Oversight Committee

James M. Mansour, Chairman

Barbara Canales
The Honorable Faith Johnson, J.D
Alexander Meade
Walker Moody
Charles Tate
Mark E. Watson Jr.

The Honorable Greg Abbott
The Honorable Susan Combs
LETTER FROM THE EXECUTIVE DIRECTOR

December 31, 2011

Dear Governor Perry, Lieutenant Governor Dewhurst and Speaker Straus,

It is my pleasure to present to you CPRIT’s second annual report. In the pages that follow, you will learn about how CPRIT is fulfilling our mission of reducing the burden of cancer in Texas, while maximizing the efficiency of our operations and the results of our programs.

Cancer is the leading cause of death among Texans younger than 85 years of age. On average, more than 100 Texans die from cancer every day. Apart from the unacceptable emotional and physical toll the disease exacts on Texans, this figure translates into a daily cost to the state of approximately $77 million in medical fees and lost productivity.

But this is not the full story. CPRIT is helping Texas write its own ending. By encouraging communities to pull together in the face of the cancer challenge, CPRIT is enabling an environment ripe for a significant reduction in incidence, morbidity and mortality rates. Meanwhile, business leaders across the globe are taking notice as CPRIT programs are helping establish the brain trust and infrastructure to elevate Texas’ position as a life sciences hub and attract additional revenue to the state. Beyond Texas, CPRIT plays an ever more critical role in the national fight against cancer as federal funding to support cancer research continues to dwindle. Now the second largest funder of cancer research in the U.S., CPRIT has awarded 238 grants worth nearly $455 million, including 205 research awards and 79 prevention awards. These grants have been instrumental in the creation of 14,000 Texas-based jobs.

While the Institute’s commercialization pursuits are designed first and foremost to accelerate the time it takes for promising cancer treatments in the laboratory to reach the patients who need them most, another key benefit is the additional revenue they attract to the state. All contracts CPRIT enters into with its grantees include terms related to revenue sharing with the state.

In addition, CPRIT grants have helped recruit 28 outstanding researchers to Texas who, over the course of their careers, are poised to attract more than $1 billion in follow-on
funding to the state. These include a number of scholars from leading institutions such as Harvard, Stanford, California Institute of Technology and Johns Hopkins University. CPRIT awards also have enabled clinical services for more than 100,000 Texans, including 30,000 who have never been screened for cancer. These screenings revealed 5,000 abnormal results and 225 cancer detections in Texans who otherwise may not have received the care they need.

Thank you for this opportunity to highlight our work over the last year. We look forward to the years to come and the additional opportunities CPRIT will have to make a difference in the health and life of our fellow Texans.

Sincerely,

Bill Gimson
Executive Director
An Economic Assessment of the Cost of Cancer in Texas and the Benefits of the Cancer Prevention and Research Institute of Texas (CPRIT) and its Programs: 2011 Update

The Perryman Group recently completed a study of the cost of cancer in Texas and well as the economic benefits of CPRIT and its screening/prevention and research programs. (Selected results are summarized below.) The Perryman Group’s analysis indicates that cancer costs the Texas economy some $139.5 billion in reduced annual spending, $68.8 billion in output losses per annum, and 731,870 lost jobs from cancer treatment, morbidity, and mortality and the associated spillover effects.

Returns on Investments Through CPRIT

In FY 2011, CPRIT awarded a total of $238.8 million for research and prevention of cancer to various entities including universities, hospitals, and private companies.

- The current total annual impact of all prevention and research programs (including initial outlays and downstream effects) associated with CPRIT on Texas business activity was found to be $1.1 billion in output and 14,212 jobs.

- This incremental business activity also generates taxes for the state and local governments. For Texas, tax receipts associated with CPRIT activities from all sources in 2011 total $60.6 million, while local public entities receive $30.9 million. By the tenth year, these annual increases rise to $472.1 million and $225.3 million, respectively.

Other Positive Effects

In addition to these benefits, CPRIT’s activity works to decrease the costs of cancer (both in economic terms and the enormous human costs of the disease). By establishing Texas as a center for cancer research, CPRIT also is helping to enhance the future development of biosciences industries in the state.
Every Dollar Invested Through CPRIT Returns:
(Including Initial Outlays and Downstream Effects)

<table>
<thead>
<tr>
<th>Return Amount</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>$9.48</td>
<td>In Economic Activity (Total Expenditures)</td>
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<tr>
<td>$4.78</td>
<td>In Output (Real Gross Product)</td>
</tr>
<tr>
<td>$1.98</td>
<td>In State Tax Receipts as of the 10th Year of Operation (assuming current levels of awards)</td>
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<tr>
<td>$0.94</td>
<td>In Local Government Tax Receipts as of the 10th Year of Operation (assuming current levels of awards)</td>
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Source: The Perryman Group
# CPRIT’S GRANT AWARD RECIPIENTS

## Grant Award Recipients

**CPRIT Awards through August 31, 2011**

### Investments in Cancer Prevention

<table>
<thead>
<tr>
<th>Institution</th>
<th>Amount</th>
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</thead>
<tbody>
<tr>
<td>Angelo State University</td>
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<tr>
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<tr>
<td>Baylor College of Dentistry (TAMU Health Science Center)</td>
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<td>Baylor College of Medicine</td>
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<td>Cancer Services Network</td>
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<td>Centro San Vicente</td>
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<td>Daughters of Charity Health Services (dba Seton Healthcare Network)</td>
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<td>Funding Solutions</td>
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<tr>
<td>Healthy Tarrant County Collaboration</td>
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<tr>
<td>Lance Armstrong Foundation</td>
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<tr>
<td>Light and Salt Association</td>
<td>$ 329,933</td>
</tr>
<tr>
<td>LRGV Community Health Management Corporation, Inc. (dba El Milagro Clinic)</td>
<td>$ 149,100</td>
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<tr>
<td>Mercy Ministries of Laredo</td>
<td>$ 300,000</td>
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<tr>
<td>MHMR of Tarrant County</td>
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<tr>
<td>Migrant Clinicians Network</td>
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<tr>
<td>National Center for Farmworker Health, Inc.</td>
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<tr>
<td>SETON Family of Hospitals</td>
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<td>Shannon Business Services</td>
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<td>Texas Medial Association</td>
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<td>Texas Nurses Foundation</td>
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<tr>
<td>Texas Tech University</td>
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</table>
Texas Tech University Health Science Center $ 4,831,994
The Bridge Breast Network $ 977,603
The Cooper Institute $ 591,384
The Rose $ 1,145,625
The University of North Texas Health Science Center at Fort Worth $ 2,282,374
The University of Texas at Austin $ 266,920
The University of Texas Health Science Center at Houston $ 2,283,074
The University of Texas Health Science Center at San Antonio $ 1,532,074
The University of Texas M.D. Anderson Cancer Center $ 2,151,390
The University of Texas Medical Branch at Galveston $ 15,000
The University of Texas Southwestern Medical Center $ 4,599,972
University Health System $ 1,606,693
University of Houston $ 272,753

