self-reported acknowledgement is recorded in the Peer Review Management Information System. Select peer reviewers are assigned to review applications during the initial peer review process. At the start of the full peer review committee discussion for an application, a peer reviewer with a conflict of interest is required to be recused from the discussion and sign a pre-meeting certification to document being recused from the discussion. At the conclusion of the peer review process, all peer reviewers must sign a post-meeting certification statement to re-affirm recusal from the peer review for all applications for which a potential conflict of interest was self-reported. Source: CPRIT.

PRIT did not have pre-meeting certifications for 23 (74.2 percent) of 31 peer review meetings tested. In addition, for 7 (22.6 percent) of the 31 peer review meetings, the pre-meeting certifications were unreliable because the certifications were either not dated or were dated July 2012. Only one peer review meeting tested had pre-meeting certifications that appeared to be reliable.

2012 and identified the following:

CPRIT did not have post-meeting certifications for 15 (33.3 percent) of 45 peer review meetings tested. Those 15 post certifications were for peer reviews performed during fiscal year 2010. CPRIT had the post-meeting certifications for 30

peer review meetings that auditors tested for fiscal years 2011 and 2012.

As previously discussed, CPRIT's rules allow peer reviewers with a conflict of interest to participate in a peer review process as long as the peer reviewer does not review the application for which there is a conflict. The pre-meeting and post-meeting certifications provide added assurances that the peer review process is impartial and fair.

Members of CPRIT's commercialization review council had residences in Texas; members of CPRIT's prevention and scientific review councils did not.

CPRIT specified in its strategic plan for fiscal years 2011 through 2015 that, to minimize the potential of conflicts of interest and create a firewall around its peer review process, members of the prevention and scientific review councils live and work outside of Texas. Members of the commercialization review councils do not have the same restrictions to live and work outside Texas. For fiscal years 2011 and 2012, 7 (36.8 percent) of 19 members of the commercialization review council had their honorarium payments sent to Texas addresses. Payments to all members of the prevention and scientific review councils tested were sent to out-of-state addresses. By not holding its commercialization review council to the same standards as its prevention and scientific review councils, CPRIT increases the risk that commercialization grant decisions may be impaired or influenced by financial or personal interests that commercialization peer reviewers may have in Texas.

Recommendations

The CPRIT oversight committee, executive director, and staff should:

- Establish and implement rules that prohibit the executive director from discussing grant recommendations with individual members of the oversight committee before presenting those recommendations to the full oversight committee.
- Refrain from leasing office space from grantees and consider locating the offices of the chief commercialization officer, chief scientific officer, and director of scientific research in the same office location as CPRIT executive management.
- Revise CPRIT's rules to prohibit members of the oversight committee, peer reviewers, and employees from engaging in business activities with grant applicants and grantees.
- Establish and implement a process to prevent CPRIT from awarding grants to applicants that made contributions to the CPRIT Foundation, as required by the General Appropriations Acts (81st and 82nd Legislatures).

- Upon the receipt of grant applications, require the CPRIT chief prevention officer, chief scientific officer, and chief commercialization officer to compare the list of grant applicants to the list of donors to the CPRIT Foundation. In addition, CPRIT should consider requiring the compliance officer to review the grant applicants to ensure that there are no conflicts between grant applicants and the CPRIT Foundation.
- Establish and implement a policy that prohibits a peer reviewer with a
 conflict of interest from evaluating grant applications competing for the
 same grant funds as the applicant for which the peer reviewer has a
 conflict of interest.
- Consistently maintain documentation to show that CPRIT identifies and takes action to address its peer reviewers' conflicts of interests.
- Establish and implement a documented policy on residency requirements for members of its commercialization review council.

Management's Response

CPRIT agrees with all eight recommendations and will adopt administrative rules and revise its policies to implement them fully. CPRIT expands upon certain recommendations related to the review process below.

- 1) CPRIT has begun implementing a process to compare all grant applicants with donors to the CPRIT Foundation. The review will occur when applications are submitted to CPRIT and verification of the results will be part of the compliance officer's certification of an award slate presented to the Oversight Committee.
- 2) With regard to the recommendation that CPRIT establish and implement a policy that prohibits a peer reviewer's conflict of interest with one application from evaluating any grant application during that review cycle, CPRIT notes that this is not an industry standard. Implementing the policy will significantly reduce the reviewer pool to the extent that it may impair both the quality and timeliness of CPRIT's overall review process. However, CPRIT agrees with the auditor's position that there may be certain conflicts that warrant recusal from the entire review cycle. To meet the intent of this recommendation while also ensuring an adequate pool of expert reviewers, CPRIT will adopt rules and change its review policies to specify when an identified conflict is so significant that the reviewer should be recused from participating in the entire review cycle.
- 3) State law and CPRIT's administrative rules permit, but do not require outof-state reviewers. As of April 1, 2012, all CPRIT reviewers, with the exception of the former Commercialization Review Council chair, live and work outside of Texas. The Commercialization Review Council chair

resigned on November 30, 2012, and was replaced by a non-Texas resident. However, CPRIT cautions that mandating that only non-Texas residents serve as peer reviewers may have unintended consequences. This requirement, in conjunction with the recommendations to impose an absolute bar against reviewer participation for any conflict, may affect CPRIT's ability to find qualified out-of-state reviewers and result in use of in-state reviewers. In addition, it would limit CPRIT's flexibility to use occasional in-state reviewers whose expertise is uniquely beneficial for the review process.

Person Responsible for Corrective Actions: General Counsel / Compliance Officer

Implementation Date: On or Before August 31, 2013

Chapter 1-B

CPRIT Should Ensure the Transparency and Accountability of Its Peer Review Process

CPRIT did not follow its policies and procedures for awarding research and commercialization grants.

The peer review processes that CPRIT followed for making its grant decisions were not consistent with its documented policies and procedures (see Appendix 5 for an overview of the CPRIT peer review process.) CPRIT has not updated its documented policies and procedures since November 2009, and its policies and procedures do not reflect the processes CPRIT followed for reviewing commercialization and certain research grant applications. Auditors determined the following:

CPRIT's policies and procedures do not include requirements for due diligence reviews to be performed for commercialization grant applications.
 CPRIT reported that due diligence reviews provide a quality assessment of a company applying for a commercialization grant (see the text box for more information about due diligence reviews). However, CPRIT did not define

Due Diligence Reviews

According to CPRIT, a due diligence review evaluates the quality of a company and the potential for continued product development, including the potential to commercially develop a proposed drug, diagnostic, or device, as well as to evaluate a company's existing patents and investment agreements. Source: CPRIT.

its requirements or specify other criteria that due diligence reviews should follow. Auditors tested 8 (66.7 percent) of 12 commercialization grants and identified 6 grants for which there were inconsistencies in what the due diligence reviews evaluated. Specifically:

• The due diligence reviews for three grants that were awarded approximately \$18.3 million in fiscal year 2010 were inconsistent in

the information that was reviewed and reported. One review included an overview, research plan, discussion notes, and a summary of the application. The other two reviews included more of a detailed and technical assessment of the applications that included strengths, weaknesses, summary of on-site discussions including enhancements, funding, research strategy, collaborations, competition, clinical development issues, commercial issues, proposal issues, intellectual property issues, clinical need, market opportunity, commercialization plan, manufacturing, operations, overall conclusion, and recommendations. These reviews were performed by members of the commercialization review council.

- The due diligence review of the other three grants, which were awarded approximately \$26.4 million (two were awarded in fiscal year 2011 and the other grant was awarded in fiscal year 2012), were consistent in the information that was reviewed and reported. These due diligence reviews were performed by a subcontractor of CPRIT's grant management services contractor (see Chapter 4-A for more information concerning the subcontractor). The reviews included a development plan, disciplinary review, company management, company funding, development milestones, other peer reviews, risk and risk mitigation, and a summary.
- CPRIT's policies and procedures did not include criteria that describe the number of grant applications to be reviewed for individual investigator research grants. A certain number of grant applications are withdrawn based on the peer review scores after the first stage of the peer review process. However, the grant applications that are withdrawn do not receive further consideration for an individual investigator research grant.

Two commercialization grant applications did not receive a scientific review, due diligence review, or intellectual property review. However, the CPRIT executive director recommended both applications for grants.

Auditors tested eight commercialization grant applications that received a total of \$75.8 million in grants to determine whether they received a commercialization review, a scientific review, a due diligence review, and an intellectual property review. Two of those grant applications did not receive required reviews. Specifically:

A commercialization grant application submitted by Damascus Pharmaceuticals (currently known as Peloton Therapeutics) for a company recruitment grant did not receive a commercialization review, scientific review, due diligence review, or intellectual property review. However, the CPRIT executive director recommended that application for a grant of approximately \$11.0 million in June 2010. The oversight committee specified that the commercialization grant recommendations presented in June 2010 were subject to the satisfactory completion of a due diligence

review. CPRIT also did not ensure that Peloton Therapeutics complied with matching funds requirements at the time of the grant recommendation (see Chapter 1-C for additional information).

CPRIT added a research proposal from the Institute of Applied Cancer Science (IACS) as an attachment to a commercialization grant application submitted by the Houston-Area Translational Research Consortium (HATRC) for a Texas life sciences incubator commercialization grant totaling approximately \$20.0 million. The research proposal from IACS did not receive a commercialization review, scientific review, due diligence review, or intellectual property review. IACS submitted the research proposal after the HATRC grant application received a commercialization review. However, neither the HATRC grant application nor the IACS research proposal received a scientific review, a due diligence, or an intellectual property review. CPRIT reported it rescinded the incubator grant awarded to HATRC and IACS in May 2012 after IACS requested to resubmit the research proposal for commercialization and scientific review.

Recruitment grant applications are not subject to the same peer review process used for other research grant applications.

Applications for recruitment grants are not evaluated using the two-stage peer review process used for other research grant applications (see text box for

Recruitment Grants

Recruitment grants, which are a type of research grant, are for the recruitment of investigators with the ability to make outstanding contributions to the field of cancer research, promote inquiry into new areas, foster collaboration, and stimulate growth in the field

Source: CPRIT.

more information on recruitment grants). Other research grant applications are first reviewed by members of the scientific review committee, and the results of those reviews are discussed among the full scientific review committee. Based on the review results of the full scientific review committee, the scientific review council then makes grant recommendations to the executive director. However, for recruitment grant applications, members of the scientific review council review grant applications, perform the peer review, and base their

recommendation to the executive director on their reviews. Unlike other research grant applications, recruitment grant applications do not receive an evaluation score; instead, recruitment grant applications receive an affirmative or negative vote.

In addition, peer reviews for recruitment grant applications were not documented and maintained in CPRIT's Peer Review Management Information System (where all other peer reviews are maintained). The only documentation maintained for peer reviews of recruitment grant applications were one-page summary statements that indicated whether the scientific review council recommended the award of a recruitment grant to the CPRIT executive director. As of August 2012, CPRIT had awarded 60 recruitment grants totaling \$184.9 million.

CPRIT did not have reliable data to support that it consistently followed its process for withdrawing grant applications from the peer review process.

CPRIT was unable to provide reliable data to support grant applications that had been withdrawn from the peer review process. CPRIT withdraws a

Grant Application Withdrawals

Applicants are required to ensure the accurate and complete submission of all components of a grant application. Submissions that are missing one or more components or do not meet the eligibility requirements for grant funds are administratively withdrawn without review

In addition, an application for individual investigator research grants and commercialization grants may be withdrawn from the full peer review process if that application receives an unfavorable initial peer review score.

Source: CPRIT.

portion of grant applications from the peer review process (see text box for more information). However, without complete and accurate data CPRIT cannot ensure that the most qualified applications received a full peer review and were presented to the oversight committee for consideration.

CPRIT provided data to auditors that was reportedly from its Peer Review Management Information System for 958 grant applications that CPRIT reported were withdrawn from the peer review process during the grant award cycles from September 2010 through June 2012. However, CPRIT's grant management contractor reported that the data provided to auditors was data that had been extracted from CPRIT's Peer

Review Management Information System after the initial peer review process and maintained in a separate database accessible only by that contractor's staff. Auditors did not test the security surrounding that separate database or access controls for that database. In addition, because CPRIT did not ensure that its Peer Review Management Information System had adequate security and access controls, auditors were unable to obtain assurances that the extracted data had not been altered; therefore, auditors were unable to verify that data provided on withdrawn grant applications was reliable. Auditors identified additional issues with the data in the Peer Review Management Information System (see Chapter 5 for additional information).

CPRIT's peer review councils did not always document the factors they used to support their grant recommendations to the executive director.

Auditors reviewed the peer review scores for 218 grant applications³ (5.9 percent of the 3,698 grant applications that CPRIT reported receiving from September 2009 through June 2012) recommended for grants from January 2010 through March 2012. For 4 (1.8 percent) of the 218 applications reviewed by auditors, the peer review scores were inconsistent with receiving a grant recommendation. In addition, CPRIT did not have documentation to support the factors used in making grant recommendations to the executive director. Specifically:

Two applications recommended for multi-investigator research grants for CTNeT and the University of Texas Health Science Center at San Antonio received evaluation scores of 4.64 and 4.67, respectively. (CPRIT evaluated grant applications on a scale of 1 to 9, with 1 being the highest.) Those scores were less favorable than the scores for 9 other applications

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³ Auditors reviewed 159 research grant applications, 49 prevention grant applications, and 10 commercial grant applications.

that were not recommended for grants. The 9 other applications had scores ranging from 3.93 to 4.40. CPRIT reported that applications typically must score from 1.00 to 3.50 to be recommended for a grant. Six other applications for which grants were recommended had scores ranging from 1.50 to 2.93. CPRIT also did not have documentation to support that the scientific review council recommended the CTNeT application for a grant. Auditors identified other concerns related to the grant recommendation for CTNeT (see Chapter 3 for additional information).

- One grant application that the Baylor College of Medicine submitted for an individual investigator research grant was recommended for a grant when its evaluation score of 3.18 was less favorable than the evaluation scores for 3 other applications that were not recommended for grants (those applications' scores ranged from 3.08 to 3.15). Eight other grant applications that were recommended for grants had scores ranging from 1.08 through 2.75.
- One grant application that Kalon Biotherapeutics, LLC submitted for a company formation grant was recommended for a grant, but it received a less favorable score (3.45) than another grant application that was not recommended for a grant (3.00).

Title 25, Texas Administrative Code, Section 703.6 (f), requires that grant funding recommendations include a statement of how the grant applications recommended for funding meet one or more of the recommendation standards (see the text box on page 3 for a list of recommendation standards that should be considered).

The CPRIT executive director recommended grants for Peloton Therapeutics and CTNeT when those grants were not recommended by the appropriate review councils.

Auditors identified two grant recommendations that were not supported by recommendations from the peer review councils. Specifically:

- The executive director recommended a \$23.5 million multi-investigator research grant to CTNeT. That application was not recommended for a grant by the scientific review council. The application received a 4.64 evaluation score. (See Chapter 3 for additional concerns auditors identified regarding the CTNeT grant.)
- The executive director recommended an \$11.0 million company recruitment commercialization grant to Damascus Pharmaceuticals (currently know as Peloton Therapeutics). However, that grant application did not receive any required reviews and there was not a documented recommendation from the commercialization review council to the executive director.

In addition, the executive director did not document which factors were considered for recommending these grants to the oversight committee. As discussed previously, Title 25, Texas Administrative Code, Section 703.6(f), requires that grant funding recommendations include a statement of how the grant applications recommended for funding meet one or more of the recommendation standards.

CPRIT did not consistently maintain documentation to support the basis for the amounts of the grants it awarded to grantees.

Auditors tested funding amounts for grants and identified differences of more than 5 percent between (1) the amount requested in grant applications, (2) the amount peer review councils recommended, (3) the amount the CPRIT executive director recommended to the oversight committee, and (4) the final grant amount awarded. Specifically, auditors reviewed a non-statistically selected sample of 27 applicable grants and identified the following:

- The amounts proposed in grant applications compared to peer review councils' recommendation had increases of more than 5 percent for 8 (44.4 percent) of 18 grant applications tested. The funding increases ranged from approximately \$310,000 to \$2.3 million. For nine other grant applications, the peer review councils did not provide a recommended grant amount.
- The executive director changed the award amounts recommended by the peer review councils. Specifically, the amounts peer review councils recommended compared to the executive director's recommendations to the oversight committee had differences of more than 5 percent for 6 (33.3 percent) of the 18 grant applications tested. The differences ranged from a reduction in the recommended amount of approximately \$1.5 million to an increase of \$1.7 million.
- The amount the executive director recommended compared to the final grant amount had differences of more than 5 percent for 4 (14.8 percent) of 27 grants tested.