Investments in Cancer Company and Academic Research

Apollo Endosurgery $ 5,001,063
Baylor College of Medicine $ 54,619,832
Baylor Research Institute $ 2,108,180
Baylor University $ 200,000
Bellicum Pharmaceuticals, Inc. $ 5,680,310
Clinical Trials Network of Texas $ 25,213,675
Peloton Pharmaceuticals $ 11,044,931
Ingeneron, Inc $ 198,011
Mirna Therapeutics, Inc. $ 10,297,454
Rice University $ 16,076,267
Rules-Based Medicine $ 3,024,432
Texas A&M University $ 399,894
Texas A&M University System Health Science Center $ 1,746,312
Texas Life Science Foundation $ 7,745
Texas Tech University $ 199,796
Texas Tech University System Health Sciences Center $ 5,460,659
The Methodist Hospital Research Institute $ 23,379,260
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<td>The University of Texas at Dallas</td>
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<td>The University of Texas at El Paso</td>
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<tr>
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<tr>
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<td>University of North Texas</td>
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<tr>
<td>Visualase, Inc.</td>
<td>$2,151,776</td>
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</table>
Research

Committed to Funding Only the Best of the Best

Thanks to its citizens, Texas is perfectly positioned to transform the discovery and development of new ideas into positive outcomes for patients with cancer. From its inception, CPRIT has distinguished itself from other funding agencies by our willingness to share risk with excellent researchers if they are pursuing very worthy goals. We strive to move beyond research projects that promise predictable outcomes resulting in only incremental progress. CPRIT’s selection process is distinctive also because of the collective expertise of superior cancer scientists and practitioners on CPRIT’s seven application review committees.

CPRIT’s Cancer Research Awards

CPRIT’s research awards span the spectrum from basic science to translational research and clinical applications and vary in amount and duration from relatively modest short-term projects targeting early-stage ideas to complex, multi-year research programs at laboratories and research facilities throughout the state.

- **Recruitment awards** help to bring superior cancer researchers at different career stages to Texas academic institutions to establish laboratories or clinical research programs and contribute to the research talent in the state.
- **High Impact-High Risk awards** are designed as relatively inexpensive, short-term awards ($200,000 over 24 months) to give investigators seed money to explore especially exciting but risky approaches to cancer research.
- **Individual Investigator awards** support innovative research projects directed by one scientist addressing critically important questions that will significantly advance knowledge of the causes, prevention, and/or treatment of cancer.
- **Multi-Investigator awards** fund large-scale, collaborative, cross-disciplinary research among several investigators for projects that cannot be effectively addressed by an individual researcher or a group of researchers within the same discipline.
- **Training awards** sustain specialized cancer research training programs to promote the next generation of investigators and leaders in cancer research. Individuals from underrepresented racial and ethnic groups, individuals with disabilities, and individuals from disadvantaged backgrounds are especially encouraged to participate in CPRIT’s training programs.
- **Shared Instrumentation awards** underwrite the acquisition of major research equipment and instruments at Texas research institutions whose purchase can be justified on a share-use basis among a group of investigators to support the goals of scientifically significant cancer research projects.
- **Core Facilities awards** fund the development or enhancement of core facilities that will provide valuable services to enhance the outcomes of scientifically meritorious cancer research projects.
- **Bridging The Gap: Early Translational Research awards** support projects that "bridge the gap" between promising new discoveries achieved in the research laboratory and commercial development for a therapeutic, device, or diagnostic assay through activities up to and including preclinical proof-of-principle data that demonstrate applicability to the planned clinical scenario.
CPRIT reviewers are asked to stress the potential impact of the proposed research and identify projects that will make a real difference if successful. CPRIT boasts of the best peer review committees in the world and is committed to following their counsel – free from political influences or conflicts of interest.

The seven peer review committees are chaired by an outstanding group of scientists, many of whom are members of the United States National Academy of Sciences, the Institute of Medicine of the National Academies, and the Howard Hughes Medical Institute. The seven committee chairs comprise CPRIT’s Scientific Review Council, which is led by Dr. Philip Sharp, a distinguished faculty member at the Massachusetts Institute of Technology and recipient of a Nobel Prize in 1993. In addition to recommending research projects to be funded, the Scientific Review Council evaluates the recruitment applications and provides strategic guidance to the Institute.

One of CPRIT’s peer review committees at work
Because CPRIT’s priority is to elicit the best and most creative ideas from the finest cancer researchers in Texas, these talented scientists are not told what to work on, nor are arbitrary quotas imposed on areas to be funded. There are no “set asides” for types of research or types of cancer. Rather, broadly qualified expert panels review a wide range of proposals, and the best and the most promising are selected, without regard to topic or cancer site. **You are unlikely to solve problems, no matter how important, if you do not have good ideas about how to find solutions.** CPRIT’s strategy is to set the stage, let the best ideas come forth, and fund those.

**Groundbreaking Discoveries Today**
It is now clear that most cancers are genetic diseases, meaning that tumors are caused by a sequential series of mutations (errors) occurring in the genetic code of tumor cells. These mutations cause the dysregulation of normal cellular processes, resulting in cancer cells that divide and proliferate uncontrollably and invade normal tissues. In the past, technological limitations forced researchers to analyze mutations in tumors one gene at a time, making the discovery of new cancer genes an extremely laborious, inefficient, and time-intensive process. Remarkably, recent advances in sequencing technologies now allow the entire genetic code (“the genome”, including more than 20,000 genes) of an individual’s tumor to be analyzed – quickly and economically. These methods are now being utilized at places like the Human Genome Sequencing Center at Baylor College of Medicine to provide a novel and comprehensive view of the mutations causing human cancers. CPRIT has provided funding to the Sequencing Center at Baylor, as well as to a newly established Cancer Genetics Laboratory, to further insights into the causes of specific cancers and to provide guidance into the optimal treatment of cancers in individual patients.

Characterization of the mutated genes causing human cancers has led to fundamental insights into cancer biology. First of all, the genetic landscape of cancer is much more complex than previously anticipated: An individual patient’s cancer contains tens to hundreds of mutated genes that may be contributing to tumor growth; not just one or two. Second, each patient’s cancer is unique. Although there are some specific genes that are frequently mutated in any cancer type, the spectrum of mutations in any two patients is distinct. Third, despite this incredible complexity, a small number of core biological pathways are critical to the growth of all cancers. Fourth, recent studies have revealed a number of previously-unknown genes and genetic pathways that are mutated in human cancers, providing critical new clues about how cancers develop and revealing insights that are applicable to many different types of cancer.

The rapidly expanding field of personalized medicine provides significant opportunities for CPRIT-funded research as cancer-causing genetic alterations are identified with increasing frequency. By aligning information technology platforms that combine patient information and clinical research data, more opportunities develop for targeted intervention and new methods of care – ultimately expediting the transition of research from the bench to the bedside. For example, decoding (sequencing) an individual’s cancer genome will assist in identifying whether a patient is at risk for certain cancers or will respond to a particular drug, and help the patient avoid treatments that will not work.
Several CPRIT-funded investigators are focusing all of the major new technologies that have been developed over the past decade on glioblastoma multiforme (GBM). A symposium featuring four of these individuals was a highlight of CPRIT’s Second Annual Meeting held in November, 2011 in Austin. GBM is the most common, aggressive, and malignant form of brain cancer. Patients with GBM have an exceedingly poor prognosis – most dying within 15 months of diagnosis. The current treatment for these tumors is surgical removal when possible, followed by radiation and chemotherapy. However, this treatment is ineffective at blocking eventual regrowth of the tumor.

**Unique Mutations in Cancer.** The work of Donald (Will) Parsons at the Baylor College of Medicine provides an excellent example of discovery of previously unknown genes and genetic pathways that are mutated in human cancers. Parsons’ genome sequencing studies of human cancers have identified a number of critical cancer genes, including his discovery (in collaboration with investigators at Johns Hopkins University) of mutations of the isocitrate dehydrogenase genes ($IDH1$ and $IDH2$) in GBM. Prior to the genomic sequencing of GBM, these metabolic enzymes were not suspected to have any connection to cancer; now they are known to be critically important for the development of GBM as well as other types of brain tumors, leukemias, and soft tissue tumors.
Most excitingly, the identification of such key genes causing human GBM is leading to profound changes in the care of children and adults afflicted by this deadly disease by providing novel targets for molecular diagnostics and therapeutics. Significant progress is being made toward the development of improved classification systems that can more accurately predict individual patient outcomes and provide clues about the best treatment options for each individual patient. Cancers that look similar under the microscope can be caused by mutations affecting entirely different genes and genetic pathways, suggesting that they might be expected to respond to different molecularly-targeted therapies. GBMs (and other cancers) containing \textit{IDH1} or \textit{IDH2} mutations, for example, represent a unique subset of tumors with a different biology and different prognosis that in the future will be treated using different chemotherapeutic strategies. Diagnostic tests for \textit{IDH1} and \textit{IDH2} mutations have already entered the oncologic clinic and new drugs targeting them will not be far behind.

The goal of the Pediatric Center for Personal Cancer Genomics and Therapeutics (PCGT) at Baylor College of Medicine, a partnership between Texas Children’s Cancer Center and the Human Genome Sequencing Center directed by Dr. Parsons, is to bring genomic sequencing technologies from the laboratory into the pediatric oncology clinic, providing real-time genetic information that will help to guide the personalized care of every pediatric oncology patient and family in the state of Texas. These efforts, supported by CPRIT research funding, are resulting in the discovery of critical new cancer genes with application to both pediatric and adult cancer care. A significant focus of the Center is on the actual clinical implementation of genomic sequencing technologies, reflected by the recent award of a groundbreaking multimillion dollar grant from the National Human Genome Research Institute (NHGRI) to incorporate clinical genome sequencing into the routine care of children with solid tumors and brain tumors at Texas Children’s Cancer Center. It is anticipated that this initiative will provide a model for the application of genomics to clinical cancer care and establish the state of Texas as a world leader in this critical area of cancer research.

CPRIT-supported research advances such as these are providing an unprecedented view of the molecular biology of cancer and enabling us to enter an era of truly personalized cancer care, with “smarter” diagnostic tests, molecular classification strategies, and medicines. It is anticipated that these breakthroughs in the laboratory will lead to even more important breakthroughs for our patients.
Translating the Advances to Patients. Dr. Elizabeth Maher and her colleagues at UT Southwestern Medical Center are combining cutting edge imaging research with clinical care. The finding that IDH1 and IDH2 mutant tumor cells produce excessive amounts of a metabolite, 2-hydroxyglutarate (2HG), which builds up in the cells, led them to investigate whether 2HG might be useful as a novel imaging biomarker. Dr. Changho Choi, a physicist in the Advanced Imaging Research Center at UT Southwestern, developed the methods to detect 2HG by proton magnetic resonance spectroscopy, a technique that can be used to show where specific chemicals are found in cells and which can be done as part of a routine brain magnetic resonance imaging (MRI) scan. Patients in the neuro-oncology program participated in a research imaging study that enabled Drs. Maher and Choi to show that the presence of 2HG in the brain MRI scan was proof that the tumor carried an IDH mutation. Since 2HG is not detectable in normal brain cells, this major advance has important implications for patient care. First, when the tumor is in a region that is dangerous to biopsy, the presence of 2HG can permit the diagnosis of a glioma to be made without surgery. Moreover, because IDH-mutated tumors have a better prognosis than those without the mutation, detection of 2HG allows the physician to discuss prognosis based solely on the MRI scan. In standard practice, patients with grade 2, low grade gliomas are followed with regular MRI scans for several years before needing treatment. In ongoing studies, the investigators are now looking at whether 2HG levels measured on serial MRI scans over time can give accurate information about tumor stability or growth, and ultimately whether 2HG will be a useful biomarker of response or lack of response to treatment.