Auditors were unable to determine whether the reductions or increases of more than 5 percent were reasonable because CPRIT did not have documentation to show how it determined the final grant amounts. The lack of documentation hinders CPRIT's ability to provide assurances that final grant amounts awarded are appropriate.

The oversight committee does not vote on individual grant recommendations.

Title 25, Texas Administrative Code, Sections 703.7 and 703.8, require the executive director to present lists of grant recommendations for each grant type (prevention, research, and commercialization) to the oversight committee, which votes on whether to disapprove the entire list for each grant type. That approach creates an "all or none" vote on the executive director's recommendations, which could cause the oversight committee to approve recommendations it might otherwise have rejected on an individual basis.

Recommendations

The CPRIT oversight committee, executive director, and staff should:

- Update and consistently follow agency policies and procedures for reviewing grant applications.
- Require the executive director to provide a written affidavit for each grant recommendation presented to the oversight committee certifying that the grant application was subject to the peer review process with the attached peer review score, including due diligence reviews and intellectual property reviews, when applicable.
- Ensure that reviews of all research grant applications, including recruitment grant applications, are subject to the same review process, including processes for documenting peer reviews in the Peer Review Management Information System.
- Maintain and secure data that supports why grant applications are withdrawn from the peer review process.
- Require peer review councils to document how applications recommended for grants meet one or more of the recommendation standards.
- Ensure that the executive director documents the factors considered in deciding on grant recommendations and that those grant recommendations are substantially supported by the grant recommendations made by CPRIT's peer review councils.
- Maintain documentation that supports how recommended grant amounts are determined by the peer review councils and the executive director.

Management's Response

CPRIT agrees with all seven of the recommendations and will adopt administrative rules and revise policies to implement them fully, including working with the grant management contractor to ensure that it maintains and secures data as outlined by the auditor's report. With regard to the recommendation that the executive director provide a written affidavit for each grant recommendation, CPRIT notes that it has already implemented a process in which CPRIT's compliance officer certifies the award slate at the Oversight Committee meeting. CPRIT expands upon certain issues below.

- 1) On page 12, the report states that the incubator commercialization grant did not receive commercialization, scientific, due diligence, or intellectual property reviews. Both the HATRC and the IACS components of the incubator application, collectively referred to as the Houston Area Incubator, received a commercialization review and were recommended for funding by the Commercialization Review Council in a written communication sent from the Commercialization Review Council Chairman to the executive director on March 27, 2012. Pursuant to the terms of the incubator Request For Applications (RFA) approved by the Oversight Committee and posted by CPRIT, scientific review was not part of review process. Due to the unique nature of the incubator applications, due diligence and intellectual property reviews were not applicable and not described as a part of the review process in the incubator RFA.
- 2) On pages 13 and 14, the report references the scores of some grant applications recommended for funding that were less favorable than scores assigned to other applications that were not funded. Neither CPRIT's statute nor its administrative rules require that the grant score solely determine the reviewer's decision to recommend an application for a grant award. Instead, the peer reviewers may consider other criteria, e.g., the benefit of funding a one-of-a-kind collaboration addressing the genetics and biology of a pediatric liver cancer, such as the award to The University of Texas Health Science Center at San Antonio. Furthermore, with regard to Kalon, the auditor references only the commercialization score, but the application received a more favorable scientific score than the application to which it is compared in the report. CPRIT will increase transparency in the grant award process and will require a statement of necessity to be presented when award recommendations are considered by the Oversight Committee if the review council recommends an award that did not score as favorably as others that were not recommended.
- 3) On page 15, the auditor notes that the executive director did not document which factors were considered for recommending these grants to the Oversight Committee. The review record for each application recommended for an award contains extensive comments made by the peer

reviewers, including the reasons for recommending the application for funding. CPRIT has implemented a policy that provides Oversight Committee members with the review records several days prior to the Oversight Committee meeting. CPRIT will implement a process to document the list of factors reviewers considered in making recommendations for funding and make the information available publicly when awards are announced.

4) With regard to the issue raised on page 16 that the Oversight Committee votes on the entire award slate versus a vote on each grant recommendation individually, CPRIT's policy is consistent with the statutory objective to minimize the potential for regionalism that may occur if one application is pitted against another. This process was adopted by the Oversight Committee and codified in CPRIT's administrative rules. CPRIT notes that in the event the Oversight Committee votes to reject a slate due to concerns raised over one or more grant recommendations, the rules (Texas Administrative Code, Title 25, Rule 703.8(b)) already provide an immediate process for the committee to direct the executive director to propose a new slate for consideration.

Closely related to this issue is the auditor's recommendation that state law be changed to allow Oversight Committee members to vote affirmatively to approve the executive director's recommendations (see page vii and page 42). If this recommendation is implemented, then the statutory provision requiring a two-thirds vote of the Oversight Committee to reject an award slate should be deleted. Failing to do so creates the potential for an award slate not to receive sufficient affirmative votes for approval as well as not enough negative votes to reject the slate.

Person Responsible for Corrective Actions: General Counsel / Compliance Officer

Implementation Date: On or Before August 31, 2013

Chapter 1-C

CPRIT Should Verify the Accuracy and Availability of Grantees' Matching Funds

CPRIT does not verify and confirm the availability of matching funds that grantees self-report.

CPRIT requires grantees to certify the amount of matching funds that are available for research at the time of contract execution and on an annual basis thereafter. However, CPRIT has not established a process to verify the accuracy and availability of the matching funds that grantees reported at the time a contract is awarded. Therefore, CPRIT lacks assurances that grantees have provided the required matching funds for cancer research that is the subject of the grant.

The Texas Constitution, Article III, Section 67 (a)(3)(i), requires that before CPRIT awards a grant, the grantee must have funds equal to one-half the amount of the grant dedicated to the research that is the subject of the grant.

CPRIT allows grantees to report funds as matching funds when grantees do not spend those funds on CPRIT-funded cancer projects.

Auditors identified two reporting methodologies for determining matching funds amounts to report to CPRIT. Under both methodologies, grantees included funds in their matching funds calculations that they did not spend on CPRIT-funded cancer research. Specifically:

- Auditors interviewed staff at the University of Texas M.D. Anderson Cancer Center, the University of Texas Southwestern Medical Center, and the Baylor College of Medicine, which had received a total of 331 grants totaling \$402.4 million as of August 2012. Those grantees reported that the matching funds they reported to CPRIT were based on cumulative funding available to them for cancer research, excluding CPRIT funding. The matching funds amounts those grantees reported were typically cancer research grants, such as federal grants, which may be unrelated to research projects funded by CPRIT.
- CTNeT, which received a \$25.2 million research grant, did not dedicate \$12.6 million in matching funds as required. Instead, CPRIT accepted certifications that the University of Texas M.D. Anderson Cancer Center and the Baylor College of Medicine would fulfill CTNeT's matching funds requirement for the grant amount to be disbursed for the first and second years of the grant agreement term, respectively. However, CTNeT did not receive those matching funds. For the first year of CTNeT's grant (July 2010 through June 2011), CTNeT reported that the CPRIT grant accounted for 98 percent of its total revenue (see Chapter 3 for additional concerns auditors identified regarding the CTNeT grant).

CPRIT Cancer Research Categories

The five cancer research categories defined by CPRIT are:

- Cancer biology and genetics (includes molecular characterization of tumors).
- Cancer immunology (includes vaccines).
- · Cancer imaging and diagnostics.
- Cancer epidemiology, population research, behavioral research, and outcomes.
- Cancer treatment (includes drug discovery and development and clinical trials).

Source: CPRIT.

CPRIT allowed grantees to demonstrate that matching funds were dedicated to and spent on cancer research that was in the same CPRIT-defined category (see text box) as the research funded by the CPRIT grant. As a result, CPRIT cannot ensure that matching funds were dedicated to and spent on the specific research funded by the CPRIT grant. Auditors made recommendations to the Legislature to clarify the statutory intent of matching funds requirements in Chapter 6.

CPRIT entered into a grant contract with Peloton Therapeutics when that grantee did not have the required \$5.5 million in matching funds in place.

CPRIT awarded an \$11 million commercialization grant to Peloton Therapeutics in June 2010. A grant contract between CPRIT and Peloton Therapeutics was executed in August 2010, before Peloton

Therapeutics secured required matching funds. CPRIT reported that Peloton Therapeutics did not secure matching funds until a year after the grant contract was executed. CPRIT reported that it made a \$3.2 million advance payment to Peloton Therapeutics in August 2011 after Peloton Therapeutics met the matching funds requirements. Title 25, Texas Administrative Code, Section 703.11 (a), requires that, at the time of awarding a grant, a grantee must certify that encumbered funds equal to one-half of the amount of the total grant are available and not yet expended for research that is the subject of the grant.

Recommendations

The CPRIT oversight committee, executive director, and staff should:

- Obtain documentation to verify the amount and availability of matching funds that grantees report.
- Require grantees to comply with matching funds requirements in statute and CPRIT rules.

Management's Response

CPRIT agrees with the two recommendations and expands upon certain issues raised in this section of the report.

1) CPRIT adopted administrative rule 703.11 in November 2009 to interpret the statute and provide guidance for grant recipients to comply with the matching funds requirement. The rule defines encumbered funds, specifies the types of encumbered funds that may or may not be considered for the match, and codifies five cancer research subject areas. The five subject areas encompass most cancer projects and were established to help grant

recipients, particularly those that are certifying the availability of matching funds on an institutional level and/or a year-by-year basis, to classify funds dedicated to research in the same subject of the grant, as required by statute. As the auditor indicates, using the five cancer research subject areas to facilitate reporting may result in some encumbered funds not spent directly on CPRIT-funded research projects. However, CPRIT disagrees with the conclusion that this is inconsistent with the constitutional and statutory mandate. The rule preserves the requirement that matching funds must be spent on research that is the subject of the grant by requiring that encumbered funds be dedicated to research in the same subject category. Anecdotally, several research institutions have reported to CPRIT that changing the administrative rule to require a demonstration of matching funds dedicated specifically to the grant rather than the cancer research subject of the grant will mean that the institutions will no longer be able to solicit CPRIT grants.

2) CPRIT requires the grant recipient to comply with state law and its administrative rules by certifying matching funds in writing as part of the award contract. CPRIT also requires the grant recipient to file an end-of-year report indicating how matching funds were spent over that year. Any material misstatement in the contract or financial status reports, including the matching funds certification, is grounds for contract termination and repayment of grant proceeds to the state. CPRIT will work with its internal auditor to develop a process for assessing a statistically significant portion of grant awards to test the accuracy of grantees' matching fund certifications and end-of-year reports.

Person Responsible for Corrective Actions: General Counsel / Compliance Officer

Implementation Date: On or Before August 31, 2013

CPRIT Should Develop or Strengthen Monitoring Processes to Ensure That Grantees Use State Funds Properly and Achieve Results

CPRIT should develop or strengthen several processes for monitoring (1) grantees' use of state funds and (2) the results that grantees achieve when they spend those funds.

CPRIT did not have criteria for assessing the reasonableness of grantees' requests for advance payments. As a result, two grantees reported they had balances of \$3.9 million and \$1.6 million remaining after receiving advance funds for the first year of their grants.

In addition, CPRIT did not consistently follow its policies and procedures for ensuring that all grantees submitted required financial and progress reports. CPRIT also did not perform desk reviews of grantees' financial processes and financial reports.

CPRIT did not develop a process for the renewal of grants and closing out expired grants. It also did not consistently include certain reporting requirements in its grants.

Chapter 2-A

CPRIT Should Establish Requirements for Advance Payments and Reimbursements It Makes to Grantees

CPRIT did not have criteria for assessing and approving grantees' requests for advance payments.

While CPRIT's policies and procedures specify that CPRIT will distribute funds on a reimbursement basis, CPRIT has made advance payments to grantees. CPRIT requires grantees to request and receive approval to receive advance payments. However, it has not established criteria for assessing and approving those requests. CPRIT did not document the factors it considered when assessing a grantee's actual and immediate need for funds as recommended by the State's *Uniform Grant Management Standards*. From September 2009 through August 2012, CPRIT reported that it made 18 advance payments totaling \$40,233,360 to 10 grantees. Table 2 on the next page summarizes those advance payments.

Table 2

Advance Payments CPRIT Made to Grantees September 2009 through August 2012					
Grantee	Grant Type	Total Advance Payments			
Cell Medica, Inc.	Commercialization	\$ 7,785,656			
CTNeT	Research	6,786,915			
Mirna Therapeutics, Inc.	Research	6,309,461			
Apollo Endosurgery	Research	5,001,063			
Caliber Biotherapeutics, LLC	Commercialization	4,215,004			
Peloton Therapeutics, Inc.	Commercialization	3,201,002			
Bellicum Pharmaceuticals, Inc.	Research	2,779,166			
Rules-Based Medicine, Inc.	Research	2,015,129			
Visualase, Inc.	Research	1,439,964			
Baylor College of Medicine	Research	700,000			
	Total	\$40,233,360			

Source: CPRIT.

In addition, making advance payments to grantees does not appear reasonable because grantees are required to have matching funds. Title 25, Texas Administrative Code, Section 703.11(a), requires that at the time of award, grantees must certify that encumbered funds equal to one-half of the amount of the total grant are available and not yet expended for research that is the subject of the grant.

Grantees that received advance payments have reported they have significant balances remaining.

Two grantees reported they had significant balances remaining after receiving advance funds for the first year of their grants. Specifically:

- CTNeT received two advance payments during the first year of its grant, July 10, 2010, through July 9, 2011. It received one advance payment of approximately \$84,000 in November 2010, and in January 2011 it received another advance payment of approximately \$4.8 million, which was CTNeT's remaining budgeted amount for the year. CTNeT reported that, as of August 2011, it had a cash balance of \$3.9 million remaining. See Chapter 3 for more information on CPRIT's payments to CTNeT.
- Mirna Therapeutics, which was awarded a research grant for \$10.2 million, received an advance payment in August 2010 of approximately \$3.2 million for the first year of its award, August 2010 through July 2011. Mirna Therapeutics reported that approximately \$1.6 million of that amount was still available as of August 2011.

The State's *Uniform Grant Management Standards* require state entities to ensure that grantees minimize the length of time between the receipt of advance payments and the disbursement of those funds. The significant cash balances remaining at the end of the grant terms suggest that CPRIT is not properly ensuring that advance payments address grantees' immediate funding needs.

CPRIT did not consistently obtain documentation to support its reimbursements of grantees' reported research expenditures.

Auditors tested 101 reimbursements totaling approximately \$11.0 million that CPRIT made on 19 grants to 4 grantees from September 2009 through June 2012. CPRIT reported that grantees are required to submit transaction-level detail support such as timesheets, invoices, or contract agreements with their reimbursement requests. However, for 85 (84.1 percent) of the 101 reimbursements, or approximately \$9.4 million in reimbursements, CPRIT did not obtain detail to support that reimbursed expenditures such as payroll expenses, travel expenses, purchases, and service expenses were reasonable, necessary, and allowable. For those 85 reimbursements, grantees typically provided CPRIT with spreadsheets that summarized the expenditures they reported were related to the CPRIT grant for the applicable reporting period. However, CPRIT cannot ensure the accuracy and appropriateness of grantees' reported expenditures without obtaining detailed information and adequate documentation to support the expenditures reported on the spreadsheets.

Recommendations

CPRIT's oversight committee, executive director, and staff should:

- Adopt and implement a policy regarding advance payments to grantees.
- Obtain sufficient documentation to support the appropriateness of all payments it makes to grantees.

Management's Response

CPRIT agrees with the two recommendations on advancing grant funds.

1) In open meeting, the CPRIT Oversight Committee authorized CPRIT staff to provide advance payments for awards limited to recruitment and commercialization grants under the authority of House Bill No. 1, 81st Legislature, R.S., 2009, and House Bill No. 1, 82nd Legislature, R.S., 2011, p. IX-22 (General Appropriations Act, Article IX, Section 4.03(a)). CPRIT will amend its administrative rules to adopt this procedure to authorize advance payments.

2) With respect to the criteria for assessing the reasonableness of grantees' requests for advance payments, CPRIT has used the scientific and commercialization peer review committees' recommendations for annual budgeted amounts of the approved research projects as the basis for advance payment decisions. In addition, CPRIT staff review requests to ascertain they include only allowable project costs. A grantee's failure to expend advanced funds results in excess cash. To reduce the possibility of grantee fund balances and encourage grantees to expend funds on project costs, CPRIT will pursue options to reduce the amount of funds advanced or reduce the one-year timeframe in which funds are advanced.

Person Responsible for Corrective Actions: General Counsel / Chief Operating Officer

Implementation Date: On or Before August 31, 2013

Chapter 2-B

CPRIT Should Improve Processes for Monitoring Grantee Expenditures and Research Progress

Effectively monitoring grantees' expenditures and research progress is fundamental to ensuring that grantees spend funds appropriately and make progress toward or achieve desired results. While CPRIT established monitoring processes, auditors identified weaknesses in those processes.

CPRIT did not consistently follow its policies and procedures for ensuring that all grantees submitted required financial and annual progress reports.

CPRIT grants require grantees to provide various periodic financial reports and progress reports. Auditors attempted to review those reports for 20 grants and determined that CPRIT had not ensured the timely receipt of those reports. Specifically:

- Financial reports. CPRIT did not have complete records of the quarterly financial status reports, inventory reports, and audit reports for 20 grants tested. Specifically, CPRIT:
 - Did not have 7 (46.7 percent) of 15 quarterly financial status reports that were due during fiscal years 2011 and 2012 for 2 grants. One grant was missing 3 (37.5 percent) of 8 reports due. The other grant was missing 4 (57.1 percent) of 7 reports due. Grantees informed auditors that there had been instances in which reports they submitted to the CPRIT Application Receipt System were overwritten by newer reports they submitted.
 - Did not have 8 (80 percent) of 10 annual inventory reports for 8 grants. The grant agreements require grantees to report an inventory of

- equipment purchased for research using grant funds in their annual reports, which are due to CPRIT within 60 days of the anniversary of the effective dates of the grants.
- Did not have 7 (43.8 percent) of 16 audit determination forms for 7 grants. CPRIT requires a grantee to complete and submit an annual audit determination form. If the grantee determines that it will spend more than \$500,000 in annual awards funds, it must obtain an audit and provide a copy of the audit results to CPRIT.
- Annual progress reports. While CPRIT developed monitoring tools for tracking the dates on which grantees' annual progress reports were due and received, it did not have documentation to show that it used those monitoring tools consistently. CPRIT did not receive 12 (60.0 percent) of 20 annual progress reports that were due between September 2011 and June 2012. CPRIT's records indicated that CPRIT began following up with grantees about missing reports beginning in May 2012. In addition, for one grantee, CTNeT, the first annual progress report was due by September 2011. However, CPRIT did not receive that report until after auditors requested a copy of the report in July 2012. CPRIT reported that it did not ensure that grantees submitted annual progress reports in a timely manner; it ensured only that reports received were reviewed by peer reviewers.

CPRIT did not perform desk reviews of grantees' financial processes and financial reports.

CPRIT established a desk review process to assess the adequacy and appropriateness of grantees' financial processes for managing grant awards and self-reported expenditures. However, CPRIT reported that from April 2010 through June 2010 it had performed desk reviews only for the prevention grants that the former Texas Cancer Council had awarded. As of June 2012, CPRIT had not performed desk reviews for any of the 487 grants totaling approximately \$683 million that CPRIT had awarded.

CPRIT did not have criteria for evaluating and measuring grantees' research progress and compliance with grant milestones.

CPRIT allows the peer reviewers that evaluated a grantee's research grant application to review that grantee's annual progress report because the peer reviewers will be familiar with the grantee's research. However, the peer reviewers did not document whether a grantee's reported progress met grant milestones or whether any problems had been identified that could affect the grantee's ability to complete the research project.

CPRIT reported that it received emails from peer reviewers indicating that a review was complete and that no issues had been reported by reviewers.

Audits Required by Uniform Grant Management Standards

The audit will include either the operations of the grantee or, at the option of the grantee, a series of audits that cover departments and other organizational units which expended or otherwise administered state awards during a fiscal year, provided that each audit encompasses the financial statements and schedule of expenditures of state awards for each such department, agency, and other organizational unit, which shall be considered to be a non-state entity.

The audit will also report whether the financial statements of the auditee conform with generally accepted accounting principles. The auditor will determine whether the schedule of expenditures of state awards is presented fairly in all material respects in relation to the auditee's financial statements taken as a whole.

Source: *Uniform Grant Management Standards*, Governor's Office of Budget and Planning.

However, CPRIT reported that emails older than one year would have been deleted.

CPRIT did not ensure that public higher education institutions obtained annual audits as required by the State's *Uniform Grant Management Standards*.

The State's *Uniform Grant Management Standards* require each grantee that receives an award and expends \$500,000 or more to obtain an annual audit of state grants and to provide the audit results to the funding source (see text box for additional information).

Auditors reviewed the audit reports that five grantees submitted to CPRIT. CPRIT did not ensure that two grantees, the University of Texas Southwestern Medical Center and the University of Texas M.D. Anderson Cancer Center, obtained proper audits. Instead of providing audit reports on their CPRIT grants, CPRIT allowed those higher education institutions to provide copies of the audit reports for federal awards they had received.

Recommendations

CPRIT's oversight committee, executive director, and staff should:

- Retain documentation of all financial and progress reports received and all reviews of those reports.
- Establish and implement a process to track the dates on which grantees' reports are due and received, and follow up on all missing reports.
- Follow the process established by CPRIT to perform desk reviews of financial reports that grantees submit.
- Establish criteria for peer reviewers to follow when evaluating and documenting reviews of grantees' progress reports.
- Ensure that public higher education institutions obtain and submit reports from required audits.

Management's Response

- 1) CPRIT agrees to continue to maintain documentation of all financial and progress reports and retain all fiscal documentation of approved reports. The Grants Management System now provides an electronic repository of all documents. Approved fiscal documents are also maintained in hard copy with payment vouchers in CPRIT's financial records.
- 2) CPRIT has implemented a process to track the dates when grant reports are due and received through a Grants Management System, a component of the CPRIT Application Receipt System to support post-award management of all CPRIT grant awards. With this tracking in place, CPRIT can follow up on any missing reports to complete submission. The Grants Management System is a repository of grant applications, grant contracts, progress and financial reports, correspondence, and other reporting requirements for each grant awarded by CPRIT. It records the date, time, and the submitter of all submissions from CPRIT grantees and the corresponding information for all actions on grant awards by CPRIT staff. This system will not allow grants to overwrite previously submitted reports.
- 3) CPRIT will perform desk reviews of financial reports submitted by grantees. CPRIT has performed a limited number of desk reviews of the financial statements submitted by grantees using a risk assessment based on the type of organization and award amount and integrated its internal auditor into the process to conduct field audits in February 2012. CPRIT will continue to perform risk assessments based on this methodology and expand the number of desk reviews and field audits of grantees.
- 4) CPRIT agrees that written evaluation of progress reports must document the opinions of reviewers and has criteria to measure progress as part of each grant award contract. Previously peer reviewers conducted reviews of grantees' reports against these criteria but did not document those evaluations in writing. CPRIT is currently attempting to contract with science managers instead of CPRIT peer reviewers to perform written evaluations of grantee progress reports against the established criteria.
- 5) CPRIT agrees that public higher education institutions should obtain and submit reports on audits for expenditures in excess of \$500,000 from CPRIT grants. CPRIT accepted the Statewide Single Audit Report believing this audit covered state as well as federal grants. CPRIT will clarify guidance on this audit requirement in its Policies and Procedures Guide by requiring public higher education institutions to obtain an independent audit of CPRIT awards beginning in fiscal year 2014. To allow the public higher education institutions to transition to this new audit process, CPRIT will allow public higher education institutions to

submit the Statewide Single Audit Report for its review of financial processes of grant awards in conjunction with an audit of CPRIT grant expenditures performed by their internal auditor to address the requirement in fiscal year 2013.

Person Responsible for Corrective Actions: Chief Operating Officer / Finance Manager

Implementation Date: On or Before August 31, 2013

Chapter 2-C

CPRIT Should Strengthen Certain Contract Management Processes

CPRIT did not have documented policies and procedures to ensure that it extends grants in a consistent manner and in accordance with grant terms. The omission of important terms from grants also could put the State at risk if legal action arises.

CPRIT has policies available online that provide guidance to grants applicants and grantees. However, those policies do not include procedures for what to expect when CPRIT closes out an expired grant, how to renew a grant, or how to apply for a grant extension.

CPRIT did not develop a process for closing out expired grants and grant renewals.

According to CPRIT, it does not have a process to close out expired grants and it has not closed out any grants. However, CPRIT asserted that 12 grants totaling approximately \$924,000 had expired as of October 2012. The State's *Uniform Grant Management Standards* provide guidance and standards for state agencies that administer grants and specify the deliverables related to closing out an expired grant to ensure that all required work of a grant was completed.

Without a process for closing out expired grants, CPRIT could fail to identify unallowable costs that grantees should reimburse or fail to obtain a grantee's final financial status report and any invention disclosures applicable to the grant.

CPRIT has not renewed any of the grants it has awarded, and it has not developed a process for grant renewals. Without a grant renewal process, grantees that would like to be considered for a grant renewal do not have guidance to follow.

CPRIT does not have documented procedures to ensure that it extends grants in a consistent manner and in accordance with grant terms.

Auditors tested nine grants to which CPRIT gave extensions. Each of those nine grants had written requests from the grantee to extend the grant, and CPRIT had approved those requests without changing the amount of the original grant agreement. However, auditors identified the following:

- Four (44.4 percent) of the 9 extended grants had grant agreements that did not include a provision regarding the extension of the grant.
- Three (75.0 percent) of the 4 extended grants that included provisions for extending grants received extensions that were longer than the six-month maximum for extensions specified in those grants.
- Two (25.0 percent) of the 8 extended grants did not go through CPRIT's finance manager for approval.
- One (11.1 percent) of the 9 extended grants was approved 5 months after the grant had expired; the extension of the grant was backdated to the expiration date July 30, 2011; and the grant was extended until December 2012.

CPRIT's amendments to extend grants also did not include any performance requirements as a condition of the extension. CPRIT used extensions to extend the funding period for a grantee to expend remaining grant funds.

CPRIT did not consistently include certain reporting requirements in its grants.

Auditors reviewed the terms and conditions of 26 grants, which include grants from each of the three grant types that CPRIT awards, and identified the following:

- Twelve (46.2 percent) of the 26 grants did not include requirements related to intellectual property requirements.
- Seven (26.9 percent) of the 26 grants did not include payment requirements for reimbursements.
- Six (23.1 percent) of the 26 grants did not include carry forward requirements for unexpended budgets.
- Five (19.2 percent) of the 26 grants did not include signature requirements related to the submission of annual reports.
- One (3.8 percent) of the 26 grants did not include the requirement regarding quarterly submission of financial reports.

Recommendations

CPRIT's oversight committee, executive director, and staff should:

- Develop, document, and implement a process for closing out grants and renewing grants, as well as develop, document, and implement procedures for extending grants.
- Ensure that grant agreements include all reporting requirements.

Management's Response

CPRIT agrees with the two recommendations and has already begun developing, documenting, and implementing a process for closing out grants and renewing or extending grants.

With regard to the finding that CPRIT did not consistently include certain reporting requirements, CPRIT notes that the differences identified by the auditor resulted from changes made to the standard grant contract over the past three years. All CPRIT grant contracts include terms to protect the state's interest, including prohibiting use of grant funds for purposes not intended in the grant award. The new Grants Management System will also ensure that all reporting requirements are specified in the grant contract and tracked automatically for CPRIT and the grant recipient.

CPRIT notes that with the exception of planning grant awards (<\$25,000 each) that were discontinued after fiscal year 2010 and renewals of Texas Cancer Council grants approved in fiscal year 2009, all CPRIT grant contracts specify intellectual property and revenue sharing requirements for CPRIT grant projects.

Person Responsible for Corrective Actions: General Counsel / Compliance Officer

Implementation Date: On or Before August 31, 2013

CPRIT Should Improve Its Management of the CTNeT Research Grant and Other Administrative Practices

Auditors identified significant weaknesses in CPRIT's award decision and management of the \$25.2 million multi-investigator research grant awarded to

Statewide Clinical Trials Network of Texas

The Statewide Clinical Trials Network of Texas (CTNeT) is a non-profit company whose purpose is to develop an efficient statewide cancer clinical trial network for evaluating therapeutic drugs and treatments for cancer in adults and children.

CTNeT's grant from CPRIT identifies the following objectives to be achieved during the three-year grant term:

- Establish governance, oversight, advisory boards, and committees.
- Develop a center that will centralize administrative, regulatory, legal, financial, and pharmacy duties and responsibilities.
- Adopt community-based practices into CTNeT operations.
- Hire experienced biostatistics staff to manage clinical trials design, analysis, and reporting.
- Establish performance metrics to assess network efficiencies and effectiveness.
- Established a centralized institutional review board.
- Establish an independent data and safety monitoring board
- Create a tissue/biobank and cancer genetics lab.
- Facilitate commercialization opportunities with pharmaceutical and biotechnology companies.

CTNeT also intends to establish collaborations with other research projects funded by CPRIT. CTNeT plans to provide resources and funding to 14 selected institutions and community-based practices to ensure adequate clinical research infrastructure for the conduct of CTNeT trials.

Source: CPRIT.

\$25.2 million multi-investigator research grant awarded to the Statewide Clinical Trials Network of Texas (CTNeT) (see text box for more information on CTNeT), which was the largest single grant awarded by CPRIT as of June 2012. Those weaknesses concern the appropriateness of CPRIT's decision to award a grant to CTNeT and CPRIT's independence and professional judgment in monitoring CTNeT's use of grant funds and compliance with grant requirements.

CPRIT did not have adequate documentation to support the grant to CTNeT.

Auditors identified the following issues related to the CTNeT grant:

CTNeT did not exist as a non-profit company until after the CPRIT oversight committee accepted the recommendation of CPRIT's executive director to award CTNeT a grant. The University of Texas M.D. Anderson Cancer Center submitted the grant application. CPRIT awarded the grant to the University of Texas M.D. Anderson Cancer Center in June 2010. Subsequent to the award, in August 2010, CTNeT registered to become a Texas-based, non-profit company. It is unclear what allowed CPRIT to transfer the award from the University of Texas M.D. Anderson Cancer Center to CTNeT. The registered agent for CTNeT was not an employee or representative of the University of Texas M.D.

Anderson Cancer Center, but was the executive director of the O'Donnell Foundation. The O'Donnell Foundation made \$1.6 million in contributions to the CPRIT Foundation from April 2009 through August 2012 (see Appendix 6 for more information on contributions to the CPRIT Foundation).

• CTNeT's grant application did not receive a favorable peer review score. The CTNeT grant application received a peer review score of 4.64. Auditors reviewed the peer review scores for 44 other applications for multi-investigator research grants during the same awarding period and determined that the 6 other applications that were awarded a grant received peer review scores ranging from 1.50 to 2.93. In addition, 9

- other grant applications that were not awarded grants received peer review scores ranging from 3.93 to 4.40.
- CTNeT did not include a research plan in its grant application for a multi-investigator research grant. After the CPRIT oversight committee accepted the grant award recommendation for CTNeT in June 2010, CPRIT required the University of Texas M.D. Anderson Cancer Center to resubmit its grant application for a second peer review in August 2010. Following the resubmission and re-evaluation of the grant application in August 2010, CPRIT executed a grant agreement in September 2010 that included an amendment requiring CTNeT to submit a research plan before CPRIT would disburse grant funds.
- CPRIT did not have documentation to support that the scientific review council made a recommendation to the executive director to award a grant to CTNeT.
- CPRIT did not have documentation to support how it determined that the amount of the CTNeT grant would be \$25.2 million. The grant application proposed a budget of approximately \$20.1 million for a three-year period. The CPRIT executive director recommended a grant amount of approximately \$23.5 million to the oversight committee for a three-year period. The grant agreement between CPRIT and CTNeT was for approximately \$25.2 million for a three-year period.

CPRIT has a role in CTNeT's business operations.

Auditors identified business and professional relationships between CPRIT's management and CTNeT that significantly impair CPRIT's ability to ensure that CTNeT uses funds properly and complies with grant requirements. Specifically:

- CPRIT's oversight committee chair, vice-chair, and executive director interviewed and hired CTNeT's chief operating officer before the contract was executed.
- CPRIT's executive director, chief scientific officer, and a member of its commercialization review council are members of CTNeT's board of directors.
- The CPRIT Foundation provided additional funding to CTNeT. According to CTNeT, the additional funding was provided at the request of CPRIT's executive director. Specifically, the CPRIT Foundation:
 - Provided \$50,000 to pay for a recruitment bonus for CTNeT's chief medical officer during fiscal year 2011.

• Budgeted to provide approximately \$33,000 during fiscal year 2012 to pay for travel, meal, and lodging expenses that are above the state per diem rates for CTNeT's board of directors.