In another translational study at UT Southwestern, Dr. Maher has partnered with experts in metabolism research to study brain tumor metabolism directly in patients. In an innovative clinical protocol, the investigators infuse glucose labeled with $^{13}$C in brain tumor patients undergoing surgical resection of the tumor. $^{13}$C is a naturally
occurring isotope of carbon that makes up 1% of all carbon in our environment and is completely safe to administer to patients. The $^{13}$C-glucose is taken up by the tumor cells and then the label is passed onto the breakdown products as glucose is metabolized. When the tumor is removed by the surgeon, a piece is saved for analysis of the $^{13}$C labeling pattern of the breakdown products by nuclear magnetic resonance spectroscopy. A “roadmap” then can be constructed that identifies all the key steps that glucose uses in fueling the tumor cell. The ability to study tumors while still in the brain, unperturbed by treatment, has yielded unexpected insights that challenge long held views of cancer metabolism that were largely based on studying tumor cells in cell culture. Ongoing studies are directed at determining the key metabolic steps that may serve as new therapeutic targets for brain tumors.

**Development of New Drugs for GBM.** One of the major goals being pursued by Luis Parada and his colleagues at UT Southwestern Medical Center is to identify novel drugs to treat GBM and prevent its regrowth. One powerful way to study human disease is to use mouse models, where one can investigate the mechanisms of cancer initiation and progression in ways that cannot be done in humans. Over the past 15 years, Parada and coworkers have generated and studied a mouse model of GBM by creating mutations in genes that are frequently mutated in human GBM. All of these mutant mice develop GBM that by all pathological, clinical, and molecular criteria, mimics the human disease. Using this mouse model, Parada identified and isolated a small population of tumor cells that he believes are responsible for tumor growth. In other words, many or most of the tumor-derived cells no longer propagate the tumor but instead, a specific subpopulation of cells (cancer stem cells; see figure below) are the ones that continuously make new tumor cells. Therefore, these cells are the ones that must be understood and ultimately targeted by therapies. The ability to identify and isolate these cells from the genetically defined mouse tumors has motivated a search
for drugs that would block the growth of these cells and thus, hopefully block tumor progression. Using the power of robotic technology and the isolated cancer stem cells, Parada and colleagues screened a large collection of chemical compounds (a library of over 200,000 compounds) to search for chemicals that block the growth of the “tumor propagating” cells. Similar approaches are routinely used by pharmaceutical companies, but with the significant difference that the cells they use to represent GBM cells are not truly representative of the tumors for a variety of reasons that we now understand and circumvent.

Parada has identified many promising drug candidates. At surprisingly low doses, these candidates have specific growth-blocking activity on GBM stem cells while not on many other types of cells. This already distinguishes these compounds from most chemotherapeutic drugs that are toxic to all dividing cells, explaining why they have such dire side effects. Current work on this project involves the detailed characterization of these potential drugs, both in the GBM cancer stem cells and in the mouse GBM models. An important component of this project is to identify the cellular targets of the drugs. That is, how exactly do they disrupt tumor cell growth specifically without apparently affecting the growth of non-tumor cells? These experiments are technically difficult, but a variety of different genetic and biochemical strategies will be employed. Knowing the targets of the drug candidates is key to understanding how these targets are acting within the cell to promote tumor growth. In collaboration with medicinal chemists at UT Southwestern, the Parada group is in the process of chemically modifying these drug candidates in order to improve their efficacy as therapeutic agents. These studies will not only provide valuable information regarding the mechanisms underlying GBM tumorigenesis, but could also lead to novel drugs for treating this terrible disease. As these drugs target a particular population of tumor cells that are responsible for tumor growth, they could lead to breakthrough therapies that significantly impact the long-term survival rate of GBM patients and, importantly, change the conceptual landscape for how anticancer drugs are developed.
**T Cell Therapy for Glioblastoma.** Malcolm Brenner and his colleagues at the Baylor College of Medicine have been developing an approach to treat patients with GBM by directing the patients’ own immune system to destroy the tumor. In this approach they take T cells, a type of white blood cell with cancer-cell killing capability, from patients’ blood, and engineer them in the laboratory to target the tumor before injecting them back into patients. Using this technology, the Brenner group can induce T cells to migrate to tumor sites, expand, persist, and destroy tumor cells (*Figures 1 and 2*).

It is now evident that many GBM also carry a latent virus called cytomegalovirus (CMV). Although it is not known if this virus actively contributes to the malignant process, the presence of CMV viral antigens provides an additional target for their T cell therapy. Brenner and co-investigators have used this knowledge to engineer T cells that recognize multiple targets on the cancer, enabling them to kill larger numbers of tumor cells more efficiently; they are now applying this approach to treat patients with advanced GBM.

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**Figure 1: Engineered T cells eradicate human GBM (stem) cells in culture.** (A) GBM cells (green) were incubated with (B) unmodified or (C) engineered T cells. Only engineered T cells eradicated GBM cells.

Below is a filmstrip showing the killing of GBM cells by engineered T cells

[http://www.youtube.com/watch?v=ktSjBDnGeQA](http://www.youtube.com/watch?v=ktSjBDnGeQA)

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**Figure 2: Engineered T cells eradicate human brain tumors (GBM) grown in mice.** Human brain tumors were grown in the brains of mice (blue/red areas indicate human brain tumors). Mice were then treated with ordinary T cells or engineered T cells (called “HER2-CAR”). Only engineered T cells eradicated the brain tumors.
Vision and Mission Statement

Participation in clinical research inevitably improves the standard of care for all patients. The April, 2010 Institute of Medicine (IOM) report concluded that the infrastructure supporting cooperative NCI-funded research is wrought with inefficiencies and delays, hampering its ability to rapidly test new ideas and innovative research strategies. The Statewide Clinical Trials Network of Texas (CTNeT) is a non-profit oncology research initiative that will be responsive to the vision and overarching recommendations of the IOM to guide improvements to a cancer clinical trials model that will deliver an effective system across the state of Texas. CTNeT represents an unprecedented collaboration of academic and community physicians committed to integrating innovative science with streamlined core operational processes to improve cancer care for Texans by rapidly translating scientific advances from the laboratory to the patient.