CPRIT made advance payments to CTNeT when its grant agreement with CTNeT allowed only reimbursement payments.

From September 2010 through August 2012, CPRIT provided a total of \$7.0 million to CTNeT. CPRIT paid approximately \$6.8 million of that amount through advance payments to CTNeT. However, the grant agreement requires funding to be provided to CTNeT only on a reimbursement basis.

In addition, of the \$6.8 million in advance payments made to CTNeT, approximately \$2.0 million of the advance payments were made <u>after CPRIT</u> determined that CTNeT spent grant funds on unallowable costs. CPRIT did not recover the funds CTNeT spent on unallowable costs before it made additional advance payments to CTNeT. CPRIT reported that, for the period from October 2010 through January 2012, it identified approximately \$301,000 in costs that are unallowable or questionable for a research grant according to its agency rules and the State's *Uniform Grant Management Standards*. Those costs included:

- Three bonuses for CTNeT's chief operating officer totaling \$100,000.
- One merit increase for CTNeT's chief operating officer totaling \$60,000.
- Moving costs for CTNeT's chief operating officer totaling \$16,288.
- Two signing bonuses for CTNeT employees totaling \$4,500.
- Travel-related reimbursements for CTNeT employees totaling \$4,223.
- Questionable costs related to interior decoration, furniture, salary increases, a signing bonus, and fuel for rental cars totaling \$116,872.

As of September 2012, CPRIT had not requested repayment of any of those costs from CTNeT.

CTNeT did not comply with certain grant requirements.

CTNeT did not comply with matching funds requirements and annual progress reporting requirements. Specifically:

• CTNeT did not maintain or dedicate funds to comply with the matching funds requirements of its grant agreement. CTNeT did not have dedicated funds in the required amount of approximately \$12.6 million at the time of the award decision (see Chapter 1-C for more information on matching funds). Instead, CPRIT allowed CTNeT to report funds held by the University of Texas M.D. Anderson Cancer Center and the Baylor College of Medicine as CTNeT's matching funds. While both of those entities

reported they had funds available for CTNeT's use, CTNeT did not receive any funds from them. CTNeT's annual financial report for the year ended August 31, 2011, specified that 98 percent of CTNeT's revenue was from its CPRIT grant. In addition, during fiscal year 2012, CPRIT made approximately \$2 million in advance payments to CTNeT to cover operational costs. The grant agreement required CTNeT to have an amount of funds equal to one-half of the amount of the grant to be disbursed each fiscal year of the grant.

• CTNeT did not submit the required annual progress report to CPRIT for the first year of its grant until July 2012. The grant agreement required CTNeT to submit annual progress reports to CPRIT within 60 days of the anniversary of the effective date of the grant agreement or at such other time as may be specified in the agreement. The effective date of the grant was July 2010; therefore, the due date for the first annual progress report was September 2011. CPRIT reported that it did not ensure that grantees submitted annual progress reports in a timely manner; it ensured only that the reports received were reviewed by peer reviewers.

Recommendations

CPRIT's oversight committee, executive director, and staff should:

- Refrain from involvement in CTNeT's business decisions.
- Prohibit CPRIT employees from serving on CTNeT's board of directors.
- Prohibit CTNeT board members from serving on CPRIT's commercialization review council.
- Ensure that all payments to CTNeT comply with the terms of the grant.
- Withhold payments to CTNeT until after CPRIT has recovered the advanced funds that CTNeT spent on unallowable costs.
- Require CTNeT to comply with requirements regarding matching funds and annual progress reporting.

Management's Response

CPRIT generally agrees with all six recommendations concerning CTNeT. It will not participate in CTNeT's business decisions. CPRIT will adopt rules to prohibit CPRIT employees from participating on grantees' boards and will prohibit future peer reviewers from participating on grantee boards. CPRIT will also ensure that all payments comply with the terms of the grant and require CTNeT to comply with matching fund and reporting requirements.

CPRIT wishes to provide additional information concerning a statement on page 29 of the report that says: "As of September 2012, CPRIT had not requested repayment of any of those costs from CTNeT." CPRIT believes that this statement does not fully represent what occurred. The executive director wrote to CTNeT concerning \$256,292 in unallowable costs paid with grant funds. The letter states that CTNeT must "find a remedy to address these unallowable costs ... over the next six months ... Should CTNeT be unable to find a remedy for these unallowable costs... CPRIT will reduce CTNeT's total award of \$25,213,675 by \$256,292.... CTNeT must adhere to CPRIT's Grant Policies and Procedures Guide regarding allowable and unallowable costs." CTNeT has been operating under the assumption that this reduction in the total grant amount was the suitable remedy.

Although this grant reduction is less than satisfactory, it was an affirmative response that assures the state is, in effect, made whole with respect to the unallowable expenditures. CTNeT's revenue from clinical trial partners has been slower to materialize than originally projected. In an effort to keep a medically significant and socially desirable project viable, advances were continued and, as an interim alternative to direct reimbursement, grant reduction was proposed and evidently accepted.

As of this writing significant issues concerning advance payments to CTNeT and use of those funds have not been resolved. CPRIT believes that the statewide clinical trials concept has significant innovative cancer treatment value. However, poor management decisions on the part of CTNeT combined with inappropriate involvement from CPRIT staff that should not have occurred in CTNeT decision making has led to an unfortunate situation where restructuring of CTNeT management, business plan, and contractual agreement with CPRIT may need to occur and are being evaluated.

Person Responsible for Corrective Actions: Interim Executive Director / General Counsel

Implementation Date: On or Before August 31, 2013

CPRIT Should Improve Certain Procurement and Payment Practices for Vendors and Other Professional Services

CPRIT should improve its vendor procurement and payment practices and management of contracted services to help ensure that the costs of contracted services are reasonable and that the appropriate services are being performed. In addition, CPRIT should ensure that its honorarium payments for peer review services are appropriate and that the amounts paid to peer reviewers are reasonable.

Chapter 4-A

CPRIT Should Ensure That Contracted Services and Related Costs Are Reasonable and Necessary

CPRIT should strengthen certain procurement and payment practices to ensure that its contracts for grant management services and virtual management company services are reasonable and necessary.

Contract amendments to the scope of work for grant management services and virtual management company services significantly increased costs.

Contract costs for grant management services and virtual management company services have increased significantly. Specifically:

- Grant management services contract costs increased approximately 35.2 percent during the first three years of the contract. The grant management services contract is a five-year agreement (from July 2009 to August 2014), at an initial cost of approximately \$15.7 million. However, CPRIT amended the contract costs, which resulted in the contract costs increasing by 35.2 percent from the initial estimate of \$15.7 million to \$21.2 million. Specifically:
 - CPRIT amended the contract in December 2010 to increase the cost from \$6.4 million to \$9.0 million for the period from July 2009 through August 2011. The cost increase was based on increases in the workloads for managing the peer review process and the development of a grant management system.
 - CPRIT renewed the contract in September 2011 at an increased cost of \$1.9 million (from approximately \$3.0 million to \$4.9 million). The cost increase was attributed to increases in costs related to grant management and the development of a grant management system.
 - CPRIT amended the contract in July 2012 to increase the cost by approximately \$1.0 million (from \$4.9 million to \$5.9 million). The cost increase was attributed to increases in costs related to the peer review process and help desk support for the grant management system.

 Virtual management company services contract costs increased approximately 166.7 percent during the first two years of the contract. The best and final offer for

the four-year (September 2010 through August 2014) virtual management company services contract was approximately \$5.7 million (see text box for more information about those services). However, an amendment and a change to the contract renewal terms within the first two years resulted in contract costs increasing by approximately 166.7 percent, from approximately \$1.5 million to \$4.0 million. Specifically:

- CPRIT amended the contract in April 2011 to include an entrepreneur in residence (EIR) program (see text box for more information about the EIR Program) for the first year of the contract (September 2010 through August 2011). While the EIR program was a part of the original scope of work listed in the request for proposal (RFP), the contract did not include a scope of work for the EIR program. The amendment resulted in the first-year contract costs increasing by 113.5 percent, from approximately \$500,000 to approximately \$1.1 million. As of July 2012, CPRIT reported that only one entrepreneur was participating in the EIR program. CPRIT's contract with its virtual management services company anticipated that there would be four EIR program participants on an annual basis.
- CPRIT renewed the contract for a second year (September 2011 through August 2012) for approximately \$3.0 million, which was an increase of approximately 204.2 percent from the projected contract renewal amount of \$975,000. The cost increase was attributed to salaries for additional executive positions that were added to the contractor's staff and other direct costs.

The significant cost increases resulting from the amendments to the grant management services and virtual management company services contracts suggest that CPRIT did not understand the scope of work that it needed.

The vendor that was awarded the contract for virtual management company services assisted in CPRIT's needs assessment process.

CPRIT received only one response to its RFP for virtual management company services. That vendor's chief executive officer participated in meetings with the CPRIT subcommittee that recommended to the CPRIT oversight committee that it pursue a virtual management company services contract. In addition, that vendor's response to the RFP included specific language and details that had been included in a subcommittee presentation to CPRIT's oversight committee at a June 2009 quarterly meeting. The

Virtual Management Company Services

CPRIT contracted with a virtual management services company to provide the following services:

- Leveraging skills of commercial experts throughout the world to support the development and growth of successful Texas-based oncology product companies.
- Providing specialized support infrastructure for both cancer scientific research programs and companies focused on cancer product development.
- Establishing an entrepreneur in residence program.
- Supporting the CPRIT commercialization review council.

Source: CPRIT.

Entrepreneur in Residence (EIR) Program

The EIR program recruits experienced entrepreneurs to build Texas-based life sciences companies in collaboration with qualified investment firms. It is aligned with CPRIT's efforts to fund the commercialization of cancer research and build a critical mass of life science companies within Texas. The virtual management company services contractor administers the EIR program for CPRIT

Annual funding for each EIR participant includes \$200,000 provided by CPRIT and \$100,000 from the participating investment firms. Participants also have access to CPRIT-funded virtual management company services.

Source: CPRIT.

subcommittee's recommendations were not included in the RFP document and were not available to other potential vendors. In addition, a member of that vendor's board of directors served on the oversight committee at the time the subcommittee made its recommendation to pursue a virtual management company services contract. That member resigned from the oversight committee in January 2010, prior to CPRIT releasing the RFP for virtual management company services in May 2010.

Contractor invoices did not have sufficient detail to determine whether the costs billed were reasonable, necessary, and appropriate.

The invoices for the payments that CPRIT made to the virtual management company services contractor that auditors reviewed did not contain sufficient details showing that the amounts billed were reasonable and necessary. Specifically:

- From September 2010 through July 2012, CPRIT paid approximately \$2.0 million to the virtual management company services contractor. Auditors reviewed payments totaling approximately \$208,000 that CPRIT made to the virtual management contractor for services provided in May 2012. However, the invoice details were insufficient to determine whether the costs billed were reasonable, necessary, and appropriate. For example, the virtual management company services contractor's chief executive officer billed CPRIT for \$26,595 based on 98.5 hours worked at \$270 per hour for "overall management; meetings and calls with experts, planning for CPRIT conference, attended Commercialization Review Council meeting, various projects to support CPRIT Executive Director, and discussion with prospective candidates." The invoice did not list the meeting dates or the names of individuals at those meetings, and it did not describe the work products produced. Without those details, and items such as time sheets to support the hours charged, CPRIT cannot determine whether the amounts billed were reasonable and necessary.
- CPRIT's contract with the virtual management company services contractor does not specify what documentation the contractor should provide to support its monthly invoices to CPRIT. In addition, the deliverables for virtual management company services are not clearly defined in the contract and are difficult to measure. For example, the contract states that the vendor will "create a value proposition" and "implement and further refine the [virtual management company's] approach during this strategic demonstration project." The contract also states that the vendor "will be able to advise at least 10–15 projects/companies in year one."

Without sufficient details in invoices and clearly defined deliverables, it is not possible for CPRIT to determine whether it is properly paying its contractors for required services.

CPRIT recommended that its grant management services contractor use a preferred subcontractor for due diligence reviews.

CPRIT recommended that its grant management services contractor use a preferred subcontractor for due diligence services. The grant management services contractor did not select that subcontractor through a competitive procurement process. Instead, according to CPRIT management, CPRIT based the selection of the subcontractor on the chief commercialization officer's experience and expertise in the area. The first contract term between the grant management services contractor and the due diligence services subcontractor was from February 1, 2011, to January 31, 2012. That contract was extended for three months while due diligence services were procured. After the procurement process for due diligence services was completed, the grant management services contractor renewed the due diligence contract with the existing subcontractor from May 1, 2012, to August 31, 2012.

In addition, as of December 2012, a former member of CPRIT's commercialization review council served on the subcontractor's board of directors.

Recommendations

CPRIT's oversight committee, executive director, and staff should:

- Ensure that CPRIT properly identifies and defines its services needs and the associated costs prior to executing service contracts.
- Prohibit the awarding of contracts to parties that assist in the needs assessment process for the contracted services.
- Require vendor invoices to include specific information that clarifies the work products and services the vendors provided during the billing cycle.
- Competitively procure all contracted services, and require CPRIT's contractors to competitively procure all subcontracted services.

Management's Response

1) CPRIT will identify and define its service needs and associated costs prior to executing service contracts and attempted to do this, albeit inadequately, at the outset of both the grants management services contract and the virtual management services contract. With respect to the grants management services contract, CPRIT's grant award programs did not exist at the time that the services were procured, so the procurement was based on estimates of the types of award mechanisms, peer review processes, and number of peer review meetings in any given year. Start-up difficulties are common in many new state programs and

agencies especially with respect to phasing in expanding programs. In CPRIT's case ramping up of grant programs was assumed in the original assessment of service needs, but it was not possible to envision the entire scope of the grant programs as they currently exist after some four years of operation. Similarly, CPRIT had a novel concept for the virtual management services program never tried previously anywhere. The needs assessment for the procurement could not have envisioned the full scope of the services of a mature program.

- 2) CPRIT agrees that contracts should not be awarded to parties that assist in the needs assessment. CPRIT will develop guidelines for this situation in the agency's procurement process, including an assessment by the compliance officer that processes are followed.
- 3) CPRIT agrees that the documentation provided by vendors should support the work they are performing for CPRIT. We will require additional detail to support vendor invoices as necessary.
- 4) CPRIT agrees to procure competitively contracted services consistent with state procurement law. CPRIT strives to procure services competitively and the use of a preferred subcontractor for due diligence reviews was not typical. The reprocurement of these services for the period of May, 1, 2012, to August 31, 2012, referenced in the report was done competitively.

Person Responsible for Corrective Actions: Chief Operating Officer / Operations Manager

Implementation Date: On or Before August 31, 2013

Chapter 4-B

CPRIT Should Ensure That Its Honorarium Payments Are Appropriate

CPRIT's peer review council chairs and peer reviewers receive honorarium payments for the services they provide (see text box for more information on peer reviewers). Of the approximately \$6.7 million in total honorarium

payments from September 2009 through June 2012, approximately \$4.0 million were honorarium payments paid by CPRIT. The remaining \$2.7 million was paid to scientific and prevention peer reviewers through CPRIT's grants management services contractor. Auditors identified several weaknesses in CPRIT's processes for making honorarium payments to its peer reviewers.

CPRIT did not consistently obtain sufficient documentation to support the appropriateness of honorarium payments it made to peer reviewers.

Auditors tested a sample of honorarium payments made by CPRIT and its grant management contractor and identified the following issues:

Auditors reviewed 52 honorarium payments made by CPRIT that totaled \$472,583 and determined that 3 payments totaling \$12,000 (5.8 percent of the 52 payments tested) lacked sufficient documentation to support when the reviews were performed or which grants applications were reviewed. After auditors brought this to CPRIT's attention, CPRIT requested additional documentation from its grant management services contractor to support the appropriateness of the expenditures; however, CPRIT had not reviewed that documentation at the

contractor to support the appropriateness of the expenditures; however, CPRIT had not reviewed that documentation at the time it approved the payments.

Auditors reviewed 53 payments made by the grant management services contractor that totaled \$160,000 and determined that 13 payments totaling \$32,000 (24.5 percent of the 53 payments tested) lacked sufficient information to support the project with which the peer review was

CPRIT lacked documentation to justify increases in honorarium payments to officers of its peer review committees.

associated and the date when the reviews were performed.

Quarterly honorarium payment amounts to several peer reviewers for their services increased from \$6,250 to \$9,735, and the quarterly honorarium payments to the chair of the prevention review council increased from \$12,500 to \$15,000. However, CPRIT did not have any documentation supporting the decisions to increase the quarterly payments to those reviewers. CPRIT management informed auditors that the decision process was informal

Peer Reviewers

CPRIT has three review councils—the prevention review council, the scientific research council, and the commercialization review council—that oversee the peer review of grant applications submitted to CPRIT. Each of those review councils has a chairman and members who chair the peer review committees.

The scientific review council has 105 review committee members, the prevention review council has 33 review committee members, and the commercial review council has 30 review committee members.

The peer reviewers are experts in the field of cancer research and prevention. They review grant applications and make recommendations regarding the award of CPRIT funds for cancer research and prevention programs.

The scientific, prevention, and commercial council chairs and committee chairs receive quarterly payments ranging from \$3,750 to \$18,750 for their review services.

The chairs and peer reviewers for the scientific council receive \$2,000 per day for each two-day meeting. Prevention peer reviewers receive \$2,000 for each meeting, which usually occur twice per year.

Source: CPRIT.

and undocumented. CPRIT does not have established criteria for determining the amount of honorarium payments or a process for approving increases to the payment amounts.

The honorarium payment amounts for certain peer reviewers are significantly higher than the payment amounts that the National Cancer Institute pays its peer reviewers.

CPRIT paid members of the prevention, scientific, and commercialization review councils quarterly payments that ranged from \$1,250 per quarter to \$18,750 per quarter. The fixed quarterly payment amounts varied among the three councils. In addition to those quarterly payments, review council members were paid \$2,000 per day for each research or prevention peer review meeting, which are usually 2 days long and occur twice a year.

Daily honorarium payment rates for the National Cancer Institute, a federal grant-awarding entity similar to CPRIT, are significantly lower than CPRIT's payment amounts. The National Cancer Institute published a schedule of nonfederal peer reviewer reimbursement rates dated July 2012, which provides a breakdown of reimbursements for non-local reviewers, local reviewers, and electronic or mail reviews. In each instance, the daily honorarium rate for a reviewer did not exceed \$200 per day (that does not include reimbursement for travel costs). CPRIT's honorarium for review committee members is \$2,000 per day, not including travel costs.

Recommendations

CPRIT's oversight committee, executive director, and agency staff should:

- Establish minimum requirements for documentation that must be submitted for payments to reviewers for their services.
- Implement a documented process to support and justify all changes in the amount of honorarium paid to reviewers.
- Review honorarium rates to ensure that they are reasonable and competitive for the value CPRIT receives.

Management's Response

- 1) CPRIT agrees that minimum requirements to document payments to reviewers for their services must include and may not be limited to timely and satisfactory completion of assigned responsibilities, i.e., written critiques and justified participation on assigned panels.
- 2) CPRIT agrees to document justified changes in the amounts of honoraria paid to reviewers and will implement this immediately.

3) CPRIT agrees with the recommendation that CPRIT review honorarium rates to ensure that they are reasonable and competitive for the value CPRIT receives.

Person Responsible for Corrective Actions: General Counsel / Chief Operating Officer

Implementation Date: On or Before May 31, 2013

CPRIT Should Ensure That Its Outsourced Information Systems Maintain Valid and Reliable Grant Management Data

In testing CPRIT's peer review and grant monitoring processes, auditors used data provided by two proprietary information systems supported by CPRIT's grant management services contractor. Those information systems support CPRIT's peer review process and grant management processes. Specifically:

- The Peer Review Management Information System is a Web-based information system that CPRIT uses as its system of record for the peer review process, including disclosures of conflicts of interest and peer review evaluation comments and scores.
- The CPRIT Application Receipt System is a Web-based application designed to allow grant applicants to submit their applications electronically through a secure connection. This application includes a document exchange system to facilitate the receipt and distribution of grant performance reports.

CPRIT had not examined the controls over those two systems. Therefore, CPRIT has no assurances that the data in and the reports generated from those systems are sufficiently reliable to support management decisions for awarding grant and managing grants. As a result, auditors were unable to determine whether the proprietary systems contained adequately designed controls to ensure data reliability. In addition, auditors identified incomplete records that should have been maintained by those systems. CPRIT relies on those records to be available to manage and monitor its grants.

CPRIT has not ensured the reliability of data processed by the Peer Review Management Information System and the CPRIT Application Receipt System.

As of December 2012, CPRIT had not obtained audits of the controls intended to ensure the reliability of data entered into and processed by its Peer Review Management Information System and the CPRIT Application Receipt System. The only audits performed involved a review of the Web security infrastructure surrounding the Peer Review Management Information System and the CPRIT Application Receipt System. Without ensuring that those two systems have adequately designed controls, CPRIT cannot ensure that the data processed by those two systems is valid and reliable and properly safeguarded from inadvertent or unauthorized alteration or deletion.

The Peer Review Management Information System did not maintain complete records.

 As discussed in Chapter 1-B, the grant management contractor reported that it extracted grant applications that were administratively withdrawn or were not qualified for full review from the Peer Review Management Information System and maintained the data for those grant applications in a separate external database maintained by the grant management services contractor's staff.

Recommendations

CPRIT's oversight committee, executive director, and agency staff should:

- Obtain audits of the Peer Review Management Information System and the CPRIT Application Receipt System and ensure that the grant management contractor corrects all weaknesses identified.
- Ensure that the Peer Review Management Information System maintains a complete record of all grant applications that receive a peer review and the score associated with the review.

Management's Response

- 1) CPRIT will obtain audits of the Peer Review Management Information System and the CPRIT Application Receipt System. CPRIT will require the grant management contractor to correct any weaknesses identified.
- 2) CPRIT agrees that the Peer Review Management Information System must contain the complete record of the review and score of all grant applications that are reviewed. CPRIT will ensure that all review records are maintained in the system.

Person Responsible for Corrective Actions: Chief Operating Officer / Compliance Officer

Implementation Date: On or Before August 31, 2013

The Legislature Should Consider Clarifying Certain Statutory Requirements to Increase Transparency and Accountability at CPRIT

The Legislature should consider clarifying statutory requirements to strengthen the independence and professional judgment of CPRIT's grant decisions and governance structure. Specifically, the Legislature should consider implementing statutory requirements in the following areas:

- Ensuring the transparency of peer reviewers' recommendations. Texas Health and Safety Code, Section 102.251(a)(1), currently restricts CPRIT's peer review councils to providing their grant recommendations only to the executive director. However, allowing the peer review councils to also provide their recommendations to CPRIT's oversight committee would enhance the transparency and accountability of the process by ensuring that the oversight committee is aware of any differences in the grant recommendations made by the peer review councils and by CPRIT's executive director. In addition, Texas Health and Safety Code, Section 102.251(a)(2), requires the executive director to provide only a list of recommendations to the oversight committee. However, allowing the executive director to provide the oversight committee recommendations along with the other factors that the executive director considered would improve the transparency of the executive director's recommendations and CPRIT's grant awarding decisions.
- Clarifying the Legislature's expectations of how matching funds should be used. As discussed in Chapter 1-C, CPRIT allowed grantees to report funding that was not used on CPRIT-funded research as matching funds. The Texas Constitution, Article III, Section 67, and Texas Health and Safety Code, Section 102.255(d), specify that the recipient of a CPRIT grant must have matching funds equal to one-half the total CPRIT grant amount, and those funds must be dedicated to the research that is the subject of the CPRIT grant request. Texas Health and Safety Code, Section 102.251(2)(F), states that CPRIT's executive director shall give priority to grant applications that are matched with funds available by a private or nonprofit entity and institution or institutions of higher education. Federal matching funds requirements obligate grantees to share in the cost and risk of the actual research being funded by a federal grant.
- Strengthening the restrictions over contributions made to the CPRIT Foundation. The General Appropriations Acts (81st and 82nd Legislatures) prohibit an individual, organization, CPRIT employee, or family member of a CPRIT employee who makes a donation to the CPRIT Foundation from being eligible to receive grants from CPRIT. However, as discussed in Chapter 1-A, several non-profit foundations affiliated with certain CPRIT grantees made contributions to the CPRIT Foundation. While CPRIT did not directly grant funds to those non-profit foundations, the foundations may

- be managed by or employ individuals who also manage or work for entities that receive a grant from CPRIT.
- Strengthening the governance structure related to the CPRIT Foundation. Currently, three members of CPRIT's oversight committee are also members of the CPRIT Foundation's board of directors. Allowing an interlocking directorate between CPRIT and the CPRIT Foundation increases the risk of impairments to the independence and professional judgment of CPRIT's oversight committee. (See Appendix 7 for more information about the CPRIT Foundation.)
- Ensuring the independence of CPRIT management and staff. Auditors determined that CPRIT's executive director, chief scientific officer, and a member of its commercialization review council served as members of CTNeT's board of directors. The business and professional relationship between these individuals and the grantee impairs CPRIT's ability to ensure that CTNeT uses funds properly and complies with grant requirements.
- Strengthening the governance structure of the oversight committee. Texas Health and Safety Code, Section 102.104, states that the oversight committee shall select a presiding officer from among its members. There is no written guidance concerning the term of the presiding officer or the primary responsibilities of the presiding officer or other executive positions on the oversight committee.
- Ensuring that the oversight committee is held accountable for its grant decisions. Texas Health and Safety Code, Section 102.252, requires CPRIT's oversight committee to follow the funding recommendations of the executive director in the order that the executive director submits the applications to the oversight committee, unless two-thirds of the committee's members vote to disregard the executive director's recommendations. Although the oversight committee is authorized to veto recommendations, it does not explicitly authorize the oversight committee to approve recommendations.
- Strengthening the membership of the oversight committee. Texas Health and Safety Code, Section 102.101(b), lists the Comptroller of Public Accounts (Comptroller) or the Comptroller' designee, and the Attorney General or the Attorney General's designee as members of the oversight committee. However, the Comptroller's and Attorney General's membership on the oversight committee could impair their independence or professional judgment as elected officials who are responsible for ensuring the enforcement of state laws and regulations over state entities, including CPRIT and its grantees.
- Improving the transparency and accountability of contributions to the CPRIT Foundation. The CPRIT Foundation should make publicly available all financial information related to its revenues, including the names of

donors and the amount of their contributions and expenditures, including vendor names and contract agreements. Texas Business Organization Code, Section 22.353, requires nonprofit corporations to make records, books, and reports related to nonprofit corporations' financial activities available to the public for inspection. Without the donor information, CPRIT management cannot effectively ensure that CPRIT does not award grants to entities that make contributions to the CPRIT Foundation.

Recommendations

The Legislature should consider implementing statutory requirements that:

- Allow peer reviewers to provide their grant recommendations to the executive director and members of the CPRIT oversight committee at the same time.
- Clarify what funds can be used and the intended use of matching funds reported by grantees.
- Clarify whether contributions made by non-profit foundations affiliated with grantees are appropriate.
- Prohibit an interlocking directorate between CPRIT and the CPRIT Foundation.
- Prohibit CPRIT employees from serving on a grantee's board of directors and related foundations.
- Clarify the positions of the oversight committee's presiding officer and other officers, including the responsibilities and specific term of service for those positions.
- Allow members of the oversight committee to affirmatively vote to approve the executive director's recommendations.
- Remove the Attorney General and the Comptroller of Public Accounts from CPRIT's oversight committee so that their statutory duties and responsibilities would not be impaired.
- Allow the executive director to provide CPRIT's oversight committee, along with grant recommendations, documentation of the other factors that the executive director considered when making grant recommendations.
- Require the CPRIT Foundation to make its records, books, and reports available to the public.

Appendices

Appendix 1

Objectives, Scope, and Methodology

Objectives

The objectives of this audit were to:

- Determine whether the Cancer Prevention and Research Institute of Texas (CPRIT) has processes and related controls to help ensure that grantees perform in accordance with the terms of their grants.
- Determine whether CPRIT has processes and related controls to help ensure that grants are awarded in accordance with state law, rules, and CPRIT policies and procedures.

Scope

The scope of this audit covered the period from September 1, 2008, through June 30, 2012.

Methodology

The audit methodology consisted of collecting information and documentation, performing selected tests and other procedures, analyzing and evaluating the results of the tests, and conducting interviews with CPRIT management and staff.

In addition, the audit methodology included collecting financial information related to the revenues and expenditures of the CPRIT Foundation and conducting interviews with CPRIT Foundation management and staff. The CPRIT Foundation was not the subject of this audit of CPRIT. However, auditors collected financial information from the CPRIT Foundation related to the source and use of funds for salary supplements of CPRIT management, costs related to the peer review process, and support of certain grantee costs.

Auditors also performed site visits at five grantees. Auditors selected the top three grantees that were awarded the most grants, a commercialization grantee that received the most advance payments, and a research grantee that received the largest grant. Those visits included performing physical inspections of laboratories and equipment purchases, testing samples of research expenditures and matching funds certifications, and conducting interviews with grantee staff. Those five grantees were:

- Baylor College of Medicine.
- Mirna Therapeutics.
- Statewide Clinical Trials Network of Texas (CTNeT).
- The University of Texas Southwestern Medical Center.
- The University of Texas M.D. Anderson Cancer Center.

Additional samples selected for the audit included grantees, grantee expenditures, grantee financial deliverables, grantee annual progress reports, grant applications, peer review cycles, advance payments, reimbursements, and honorarium payments. Auditors used non-statistical sampling methods to select the samples. The test results from the samples selected cannot be projected to the entire population.

Auditors' assessment of the reliability of accounting data relied upon prior audit work performed for the Uniform Statewide Accounting System (USAS). Auditors determined that data provided by USAS was sufficiently reliable. In addition, auditors performed a general controls review of logical security of the applicable network and network folders.

Auditors did not assess the reliability of the data provided by CPRIT's Peer Review Management Information System and the CPRIT Application Receipt System. Both information systems are proprietary systems supported by CPRIT's grant management contractor and were physically located outside of Texas. CPRIT had not examined the controls over those two systems. Therefore, CPRIT has no assurances that the data and reports from those systems are sufficiently reliable to support management decisions for awarding and managing grants. Auditors were unable to determine whether the data in CPRIT's Peer Review Management Information System and the CPRIT Application Receipt System was sufficiently reliable for purposes of this audit.

<u>Information collected and reviewed</u> included the following:

- Grant agreements between CPRIT and grantees.
- Contracts between CPRIT and selected contractors.
- CPRIT's strategic plan.
- CPRIT's grant management policies and procedures.
- CPRIT's organization chart.
- CPRIT's oversight committee meeting minutes.

- Award documentation, including requests for applications, grant applications, pre-meeting and post-meeting conflict of interest certifications, peer reviewer scores, summary statements, due diligence reports, and limited information on intellectual property reviews.
- CPRIT annual financial reports, audited financial statements, and internal audit report.
- The CPRIT Foundation's annual reports.
- Conflict of interest statements and non-disclosure agreements signed by members of CPRIT's oversight committee, management, peer reviewers, and staff.
- Annual progress reports, financial deliverables, and other information that grantees prepared.
- Award recommendations made by CPRIT's prevention, scientific, and commercialization review councils and executive director.
- CPRIT expenditure data for fiscal years 2010, 2011, and 2012.
- Selected grantee expenditure data for fiscal years 2010, 2011, and 2012.
- CPRIT honorarium payment data for September 2009 through June 2012.
- Grant management contractor honorarium payment data for September 2009 through June 2012.
- The CPRIT Foundation's contribution data for April 2009 through August 2012.
- The CPRIT Foundation's financial data for fiscal year 2010 related to supplemental salaries for CPRIT's executive director and chief scientific officer.

<u>Procedures and tests</u> conducted included the following:

- Interviewed members of CPRIT's oversight committee, management, and staff.
- Interviewed members of the CPRIT Foundation's management.
- Interviewed grant management contractor staff.
- Interview selected grantee researchers and administrative staff.
- Reviewed payment documentation.
- Inspected selected capital equipment purchases that grantees made.

- Reviewed logical access controls.
- Reviewed pre-meeting and post-meeting conflict of interest certifications, peer reviewer scores and summary statements, due diligence reports, and limited intellectual property information.
- Reviewed annual progress reports and financial deliverables.
- Tested samples of advance payments and reimbursements to grantees for fiscal years 2010, 2011, and 2012.
- Tested a sample of honorarium payments made by CPRIT and the grant management contractor for fiscal years 2010, 2011, and 2012.
- Tested a sample of grants awarded during fiscal years 2010 and 2011.
- Compared a sample of grant agreements to The State of Texas Contract Management Guide.
- Compared a sample of grant amounts recommended by review councils and the executive director to final grant amounts.
- Compared CPRIT's conflict of interest policies and procedures to the National Institutes of Health's policies and procedures.
- Reviewed a sample of withdrawn grant applications from fiscal years 2010, 2011, and 2012.
- Reviewed renewals of grants that occurred in fiscal years 2010, 2011, and 2012.
- Tested a sample of extensions for grant contracts that occurred in fiscal years 2011 and 2012.
- Reviewed close-out procedures for a sample of grant contracts that expired in fiscal years 2011 and 2012.
- Reviewed procurement files for the grant management services contractor and the virtual management company services contractor.