Key Objectives

- Establish governance, oversight, advisory boards, and committees enabling Texas academic institutions and community-based practices to work together to develop and conduct new therapeutic studies, focused on broader and more representative accrual of patients.
- Conduct tissue-based, biomarker-driven studies with novel targeted agents and innovative statistical designs. CTNeT’s focus on personalized medicine and biomarker-driven studies will be significantly enhanced by close interactions with the CPRIT-funded specimen biorepository, directed by Dr. Richard Gibbs, and the creation of a new, CLIA certified, Cancer Genetics Laboratory (CGL), directed by Dr. Art Beaudet; both the biorepository and CGL are housed at the Baylor College of Medicine (BCM) and will have grant sub-awards.
- Develop a Coordinating Center to provide essential and centralized administrative, regulatory, legal, financial, pharmacy, and informatics components. MD Anderson Cancer Center (MDACC) will be granted a sub-award to hold the Investigational New Drug (IND), and manage several of the initial central study management services. Once CTNeT staffs and trains its team, these services (in whole or in part) will transition to the 501(c)3.
- Provide for an expedited protocol review process that enables rapid feedback on solicited clinical trial concepts, centralize Institutional Review Board (IRB) review
to eliminate redundant reviews at each institution, and utilize standard “master”
clinical trial contractual agreements and protocol templates.

- Define near- and long-term informatics strategies to establish a unified
technology platform for performing trials, collecting data, and intergroup
communication.
- Align compensation policies to appropriately support and incentivize network
participants.
- Create a metric-driven decision-support system that reviews, reports, and refines
the efficiency and effectiveness of the model.

Organizational Structure and Leadership

The CTNeT leadership includes its Chief Medical Officer (CMO) and Chief Operating
Officer (COO); together, these positions are responsible for executing the plan toward a
long-term, financially self-sustaining business model. Each reports into the CTNeT
Board of Directors whose current members include Drs. Robert Young of Fox Chase,
Richard Gaynor of Eli Lilly, and Ms. Carolyn Bacon-Dickson of the O’Donnell
Foundation, and ex officio members Dr. Alfred Gilman and William “Bill” Gimson of
CPRIT. Additionally, they receive scientific and operational guidance from its Strategic
Steering Committee chaired by Dr. James Abbruzzese of MD Anderson. Like its Board
of Directors, the Strategic Steering Committee members have attained thought
leadership status in their respective fields representing academic and community adult
and pediatric oncology, surgical and radiation oncology, IT, and ethics. While a retained
national search by Spencer Stuart is underway to recruit its CMO, its COO, Patricia
Winger, joined CTNeT in July and brings with her 20 years of experience managing
oncology research networks including executive roles at US Oncology Research and
Sarah Cannon Research Institute. Ms. Winger is responsible for the hiring and
oversight of central and field-based staff and estimates that in fiscal years one through
three, CTNeT will employ a team of 50 support staff. Additionally, CTNeT will help
support the hiring of dedicated research staff at participating member sites that will
support the initiative locally and help drive accrual to its trials.

Implementation and Expansion

Noted below are some of the accomplishments to date of the CTNeT and features we
believe will set it apart from existing clinical trial cooperative groups and consortia:

- CTNeT was awarded a $25.2 Million 3-year grant by the Cancer Prevention
Research Institute of Texas to establish the 501(c)3 and support the initiatives as
outlined in the business plan.
- CTNeT’s Board of Directors, Strategic Steering Committee, and Council of Principal
Investigators have been established with Network members and other Texan and
non-Texan experts representing major areas of cancer care.
- CTNeT has released its initial Request for Applications (RFA) to solicit trial concept
ideas from its membership and identified an investigator-initiated study with
supplemental pharmaceutical support and a tissue-based registration strategy as its first network trials.

- CTNeT has established offices in both Austin [co-located with CPRIT] and in Houston’s Medical Center area at the Rice BioScience Research Collaborative (BRC) and has hired its legal counsel, controller, marketing manager, initial site liaison, and admin support. The recruitment process has been initiated for an IT Systems Engineer and Quality Compliance Manager.
- CTNeT legal counsel is drafting master contractual agreements with its founding member sites and sub-award agreements for services.
- CTNeT has solicited names from its members to constitute its central IRB (under MDACC FWA).
- CTNeT had a poster accepted for presentation at the 2010 CPRIT annual conference. Additionally, the CTNeT business plan was selected as the topic of discussion for the CPRIT roundtable session comprised of a distinguished panel of scientific thought leaders and others representing the NCI, the American Cancer Society, academic and community practices, pharma, and state government agencies.

The founding institutions and organizations that make up CTNeT include: Baylor College of Medicine - Dan L. Duncan Cancer Center (Houston); Mary Crowley Cancer Research Center (Dallas); Texas Children’s Cancer Center (Houston); Texas A&M/Scott & White Hospital System (Temple); Texas Oncology (Austin, Fort Worth, and Tyler); Texas Tech University Health Science Center School of Medicine Cancer Center (Lubbock); Texas Society of Medical Oncology - Oncology Consultants (Houston sites), the START Center for Cancer Care (San Antonio), the Center for Cancer and Blood Disorders (Fort Worth); the Cancer Therapy & Research Center at The University of Texas Health Science Center at San Antonio (San Antonio); the University of Texas MD Anderson Cancer Center (Houston); and the University of Texas Southwestern Medical Center (Dallas).