<u>Criteria used</u> included the following:

- Texas Constitution, Article III, Section 67.
- Texas Health and Safety Code, Chapter 102.
- Texas Government Code, Chapters 2155 and 2255.
- Texas Business Organizations Code, Chapter 22.

- Title 25, Texas Administrative Code, Chapters 702 and 703.
- The General Appropriations Acts (81st and 82nd Legislatures).
- *Uniform Grant Management Standards*, Governor's Office of Budget and Planning, as adopted June 2004.
- CPRIT's grant agreements with grantees and contracts with contractors.
- CPRIT's policies and procedures.
- *The State of Texas Procurement Manual.*
- The State of Texas Contract Management Guide.
- National Institutes of Health's policies and procedures for its peer review process, conflicts of interest, and honorarium payments.

Project Information

Audit fieldwork was conducted from June 2012 through November 2012. We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

The following members of the State Auditor's staff performed the audit:

- Willie J. Hicks, MBA, CGAP (Project Manager)
- Kathy Aven, CIA, CFE (Assistant Project Manager)
- Robert H. Bollinger, CPA, CFE
- John Boyd, CIDA
- Mark Cavazos
- Michael O. Clayton, CPA, CISA, CIDA, CFE
- Michael Gieringer, CFE
- Lucien Hughes
- Tracy Jarratt, CPA, CISA
- Jennifer Ranea Robinson, CPA, MBA
- Juan R. Sanchez, MPA, CGAP, CIA

- Sherry Sewell, CGAP
- Jessica Volkmann
- Brenda Zamarripa, CGAP
- J. Scott Killingsworth, CIA, CGAP, CGFM (Quality Control Reviewer)
- Cesar Saldivar, CGAP, CICA (Audit Manager)

Appendix 2

Summary of CPRIT Grants Awarded from September 2009 through August 2012

Table 3 lists the entities that received grants from the Cancer Prevention and Research Institute of Texas (CPRIT) sorted by the total dollar value of funds awarded to each grantee from September 2009 through August 2012.⁴

Table 3

	Entities that Received CPRIT Grants										
	September 2009 through August 2012										
			Research Grants		Prevention Grants		Commercialization Grants		Total Grants		
Rank	Grantee	Number of Grants	Total Funds Awarded	Number of Grants	Total Funds Awarded	Number of Grants	Total Funds Awarded	Number of Grants	Total Funds Awarded	Percentage of Total Number of Grants	
1	The University of Texas Southwestern Medical Center	134	\$164,030,875	7	\$9,549,709	0	0	141	\$173,580,584	24.5%	
2	The University of Texas M.D. Anderson Cancer Center	97	137,037,093	10 ^a	4,305,419	0	\$0	107	141,342,512	18.6%	
3	Baylor College of Medicine	80	82,385,030	3	5,066,713	0	0	83	87,451,743	14.4%	
4	The University of Texas at Austin	25	35,583,678	1	266,920	0	0	26	35,850,598	4.5%	
5	The Methodist Hospital Research Institute	11	25,283,225	0	0	0	0	11	25,283,225	1.9%	
6	Statewide Clinical Trials Network of Texas (CTNeT)	1	25,213,675	0	0	0	0	1	25,213,675	0.2%	
7	The University of Texas Health Science Center at San Antonio	21	17,552,511	7	6,741,439	0	0	28	24,293,950	4.9%	
8	Rice University	8	23,472,111	0	0	0	0	8	23,472,111	1.4%	

⁴CPRIT provided the data presented in Appendices 2 and 4. As discussed previously in this report, the data in CPRIT's information systems may not be complete or reliable (see Chapter 5).

Entities that Received CPRIT Grants September 2009 through August 2012										
		Rese	earch Grants	Preve	ntion Grants	Commerc	ialization Grants	Total Grants		
Rank	Grantee	Number of Grants	Total Funds Awarded	Percentage of Total Number of Grants						
9	The University of Texas Health Science Center at Houston	14	18,442,131	5	4,983,062	0	0	19	23,425,193	3.3%
10	Houston-Area Translational Research Consortium and the Institute for Applied Cancer Science	0	0	0	0	1	20,000,000	1	20,000,000	0.2%
11	Cell Medica	0	0	0	0	1	15,571,303	1	15,571,303	0.2%
12	Caliber Biotherapeu- tics, LLC	0	0	0	0	1	12,808,151	1	12,808,151	0.2%
13	Texas Tech University Health Sciences Center	8	6,460,659	4 ^C	4,831,994	0	0	12	11,292,653	2.1%
14	Peloton Therapeutics, Inc.	0	0	0	0	1	11,044,931	1	11,044,931	0.2%
15	Molecular Templates, Inc.	0	0	0	0	1	10,600,000	1	10,600,000	0.2%
16	Mirna Therapeutics, Inc.	0	0	0	0	1	10,297,454	1	10,297,454	0.2%
17	Kalon Biotherapeu- tics, LLC	0	0	0	0	1	7,901,420	1	7,901,420	0.2%
18	The University of Texas Medical Branch at Galveston	9	6,512,077	2	1,239,025	0	0	11	7,751,102	1.9%
19	Texas A&M University	6	6,627,777	2	839,227	0	0	8	7,467,004	1.4%
20	Pulmotect, Inc.	0	0	0	0	1	7,126,398	1	7,126,398	0.2%
21	Texas A&M University System Health Science Center	3	3,201,312	4	3,830,498	0	0	7	7,031,810	1.2%

Entities that Received CPRIT Grants September 2009 through August 2012

	September 2007 through August 2012									
			arch Grants	Prever	Prevention Grants		Commercialization Grants		Total Grants	
Rank	Grantee	Number of Grants	Total Funds Awarded	Number of Grants	Total Funds Awarded	Number of Grants	Total Funds Awarded	Number of Grants	Total Funds Awarded	Percentage of Total Number of Grants
22	University of Houston	7	6,597,188	1	272,753	0	0	8	6,869,941	1.4%
23	Asuragen, Inc.	0	0		0	1	6,837,265	1	6,837,265	0.2%
24	University Health System	0	0	6	6,218,267	0	0	6	6,218,267	1.0%
25	The University of Texas at Dallas	5	5,909,898	0	0	0	0	5	5,909,898	0.9%
26	Bellicum Pharmaceuti- cals, Inc.	0	0	0	0	1	5,680,310	1	5,680,310	0.2%
27	Apollo Endosurgery	0	0	0	0	1	5,001,063	1	5,001,063	0.2%
28	The University of Texas System	1	5,000,000	0	0	0	0	1	5,000,000	0.2%
29	The University of North Texas Health Science Center at Fort Worth	2	179,834	5	4,350,995	0	0	7	4,530,829	1.2%
30	The Rose	0	0	3	3,845,471	0	0	3	3,845,471	0.5%
31	Scott and White Healthcare	1	3,584,521	0	0	0	0	1	3,584,521	0.2%
32	Texas Tech University	3	2,899,790	2	592,546	0	0	5	3,492,336	0.9%
33	Texas A&M AgriLife Extension Service	0	0	3 ^d	3,410,830	0	0	3	3,410,830	0.5%
34	Rules-Based Medicine	0	0	0	0	1	3,024,432	1	3,024,432	0.2%
35	Department of State Health Services	0	0	1	2,936,382	0	0	1	2,936,382	0.2%
36	Baylor University Medical Center at Dallas	1	2,500,000	0	0	0	0	1	2,500,000	0.2%

					s that Received per 2009 throug					
		Research Grants		Preve	Prevention Grants		Commercialization Grants		Total Grants	
Rank	Grantee	Number of Grants	Total Funds Awarded	Number of Grants	Total Funds Awarded	Number of Grants	Total Funds Awarded	Number of Grants	Total Funds Awarded	Percentage of Total Number of Grants
37	Texas Tech University Health Science Center at Dallas	1	2,500,000	0	0	0	0	1	2,500,000	0.2%
38	City of Laredo Health Department	0	0	1	2,497,500	0	0	1	2,497,500	0.2%
39	Mental Health Mental Retardation of Tarrant County	0	0	2	2,397,784	0	0	2	2,397,784	0.3%
40	The University of Texas at Arlington	4	2,285,375	0	0	0	0	4	2,285,375	0.7%
41	Cancer and Chronic Disease Consortium	0	0	1	2,177,340	0	0	1	2,177,340	0.2%
42	Visualase, Inc.	1	2,151,776	0	0	0	0	1	2,151,776	0.2%
43	Baylor Research Institute	2	2,108,180	0	0	0	0	2	2,108,180	0.3%
44	Texas Nurses Foundation	0	0	5 ^e	2,107,901	0	0	5	2,107,901	0.9%
45	The University of Texas Medical School at Houston	1	2,000,000	0	0	0	0	1	2,000,000	0.2%
46	Centro San Vicente	0	0	1	1,937,461	0	0	1	1,937,461	0.2%
47	Texas Tech University Health Science Center at El Paso	1	1,500,000	0	0	0	0	1	1,500,000	0.2%
48	Asian American Health Coalition of Greater Houston (doing business as Hope Clinic)	0	0	3	1,450,887	0	0	3	1,450,887	0.5%

Entities that Received CPRIT Grants September 2009 through August 2012 **Research Grants Prevention Grants Commercialization Grants Total Grants** Percentage of Total of Grants of Grants **Total Funds Total Funds Total Funds Total Funds** Number of Grants Rank Grantee Awarded **Awarded** Awarded Awarded 49 Angelo State 0 0 1 1,120,825 0 0 1 1,120,825 0.2% University 50 999,992 0 0 1 The University 1 0 0 999,992 0.2% of Texas at El Paso 51 The Bridge 0 0 0 0 1 977,603 0.2% 1 977,603 Breast Network 52 Texas Medical 0 ₂ f 967,425 0 0 2 967,425 0.3% 0 Association 0 2 53 Texas Tech 2 936,652 0 0 0 936,652 0.3% University Health Science Center at Amarillo 54 2 0 2 The University 898,026 0 0 0 898,026 0.3% of Texas at San Antonio 0 0.2% 55 Texas Tech 1 756,644 0 0 0 1 756,644 University

0

608,579

600,000

599,571

591,384

562,004

551,221

0

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748,905

608,579

600,000

599,571

591,384

562,004

551,221

0.2%

0.3%

0.3%

0.2%

0.2%

0.2%

0.2%

Health Science Center -Abilene Gradalis, Inc.

(MIRA Subaward)

Ministries of Laredo

Mercy

Lance

Armstrong Foundation

Methodist

The Cooper

Seton Family

of Hospitals -Austin Cancer Center

Institute

National

Center for Farmworker Health, Inc.

Dallas Medical Center

57

58

59

60

61

62

1

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1

Entities that Received CPRIT Grants										
				Septemb	er 2009 throu	gh August	2012			
		Rese	arch Grants	Preve	Prevention Grants		Commercialization Grants		Total Grants	
Rank	Grantee	Number of Grants	Total Funds Awarded	Number of Grants	Total Funds Awarded	Number of Grants	Total Funds Awarded	Number of Grants	Total Funds Awarded	Percentage of Total Number of Grants
63	Methodist Richardson Medical Center	0	0	1	535,540	0	0	1	535,540	0.2%
64	Migrant Clinicians Network	0	0	1	473,405	0	0	1	473,405	0.2%
65	Texas A&M University System Health Science Center Research Foundation	0	0	1 ^g	339,932	0	0	1	339,932	0.2%
66	Department of State Health Services	0	0	1 ^g	335,271	0	0	1	335,271	0.2%
67	Light and Salt Association	0	0	1	329,933	0	0	1	329,933	0.2%
68	Shannon Business Services	0	0	1	255,198	0	0	1	255,198	0.2%
69	Healthy Tarrant County Collaboration	0	0	1	212,535	0	0	1	212,535	0.2%
70	Texas A&M Health Science Center Baylor College of Dentistry	0	0	1 ^g	203,244	0	0	1	203,244	0.2%
71	University of North Texas	1	200,000	0	0	0	0	1	200,000	0.2%
72	Baylor University	1	200,000	0	0	0	0	1	200,000	0.2%
73	Ingeneron, Inc.	1	198,111	0	0	0	0	1	198,111	0.2%
74	Funding Solutions	0	0	1 ^g	157,494	0	0	1	157,494	0.2%

149,971

0

0

149,971

0.2%

South Texas Rural Health

Services, Inc.

0

0

75

					s that Received oer 2009 throug					
		Research Grants		Preve	Prevention Grants		Commercialization Grants		Total Grants	
Rank	Grantee	Number of Grants	Total Funds Awarded	Number of Grants	Total Funds Awarded	Number of Grants	Total Funds Awarded	Number of Grants	Total Funds Awarded	Percentage of Total Number of Grants
76	LRGV Community Health Management Corporation, Inc. (doing business as El Milagro Clinic)	0	0	1	149,100	0	0	1	149,100	0.2%
77	Daughters of Charity Health Services of Austin (doing business as SETON Healthcare Network)	0	0	1 ⁹	128,640	0	0	1	128,640	0.2%
78	Cancer Foundation for Life	0	0	1 ^g	100,000	0	0	1	100,000	0.2%
79	Cancer Services Network	0	0	1 ^g	99,581	0	0	1	99,581	0.2%
80	Texas Life Science Foundation	1	7,745	0	0	0	0	1	7,745	0.2%

^a The number of prevention grants includes two grants totaling \$521,300 that CPRIT reported were awarded before September 1, 2009.

\$85,898,579

458

Grand Totals

105

\$595,964,791

575 h

\$797,756,097

\$115,892,727

12

100.0%

Source: CPRIT.

 $^{^{\}mbox{\scriptsize b}}$ CPRIT reported it rescinded the incubator award in May 2012.

^C The number of prevention grants includes a grant totaling \$165,891 that CPRIT reported was awarded before September 1, 2009.

 $^{^{}m d}$ The number of prevention grants includes a grant totaling \$412,125 that CPRIT reported was awarded before September 1, 2009.

^e The number of prevention grants includes a grant totaling \$713,588 that CPRIT reported was awarded before September 1, 2009.

 $^{^{\}rm f}$ The number of prevention grants includes a grant totaling \$467,425 that CPRIT reported was awarded before September 1, 2009.

^g CPRIT reported that the prevention grant was awarded before September 1, 2009.

h The number of grants reported includes sub-awards for multi-investigator research awards; a multi-investigator research grant awarded to one grantee may have one or more sub-awards to additional grantees.

i Column does not sum exactly to 100.0 due to rounding.

Summary of Grants Awarded to Texas Entities by the National Cancer Institute as of September 2011

Table 4 shows the federal grants that the National Cancer Institute awarded to Texas-based grantees from October 2010 through September 2011, as reported by the National Cancer Institute.

Table 4

	Grants Awarded to Texas Entities by the National Cancer Institute				
	October 2010 through September 2011				
Item	Grantee	Number of Grants	Funded Amount	Percentage of Total Number of Grants	
1	The University of Texas M.D. Anderson Cancer Center	237	\$116,394,027	42.8%	
2	Baylor College of Medicine	81	31,139,052	14.6%	
3	The University of Texas Southwestern Medical Center	53	21,731,120	9.6%	
4	The University of Texas Health Science Center at San Antonio	39	15,523,469	7.0%	
5	The University of Texas at Austin	25	5,988,953	4.5%	
6	The University of Texas Medical Branch at Galveston	21	4,832,529	3.8%	
7	The University of Texas Health Science Center at Houston	18	7,250,290	3.2%	
8	Methodist Hospital Research Institute	10	6,482,944	1.8%	
9	Texas Tech University Health Sciences Center	10	2,846,094	1.8%	
10	Texas A&M University System	9	1,879,635	1.6%	
11	Rice University	7	2,918,870	1.3%	
12	University of Houston	5	806,341	0.9%	
13	The University of Texas M.D. Anderson Cancer Center	4	3,052,339	0.7%	
14	Baylor Research Institute	4	1,569,988	0.7%	
15	Texas A&M University Health Science Center	4	992,323	0.7%	
16	The University of Texas at Arlington	3	557,143	0.5%	
17	University of North Texas Health Science Center at Fort Worth	3	388,446	0.5%	
18	Scott and White Memorial Hospital	2	481,207	0.4%	
19	The University of Texas-Pan American	2	251,696	0.4%	
20	Asuragen, Inc.	1	590,860	0.2%	

	Grants Awarded to Texas Entities by the National Cancer Institute October 2010 through September 2011			
Item	Grantee	Number of Grants	Funded Amount	Percentage of Total Number of Grants
21	Radiant Creative Group, LLC	1	573,567	0.2%
22	Texas A&M University	1	533,060	0.2%
23	The University of Texas at Dallas	1	473,745	0.2%
24	Nanospectra Biosciences, Inc.	1	445,017	0.2%
25	Texas A&M Engineering Experiment Station	1	300,362	0.2%
26	Baylor University	1	282,992	0.2%
27	Stellarray, Inc.	1	244,537	0.2%
28	Caisson Biotech, LLC	1	282,450	0.2%
29	Omm Scientific, Inc.	1	199,931	0.2%
30	Radix Therapeutics, LLC	1	199,757	0.2%
31	Apocell, Inc.	1	198,812	0.2%
32	Biotex, Inc.	1	149,919	0.2%
33	The University of Texas at San Antonio	1	139,050	0.2%
34	Houston Department of Health and Human Services	1	59,869	0.2%
35	Gradalis, Inc.	1	50,000	0.2%
36	The University of Texas at El Paso	1	0	0.2%
	Grand Totals	554	\$229,810,394	99.5% ^a
a Perce	entage does not sum to 100 percent	due to rounding.		

Source: National Cancer Institute.

Summary of Payments to CPRIT Grantees from September 2009 through August 2012

From September 2009 through August 2012, the Cancer Prevention and Research Institute of Texas (CPRIT) made payments to grantees totaling \$144.4 million. Approximately \$40.2 million were advance payments to grantees and approximately \$104.2 million were reimbursements. Table 5 ranks each grantee based on the total dollar value of advance payments CPRIT made from September 2009 through August 2012.

Table 5

	Advance Payments CPRIT Made to Grantees September 2009 through August 2012				
Rank	Grantee	Total Advance Payments			
1	Cell Medica, Inc.	\$ 7,785,656			
2	Statewide Clinical Trials Network (CTNeT) ^a	6,786,915			
3	Mirna Therapeutics, Inc.	6,309,461			
4	Apollo Endosurgery	5,001,063			
5	Caliber Biotherapeutics, LLC	4,215,004			
6	Peloton Therapeutics, Inc.	3,201,002			
7	Bellicum Pharmaceuticals, Inc.	2,779,166			
8	Rules-Based Medicine, Inc.	2,015,129			
9	Visualase, Inc. b	1,439,964			
10	Baylor College of Medicine C	700,000			
	Grand Total	\$40,233,360			

^a CTNeT also received \$165,627 in reimbursements.

Source: CPRIT.

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^b Visualase, Inc. also received \$704,765 in reimbursements.

^C The Baylor College of Medicine received an advance payment for a recruitment research award. It also received \$18,995,014 in reimbursements on other research and prevention grants awarded by CPRIT.

⁵ CPRIT provided the data presented in Appendices 2 and 4. As discussed previously in this report, the data in CPRIT's information systems may not be complete or reliable (see Chapter 5).

Table 6 lists each grantee based on the total dollar value of reimbursements that CPRIT made from September 2009 through August 2012 as reported by CPRIT.

Table 6

	Reimbursements CPRIT Made to Grantees	
	September 2009 through August 2012	
Item	Grantee	Total Reimbursements
1	The University of Texas Southwestern Medical Center	\$ 20,631,574
2	Baylor College of Medicine	18,995,014
3	The University of Texas M.D. Anderson Cancer Center	15,736,170
4	The University of Texas Health Science Center at Houston	7,167,673
5	The University of Texas at Austin	6,118,709
6	The University of Texas Health Science Center at San Antonio	4,314,093
7	Texas Tech University Health Sciences Center	4,053,831
8	The University of Texas Medical Branch at Galveston	3,108,058
9	University of Houston	2,106,255
10	Rice University	1,872,639
11	Texas Nurses Foundation	1,792,914
12	The Rose	1,308,527
13	Texas Medical Association	1,067,846
14	The Methodist Hospital Research Institute	930,713
15	Texas A&M Research Foundation	877,930
16	Texas A&M University System Health Science Center Research Foundation	851,642
17	University of North Texas Health Science Center at Fort Worth	824,117
18	City of Laredo Health Department	811,063
19	Texas A&M AgriLife Extension Service	715,210
20	Visualase, Inc.	704,765
21	The University of Texas at Dallas	643,404
22	Asian American Health Coalition (doing business as Hope Clinic)	642,435
23	The Bridge Breast Network	580,806
24	The Methodist Research Institute	494,832
25	Department of State Health Services	457,275
26	City of Laredo	447,130
27	The Cooper Institute	398,584
28	University Health System	386,024
29	Texas A&M University	366,199
30	Methodist Hospital Research Institute	357,816
31	The University of Texas M.D. Anderson Cancer Center at Dallas	335,170
32	Texas A&M AgriLife Research	312,117

Reimbursements CPRIT Made to Grantees September 2009 through August 2012

Item	Grantee	Total Reimbursements
33	Texas A&M University System Health Science Center	311,855
34	Texas Tech University	277,685
35	Mercy Ministries of Laredo	266,177
36	Gradalis, Inc.	226,181
37	Cancer Foundation for Life	220,391
38	Funding Solutions	217,496
39	Lance Armstrong Foundation	200,000
40	Cancer Services Network	195,691
41	Baylor University	180,303
42	Shannon Business Services	170,975
43	The University of Texas at El Paso	167,154
44	Statewide Clinical Trials Network (CTNeT)	165,627
45	Methodist Richardson Medical Center	161,314
46	Bexar County University Health System	159,704
47	The University of Texas at Arlington	154,004
48	Lower Rio Grande Valley Community Health Management (doing business as El Milagro Clinic)	147,997
49	University of North Texas	138,115
50	Mental Health Mental Retardation of Tarrant County	122,178
51	Migrant Clinicians Network, Inc.	116,467
52	National Center for Farmworker Health	107,516
53	The University of Texas at Brownsville and Texas Southmost College	98,419
54	The University of Texas at San Antonio	94,739
55	Asian American Health Coalition	92,339
56	University Health System	80,036
57	South Texas Rural Health Services	75,923
58	Austin Cancer Center	67,573
59	Texas Tech University Health Sciences Center - Amarillo	63,688
60	Seton Family of Hospitals	59,160
61	The University of Texas Medical Branch at Galveston	57,000
62	Healthy Tarrant County Collaboration	46,097
63	Texas Medical Association	42,858
64	Centro San Vicente	36,394
65	Austin Cancer Center, Cancer Care Team	34,953
66	Texas Tech University Health Sciences Center - Dallas	34,895
67	Shannon Business Services	29,738
68	South Texas Rural Health Services	25,089

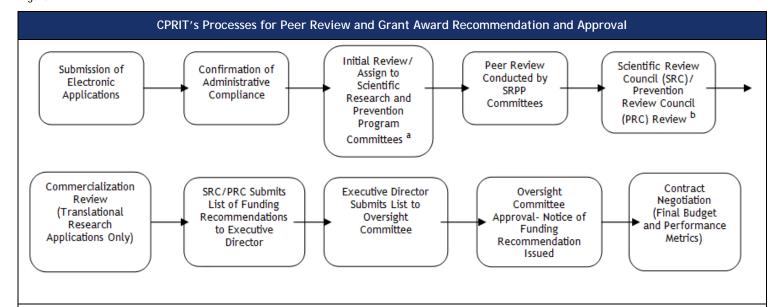
	Reimbursements CPRIT Made to Grantees September 2009 through August 2012	
Item	Grantee	Total Reimbursements
69	Texas Tech University Health Sciences Center - El Paso	25,012
70	Mercy Ministries	23,716
71	Light and Salt Association	18,174
72	Baylor Research Institute	16,954
73	Rice University	10,648
74	Texas Tech University	10,330
75	City of Laredo Health Department	8,824
76	Funding Solutions	5,800
77	Center for Health Evaluation, Education, & Resources (Cheer)	4,900
78	Candlelighters of the El Paso Area	4,100
79	Partners Together for Health	4,100
80	Texas Life Science Foundation	3,423
81	Vannie E. Cook Cancer Foundation	2,800
82	Cancer Connection, Patient Care Fund	2,800
83	University Medical Center Foundation of El Paso	2,800
84	Combined Community Action	2,100
85	The University of Texas Southwestern Medical Center Moncrief Cancer Institute	2,100
86	Sisters Network, Inc Dallas Chapter	2,100
87	Breast Cancer Resource Center of Texas	2,081
88	Covenant Health System Foundation	2,000
89	Compassionate Touch	2,000
90	Lee County Area Cancer Resource Center	1,857
91	CHRISTUS Spohn Cancer Center	887
	Grand Total	\$104,215,772

Source: CPRIT.

Overview of CPRIT's Peer Review Process

Figure 1 shows the Cancer Prevention and Research Institute of Texas's (CPRIT) key processes for peer review, award recommendation, and approval of grant applications as illustrated in CPRIT's *Policies and Procedures Guide, CPRIT Applications and Funding Awards* dated November 18, 2009.

Figure 1



^a Scientific research and prevention program (SRPP) committee members are experts in the field of cancer research and prevention who are appointed by CPRIT's executive director and approved by its oversight committee for the purpose of reviewing applications and making recommendations to the executive director regarding the award of CPRIT funds for cancer research and prevention programs.

The prevention review council (PRC) is a group of individuals designated as chairs of the SRPP committees created to review cancer prevention program applications. The PRC evaluates the analysis completed by the SRPP committees and, based upon those findings and in consideration of programmatic goals, creates a list of cancer prevention funding recommendations for CPRIT's executive director.

Source: CPRIT.

b The scientific review council (SRC) is a group of individuals designated as chairs of the SRPP committees with responsibility to review cancer research applications. The SRC evaluates the analysis completed by the SRPP committees and, based upon those findings and in consideration of programmatic goals, creates a list of cancer research funding recommendations for CPRIT's executive director.

Summary of Contributions from Donors to the CPRIT Foundation from April 2009 through August 2012

Table 7 lists the approximately \$3.7 million in donor contributions that the Cancer Prevention and Research Institute of Texas (CPRIT) Foundation reported it received from April 30, 2009 through August 1, 2012.⁶

Table 7

Contributions to the CPRIT Foundation April 30, 2009 through August 1, 2012		
Donor	Total Contribution	
O'Donnell Foundation	\$1,600,000	
Eisai Inc.	200,000	
Novartis Pharmaceuticals Corp.	185,000	
Amgen USA	135,000	
Genentech USA	135,000	
Pfizer, Inc.	110,000	
Charles Tate	60,000	
Southwestern Medical Foundation	52,500	
Eli Lilly and Company	50,000	
Texas A&M University HSC Foundation	37,500	
Vinson & Elkins LLP	37,000	
Texas Tech University System - Foundation	35,000	
Texas Tech University System Foundation	35,000	
The Methodist Hospital System - Foundation	35,000	
Barry G. Andrews	35,000	
Daiichii Sankyo, Inc.	35,000	
Mary Crowley Cancer Foundation	35,000	
Astellas USA Foundation	30,000	
Texas A&M Foundation	30,000	
Serafy Foundation	30,000	
Texas Tech System Admin. Foundation	30,000	
Joseph S. Bailes	27,500	
Thomas Kaplan	27,500	
James M. Mansour (in kind)	27,323	
University of Houston Foundation	25,000	
Dee Kelly	25,000	
UNT Health Science Center Foundation	22,500	

⁶ The CPRIT Foundation provided auditors the data presented in this appendix on August 6, 2012. Auditors did not audit the CPRIT Foundation for this report and did not verify the accuracy of this data.

Contributions to the CPRIT Foundation April 30, 2009 through August 1, 2012		
Donor	Total Contribution	
UT Foundation	22,500	
Hewlett Packard Company	20,000	
Christus Health	20,000	
Al Gilman	19,124	
Ralph O'Connor	17,500	
Physicians Cancer Research Foundation Inc	17,500	
James M Mansour Foundation	15,631	
The Methodist Hospital System -Foundation	15,000	
Cephalon, Inc.	15,000	
CB Richard Ellis	15,000	
Peter O'Donnell, Jr.	15,000	
The Greater S.A. Chamber of Commerce	15,000	
TMH Foundation	15,000	
Merck Sharp & Dohme Corp.	15,000	
Law Offices of Douglas A Allison	15,000	
Moncrief Cancer Foundation	15,000	
CITI	12,500	
Hunt Family Foundation	12,000	
UT Chancellor's Fund	11,553	
Charles Schwab	10,000	
Cindy Brinker	10,000	
Lionel Sosa	10,000	
Bill Gimson	9,000	
Medical Metrics, Inc.	8,750	
The Barnabas Fund, Inc.	7,500	
Luminant	7,500	
Edelman	7,500	
Blackridge	7,500	
Susan G. Komen for the Cure	7,500	
Yvonne & Joseph Bailes	7,500	
TX Health Presbyterian Foundation	7,500	
The Biophysical Corporation	7,500	
John B. Benear II MD	7,500	
Daiichi Sankyo, Inc.	7,500	
Roche Diagnostics Corporation	7,500	
Carolyn Frost Keenan	7,500	
0: 1 0:	7.500	

7,500

7,500

Cindy Simmons

City of San Antonio Tx Educ. Fac. Corp

Contributions to the CPRIT Foundation April 30, 2009 through August 1, 2012		
Donor	Total Contribution	
RBM	7,500	
Cancer Therapy and Research Center Found.	7,500	
Thonpson Energy Group LLC	5,000	
Communities Foundation of Texas	5,000	
Kern Wildenthal, MD	5,000	
Harold Simmons Foundation	5,000	
Wm A & Elizabeth B Moncrief Foundation	5,000	
The Hicks Family Charitable Foundation	5,000	
John Cullen	4,506	
Burson-Marsteller	3,750	
Thompson Energy Group LLC	3,750	
Mike A. Myers	3,000	
Brenda Pejovich	2,500	
Sanford L. Gottesman	2,500	
John Lay	2,500	
Kristin L. Lonergan	2,500	
DCMS Foundation	2,500	
Eli Lilly Foundation	2,500	
Morris S. Gottesman	2,500	
Barbara R. Hurwitz	2,000	
Andro Diagnostics	2,000	
The Dallas Foundation	2,000	
William & Evelyn Griffin Fund	1,750	
Kenneth H Cooper	1,500	
S. Mark Powell	1,000	
David Shanahan	1,000	
Anne Brennan	1,000	
Law Offices of Douglas A. Allison	1,000	

Malcolm Gillis

John Genung

David Shaw

James Huffines

Alzheimer's Association

Lexicon Pharmaceuticals

Cammack & Strong, P.C.

Patricia & Albert Tate

Charles E. Geyer Jr.

Gregory Marchbanks

1,000

1,000

1,000

1,000

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1,000

Contributions to the CPRIT Foundation April 30, 2009 through August 1, 2012 **Total Contribution** Donor Mary Elliot 1,000 Wells Fargo 1,000 uSHVMS, LLC 1,000 Elizabeth Butler Granger 1,000 Jerry & Rebecca Lindauer 1,000 Amanda M. Beck 1,000 The Schweitzer Family Foundation 1,000 Paul Robshaw 1,000 Danziger & Dellano LLP 1,000 1,000 Michael Kasper Ralph T. Hull 750 Dee Osborne 500 **Booth Family Trust** 500 F. Jackson 500 Richard J. Trabulsi Jr. 500 Barbara Hurwitz 500 John A. Dieck Jr. 500 Ralph B. Thomas 500 Don Glendenning 500 **American Cancer Society** 500 Lewis Little 500 Texas Enterprises, Inc. 500 Deborah Holland Sheikh 500 Citigroup Payment Services 500 Catherine C. Brock 500 Joan S. Bentzin 500 Staubach, Roger or Marianne 500

Clayton Duncan

Stephen King

Kay O Miller

Keith Lauderdale

S. Joel Hastings

Rosemary Walton

Faith Johnson and Assoc.

Brandon & Heidi Hicks

Rod Edens Jr.

Graves, Daugherty, Hearon & Moody PC

Joe and Janis Pinelli

500

500

500

500

250

250

250

250

250

250

250

Contributions to the CPRIT Foundation April 30, 2009 through August 1, 2012		
Donor	Total Contribution	
Harold E. Varmus	195	
Karl Holtzman	100	
ETMG, LLC	70	
Ray L. Thompson	25	
Total Contributions	\$3,666,527	

Source: The CPRIT Foundation.

The Cancer Prevention and Research Institute of Texas (CPRIT) Foundation's Certificate of Formation (see Figure 2) shows that the initial board of directors that was responsible for managing the affairs of the CPRIT Foundation was made up of three members. The members identified were also serving as members of CPRIT's oversight committee.