Value to Texans

CTNeT has met with broad support from its leadership, investigators, and institutions who are excited about the potential that CTNeT brings for the citizens of Texas and for clinical research. Moreover, despite being in its embryonic stages, it has captured the interest of Fortune 500 companies such as IBM and Hewlett Packard and big pharma companies like Novartis, Sanofi Aventis, and Eli Lilly, who eagerly await the opportunity to scientifically align their drug development programs with CTNeT investigators. Conceptually, CTNeT should serve as a model to meaningfully transform the way in which collaborative research is done in this country and “feed and seed” commercialization efforts to drive revenue and provide a return on the state’s investment. Our vision is that every Texan living with cancer will one day be able to gain local access to cutting edge and personalized cancer treatments without barriers of geography, language, ethnicity, or finance. We recognize that these goals are not insignificant and that success will take an unparalleled commitment.
Commercialization

Accelerating Drug Development, Creating Jobs, and Returning Investment to Texas

Introduction

Because groundbreaking science is most valuable when it can be translated into products that are available to patients, a crucial component of CPRIT’s mission is to create and support programs that accelerate the progression of new cancer drugs, diagnostics, and therapies from the laboratory to the patient. The Institute’s ability to promote commercialization pathways distinguishes it from more traditional cancer research funding sources.

The guiding principles of the Commercialization program are three-fold:

1. A significant improvement in cancer patient care as a result of our commercialization efforts;

2. A substantial impact on economic development in Texas; and

3. High returns (cash on cash) from the investments made by our commercialization efforts.

Commercializing cancer research benefits Texans in a variety of ways, including the introduction of new products; the creation of new, highly-skilled jobs; increased economic activity; enhanced state revenues; and reduction of health care costs and lost productivity. CPRIT dedicates personnel and operational funding to major commercial initiatives such as the activities of the Commercialization Review Council and Virtual Management Company expert services, provided by Texas BioAlliance.

CPRIT Commercialization Milestones

- 158 company applications for CPRIT funding
- $37.4 million committed ($60.8 million*)
- 7 Texas-based companies (9*)
- Commitments as of 2011 projected to create/maintain 86 jobs in Texas over 3 years (138 jobs*)

* Higher totals include projections from the two most recent awardees, Caliber Biotherapeutics, Inc., and Molecular Templates, Inc. (contracts under
Review Process

These seven CPRIT-funded company projects were selected from a field of 158 company applicants based upon scientific merit and significant commercialization potential. In addition to the peer review process that all CPRIT applications undergo, successful company cancer research proposals are subjected to a thorough due diligence analysis to determine whether there is a viable commercial path for the prospective discovery. The commercialization review ensures that CPRIT is investing in research with strong scientific merit that has the highest probability of reaching and benefiting people and producing a return on Texas' investment.

Cancer Types Addressed

The CPRIT-funded company projects include promising drugs, diagnostics, and devices targeting a variety of cancers, including cancers of the blood (leukemia, lymphoma, and myeloma), colon and rectum, esophagus, stomach, lung, and prostate. In addition, some companies are developing approaches applicable to multiple cancer types.

Virtual Management Company

CPRIT’s Virtual Management Company (VMC) administered by Texas BioAlliance is assisting entrepreneurs and researchers in creating commercially viable companies that can take promising technologies from the bench-top to the bedside. The programs provided through the VMC services will measurably impact the start-up and growth of cancer-related companies in Texas and will in turn help build a sustainable life science industry and safeguard CPRIT’s investment in promising cancer research and companies. Forty percent of life science companies fail. Great science is not the constraint. The chances of success for these companies are much higher with a strong management team and expert guidance. To address these issues, VMC services focuses on three programs:

1) Virtual Management Company (VMC) Expert Services is the umbrella program which provides comprehensive product development guidance to prevent the common pitfalls currently experienced by life science companies and scientific investigators;

By engaging the business community in CPRIT’s commercialization efforts, Texans should expect to receive a return on the substantial outlay for cancer research, both through increased economic development and a direct revenue stream from the commercial activities of CPRIT-funded research, while also enhancing opportunities for breakthrough cancer-related technologies.
2) **The Entrepreneur in Residence (EIR) program** recruits experienced entrepreneurs interested in forming quality oncology companies in Texas in collaboration with qualified investment firms to enhance the state’s talent pool of senior level life-science entrepreneurs; and

3) **Industry Outreach** focuses on developing and executing a strategy to raise awareness of ongoing statewide initiatives to the global biotechnology, device, and pharmaceutical community.

### VMC Expert Services

The Virtual Management Company is a unique business model that provides the support necessary to bridge the experienced management gap that has historically prevented Texas from effectively capitalizing on its discoveries. Product development and commercialization experts are retained to provide strategic guidance to researchers and companies developing oncology products and technologies.

Since September 2010, VMC Expert Services has led to the successful funding of two CPRIT commercialization award applicants (Caliber Biotherapeutics and Bellicum Pharmaceutical, Inc.). CPRIT’s Commercialization Review Council (CRC) referred both companies to the VMC for expert refinement of their plans after an initial review. One other company referred to VMC Expert Services by the CRC will submit a reapplication in the first cycle of 2012. Nine others have received expert strategic advice and continue to show progress in their development plans, thereby enhancing the chances of commercial success.

### Entrepreneur in Residence (EIR) Program

The EIR program builds quality oncology companies in Texas while enhancing the state’s talent pool of senior level life-science entrepreneurs. It is synergistic with CPRIT’s efforts to fund the commercialization of cancer research and build a critical mass of life science companies. Texas BioAlliance is working with qualified investment firms to recruit entrepreneurs to the state. The expected outcomes of the program include the:

- Establishment, location, and funding of new companies in Texas; and
- Recruitment of management to Texas to support the new company.
Industry Outreach

Within the biotechnology industry, CPRIT was largely unknown outside the state of Texas. Texas BioAlliance is executing a strategy for CPRIT that raises awareness of CPRIT and its mission to the global biotechnology and pharmaceutical industry and the financial community. The goals of the Industry Outreach Program are:

- Relocation of quality start-up to mid-size oncology related biotechnology and life science companies in Texas;
- Collaboration with big pharmaceutical firms that will build industry in Texas;
- Introduction of CPRIT programs through outreach at national and international industry events; and
- Creation of new programs and initiatives to build infrastructure for sustainable industry development.
Prevention

Reaching Texans, Saving Lives, Saving Money

Ten percent of the total amount of CPRIT awards each year is devoted to supporting cancer prevention programs and services in Texas. CPRIT’s prevention grant awards make it possible for proven cancer prevention interventions and early detection services to reach many more Texans and ultimately decrease the personal and economic burden of cancer statewide.

To tackle the diverse and often complex cancer prevention and control needs of the state, CPRIT-funded initiatives must be results oriented, evidence-based, non-duplicative, and innovative in delivery. The prevention grants program addresses all areas of the cancer prevention continuum, including:

- **Primary prevention efforts**, such as vaccine-conferred immunity for prevention of cervical and liver cancers, healthy lifestyle and obesity prevention initiatives, tobacco control, and sun protection;

- **Early detection, screening, and diagnostic services** for cancers that we know can be prevented or detected early, with priority on breast, cervical, and colorectal cancers; and

- **Survivorship issues**, including physical rehabilitation and therapy, psychosocial interventions, navigation services, and palliation.

There is no question that we know how to prevent some cancers (e.g., through tobacco prevention and cessation and vaccinating against Human Papillomavirus) and how to reduce the risk of getting others. We also know that early detection, through recommended cancer screenings, can save lives. The ability to reduce cancer death rates in the state depends in part on applying some of these current approaches more broadly. There are effective evidence-based strategies available now that are not reaching all Texans. Through its prevention grants program, CPRIT invests in building and improving the capacity of communities to deliver effective interventions so that new services and technologies are made available to more Texans.

Prevention award mechanisms support comprehensive, cross-cutting strategies such as public education, outreach and access to care, clinical service delivery, professional training, and policy and systems change.

CPRIT’s Prevention Program focuses on the delivery of evidence-based programs and services, serving the people of Texas with the greatest need – those who are uninsured or underinsured, those in medically underserved areas of the state, or those with high prevalence of cancer risk factors or incidence or mortality rates.
CPRIT’s projects are already having an impact: Individuals are TAKING ACTION by getting screened, many for the first time, and by making healthier lifestyle choices. Still, there is much left to accomplish. We have work to do as long as Texans are going unscreened and untreated for cancer due to economic status, lack of health insurance, or inadequate education and awareness.

Reaching Texans

CPRIT Prevention Grants are covering the entire state of Texas; the vast majority of counties have targeted projects.

Over $65 million has been awarded to 78 projects:

- Current CPRIT projects are reaching over 3.2 million Texans (includes mass media, newsletters, etc.)

- As of December 2011, projects have served over 216,000 Texans
  - Over 145,000 public and professionals received education, outreach, navigation services, and/or training
  - Over 71,000 people have been screened (colorectal, cervical, breast)
    - 28,894 never before screened
Saving Lives

We are educating people, getting them to take action, helping them access services, and detecting cancers that would otherwise go undetected. Early detection of abnormalities and cancer precursors will save costs. Results reported to date (through December 2011) from CPRIT-funded prevention projects include:

- 534 precursors detected
- 225 cancers detected

Bringing Life-saving Programs and Services to the People of Texas. “It was a miracle for me to get treatment, a godsend to me, really. I can’t thank them enough for all their help, and I’ll never forget it.”

Faith Walker thought she had pulled a chest muscle while helping her husband repair a fence at the couple’s small ranch in rural Johnson County, south of Fort Worth. But soon, one of Faith’s breasts became red and inflamed, and within a few weeks, was painful to the touch.

“My husband is a contract worker, so we can’t afford health insurance,” the 61-year-old grandmother explained. “When you live in a poor county, you don’t think there’s any help for people like me.” But thanks to CPRIT funding and UT Southwestern Moncrief Cancer Institute of Fort Worth, there now is help for uninsured and underinsured women in Denton, Wise, Parker, Hood, and Johnson Counties.

Moncrief’s Breast Screening and Patient Navigation (BSPAN) Program was awarded $999,887 in March 2010 to provide mobile mammography and navigation to diagnostic services in those five counties. According to the Texas Cancer Registry, the counties are located in a health service region that carries one of the state’s highest reported incidences of invasive breast cancer. They also are comprised of rural, primarily ranching communities that offer limited access to cancer services, especially for the medically underserved.

Recognizing the need for cancer prevention and navigation services beyond the Tarrant County border, Moncrief began building communities of trust within the five BSPAN counties by first contacting the governmental and medical leadership there. Meetings ensued between Moncrief’s Medical Director, Dr. Keith Argenbright, and the county judges, commissioners’ courts, local hospital administrations, and key physicians in each of the five counties. At each meeting, Dr. Argenbright explained Moncrief’s vision of using CPRIT funding to bring breast cancer prevention services – in the form of mobile digital mammography – to the local people who were most in need, and when
necessary, navigating those same patients to diagnostic and treatment services within their own counties, rather than requiring the patients to travel to Fort Worth.

This particular service model was both feasible and attractive on several levels. First, Moncrief Cancer Institute leveraged CPRIT’s support by combining it with other funding sources such as Susan G. Komen for the Cure and the federal Breast and Cervical Cancer Services program, which provides Medicaid coverage for those who qualify. Secondly, the diagnostic and treatment clinicians of each county were more willing to see local patients in their private practices when they knew that Moncrief would arrange for their services to be reimbursed in an efficient and timely manner.

So what happened to Faith?

“I called Moncrief and their nurse navigator performed a free clinical breast exam and arranged for a biopsy right away. It was inflammatory breast cancer, stage III,” Faith said. “They got me on Medicaid within a week and I was able to get my surgery, chemotherapy, and radiation at Huguley (Memorial Medical Center) in Johnson County. To me, that was just amazing!”

Faith is just one example of the women helped by BSPAN. During the first 18 months of the two-year program, BSPAN has screened 2,141 women and diagnosed 56 breast cancers. Thirty one percent of the women screened had not had a mammogram within the past 10 years, and 78% of the cancers detected were diagnosed at early stage.

Currently, CPRIT’s return on its investment into the Moncrief Cancer Institute BSPAN program is very favorable: For every $1 spent on cancer prevention in this screening program, $2.70 is saved in health care costs for the state.

And CPRIT’s roll in Faith’s journey? She now is taking advantage of Moncrief’s Program for Community Survivorship (ProComS), a two-year CPRIT-funded program, still in its first 12 months of extending the continuum of cancer care to the residents of Fort Worth and the surrounding area. Focused on offering behavioral and psychosocial support to survivors of all cancers, ProComS features a walk-in clinic staffed by Oncology-Certified Registered Nurses who assess each survivor’s specific needs and concerns and then aids him or her in establishing a customized survivorship plan aimed toward healthy surveillance and avoiding recurrence.