Figure 2

CERTIFICATE OF FORMATION OF **CPRIT FOUNDATION**

MAR 2 4 2009

ARTICLE 1 ENTITY NAME AND TYPE Corporations Sec.

The filing entity being formed is a nonprofit corporation ("Corporation"). The name of the entity is:

CPRIT FOUNDATION

ARTICLE 2 REGISTERED AGENT AND REGISTERED OFFICE

The initial registered agent is an individual resident of the state whose name is set forth below:

James M. Mansour

The business address of the registered agent and the registered office address is:

111 Congress Avenue, Suite 3000 Austin, Texas 78701

ARTICLE 3 MANAGEMENT

The management of the affairs of the Corporation is vested in the board of directors. The number of directors constituting the initial board of directors is three (3). The names and addresses of the persons who are to serve as directors until their successors are elected and qualified are as follows:

James M. Mansour	111 Congress Avenue, Suite 3000 Austin, Texas 78701
Joseph S. Bailes	P.O. Box 5460 Austin, Texas 78763-5460
Cindy Brinker Simmons	KPMG Centre 717 N. Harwood St., Suite 2000 Dallas, Texas 75201

Certificate of Formation - Page 1 of 3

4252245.1 58050.1

ARTICLE 4 MEMBERS

The Corporation at all times shall have a sole member, the CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS, an agency of the State of Texas created pursuant to Article III, Section 67 of the Texas Constitution (as amended by Proposition 15, H.J.R. 90 on November 6, 2007).

ARTICLE 5 PURPOSE

The Corporation is organized and operated exclusively for the benefit of, to perform the functions of, or to carry out the purposes of, the CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS, such entity being an entity described in Section 509(a)(1) of the Internal Revenue Code of 1986, as amended ("Code"). The Corporation is intended to qualify as a "Type I" supporting organization as described in Section 509(a)(3) of the Code.

No part of the net earnings, gains, or assets of the Corporation shall inure to the benefit of or be distributable to its directors, officers, other private individuals, or organizations organized or operated for a profit (except that the Corporation shall be authorized and empowered to pay reasonable compensation for services rendered and to make payments and distributions in furtherance of the purposes as hereinabove stated).

No substantial part of the activities of the Corporation shall be the carrying on of propaganda or otherwise attempting to influence legislation, and the Corporation shall be empowered to make the election authorized under section 501(h) of the Code. The Corporation shall not participate in or intervene in (including the publishing or distributing of statements) any political campaign on behalf of or in opposition to any candidate for public office. Notwithstanding any other provision herein, the Corporation shall not carry on any activities not permitted to be carried on (a) by an organization exempt from federal income taxation under section 501(a) of the Code as an organization described in section 501(c)(3) of such Code, or (b) by an organization, contributions to which are deductible under sections 170(c)(2), 2055(a)(2), or 2522(a)(2) of the Code.

ARTICLE 6 MANNER OF DISTRIBUTION

Upon the dissolution of the Corporation, after payment or provision for payment of the Corporation's liabilities has been made, the Corporation's remaining assets shall not be transferred to private ownership, but shall be distributed exclusively to the CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS, provided that at the time of dissolution of the Corporation the CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS is a Qualified Recipient or Recipients (as hereinafter defined).

A "Qualified Recipient" shall mean either (i) an organization that is existing and qualified as exempt from federal income taxation under Section 501(a) of the Code as an organization described in Section 501(c)(3) of the Code and organized exclusively for the tax-exempt purposes as set forth in this Certificate (or such other tax-exempt purposes as may

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4252245.1 58050.1 lawfully be conducted by an organization described in Section 501(c)(3) of the Code); (ii) a federal, State or local government, exclusively for such government's public purpose; or (iii) any entity which has been declared, by court order in a duly authorized court of competent jurisdiction, as an entity which shall best accomplish the general purposes for which the Corporation was organized.

ARTICLE 7 ORGANIZER

The name and address of the organizer is:

James M. Mansour 111 Congress Avenue, Suite 3000 Austin, Texas 78701

ARTICLE 8 EFFECTIVENESS OF FILING

This document becomes effective when the document is filed by the Secretary of State.

ARTICLE 9 ACTIONS BY WRITTEN CONSENT

Any action that may be taken at a meeting of the directors or a committee may be taken without a meeting if a written consent, stating the action to be taken, is signed by the number of directors or committee members necessary to take that action at a meeting at which all of the directors or committee members are present and voting.

DATED this 23 day of March , 2009.

ORGANIZER:

Pames M. Mansour

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CPRIT Bond Issues and Debt Service Payments from September 2009 through August 2012

Table 8 shows the Cancer Prevention and Research Institute of Texas's (CPRIT) bond authority as allowed by the Texas Constitution, the amount of bond debt issued, and amount available for issuance by the Texas Public Finance Authority as of August 31, 2012.

Table 8

Issued Bond Debt and Available for Issuance for CPRIT As of August 31, 2012						
Authorization Authorization Amount Issued Unissue						
2007 Article III, Section 67 (Cancer Research)	\$3,000,000,000	\$363,500,000	\$2,636,500,000			
^a Under current law, \$150,000,000 of the authorized and unissued bond debt in the 2010-2011 biennium is not available for future use.						

Source: Texas Public Finance Authority.

Table 9 shows the bond debt outstanding and the total principal and interest payments made by the Texas Public Finance Authority as of August 31, 2012.

Table 9

Bond Debt Issued and Debt Payments Made by the Texas Public Finance Authority As of August 31, 2012					
Debt Issued	Debt Outstanding ^a	Principal Payments	Interest Payments	Total Debt Service Paid	
Commercial Paper (Series A&B)	\$ 75,700,000	\$ 3,600,000	\$ 834,181 ^a	\$ 4,434,181	
General Obligation and Refunding Bonds Taxable Series 2011	282,820,000	14,750,000 ^b	11,686,464 ^C	26,436,464	
Totals	\$358,520,000	\$18,350,000	\$12,520,645	\$30,870,645	

^a The weighted average interest rate on commercial paper (Series A&B) was 0.31 percent.

Source: Texas Public Finance Authority.

b Principal payment was made on October 1, 2012.

^C Interest payments include a payment of approximately \$6,568,305 made on April 1, 2012, and a \$5,118,160 payment made on October 1, 2012. The interest rate for the General Obligation and Refunding Bonds, Series 2011, was 4.01 percent.

Information Regarding Programs in Six Other States That Are Similar to CPRIT

Auditors identified six states with programs similar to the Cancer Prevention and Research Institute of Texas (CPRIT). Those six states and their programs are:

- California California Institute of Regenerative Medicine.
- Florida Florida BioMedical Research Advisory Council.
- Massachusetts Massachusetts Life Science Center.
- New York New York State Stem Cell Science.
- Ohio Third Frontier Commission, Ohio Office of Technology Investment.
- Pennsylvania Commonwealth Universal Research Enhancement (CURE) Program.

Table 10 lists information about the structure of those six programs.

Table 10

Structure of Six Programs Similar to CPRIT					
State	Agency Responsible for Program	Governance Structure	Board Makeup	Members of Governing Board	
Texas	Cancer Prevention and Research Institute of Texas	Oversight Committee	Governor, Lieutenant Governor, and Speaker of the House of Representatives each appoint three members; and the Comptroller of Public Accounts and Attorney General are members.	State Attorney General, Comptroller of Public Accounts (or a designee), and nine Texans appointed to the board.	
California	California Institute of Regenerative Medicine	Oversight Committee	Governor, State Controller, State Treasurer, State Senate Pro Tempore, and the Speaker of the Assembly appoint 22 members. The chancellors of the University of California (UC) at San Francisco, UC-Davis, UC-Los Angeles, UC-Irvine, and UC-San Diego each appoint an executive officer from their campuses. The board's chair and vice chair are nominated by the Governor, Lieutenant Governor, the State Controller, and State Treasurer and elected by the 27-appointed members.	Public officials with experience in California's public universities, non-profit academic and research institutions, patient advocacy groups, and the biotechnology industry.	

	Structure of Six Programs Similar to CPRIT						
State	Agency Responsible for Program	Governance Structure	Board Makeup	Members of Governing Board			
Florida	Florida Department of Health, Office of Public Health Research	Advisory Council	Governor, Senate, and House leaders, and private philanthropic organizations.	Two members who are experienced in biomedical research; one member from a research university in Florida; one member from the general public; one member who is experienced in behavioral research; one member from a professional medical organization; one member from a cancer program approved by the American College of Surgeons; one member from the Florida Division of the American Cancer Society; one member from the Puerto Rico Affiliate of the American Heart Association; and one member from the American Lung Association of Florida.			
Massachusetts	Quasi-public agency	Board of Directors	Two governor appointees and five statutory appointees.	Secretary of the Executive Office of Housing and Economic Development; Secretary of the Executive Office for Administration and Finance; and five members who are industry leaders, including the president of University of Massachusetts.			
New York	Department of Health	Board of Directors	Thirteen members; twelve appointed by the Governor and one who is the Department of Health Commissioner.	Six members appointed by the governor; two members appointed on the nomination of the temporary president of the senate; two members appointed on the nomination of the speaker of the assembly; one member appointed on the nomination of the senate minority leader; and one member appointed on the nomination of the assembly minority leader.			
Ohio	A Commission within the Development Services Agency	Commission and Advisory Board	Governor with consent of the Senate; Senate and House leaders.	Director of Development Services Agency; Chancellor of the Ohio Board of Regents; the Governor's science and technology advisor; and the chief financial officer of Jobs Ohio (a nonprofit corporation).			
Pennsylvania	Department of Health	Health Research Advisory Committee	Nine Members: Secretary of Health, Chairperson; Eight Additional Members: four are appointed by the Governor and four are appointed by the Legislature.	Program contact could not provide this information.			

Table 11 lists information on award recommendation processes, approval authority, and the types of awards for the six programs that are similar to CPRIT.

Table 11

Award Recommendation and Approval Processes of Six Programs Similar to CPRIT						
State	Who makes award recommendations?	Who approves the contract?	Does the governing board review the contract?	Who has final authority to approve funds?	Type of awards	
Texas	Executive Director makes final recommendations substantially based on peer review councils' recommendations.	Executive Director	No	Executive Director	Grants	
California	Grants Review Working Group	Governing board	No	Independent Citizens Oversight Committee	Grants and loans	
Florida	Biomedical Research Advisory Council	Funding decisions are made by the Department of Health, which usually follows the peer reviewers' recommendations.	No	State Surgeon General Department of Health	Grants	
Massachusetts	Investment committee	Board of directors	No	Board of directors	Grants and loans	
New York	Peer reviewers make recommendations to the governing board, and the governing board makes recommendations to the Department of Health Commissioner.	Department of Health Commissioner, Grants Program Director, Fiscal Department, Attorney General, and Comptroller	No	Governing board and the Department of Health Commissioner	Grants	
Ohio	Peer reviewers	Investment committee; however, the Office of Management and Budget has to certify that funds are available.	Yes	Ohio Third Frontier Commission	Grants and loans	
Pennsylvania	Department of Health's Final Review Committee	Grant administration staff	No	Grant administration	Grants	

Table 12 lists information on award funding processes, matching funds requirements, repayment requirements, equity investments, and award amounts for the six programs similar to CPRIT.

Table 12

Award Funding Processes, Matching Funds and Repayment Requirements, Equity Investments, and Award Amounts for Six Programs Similar to CPRIT						
State	Is fund self-sufficient or does it continuously receive appropriations?	Are matching funds required?	ls repayment required?	Does the state entity take equity?	Award Amounts	
Texas	Funds come from the sale of bonds of the State of Texas, which are then appropriated.	Yes	No	No ^a	\$607.7 million as of June 2012	
California	Funds come from sale of bonds of the State of California.	No (requires matching funds only for strategic partnerships).	No, except in rare cases.	No, except in rare cases.	\$1.36 billion since 2006.	
Florida	Continuously receives appropriations.	Yes, for some types of grants.	No, except in rare cases.	No	\$177.4 million since 1999.	
Massachusetts	Yes \$1 billion over 10 years: \$500 million in capital funds toward public higher education and other facilities; \$250 million on research grants, fellowships, and workforce training initiatives; and \$250 million in tax benefits targeted toward job creation.	Yes, depending on the type of grant.	Yes for loans.	No	\$51.1 million in grants and loans from June 2008 to June 2012.	
New York	Continuously receives appropriations.	No	No	No	\$196.5 million since 2007.	
Ohio	Funds come from general revenue, tobacco settlement funds, and bond sales.	Yes	No	No, not allowed by statute.	\$100 million to \$250 million average per year.	
Pennsylvania	Self-sufficient from tobacco settlement funds.	No	No	No	\$104 million in 2008 and 2009	
a As of June 201	^a As of June 2012.					

- Sec. 67. CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS. (a) The legislature shall establish the Cancer Prevention and Research Institute of Texas to:
- (1) make grants to provide funds to public or private persons to implement the Texas Cancer Plan, and to institutions of learning and to advanced medical research facilities and collaborations in this state for:
- (A) research into the causes of and cures for all forms of cancer in humans;
- (B) facilities for use in research into the causes of and cures for cancer; and
- (C) research, including translational research, to develop therapies, protocols, medical pharmaceuticals, or procedures for the cure or substantial mitigation of all types of cancer in humans;
- (2) support institutions of learning and advanced medical research facilities and collaborations in this state in all stages in the process of finding the causes of all types of cancer in humans and developing cures, from laboratory research to clinical trials and including programs to address the problem of access to advanced cancer treatment; and
- (3) establish the appropriate standards and oversight bodies to ensure the proper use of funds authorized under this provision for cancer research and facilities development.
- (b) The members of the governing body and any other decision-making body of the Cancer Prevention

and Research Institute of Texas may serve four-year terms.

- authorize the Texas Public Finance Authority to provide for, issue, and sell general obligation bonds of the State of Texas on behalf of the Cancer Prevention and Research Institute of Texas in an amount not to exceed \$3 billion and to enter into related credit agreements. The Texas Public Finance Authority may not issue more than \$300 million in bonds authorized by this subsection in a year. The bonds shall be executed in the form, on the terms, and in the denominations, bear interest, and be issued in installments as prescribed by the Texas Public Finance Authority.
- (d) Proceeds from the sale of the bonds shall be deposited in separate funds or accounts, as provided by general law, within the state treasury to be used by the Cancer Prevention and Research Institute of Texas for the purposes of this section.
- (e) Notwithstanding any other provision of this constitution, the Cancer Prevention and Research Institute of Texas, which is established in state government, may use the proceeds from bonds issued under Subsection (c) of this section and federal or private grants and gifts to pay for:
- (1) grants for cancer research, for research facilities, and for research opportunities in this state to develop therapies, protocols, medical pharmaceuticals, or procedures for the cure or substantial mitigation of all types of cancer in humans;
- (2) grants for cancer prevention and control programs in this state to mitigate the incidence of all types of cancer in humans;

- (3) the purchase, subject to approval by the Cancer Prevention and Research Institute, of laboratory facilities by or on behalf of a state agency or grant recipient; and
- (4) the operation of the Cancer Prevention and Research Institute of Texas.
- (f) The bond proceeds may be used to pay the costs of issuing the bonds and any administrative expense related to the bonds.
- (g) While any of the bonds or interest on the bonds authorized by this section is outstanding and unpaid, from the first money coming into the state treasury in each fiscal year not otherwise appropriated by this constitution, an amount sufficient to pay the principal of and interest on bonds that mature or become due during the fiscal year and to make payments that become due under a related credit agreement during the fiscal year is appropriated, less the amount in the sinking fund at the close of the previous fiscal year.
- (h) Bonds issued under this section, after approval by the attorney general, registration by the comptroller of public accounts, and delivery to the purchasers, are incontestable and are general obligations of the State of Texas under this constitution.
- (i) Before the Cancer Prevention and Research Institute of Texas may make a grant of any proceeds of the bonds issued under this section, the recipient of the grant must have an amount of funds equal to one-half the amount of the grant dedicated to the research that is the subject of the grant request.
- (j) The Texas Public Finance Authority shall consider using a business whose principal place of

business is located in the state to issue the bonds authorized by this section and shall include using a historically underutilized business as defined by general law.

(Added Nov. 6, 2007.)

Copies of this report have been distributed to the following:

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The Honorable Joe Straus III, Speaker of the House, Joint Chair

The Honorable Thomas "Tommy" Williams, Senate Finance Committee

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The Honorable Rick Perry, Governor

Cancer Prevention and Research Institute of Texas

Members of the Cancer Prevention and Research Institute of Texas Oversight Committee

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