Saving Money

We are leveraging resources and positioning Texas at the forefront of cancer prevention. Examples include leveraging federal, state, and local resources, as well as reducing costs through the early detection of cancer.
Leveraging Federal, State, and Local Resources. Dr. Samir Gupta of the University of Texas Southwestern Medical Center and his colleagues submitted a proposal to the National Cancer Institute to join a new initiative, “Population-based Research Optimizing Screening through Personalized Regimens (PROSPR).” Using preliminary data from Gupta’s CPRIT-funded prevention program, they were successful and selected as a PROSPR center supported by over $6 million in funding.

Dr. Gupta writes, “It is notable that our site is one of only three colorectal cancer sites nationwide, the only site in Texas, and the only site exclusively focused on improving colorectal cancer screening for the uninsured. …Receiving this prestigious NCI grant will allow Texas to be at the forefront of efforts to optimize colorectal cancer screening for the underserved, and could not have been possible without CPRIT support of the current evidence-based prevention program.”

Reducing Costs Through Early Detection of Cancer.

<table>
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<tr>
<th></th>
<th>Cancer Diagnosed at Local (earliest) Stage</th>
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<tr>
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<tr>
<td></td>
<td>$2,475</td>
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*For initial phase of care

Source:

Developing and Implementing the Texas Cancer Plan

By state statute, CPRIT is charged with facilitating the development and implementation of the Texas Cancer Plan. As the statewide action plan for cancer prevention and control, the Plan identifies the challenges and issues that affect our state and presents a set of goals, objectives, and strategies to help inform and guide communities in the fight against cancer. Revision of the Plan is slated for completion in early 2012. The overall outcome and success of the Plan will depend on the cooperation, collaboration, and resources of the many stakeholders that cover our great state.
CPRIT hosted its second annual Innovations in Cancer Research and Prevention Conference on November 15-17, 2011. Over 850 attendees representing the best minds in the field of cancer research, prevention, and bioscience industry gathered in Austin in celebration of CPRIT’s achievements and as a call to action to work quickly toward research, prevention, and treatment that would change the face of cancer as we know it. This year’s presentations ranged from a forward-looking plan for MD Anderson Cancer Center by its new president Dr. Ron DePinho to Dr. Judith Ottoson’s session on successful evaluation techniques to an all-star commercialization panel moderated by Oversight Committee member Mr. Charles Tate. Nearly 400 conference abstracts were presented in poster sessions at the conference, with 36 oral abstract presentations made as part of the conference program.

The 2012 conference will again provide an opportunity for colleagues and scientists from all over the country to gather and share the latest in cancer research and prevention. CPRIT’s third annual conference will be held in Austin October 24-26, 2012.
CPRIT Committees

In carrying out CPRIT’s mission, the Oversight Committee benefits from advice and input from four standing committees that are external to the governing body. These committees meet at least semi-annually and report to the CPRIT executive director and Oversight Committee executive leadership. Committee updates and reports are presented to the Oversight Committee at its quarterly meetings.

Advisory Committee on Childhood Cancers
The Advisory Committee on Childhood Cancers (ACCC) was created by statute to provide input and advice to CPRIT regarding the prevention, control, and cure of childhood cancers. ACCC membership includes childhood cancer advocates and scientists whose research targets issues in pediatric oncology.

Commercialization Strategy Committee
The Commercialization Strategy Committee was created by the Oversight Committee to provide tactical advice regarding CPRIT’s commercialization efforts and enhancing Texas’ ability to move innovative products from the laboratory bench to the patient bedside.

Scientific and Prevention Advisory Committee
The Scientific and Prevention Advisory Committee (SPAC) was created by the Oversight Committee to provide advice and support services to the Oversight Committee. The 22 SPAC members represent cancer-related fields including research, clinical trials, health care delivery, prevention programs, advocacy, and cancer survivorship.

University Advisory Committee
The University Advisory Committee was created by statute to advise the Oversight Committee regarding the role of institutions of higher education in cancer research.

Membership is comprised of representation from the following university systems:
- University of Texas
- Texas A&M University
- Texas Tech University Health Sciences Center
- University of Houston
- Texas State University
- University of North Texas
- Baylor College of Medicine
- Rice University
Financial Position of the Cancer Prevention and Research Institute of Texas

Management of the Cancer Prevention and Research Institute of Texas (CPRIT) is responsible for establishing and maintaining adequate internal control over financial reporting and for compliance with certain provisions of laws, regulations, contracts, and grant agreements and other matters. Clifton Gunderson LLP, an independent public accounting firm, has audited CPRIT’s internal control over financial reporting and compliance for the year ended August 31, 2011. As a result of the audit, Clifton Gunderson LLP has ascertained that financial statements of CPRIT “present fairly, in all material respects, the respective financial position of the governmental activities and governmental funds of CPRIT as of August 31, 2011, and the respective changes in financial position and the discretely presented component unit for the year then ended in conformity with accounting principles generally accepted in the United States of America.”

CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS
FINANCIAL SUMMARY (UNAUDITED)
For the Year Ended August 31, 2011

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| EXCESS OF REVENUES OVER EXPENSES     | $1,203,359 |
CPRIT’s Personnel

Executive Leadership

Bill Gimson
Executive Director

Alfred Gilman, M.D., Ph.D.
Chief Scientific Officer

Rebecca Garcia, Ph.D.
Chief Prevention Officer

Jerry Cobbs
Chief Investment Officer

Heidi McConnell
Chief Operating Officer

Kristen Doyle
General Counsel

Sandra Balderrama
Senior Advisor to the Executive Director

Staff

Laurie Baker
Receptionist

Ramona Magid
Prevention Program Director

JoAnn Eckert
Director of Scientific Review

Lisa Nelson
Operations Manager

Michelle Frerich
Prevention Program Manager

Ellen Read
Information Specialist

Michelle Huddleston
Accountant

Sandra Reyes
Executive Assistant

Yvette Jimenez
Administrative Assistant

Alfonso Royal
Finance Manager

Norma Kernell
Administrative Assistant

Therry Simien
Information Technology Officer